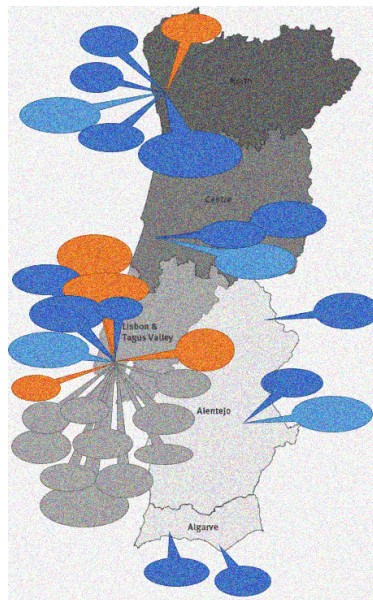


Assessment of Centralised Procurement of Medicines in Portugal



Full Report

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Assessment of Centralised Procurement of Medicines in Portugal

Full Report

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This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 “good health and well-being” and its target 3.8 “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”.

Abstract

This study assesses the performance of **centralised procurement of medicines (CPM) in Portugal** from a public health perspective and develops policy recommendations. The OECD “Methodology for Assessing Procurement Systems” (MAPS) was applied in an adapted manner. Information was retrieved from the literature and procurement documents, including bids of selected procurement procedures, and from 42 interviews, thereof 37 on-site interviews with representatives of public authorities, hospitals and regional health administrations, patients and the pharmaceutical industry. Input of procurement experts of five European countries, of Portuguese participants in a stakeholder workshop and of academics in a Delphi survey have contributed to quality-assurance, participation and acceptance.

The Shared Services of the Ministry of Health (SPMS) is responsible for performing centralised procurement processes, which comprise both open procedures (Aquisições centralizadas / AC) with one (or two) suppliers and the two-stage processes of framework agreements (Acordos Quadros / AQ). Legal implementation of CPM is compliant with European standards, and the Portuguese system was found to have several strengths. These include its contribution to **lower prices** (compared to individual purchases) in several (but not all) cases and thus to **savings** for the public sector, to **improved transparency of processes and governance**, to **more equity in access to medicines** across Portugal and to a **lower workload** for individual procurers. However, weaknesses were also identified. There is a **lack of strategy** related to CPM and a **lack of clarity** related to the roles and responsibilities of SPMS and further relevant public institutions and stakeholders with regard to their CPM activities. The **lengthy and bureaucratic processes** in centralised purchases and **delays** in the conclusion of procedures result in **non-availability** of centrally procured medicines at the beginning of a year, as scheduled, and possible launch of direct procurements by hospitals (**parallel procedures**). **Performance indicators** are lacking. SPMS communication is perceived as insufficient and there is a **low level of involvement of clinical expertise** in CPM processes. In addition, there is an **outdated list of active substances** for central purchasing (last updated in 2016), no **institutional coordination between the key public institutions** ACSS, INFARMED and SPMS and **limited knowledge of the market** by SPMS.

All addressed stakeholders were, in principle, positive towards the idea of CPM in Portugal. It is advised to maintain and extend the strengths of the current CPM system while addressing identified weaknesses. The overarching **recommendation** is **to develop an updated procurement strategy** to ensure clarity of objectives, roles and responsibilities and procurement tools. Management recommendations urge **strengthening** the following areas: the **measurement of performance, capacity, collaboration** among public authorities and with users, **stakeholder management**, the **service character** of SPMS and **procedures to prepare and conduct procurements**.

Síntese

O presente estudo avalia as **aquisições centralizadas dos medicamentos (ACM) em Portugal** numa perspetiva de saúde pública e desenvolve recomendações políticas. A “Metodologia para a avaliação dos sistemas de aquisição” (*MAPS, na sigla em inglês*) da OCDE foi aplicada de forma adaptada. As informações foram obtidas da literatura e de documentos de aquisições, incluindo propostas de procedimentos de aquisição selecionados, e de 42 entrevistas, das quais 37 realizadas no local com representantes de autoridades públicas, hospitais e administrações regionais de saúde, pacientes e indústria farmacêutica. O *input* de especialistas em aquisições de 5 países europeus, de participantes portugueses num seminário de pessoas interessadas e de académicos num inquérito Delphi contribuiu para a garantia de qualidade, participação e aceitação.

A Serviços Partilhados do Ministério da Saúde (SPMS) é responsável pela realização dos processos de aquisições centralizadas, os quais compreendem procedimentos abertos (Aquisições centralizadas / AC) com um (ou dois) fornecedores e processos de Acordos Quadros / AQ) de duas fases. A aplicação jurídica das ACM está em conformidade com as normas europeias, e concluiu-se que o sistema português tem várias forças. Trata-se nomeadamente da sua contribuição para **preços mais baixos** (em comparação com aquisições individuais) em vários casos (mas não todos) e, por conseguinte, de **poupanças** para o sector público, de uma **maior transparência dos processos e da governação**, de uma **maior equidade no acesso aos medicamentos** em Portugal, e de um **menor volume de trabalho** para os adquirentes individuais. Contudo, foram também identificadas as fraquezas. Existe uma **falta de estratégia** em relação às ACM e uma **falta de clareza** quanto às funções e responsabilidades da SPMS e de outras instituições públicas e partes interessadas relevantes no que se refere às suas atividades de ACM. Os **processos morosos e burocráticos** das aquisições centralizadas e os **atrasos** na conclusão dos procedimentos resultam na **falta de disponibilidade** de medicamentos adquiridos centralmente no início do ano, como previsto, e no eventual lançamento de aquisições diretas pelos hospitais (**procedimentos paralelos**). Falta de **indicadores de desempenho**. A comunicação da SPMS é considerada insuficiente e verifica-se um **baixo nível de envolvimento de competências clínicas** nos processos de ACM. Além disso, a **lista atual de substâncias ativas** relativa à aquisição centralizada está **desatualizada** (última atualização em 2016), não existe uma **coordenação institucional entre as principais instituições públicas** ACSS, INFARMED e SPMS e um **conhecimento limitado do mercado** por parte da SPMS.

Todas as partes interessadas contactadas foram, em princípio, favoráveis à ideia de ACM em Portugal. É aconselhável manter e alargar as forças do atual sistema de ACM, abordando simultaneamente as fraquezas identificadas. A **recomendação global é desenvolver uma estratégia de aquisições atualizada** a fim de assegurar a clareza dos objetivos, as funções e responsabilidades e as ferramentas de aquisição. As recomendações de gestão preconizam o **reforço** das seguintes áreas: **medição do desempenho, capacidade, colaboração** entre as autoridades públicas e com os utilizadores, **gestão das partes interessadas, caráter do serviço** da SPMS e **procedimentos para preparar e conduzir as aquisições**.

Executive summary

Background

In Portugal, centralised procurement of medicines (CPM) is provided through centralised purchases via open procedure (Aquisições centralizadas / AC) for defined medicines and two-stage framework agreements (Acordos Quadros / AQ) for mainly off-patent medicines. Following an interest of public authorities for an evaluation of CPM from a health system and public health perspective, Gesundheit Österreich Forschungs- und Planungs GmbH (GÖ FP / Austrian National Public Health Institute) was commissioned to perform an **assessment of CPM in Portugal** and to **develop policy recommendations**.

Methods

The study is based on a mixed methods approach.

The assessment was guided by the **analytical framework** “Methodology for Assessing Procurement Systems” (**MAPS**) of the Organisation for Economic Co-operation and Development (OECD). The framework was adapted for the purpose of this study to account for the specificities of medicines. Information and data were collected from the literature (including grey literature) and through interviews (five exploratory telephone interviews with representatives of public authorities who were members of the project’s Advisory Board and 37 on-site interviews in Portugal). These 37 face-to-face **interviews** were held with a total of 52 people, representing different stakeholder groups (public authorities, hospital management, procurement and pharmacy, regional health administrations, patients and the pharmaceutical industry) in eleven municipalities of all five mainland regions in January / February 2020. Procurement **documents**, including bids, of selected procurement procedures were analysed in terms of efficiency of the processes, the competitiveness and prices achieved.

Based on a **SWOT** (strengths, weaknesses, opportunities and threats) analysis, high-level policy recommendations, including proposals for specific projects for optimisation, were developed. Input was also gained from procurement experts in five European countries with a CPM system (Denmark, Cyprus, Estonia, Italy and Norway) mainly collected through telephone interviews conducted in May and June 2020.

A **stakeholder workshop** with approximately 40 participants (held virtually due to the COVID-19 pandemic) ensured validation of key findings of the assessment and draft recommendations. The recommendations were finalised after further comments received in a two-stage **Delphi survey** with academics.

Assessment of CPM in Portugal

SPMS (Serviços Partilhados do Ministerio de Saúde / Shared services of the Ministry of Health) is commissioned by the Central Administration of the Health System (Administração central do Sistema de Saúde / ACSS) to perform CPM.

Two CPM procedures are in place:

- » **Aquisições centralizadas (AC):** SPMS procures centrally for users such as hospitals and regional health administrations ((Administrações Regionais de Saúde / ARS) in the whole country for a period of usually one year. This is based on the needs assessment submitted by the users and their proof of availability of funds, via open procedure bids awarded to one or two suppliers (in 2020, the “winner-takes-it-all” principle was changed to a “two-winners-approach”, where possible).
- » **Acordos Quadros (AQ):** In the framework agreements, SPMS lists qualified suitable suppliers within an acceptable price range in an e-catalogue for up to four years, and users can then make call-off orders in a second stage.

Figure I:

Executive Summary – Strengths, weaknesses, opportunities and threats of CPM in Portugal

<p>Strengths</p> <ul style="list-style-type: none"> - Procurement legislation - Procurement agency - Increased transparency and improved governance - Lower workload - Lower prices / savings - Fewer appeals - e-Procurement - Publicly accessible procurement documents - Improvements - Audit and control systems 	<p>Weaknesses</p> <ul style="list-style-type: none"> - Bureaucratic, inefficient procedures - Lack of strategy and prioritisation - Lack of clarity of the roles of institutions - Overall several procurement platforms - Limitations in communication to users, limited involvement of civil society - Higher prices - Limited competition - Limited flexibility in technical specifications - Lack of performance indicators - Lack of data - No systematic market consultation
<p>Opportunities</p> <ul style="list-style-type: none"> - Positive attitude of all - Committed staff and willingness to improve - Willingness of stakeholders to collaborate and improve - Involvement of users in AQ preparation as good practice - Collaboration between hospital pharmacy and hospital procurement - Progresses over time - Budget increase for hospitals 2020 - Increased attractiveness of the Portuguese market due to CPM / higher volumes - “Two-winners” approach since 2020 - Equity potential across Portugal 	<p>Threats</p> <ul style="list-style-type: none"> - Redundancies following unclear roles - Inefficiencies and demotivation due to lack of strategy - Portuguese market gets unattractive due to low prices - Biosimilar policy (switch only after 6 months) limits savings - Parallel processes due to delayed procedures; resulting in redundancies, higher prices, higher workload and poorer governance - Risk of co-financing of other SPMS areas - Limited budgets - Misleading price information due to confidentiality - Lowest price as sole award criterion

Major findings of the assessment are as follows:

- » **Legislation** related to CPM is compliant with international standards, and mechanisms to combat fraud and ensure good governance are in place. However, the assessment suggested that **not all procurement tools** (aiming to make procurement more effective) provided for in the legislation appear to be (fully) **utilised**. Strategic guidance and prioritisation from policy-makers to support management and operational levels seemed to be missing.
- » For performing CPM, Portugal established a **dedicated procurement agency** (SPMS), which is an asset and key prerequisite. However, the role and the **responsibilities** of SPMS are not sufficiently clear, in particular in comparison to other public procurement entities (eSPap) and other public authorities responsible for pharmaceutical policies (INFARMED and ACSS). There is also room for improvement regarding the **collaboration between the public institutions** ACSS, INFARMED and SPMS. Better coordination would also be needed so that **the list of active substances** to be centrally purchased is **updated** (current list as of 2016).
- » The bids analysis identified a rather **low participation rate** in some cases. This suggests limited attractiveness of the Portuguese market for some suppliers. This can hinder competitiveness and even access to medicines (non-availability).
- » Overall, CPM was perceived to have contributed to **more transparent processes**. However, in several cases, in particular for AC, processes were considered to be **lengthy and bureaucratic**. The bids analysis also identified some **appeals and rejections** among the selected tenders. As a result, procedures may **not be concluded on time**, and medicines are not available for users at the beginning of a year, as scheduled. This resulted, in several cases, in **direct procurements** by hospitals, thus having led to **parallel procedures**.
- » In general, CPM appears to have contributed to **reduced workload** for the users, in particular the framework agreements. However, inefficient procedures (for open procedures, in particular, with redundancies due to parallel procedures) have limited this potential.
- » High-level **data** to assess the CPM in Portugal are not readily accessible, and ACSS has not yet developed **performance indicators** to routinely assess on a routine basis progress under CPM.
- » Although better knowledge of the market would be beneficial in some procurement procedures, **no systematic market research and consultation** is done by SPMS. The **involvement of hospital pharmacists** in the development of AQ in recent times is a good practice example.
- » For some centrally purchased medicines, **prices** have **decreased** compared to the earlier situation, while prices of other medicines did not change or were found to have even **increased**. Large hospitals would be able to achieve lower prices in direct procurement, while smaller hospitals would not have access to the same medicines without CPM. Thus, CPM contributed to **improved equity in access to medicines across Portugal**, possibly at the cost of higher prices in a few cases. For some medicines, particularly those under AQ (as also confirmed by selected samples of the bid analysis), significantly lower prices compared to the “base price” (estimated contract value) were achieved. This contributed to considerable **savings**. However, the **methodology** on how the savings are calculated is not transparent and needs improvement.

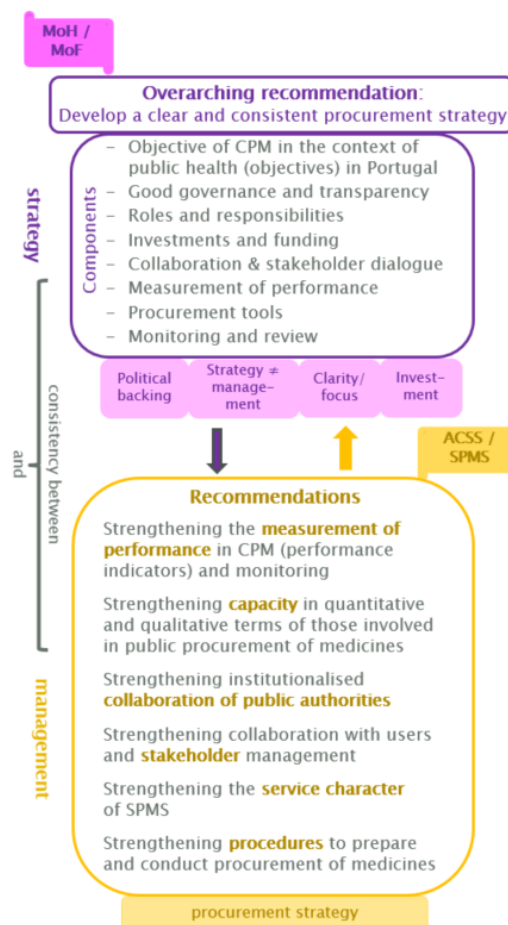
- » Portuguese CPM is based on **e-procurement** which is considered extremely helpful and appreciated by users. However, the platforms should be linked, adding to the perceived need to improve the **service character** of SPMS. This includes improved communication with users and stakeholders (e.g. currently no routine meetings of SPMS with hospital pharmacists) and the need to strengthen contract management (e.g. feedback to users in case of problems in fulfilling the contract under AC, lack of AQ management in terms of constant monitoring and feedback in case of missing competition).

Overall, the Portuguese CPM system is characterised by **strengths and weaknesses**, as also summarised in the SWOT matrix (cf. Figure I).

Recommendations

Based on the gaps analysis, a set of recommendations was developed (cf. Figure II).

Figure II:
Executive Summary – Recommendations for optimising CPM in Portugal



As several challenges and difficulties at operational levels were due to a lack of strategy and guidance, the overarching recommendation is the development and implementation of a **clear and consistent procurement strategy** by policy-makers (in particular the Ministry of Health and the Ministry of Finance). This strategy should spell out key directions with regard to the goal and role of CPM, the mandate, roles and responsibilities of SPMS and other relevant institutions (e.g. ACSS, INFARMED), the perspective on communication, collaboration and coordination with users and other stakeholders and a high-level definition of performance measurement of CPM.

The development of a procurement strategy requires strong **political will**, including a commitment of policy-makers to invest and ensure capacity, if needed. When there is political backing, the development of key components of a procurement strategy is considered feasible, even in the short-term (e.g. six months).

While further actions for addressing gaps in CPM in Portugal can be derived from the procurement strategy that has yet to be developed, the implementation of some **management recommendations** can already be started earlier. These include **strengthening the measurement of performance** (development of key performance indicators) and **monitoring**, and strengthening **capacity** (both in quantitative and qualitative terms, which could also be achieved through closer collaboration and involvement of clinical experts in the preparation of procedures by SPMS). In addition, institution-alising the **collaboration** between ACSS, INFARMED and SPMS (e.g. continuation of a working group and joint update of the list of active substances for AC) is needed as well as improved collaboration of SPMS with users and dialogue with stakeholders, and enhancing the **service character** and strengthening **procedures**.

Conclusion

CPM in Portugal is, in general, well established and has contributed to positive effects, in particular with regard to good governance, reduced workload for users and more equitable access to medicines. Nonetheless, the assessment identified several areas for improvement. To support SPMS with their operational work, guidance through a high-level procurement strategy is required.

Keywords

Public procurement, pharmaceutical, evaluation, access to medicines, processes, Portugal

Resumo completo

Antecedentes

Em Portugal, as aquisições centralizadas dos medicamentos (ACM) é efetuada através de aquisições centralizadas utilizando o procedimento aberto (Aquisições centralizadas / AC) para medicamentos definidos e Acordos Quadro / AQ) de duas fases, principalmente para medicamentos não protegidos por patente. Na sequência do interesse de autoridades públicas para uma avaliação de ACM sob a perspetiva de um sistema de saúde e de saúde pública, a Gesundheit Österreich Forschungs- und Planungs GmbH (GÖ FP / Instituto Nacional de Saúde Pública da Áustria) foi encarregada de realizar uma **avaliação das ACM em Portugal e desenvolver recomendações de política**.

Métodos

O estudo é baseado numa abordagem de métodos mistos.

A avaliação foi realizada com base no **quadro analítico** “Metodologia para a avaliação de sistemas de aquisição” (**MAPS**, na sigla em inglês) da Organização para a Cooperação e Desenvolvimento Económico (OCDE). O enquadramento foi adaptado para efeitos do presente estudo a fim de ter em conta as especificidades dos medicamentos. As informações e os dados foram recolhidos da literatura (incluindo literatura não convencional) e através de entrevistas (cinco entrevistas telefónicas exploratórias com representantes de autoridades públicas que eram membros do Conselho Consultivo do projeto e 37 entrevistas no local, em Portugal). Estas 37 **entrevistas** presenciais foram realizadas com um total de 52 pessoas, representando diferentes grupos de partes interessadas (autoridades públicas, órgãos de gestão de hospitais, de aquisições e de farmácia, administrações regionais de saúde, pacientes e indústria farmacêutica) em onze municípios de todas as cinco regiões continentais em Janeiro / Fevereiro de 2020. Foram analisados **documentos** de aquisições, incluindo propostas, procedimentos de aquisição selecionados em termos de eficiência dos processos, competitividade e preços alcançados.

Com base numa análise **SWOT** (forças, fraquezas, oportunidades e ameaças), foram elaboradas recomendações políticas de alto nível, incluindo propostas de projetos específicos de otimização. Foi igualmente obtido o *input* de especialistas em aquisições de cinco países europeus que dispõem de um sistema de ACM (Dinamarca, Chipre, Estónia, Itália e Noruega), principalmente através de entrevistas telefónicas realizadas em maio e junho de 2020.

Um **seminário de partes interessadas**, que reuniu cerca de 40 participantes (realizado virtualmente devido à pandemia da COVID-19), permitiu validar as principais conclusões da avaliação e a proposta de recomendações. As recomendações foram concluídas depois de terem sido recebidos os comentários de um **inquérito Delphi** de duas fases com académicos.

Avaliação das ACM em Portugal

A SPMS (Serviços Partilhados do Ministério da Saúde) foi encarregada pela Administração Central do Sistema de Saúde (ACSS) da realização de ACM.

Estão implementados dois procedimentos de ACM.

- » **Aquisições centralizadas (AC):** A SPMS adquire centralmente para utilizadores como hospitais e Administrações Regionais de Saúde (ARS) em todo o país por um determinado período de tempo, geralmente um ano. Isto baseia-se na avaliação das necessidades apresentadas pelos utilizadores e na sua comprovação de disponibilidade de fundos, através de propostas de procedimento aberto adjudicadas a um ou dois fornecedores (em 2020, o princípio de "o vencedor leva tudo" foi alterado para uma "abordagem de dois vencedores", sempre que possível).
- » **Acordos Quadros (AQ):** Nos acordos quadros, a SPMS elabora uma lista dos fornecedores qualificados e adequados dentro de uma gama de preços aceitável incluída num catálogo eletrónico durante um período máximo de quatro anos, podendo depois os utilizadores suspender as encomendas numa segunda fase.

As principais conclusões da avaliação são as seguintes:

- » A **legislação** relativa às ACM está em conformidade com as normas internacionais, estando os mecanismos para combater as fraudes e assegurar uma boa governação devidamente implementados. Contudo, a avaliação sugeriu que **nem todas as ferramentas de aquisição** (destinadas a tornar as aquisições mais eficazes) previstas na legislação parecem estar a ser (plenamente) **utilizadas**. Aparentemente, faltam as orientações estratégicas e a prioritização dos decisores políticos para apoiar a gestão e os níveis operacionais.
- » Para realizar as ACM, Portugal criou uma **agência de aquisições dedicada** (SPMS), o que constitui um ativo e um pré-requisito fundamental. Porém, as funções e as **responsabilidades** da SPMS não são suficientemente claras, em especial por comparação com outras entidades de aquisições públicas (eSPap) e outras autoridades públicas responsáveis pelas políticas farmacêuticas (INFARMED e ACSS). É possível também introduzir melhorias no que respeita à **colaboração entre as instituições públicas** ACSS, INFARMED e SPMS. Uma melhor coordenação será igualmente necessária para que a **lista das substâncias ativas** à adquirir centralmente seja **atualizada** (lista atualizada em 2016).
- » A análise das propostas identificou uma **taxa de participação bastante baixa** em alguns casos. Isto sugere uma atratividade reduzida do mercado português para alguns fornecedores. Este facto pode prejudicar a competitividade e até o acesso aos medicamentos (indisponibilidade).
- » De um modo geral, as ACM foram consideradas como tendo contribuído para **processos mais transparentes**. Contudo, em alguns casos, nomeadamente as AC, os processos foram considerados **morosos e burocráticos**. A análise das propostas identificou também alguns **recursos e rejeições** entre as propostas selecionadas. Como consequência, os procedimentos podem **não estar concluídos a tempo**, e os medicamentos não estarem disponíveis para os utilizadores no início do ano, conforme previsto. Isto resultou, em diversos casos, em **aquisições diretas** por parte dos hospitais, dando assim origem a **procedimentos paralelos**.
- » Em geral, as ACM, parecem ter contribuído para um **volume de trabalho reduzido** para os utilizadores, nomeadamente os acordos quadros. Todavia, a ineficiência dos procedimentos (para procedimentos abertos, em particular, com redundâncias devido a procedimentos paralelos) limitou o seu potencial.

- » Os **dados** de alto nível que permitem avaliar as ACM em Portugal não estão facilmente acessíveis, e a ACSS ainda não desenvolveu **indicadores de desempenho** para avaliar regularmente os progressos no âmbito das ACM.
- » Embora um melhor conhecimento do mercado fosse vantajoso em determinados procedimentos de aquisição, a SPMS **não realiza estudos de mercado e consultas sistemáticas**. O **envolvimento de farmacêuticos hospitalares** no desenvolvimento de AQ nos últimos tempos é um exemplo de boas práticas.

Figura I:

Resumo completo – Fortalezas, fraquezas, oportunidades e ameaças das ACM em Portugal

<p>Forças</p> <ul style="list-style-type: none"> - Legislação sobre aquisições - Entidade responsável por aquisições - Maior transparência e melhor governação - Menor volume de trabalho - Preços mais baixos / poupanças - Menos recursos - Aquisições eletrónicas - Documentos de aquisições acessíveis ao público - Melhorias - Sistemas de auditoria e controlo 	<p>Fraquezas</p> <ul style="list-style-type: none"> - Procedimentos burocráticos, ineficientes - Falta de estratégia e priorização - Falta de clareza das funções das instituições - Geralmente várias plataformas de aquisição - Limitações na comunicação aos utilizadores, reduzido envolvimento da sociedade civil - Preços mais elevados - Concorrência limitada - Reduzida flexibilidade nas especificações técnicas - Falta de indicadores de desempenho - Falta de dados - Sem consulta sistemática ao mercado
<p>Oportunidades</p> <ul style="list-style-type: none"> - Atitude positiva de todos - Pessoal empenhado e disposto a melhorar - Vontade das partes interessadas em colaborar e melhorar - Envolvimento dos utilizadores na elaboração de AQ como boas práticas - Colaboração entre farmácias hospitalares e aquisições hospitalares - Progressos ao longo do tempo - Aumento do orçamento dos hospitais em 2020 - Aumento da atratividade do mercado português devido às ACM / maiores volumes - Abordagem "Dois vencedores" desde 2020 - Equidade potencial em Portugal 	<p>Ameaças</p> <ul style="list-style-type: none"> - Redundâncias devido a funções pouco claras - Ineficiências e desmotivação devido a falta de estratégia - Mercado português torna-se pouco atrativo devido aos baixos preços - Política de biossimilares (muda apenas após 6 meses) limita as poupanças - Processos paralelos devido a procedimentos; resultando em redundâncias, preços mais elevados, maior volume de trabalho e pior governação - Risco de cofinanciamento de outras áreas da SPMS - Orçamentos limitados - Informações enganosas sobre preços devido a confidencialidade - Preço mais baixo como único critério de adjudicação

- » No caso de medicamentos adquiridos centralmente, os **preços diminuíram** em comparação com a situação anterior, enquanto os preços de outros medicamentos não sofreram alterações ou não foram mesmo **aumentados**. Os grandes hospitais poderiam obter preços mais baixos em aquisições diretas, enquanto os hospitais mais pequenos não teriam acesso aos mesmos

medicamentos sem as ACM. Por conseguinte, as ACM contribuíram para **melhorar a equidade no acesso aos medicamentos em Portugal**, possivelmente à custa de preços mais elevados em certos casos. Em relação a alguns medicamentos, especialmente os incluídos em AQ (como também confirmaram as amostras selecionadas da análise das propostas), foram obtidos preços significativamente mais baixos em comparação com o “preço base” (valor estimado do contrato). Este facto contribuiu para **poupanças** consideráveis. Contudo, a **metodologia** sobre a forma de calcular as poupanças não é transparente e deve ser melhorada.

- » As ACM portuguesas são baseadas em **aquisições eletrónicas**, o que é considerado muito útil e apreciado pelos utilizadores. Contudo, as plataformas deveriam estar ligadas, o que leva a uma maior necessidade de melhorar o **caráter do serviço**. Isto inclui a melhoria da comunicação com os utilizadores e as partes interessadas (por ex., a SPMS atualmente não tem reuniões regulares com farmacêuticos hospitalares) e a necessidade de reforçar a gestão de contratos (por ex., *feedback* aos utilizadores em caso de problemas de incumprimento de contratos no âmbito das AC, falta de gestão dos AQ em termos de monitorização constante e *feedback* em caso de falta de concorrência).

Em geral, o sistema de ACM português é caracterizado por **forças e fraquezas**, conforme também resumido na matriz SWOT (cf. Figura I).

Recomendações

Com base na análise de lacunas, foi desenvolvido um conjunto de recomendações (cf. Figura II).

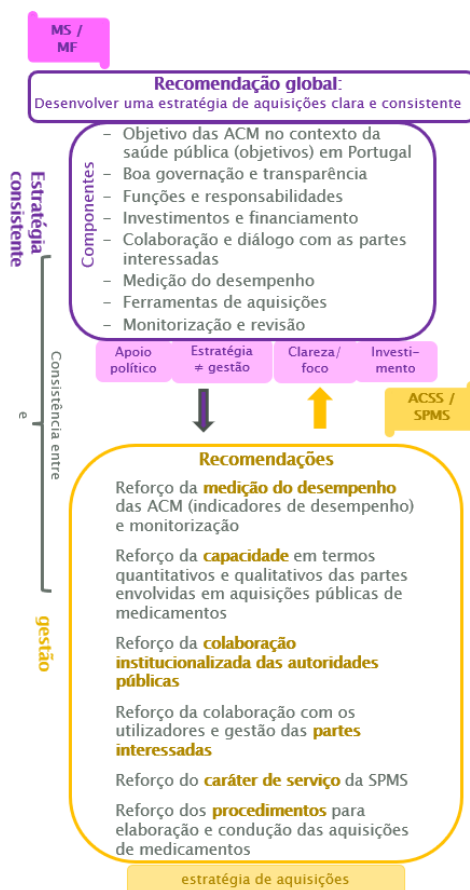
Tendo e conta que alguns desafios e dificuldades a nível operacional foram devidos a uma falta de estratégias e orientações, a recomendação global é o desenvolvimento e a implementação de uma **estratégia de aquisições clara e consistente** por parte dos decisores políticos (em especial, o Ministério de Saúde e o Ministério das Finanças). Esta estratégia deve explicar as orientações fundamentais sobre os objetivos e o papel das ACM, o mandato, as funções e as responsabilidades da SPMS e de outras instituições relevantes (por ex., ACSS, INFARMED), a perspetiva de comunicação, colaboração e coordenação com os utilizadores e outras partes interessadas e a definição de alto nível da medição do desempenho das ACM.

O desenvolvimento de uma estratégia de aquisições requer uma forte **vontade política**, incluindo um compromisso dos decisores políticos de investir e assegurar a capacidade, se necessário. Quando existe apoio político, o desenvolvimento dos componentes essenciais de uma estratégia de aquisições é considerado viável, mesmo no curto prazo (por ex., seis meses).

Embora outras ações para colmatar as lacunas nas ACM em Portugal possam ser derivadas da estratégia de aquisições que ainda tem de ser desenvolvida, a implementação de algumas **recomendações de gestão** podem ser iniciadas mais cedo. Estas incluem o **reforço da medição do desempenho** (desenvolvimento de indicadores de desempenho fundamentais), a **monitorização** e o reforço da **capacidade** (tanto em termos quantitativos como qualitativos, o que poderia ser conseguido através de uma colaboração mais estreita e do envolvimento de especialistas clínicos na elaboração dos procedimentos pela SPMS). Além disso, é necessário institucionalizar a **colaboração** entre a ACSS, o INFARMED e a SPMS (por ex., continuação do grupo de trabalho e atualização conjunta da lista de substâncias ativas das AC), assim como aumentar a colaboração da SPMS com os

utilizadores e o diálogo com as partes interessadas, melhorar o **caráter do serviço** e reforçar os **procedimentos**.

Figura II:
Resumo completo – Recomendações para otimização das ACM em Portugal



Conclusão

De uma maneira geral, as ACM em Portugal estão bem estabelecidas e contribuíram para os efeitos positivos constatados, nomeadamente em matéria de boa governação, de redução do volume de trabalho para os utilizadores e de acesso mais equitativo aos medicamentos. Não obstante, a avaliação identificou algumas áreas que podem ser melhoradas. No sentido de apoiar a SPMS no seu trabalho operacional, é necessária uma orientação através de uma estratégia de aquisições de alto nível.

Palavras-chave

Aquisições públicas, farmacêutica, avaliação, acesso aos medicamentos, processos, Portugal

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Abbreviations

AC	Aquisições centralizadas / Centralised purchases via open procedure
ACSS	Administração central do Sistema de Saúde / Central Administration of the Health System
AdC	Autoridade da Concorrência / Competition Authority
APAH	Associação Portuguesa de Administradores Hospitalares / Portuguese Association of Hospital Managers
APDI	Associação Portuguesa da Doença Inflamatória do Intestino / Portuguese Association of Inflammatory Bowel Disease
APFH	Associação Portuguesa de Farmacêuticos Hospitalares / Portuguese Association of Hospital Pharmacists
APIFARMA	Associação Portuguesa da Indústria Farmacêutica / Portuguese Pharmaceutical Industry Association
APOGEN	Associação Portuguesa de Medicamentos Genéricos e Biossimilares / Portuguese Association of Generic and Biosimilar Medicines
AQ	Acordos Quadros / Framework agreements
ARS	Administração Regional de Saúde / Regional Health Administration
ARS LVT	Administração Regional de Saúde de Lisboa e Vale do Tejo / Regional Health Administration of Lisbon and Tagus Valley
ARV	Antiretroviral
CA	Compras Agregadas / Joint procurements
CHUA	Centro Hospitalar Universitário do Algarve / University Hospital Centre of the Algarve
CHUC	Centro Hospitalar e Universitário de Coimbra / Coimbra Hospital and University Centre
CHULC	Centro Hospitalar e Universitário de Lisboa Central / Hospital and University Centre of Central Lisbon
CHUP	Centro Hospitalar Universitário do Porto / University Hospital Centre of Porto
CHUSJ	Centro Hospitalar Universitário de São João / University Hospital Centre of São João
CHVNGE	Centro Hospitalar de Vila Nova de Gaia/Espinho / Hospital Centre of Vila Nova de Gaia/Espinho

COVID-19	Coronavirus disease 2019
CPM	Centralised procurement of medicines
D	Deliverable
DAC	Development Assistance Committee
DG REFORM	Directorate-General for Structural Reform Support, European Commission
DGS	Direção-Geral da Saúde / Directorate-General of Health
DPS	Dynamic purchasing system
EASP	Escuela Andaluza de Salud Pública / Andalusian School of Public Health
EHIF	Estonian Health Insurance Fund
EMSPOS	Estrutura de Missão para a Sustentabilidade do Programa Orçamental da Saúde / Mission structure for the sustainability of the Health Budget Program
ENSP	Escola Nacional de Saúde Pública / National School of Public Health
EPE	Entidade Pública Empresarial / Public Enterprise
eSPap	Entidade de Serviços Partilhados da Administração Pública / Public Administration Shared Services Entity
EU	European Union
GAT	Grupo de Ativistas em Tratamentos / Treatment Activists Group
GÖ FP	Gesundheit Österreich Forschungs- und Planungs GmbH (subsidiary of GÖG responsible for delivering research and planning services to public institutions)
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HESE	Hospital do Espírito Santo de Évora / Espírito Santo Hospital of Évora
HGO	Hospital Garcia de Orta / Garcia de Orta Hospital
HIV	Human Immunodeficiency Virus
HTA	Health Technology Assessment
IGAS	Inspeção-Geral das Atividades em Saúde / General Inspectorate of Health Activities
INFARMED	Autoridade Nacional do Medicamento e Produtos de Saúde / National Authority of Medicines and Health Products
IPO	Instituto Português de Oncologia / Portuguese Oncology Institute

IRS	Imposto sobre o rendimento das pessoas singulares / Personal income tax
LIS	Legemiddelinnkjøpsamarbeidet
MAH	Marketing authorisation holder(s)
MAPS	Methodology for Assessing Procurement Systems
MEAT	Most Economically Advantageous Tender
MoF	Ministry of Finance
MoH	Ministry of Health
NHS	National Health Service
no.	Number
NPM	Non-prescription medicine(s)
OECD	Organisation for Economic Co-operation and Development
OF	Ordem dos Farmacêuticos / Pharmacists' association
POM	Prescription-only medicine(s)
PPC	Public Procurement Code
PPRI	Pharmaceutical Pricing and Reimbursement Information (a network of competent authorities responsible for pharmaceutical pricing and reimbursement policies in 52 countries)
SMART	Specific, measurable, achievable, realistic and time-bound
SNS	Serviço Nacional de Saúde / National Health Service
SOP	Standard Operating Procedures
SPMS	Serviços Partilhados do Ministerio de Saúde / Shared services of the Ministry of Health
SWOT	Strengths, weakness, opportunities and threats
TdC	Tribunal de Contas / Court of Auditors
ULSNA	Unidade Local De Saúde Do Norte Alentejano / Local Health Unit of the North Alentejo
WHO	World Health Organization

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1 Introduction

1.1 Background

In 2010, the Shared Services of the Ministry of Health (Serviços Partilhados do Ministério de Saúde, SPMS) was established as a public enterprise (Entidade Pública Empresarial / EPE) with the aim to “centralise, optimise and rationalise” the acquisition of goods and services in the Portuguese national health service (NHS, in Portuguese Serviço Nacional de Saúde / SNS) [1]. With regard to medicines, SPMS took over the task of purchasing for hospitals which had previously been performed by the Central Administration of the Health System (Administração Central do Sistema de Saúde / ACSS) before.

An audit report of the Court of Auditors (Tribunal de Contas / TdC) of 2012 concluded that no real **centralised procurement of medicines (CPM)** had yet been implemented but existing processes were rather continued [2].

In the years to follow, CPM was implemented in Portugal, with SPMS being responsible for preparing and conducting the centralised procurement processes. CPM is internationally known for its ability to generate savings as it makes use of improved bargaining and purchasing power due to higher volumes. Furthermore, CPM benefits from bundled expertise and offers efficiency gains due to more coordinated administrative and organisational processes [3].

Some analyses [4, 5] pointed to savings in public spending that in Portugal CPM had been able to generate. However, it has been argued that CPM should be evaluated from a broader perspective, taking the governance, institutional context and the public health perspective into consideration [6].

Against this backdrop, the government of Portugal, with the involvement of the European Commission (DG REFORM), requested technical support in the assessment of CPM in Portugal. Gesundheit Österreich Forschungs- und Planungs GmbH (GÖ FP), a subsidiary of Gesundheit Österreich (GÖG / Austrian National Public Health Institute), was commissioned to perform this assessment.

1.2 Objectives

The overall objective of this study was to **evaluate public CPM in Portugal**. By doing so, this assessment aims:

- » to **support the Portuguese authorities** (particularly the Ministry of Health and their institutions working on procurement, pricing and funding of medicines) in enhancing their capacity to formulate, develop and implement reform policies and strategies and in pursuing an integrated approach ensuring consistency between goals and means across sectors and

- » to support their efforts to define and implement appropriate **processes and methodologies** by taking into account good practices of and lessons learned by other countries in addressing similar situations.

To achieve these objectives, the study was designed in a specific project organisation architecture (cf. next chapter 1.3) and was divided into an assessment part (“diagnosis”) and a forward-looking policy support part (recommendations), embedded in stakeholder validation processes (cf. chapter 1.4).

1.3 Project organisation

Figure 1.1 describes the organisation and governance structure of the project. The study authors (researchers of the Austrian National Public Health Institute GÖ FP, in collaboration with a procurement expert of the Estonian Health Insurance Fund / EHIF) were supported by a Steering Committee and an Advisory Board:

- » The **Steering Committee** included one representative of the commissioning body (European Commission / DG REFORM) and of the following institutions representing the beneficiary Portugal: Ministry of Finance (MoF), Ministry of Health (MoH) and Estrutura de Missão para a Sustentabilidade do Programa Orçamental da Saúde (Mission structure for the sustainability of the Health Budget Program, EMSPOS).

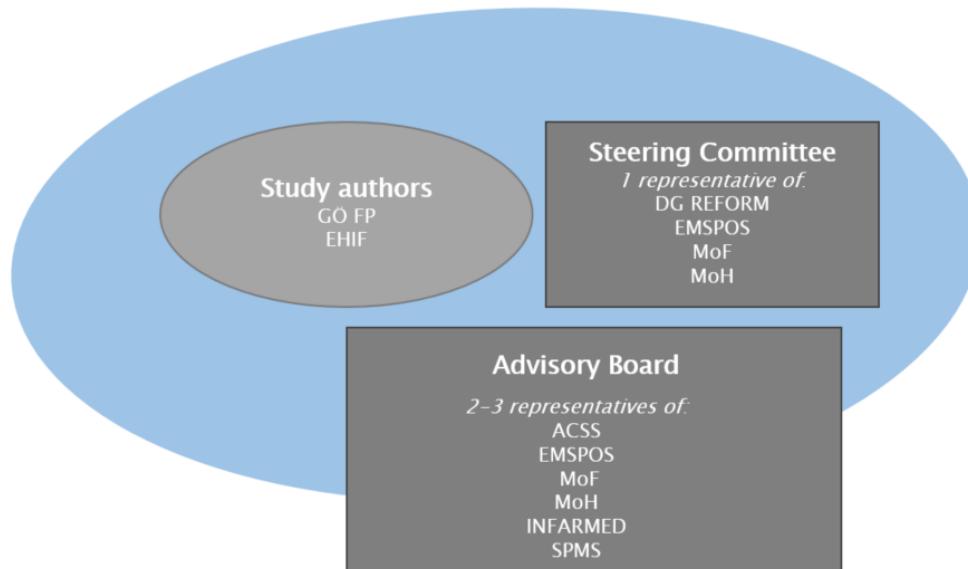
The Steering Committee ensured for a smooth functioning of the project by offering regular exchange of information (e.g. bi-weekly meetings between the study authors, DG REFORM and EMSPOS).

- » MoF, MoH and EMSPOS were also members of the **Advisory Board**. In addition, it comprised further key actors of the Portuguese pharmaceutical and procurement system: ACSS, the Medicines Agency INFARMED and SPMS.

All deliverables of the project were shared with the members of the Advisory Board (cf. Figure 1.1) for comments. Three meetings with the Advisory Board (November 2019, October 2020 and December 2020) were held, and the members of the Advisory Board were available for exploratory interviews (cf. chapter 2.2.2).

To ensure further stakeholder involvement, the findings of the assessment of CPM and preliminary recommendations were presented to public authorities, users (hospitals and regional health administrations (Administrações Regionais de Saúde / ARS)) as well as industry and patient associations in a stakeholder workshop in October 2020 (cf. chapter 2.3.2). A set of preliminary recommendations was subject to a two-scale Delphi survey in November 2020 (cf. chapter 2.3.3).

Figure 1.1:
Introduction – Project organisation



Source and presentation: the authors

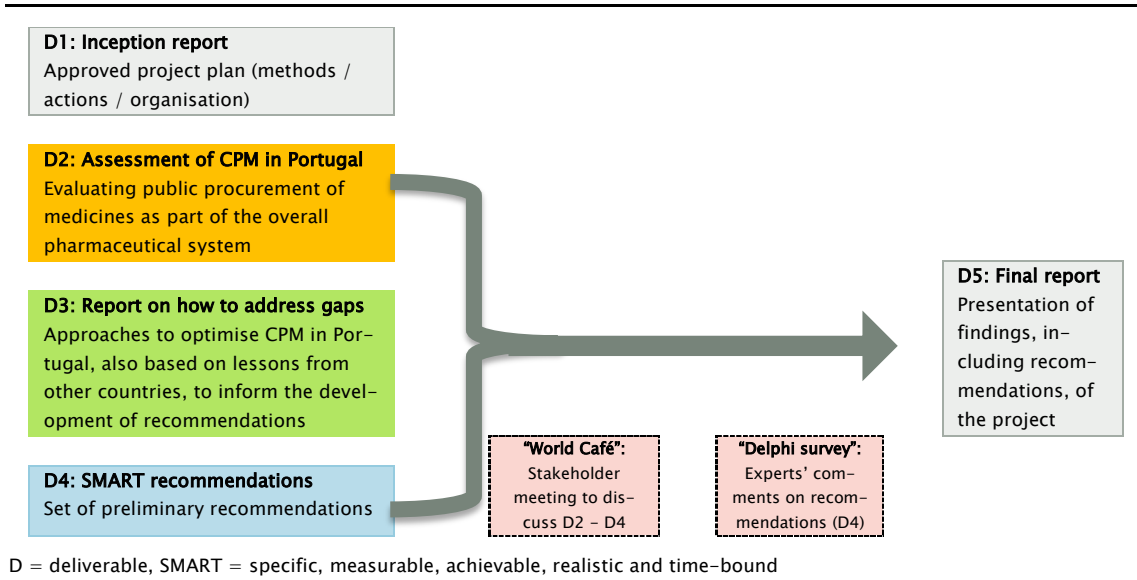
1.4 Project deliverables

According to the tender specifications [6], the project was designed to produce its deliverables in a step-wise approach. This allowed building one component on the other. It also ensured the involvement of the Steering Committee to measure the progress of the project and of the Advisory Board to provide the comments on each of the deliverables.

A total of five deliverables (D) were produced in the course of this project (cf. Figure 2.1). This final report (D5) presents the key findings of reports D1 – D4 in an updated and concise way. The main body of this technical report D5 (comprising chapters Methods, Assessment of CPM, Recommendations and Conclusions and outlook) is accompanied by an extensive Annex, which offers further details that had been included in the reports D1 – D4 [7-10].

The project started in September 2019 and was finalised in December 2020.

Figure 1.2:
Introduction – Deliverables in the context of the project plan



Source and presentation: the authors based on the tender specifications [6]

2 Methods

The study is based on a mixed methods approach of surveying and analysing the CPM system in the context of the pharmaceutical policy framework in Portugal, of several rounds of review and validation and of developing policy recommendations. The project plan was presented in the Inception Report [7] approved by the Steering Committee and Advisory Board in December 2019. Additionally, a study protocol [11] was submitted to the Ethical Committee of the NOVA Medical School in Lisbon on 30 December 2019. It was approved by the Ethical Committee on 13 March 2020.

2.1 Assessment tools

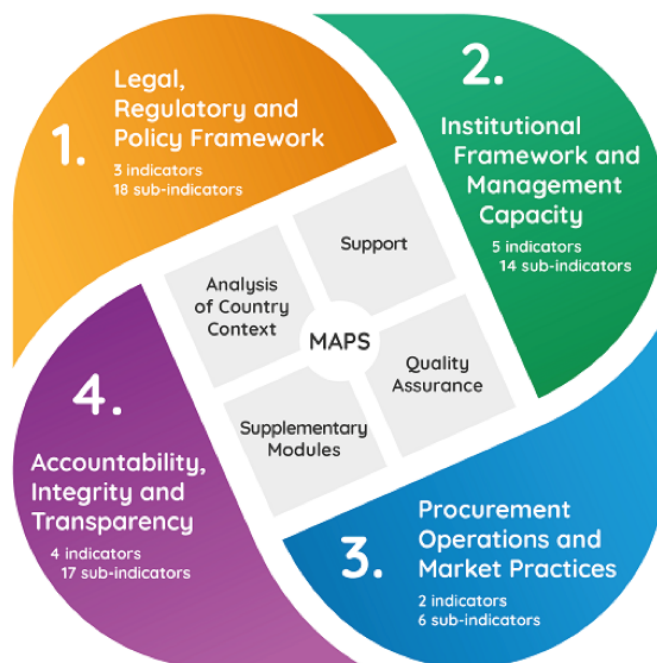
2.1.1 MAPS

The assessment of the CPM in Portugal is based on the analytical framework of the Organisation for Economic Co-operation and Development (OECD) **Methodology for Assessing Procurement Systems (MAPS)** [12]. As the MAPS methodology addresses public procurement of any goods and services, it was adapted for the purposes of this study to account for the specificities of health care in general and for medicines in particular.

The MAPS framework comprises different components: the analysis of the country context and the qualitative and quantitative indicators (“MAPS indicators”) classified into different topic areas (“pillars”, cf. chapter 7.1.2). For each indicator (14 indicators in total) and sub-indicator (55 sub-indicators) of the MAPS, the authors checked whether, or not, the indicator was relevant for the purpose of this study. If this was the case, the indicator was **operationalised** by specifying a concrete question that was to be answered through the defined data sources. Information to feed the indicators was requested in the interviews (cf. chapter 2.2.2) and, in particular for defined quantitative indicators, from SPMS.

For further information on MAPS in comparison to other assessment tools, and its suggested indicators see chapter 7.1.1 in the Annex.

Figure 2.1:
Methods – Components of the Methodology for Assessing Procurement Systems (MAPS)
framework



Source: OECD Methodology for Assessing Procurement Systems (MAPS) [12, 13]

2.1.2 SWOT

Detailed findings identified through the MAPS framework were summarized in a SWOT matrix, which highlighted major strengths, weaknesses, opportunities and threats of the Portuguese CPM.

2.2 Survey of information and data

2.2.1 Literature and documents review

Several pieces of evidence were gathered and analysed:

- » Information and data on the **Portuguese pharmaceutical system**, in particular related to pricing and procurement of medicines (e.g. studies published in technical and scientific articles, country descriptions, statistical data), which had been identified in an unsystematic literature review and upon suggestions of interviewees,

- » documents that helped assess the **indicators** defined by the OECD MAPS framework (mainly legal and regulatory documents, technical documents) and
- » **procurement documents** (cf. chapter 2.2.3 for the methodology of the bids analysis).

Documents and pieces of information not publicly accessible were obtained upon request from EMSPOS and SPMS, wherever possible.

2.2.2 Interviews

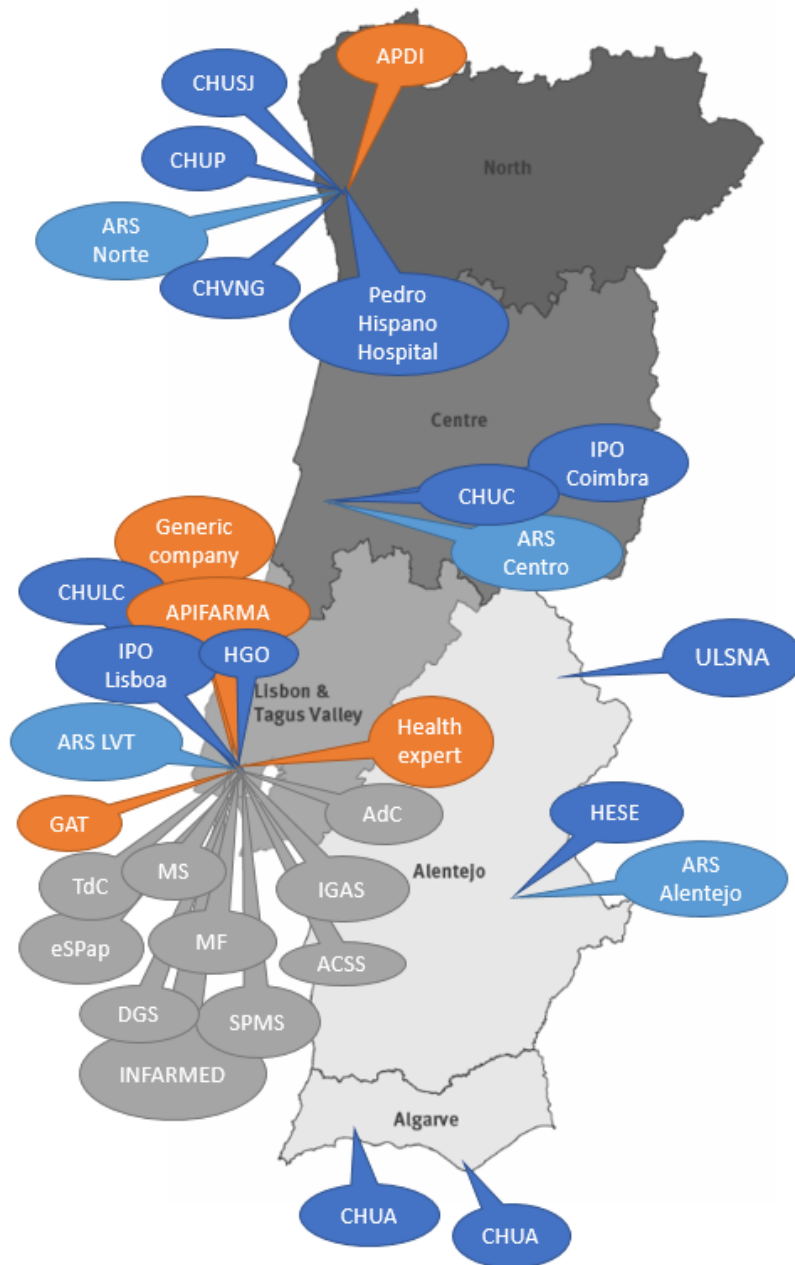
A major source of information was interviews with procurement experts, hospital managers and hospital pharmacists, policy-makers and technical experts of public authorities, patient and industry representatives and further stakeholders. In total, 42 interviews were conducted, thereof five exploratory telephone interviews with public authorities represented in the Advisory Board and 37 on-site interviews. The latter were held with stakeholders, representing different groups, in all five mainland regions of Portugal.

Table 2.1:
Methods – Methodology and specifications of the 42 interviews held

Characteristic	Exploratory interviews	In-depth interviews
Number of interviews	5 interviews (total of 5 interviewees)	37 interviews (52 interviewees)
Stakeholder group	Public authorities in pharmaceutical policy, as represented in the Advisory Board	Public authorities Users: ARS and hospitals (management, pharmacy, procurement) Further stakeholders (patients and industry)
Geographic distribution	Lisbon	11 municipalities (Almada, Coimbra, Évora, Faro, Lisbon, Matosinhos, Portalegre, Portimão, Porto, Porto Salvo and Vila Nova de Gaia) in the five mainland regions of Portugal
Purpose	To learn more about the Portuguese pharmaceutical systems, in particular public procurement of medicines, and challenges To prepare the planned mission with the on-site interviews	To get in-depth insight into the different dimensions of CPM in Portugal To learn about the stakeholders' perspectives on progress, challenges and options for further improvement
Dates	10 December – 30 December 2019	27 January – 6 February 2020
Duration	45 – 120 minutes	Usually 60 – 90 minutes
Mode	Via telephone	On-site face-to-face interviews
Language	English	English, in a few cases Portuguese (consecutive translation)
Informed consent	Verbally taken	Informed consent form (chapter 7.2.1 /Annex)
Method	Semi-structured interview, based on an interview guide, specifically developed for the respective interview (cf. chapter 7.2.2 in the Annex for the generic interview guides per stakeholder group)	
Documentation and validation	Minutes based on written notes, sent to interviewees for validation (considered accepted in case of no response within two weeks)	
Number of interviewers	1 – 3 interviewers	Usually 1 – 2 interviewers, in a few cases 3

Source and presentation: the authors

Figure 2.2:
Methods – Geographic and stakeholder distribution of the on-site interviews



For the abbreviations see the list of abbreviations

Colours: grey – authorities, blue – users (dark blue – hospitals, light blue – ARS), orange: further stakeholders (patient and industry associations)

Source and presentation: the authors

Details on the interviews are provided in Table 2.1, Figure 2.2 and in chapter 7.2 in the Annex.

2.2.3 Bids analysis

Another component of the assessment of CPM was an analysis of procurement documents of selected procurement procedures (bids analysis). This analysis aimed to gain in-depth insight into the procurement procedures and to study possible effects, in particular in terms of the efficacy of the procedures, competitiveness and prices. The bids analysis addressed both types of procedures of the CPM: Aquisições centralizadas (AC; i.e. centralised purchases through open procedure) and Acordos Quadros (AQ, framework agreements). For a more detailed description of the AC and AQ see chapter 3.1.2.2.

Selection of bids

For the selection of bids, the authors consulted the procurement platform “Vortal”¹ and performed a search for contract notices (i.e. calls for tenders) launched by SPMS in the period between 1 January 2019 and 15 April 2020. Vortal includes contract notices for both AC and AQ.

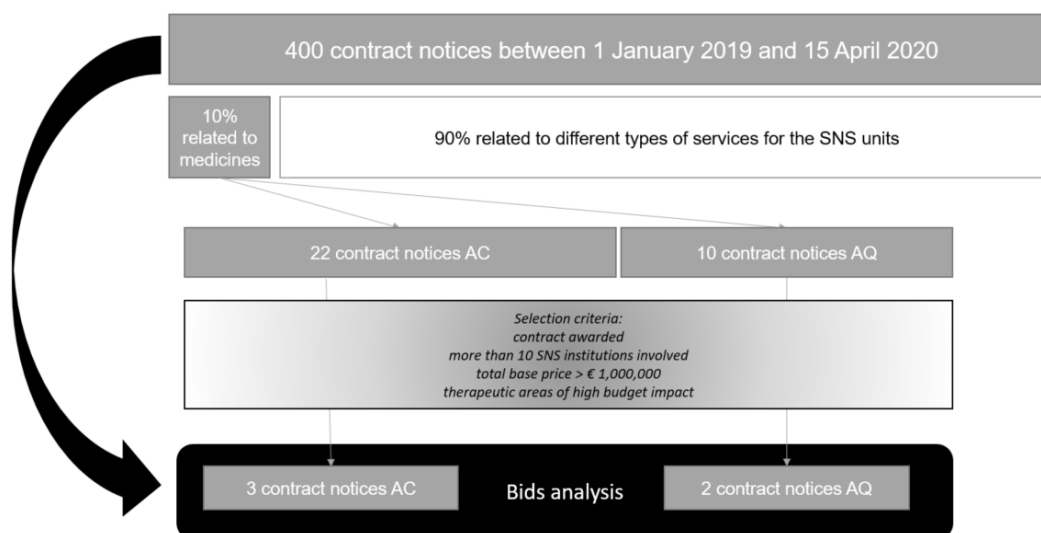
Out of the 400 contract notices identified for the given period, around 10% related to medicines, while the remaining 90% concerned different types of services for the SNS units (e.g. furniture, cars, fuel, IT procurements such as hardware, software and licenses).

In the surveyed period, 22 contract notices for open procedure (AC) and 10 contract notices for framework agreements (AQ) were identified. Thereof, three contract notices under AC and two for AQ were selected for a bids analysis, based on the application of the following criteria:

- » Status: contract awarded
- » Involved SNS institutions: more than 10 (for AC)
- » High value (total base price): more than € 1,000,000
- » Therapeutic areas of high budget impact

¹ SPMS is the only institution which is responsible for preparing and conducting the centralised procurement processes for medicines in Portugal. All contract notices are published on the e-procurement platform “Vortal” (<https://community.vortal.biz/>). This was also the primary platform used by the authors to retrieve the data for this bids analysis.

Figure 2.3:
Methods – Selection of bids for analysis



AC = Aquisições centralizadas (centralised purchases via open procedure), AQ = Acordos Quadros (framework agreements)

Source: compilation and presentations by the authors

The five examples (3 AC and 2 AQ) were selected in the therapeutic areas of cancer, hepatitis B, HIV/ AIDS and spinal muscular atrophy. Some parts of the procurement documents for the three selected AC procedures could be publicly accessed through “Vortal”, while for the AQ the authors requested them from SPMS. Information on awarded suppliers or the contract value is publicly available, but Vortal does not provide further information on the list of bidders per lot, prices of all bids submitted, number of bids submitted per lot and the content of the bids. This additional information (decision documents) was requested from SPMS. In response, SPMS provided decision documents and answers to specific questions of the authors.

For the selection process also see Figure 2.3. The five selected bids are presented in Table 2.2.

Table 2.2:
Methods – Selected bids for further analysis

Contract notice	Medicines ¹	Involved SNS institutions ²	Maximum estimated value of the contract (in €)	Source
Aquisições centralizadas (AC) / centralised purchases (open procedure)				
CP-AC-2019-10	2 lots bortezomib and entecavir	Up to 30	4,095,328.86	Link and SPMS
CP-AC-2019-15	6 lots including lopinavir+ ritonavir and metotrexato	Up to 34	1,564,156.94	Link and SPMS
CP-AC-2019-18	3 lots dasatinib, each lot for a different strength of the product	Up to 20	1,383,612.10	Link and SPMS
Acordos Quadros (AQ) / framework agreements				
CP 2019-40	60 lots for antiretroviral medicines for the treatment of HIV infections			SPMS
CP 2019-61	366 lots for miscellaneous medicines			SPMS

¹ Procurement procedures / contracts may contain more than one lot. Products in different lots in one procurement procedure / contract do not necessarily have to be products to be combined for treatment.

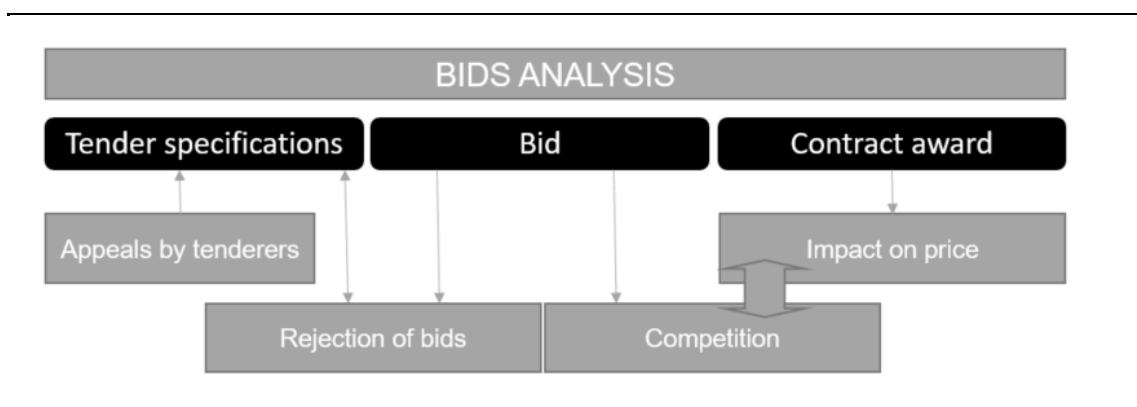
² SNS institutions include hospitals and local health units

Source: procurement platform “Vortal” and additional information by SPMS, analysis done by the authors

Areas of analysis

Figure 2.4 presents the four areas in which the selected bids were analysed.

Figure 2.4:
Methods – Four areas assessed in the bids analysis



Presentation: the authors

2.2.4 Validation

To ensure quality-assurance, including validation of surveyed information, several review processes were performed in the course of this project (for an overview see Table 2.3). Key validation processes comprised the review of each draft report (deliverable) by the Steering Committee and the Advisory Board (with subsequent revisions to address comments), the stakeholder workshop in October 2020 (cf. chapter 2.3.2) and the Delphi survey in November 2020 (cf. chapter 2.3.3).

Table 2.3:
Methods – Key validation and review processes

Scope	Reviewers / Validators	Timing	Content of review
Project plan	Steering Committee and Advisory Board	November / December 2019	Draft inception report (D1)
	Ethical Committee of the NOVA Medical School, Lisbon	December 2019 / January 2020	Study protocol
Performance of CPM in Portugal	Interviewees of the exploratory and face-to-face interviews	December 2019 – February 2020	Minutes of the interviews
Assessment of CPM in Portugal	Steering Committee and Advisory Board	May / June 2020	Draft Assessment report (D2)
	Stakeholders (authorities / users / further, e.g. patient and industry associations)	October 2020	Meeting document (handout) and presentation at the Stakeholder Workshop
Recommendations	Steering Committee and Advisory Board	October 2020	Draft Recommendations report (D4), accompanied by the D3 report (options to address gaps in CPM)
	Academics participating in the Delphi survey	November 2020	Draft Recommendations report (D4)
	Steering Committee and Advisory Board	December 2020	Draft Final Report (D5), presentation at the Closing Meeting

CPM = centralised procurement of medicines, D = Deliverable

Source and presentation: the authors

2.3 Development and revision of recommendations

An important task of the project was to develop a set of SMART recommendations for policy-makers to optimise CPM in Portugal. The authors considered suggestions made by national stakeholders in the interviews (cf. chapter 2.2.2) and in a stakeholder workshop (cf. chapter 2.3.2). In addition, procurement experts of other European countries provided major inputs for the development of the recommendations (cf. chapter 2.3.1). Comments provided by academics in a Delphi survey were considered to revise and finalise the draft recommendations (cf. chapter 2.3.3).

2.3.1 International expertise

Experiences of a CPM system implemented in other countries (Cyprus, Denmark, Estonia, Italy and Norway) as well as of cross-country joint procurements were considered (cf. Table 2.4). Except for Estonia (in-team expertise available), consultations with procurement experts in the four other countries were held through telephone **interviews**. These interviews were conducted in May and June 2020 and were based on an interview guide. In addition, information on the joint “Nordic tender” of the cross-country Nordic Pharmaceutical Forum was based on interviews that some of the authors had performed for a World Health Organization (WHO) report on cross-country collaborations [14].

The interviews were aimed at surveying learnings from the procurement experience in the selected countries and cross-country collaborations. Furthermore, the interviewees were invited to suggest possible approaches for improvements for CPM in Portugal (for details on the methodology cf. chapter 7.3 in the Annex).

Table 2.4:
Methods – International procurement expertise considered in this study

Country / institution	Methods
National procurement system	
Cyprus	Interview with a civil servant with more than 20 years of experience in national procurement, 28 May 2020
Denmark	Interview with the Director and International Affairs Officer at AMGROS, the Danish Procurement Agency for public hospitals, 10 June 2020
Estonia	Expertise provided by an Estonian procurement expert of who was involved in the project team of this study
Italy	Interview with the Head of Division of the procurement agency CONSIP, 5 June 2020, plus literature
Norway	Interview with the founder of the Norwegian medicines procurement cooperation LIS, 4 June 2020
Cross-country collaborations	
Baltic Procurement Initiative	Expertise provide by the Estonian procurement expert involved in the project team of this study. She is a leading member of the Baltic Procurement Initiative. Furthermore, information was also retrieved from a World Health Organization (WHO) report [14] on cross-country collaborations, which also described the joint procurement of vaccines of the Baltic Procurement Initiative
Nordic Pharmaceutical Forum	Information from interviews with representatives of that collaboration as part of a WHO study of an evaluation of cross-country collaborations [14]

Source and presentation: the authors

2.3.2 Stakeholder workshop

On 8 October 2020, a stakeholder workshop took place – due to the COVID-19 pandemic as an online meeting. Around 40 participants representing different stakeholder groups (public authorities, users, patient and industry associations) participated in the meeting.

The aim of the stakeholder workshop was

- » to inform stakeholders, by presenting the findings of the assessment of the CPM in Portugal and of draft recommendations and
- » to ensure validation, by inviting the participants of the meeting to comment on whether, or not, they agreed with the diagnosis and planned actions.

The stakeholder workshop was held in a “**World Café**” format which was adapted for an online meeting. Four moderated sub-groups discussed and reviewed the findings and draft recommendations.

Overall, **stakeholders shared** the assessment and suggestions for improvement. The participants

- » stressed the importance of *practical clinical expertise* to be considered in procurement procedures,
- » called for *increased transparency* between the institutions and for a *decrease in bureaucracy*,
- » urged the implementation of *performance indicators*,
- » critically discussed a possible *extension of the award criteria* beyond prices (mixed positions on this topic) and
- » called for an improved *dialogue with stakeholders*.

More information on the stakeholder workshop (e.g. methodology, agenda, meeting report, detailed comments) can be found in the Annex (cf. chapter 7.4). The visualisation of the findings and the recommendations presented in these documents provided in the Annex differ from this final report since some changes in the presentation of the findings (e.g. attribution of an identified gap to a different “pillar” of the MAPS framework) and the recommendations were made after the stakeholder workshop.

2.3.3 Delphi survey

A two-stage Delphi survey was performed to obtain feedback on the draft recommendations. The Delphi method was adapted for the purposes of this project, since the aim was to receive comments as a basis for the revision and finalisation of the recommendations. It was not intended to achieve group consensus of the survey participants, which is normally the aim of the Delphi method [15].

Participants were acknowledged **academics** in pharmacy, health policy and health economics, with specific knowledge on medicines and work experience in administration and/or policy advice. Three of them were Portuguese, and a Spanish researcher brought in the “external” perspective from abroad.

In the **first round**, the Delphi survey participants commented **in writing** on the draft report D4 which presented a total of 18 preliminary recommendations. The **second round** took place as an

online meeting on 17 November 2020, in which the participants explained the rationale behind their choices, i.e. whether they agreed with the proposed recommendations and with priority and feasibility assessments. As a preparation for the second round meeting, a summary document, which compiled the responses of the four Delphi survey participants, had been shared in advance with them.

Key comments of the Delphi participants were the following:

- » *Broadly overall agreement.* In general, the Delphi survey participants agreed with most of the recommendations.
- » *Different perceptions related to priorities and feasibility.* It was argued for a larger balance between low and high priority – not all recommendations should be considered high priority.
- » *Redundancy of recommendations.* Some recommendations were considered to be too detailed for a high level policy document. Duplication of a few recommendations was identified, and it was suggested to merge some of them into one strong overarching recommendation (i.e. a recommendation on strategy).
- » *A different way of presenting the recommendations.* It was proposed to present recommendations for two areas: strategy and (high-level) management. In this context, the establishment of a procurement strategy was considered to be the key recommendation. All further action would derive from it.

This input importantly contributed to the revision of the recommendations, which were streamlined and reduced from 18 to seven. The summary of the first round (preparatory meeting document for the second round) and the report of the meeting held in the second round are accessible in chapter 7.5 in the Annex.

2.4 Limitations

The study has some limitations, which are summarised in Table 2.5.

The outbreak of the COVID-19 pandemic during the project period was not only a “force major” challenge from a project management perspective and demanded adaptations in the methods (e.g. with regard to the stakeholder workshop), but may have also impacted public procurement processes and health policy in general, which was surveyed as of the beginning of 2020.

Table 2.5:
Methods – Limitations of the study

Limitation	Description
No methodology for the measurement of the performance of public procurement of medicines	No methodology for the measurement of public procurement of medicines, let alone CPM, exists. Therefore, based on a review of existing assessment tools for a country's pharmaceutical regulatory framework or procurement system (cf. chapter 7.1.1), the authors opted for the MAPS framework, which aims to assess public procurement in general (of any goods and services). The methodology had to be adjusted to account for the specificities of health care, in particular medicines.
Limited availability and consideration of quantitative data	Overall, the MAPS framework has a focus on qualitative indicators, but also suggests some quantitative indicators. It proved difficult to assess quantitative indicators, since basic high-level data were not accessible or could not be easily provided by the procurement agency. This is a limitation of the study, and, at a same time, a major finding (i.e. an identified gap).
Limited number of bids analysed	In this study, five bids (3 AC and 2 AQ) were analysed, with a total of 11 lots for the three AC and 396 lots for the two AQ. For the AQ, a selection of the lots based on stringent selection criteria was investigated.
Perception of stakeholders	Given the focus on qualitative indicators, a major source of information was a large number of interviews with stakeholders. Thus the assessment was impacted by the personal perspective of the interviewees. To make it transparent that, in several cases, personal opinions and impressions were surveyed, the authors included a chapter to report the "perceptions" of the interviewees. The authors asked and sought for further information and data to substantiate the opinions of the interviewees, but only few documents and figures were available given the general lack of quantitative data.
Correctness of information and data	Since a high amount of information and data was gathered through interviews, there is a risk of misunderstanding on behalf of the authors and of misreporting (errors) on behalf of the interviewees. As quality-assurance, the authors asked the interviewees to review the written minutes of the interview. Further validation processes (e.g. review of draft reports by the Advisory Board, presentation of key findings at a stakeholder workshop) were performed to reduce this risk (cf. chapter 2.2.4).
Differentiation between AC and AQ	The Portuguese CPM has two procedures (AC and AQ) which were perceived differently by interviewees. While the report aims to differentiate, this was not always consistently possible, due to limited clarity of gathered information.
Online stakeholder workshop	The stakeholder workshop was originally intended to be organised in the highly interactive format of a "World Café". Due to the COVID-19 situation, a face-to-face meeting could not be organised, and the "World Café" methodology had to be adjusted for an online meeting. Organising moderated break-out sessions was the alternative approach chosen to ensure discussion among the stakeholders.
Shift of priorities for Advisory Board members and further stakeholders due to COVID-19 crisis management	The outbreak of the COVID-19 pandemic occurred in the middle of the project. The authors were privileged to have conducted the on-site interviews before. From March 2020 on, the COVID-19 crisis management required highest attention of the Portuguese stakeholders. Interaction slowed down (e.g. delays in submission of requested data to authors), and the validation processes might have been less rigid than in normal times.
Changes after the survey due to COVID-19	The assessment in this study was based on a survey of information and data in January / February 2020. In response to COVID-19, political decisions (e.g. with regard to funding) and practical changes (e.g. closer collaboration of public institutions) might have been taken. The current situation might differ from the one assessed.

Source and presentation: the authors

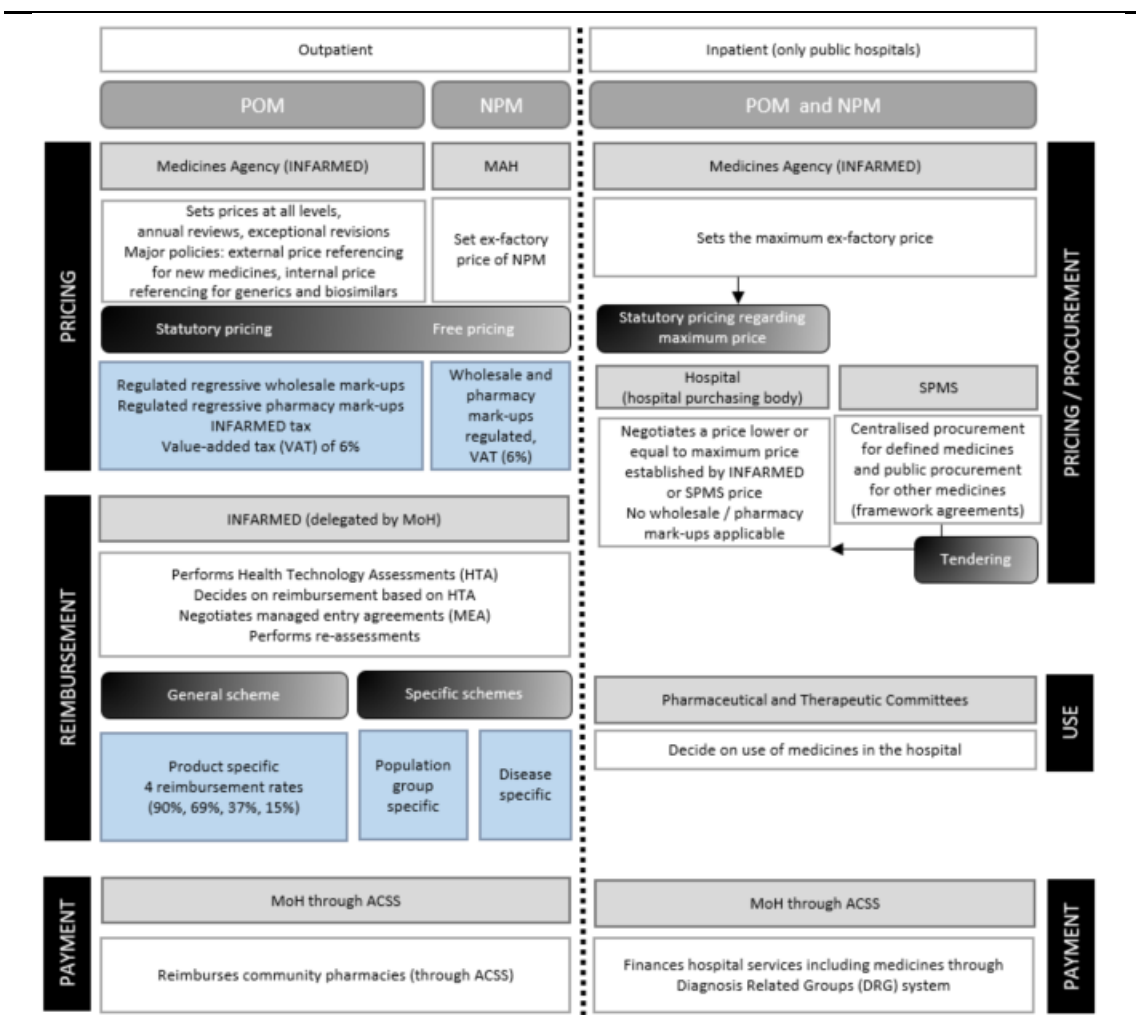
3 Assessment of centralised procurement of medicines

3.1 Country context

3.1.1 Medicines pricing and reimbursement policy framework

With regard to pricing and reimbursement of medicines, the Medicines Agency INFARMED has major competences: It defines the maximum ex-factory prices of all prescription-only medicines used in the outpatient sector and of all medicines for use in public hospitals.

Figure 3.1:
Assessment of CPM – Pricing and reimbursement of medicines in Portugal



ACSS = Administração central do Sistema de Saúde / Central Administration of the Health System, MAH = marketing authorisation holder(s), NPM = non-prescription medicine(s), POM = prescription-only medicine(s), SPMS = Serviços Partilhados do Ministério da Saúde / Shared services of the Ministry of Health
Further abbreviations are directly explained in the graph

Source and presentation: the authors based on a poster prepared by INFARMED for the PPRI Conference 2019 [16]

INFARMED is also responsible for deciding on the reimbursement of medicines (i.e. on the inclusion into the national reimbursement list which is, in principle, applicable for both outpatient and inpatient medicines). The decisions on the reimbursement status of medicines are informed by Health Technology Assessments (HTA) done in-house by INFARMED (supported by an independent commission of external experts who evaluate studies submitted by pharmaceutical companies). For new medicines with high price tags, managed-entry agreements (mostly price-volume contracts) are negotiated between INFARMED and the marketing authorisation holder (MAH) [17, 18]; the outcomes of the deals are kept confidential. List prices of medicines for outpatient use are published but not the list prices of medicines used in hospitals [19].

While price regulation is also applicable for the inpatient sector, in cases of public hospitals, the actual decisions on the use of the medicines are taken at hospital level by the respective Pharmaceutical and Therapeutic Committees. Medicines are procured by the procurement agency SPMS through centralised purchases (AC) or through framework agreements (AQ); in some cases medicines are procured directly by hospitals.

Health care providers, including public hospitals, the procurement agency SPMS and (private) community pharmacies are funded by ACSS. Figure 3.1 provides an overview of the organisation of responsibilities with regard to medicines pricing, reimbursement and procurement.

3.1.2 Public procurement of medicines

3.1.2.1 Public procurement of medicines

Portugal's legal framework on public procurement incorporates, complements and details respective EU (European Union) directives. The key document regulating public procurement in Portugal is the **Public Procurement Code (PPC)**, approved by Decree 18/2008 as of 29 January) that translates EU Directives 2004/17 and 2004/18 into national public procurement legislation (for more information cf. chapter 7.6 in the Annex).

Public procurement of medicines in Portugal is either performed centrally (cf. below chapter 3.1.2.2) or directly by "users" (i.e. hospitals). There are two types of CPM (AC and AQ) and different procedures for direct procurement (cf. Figure 3.2).

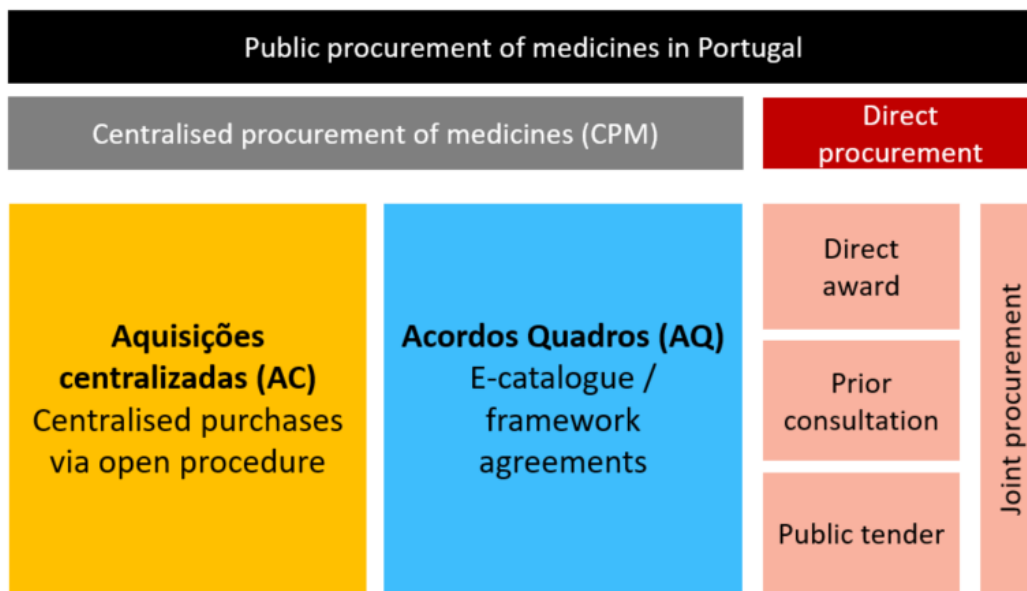
Direct procurement processes differ depending on the contracted sum:

- » Simplified direct award (up to 5,000 euro)
- » Prior consultation (between 5,000 and 75,000 euro)
- » Public tender (above 75,000 euro)

Under specific conditions, medicines provided for centralised processes (AC and AQ) can also be purchased directly.

A variation of the direct procurement is Compras Agregadas (CA / joint procurements), e.g. by a group of hospitals.

Figure 3.2:
Assessment of CPM – Public procurement procedures for medicines in Portugal



Source and presentation: the authors based on literature review, bids analysis and interviews

3.1.2.2 Centralised procurement of medicines

The establishment of CPM in Portugal was a gradual process. A milestone was the Decree-Law no. 1571B/2016 stating that **all SNS institutions are obliged to use the procurement agency SPMS** for the procurement of their goods and services. **SPMS** had been **established in 2010** under the Decree-Law no. 19/2010 as a public entity (Entidade Pública Empresarial / **EPE**). Central procurement of goods including medicines for SNS institutions is one of the tasks of SPMS (for further information cf. chapter 7.6 in the Annex). Before the establishment of SMPS, some purchasing activities at a centralised level were done by ACSS [20].

As shown in Figure 3.2, there are two major types of procedures of CPM: AC and AQ, which are summarised below and in Table 3.1. The procurement agency SPMS is responsible for conducting AC and AQ procedures.

Table 3.1:

Assessment of CPM – Characteristics of the two CPM procedures: AC and AQ

Features	Aquisições centralizadas (AC)	Acordos Quadros (AQ)
Type	Open procedure	E-catalogue / Framework agreement
Scope of medicines	Defined active substances subject to AC (indicated on a list as of 2016) and voluntary-based, typically medicines which have no or little competition	Typically medicines with competition (in particular off-patent medicines, also on-patent medicines in some cases ¹)
Stages	1 stage process coordinated by SPMS (upon input of users)	2 stages: 1 st stage: approval of eligible suppliers and determination of price range by SPMS 2 nd stage: individual call-off by users
Suppliers	Until 2019: one supplier From 2020: 1–2 suppliers, where possible (move away from the “winners-takes-it-all” principle to “two-winners” approach)	Several suppliers per call, based on a list of qualified suppliers (accreditation done by SPMS)
Country coverage	Winning bidder (or bidders in case of two) to cover the needs of the whole country	Suppliers to deliver the amount requested by individual users in their call-offs
Duration	Mainly 1 year	Up to 4 years
Price	Fixed price	Price range (1 st stage) Final price (2 nd stage) in the individual call-offs
Volume	Expected (fixed) maximum volumes	No fixed or expected volumes
Obligation to purchase	Need to purchase most of the volumes as stipulated in the call for tender	No obligation to purchase (individual call-offs)

¹ Some on-patent medicines were found to be in both AC and AQ procedures.

Source and presentation: the authors based on documents available in “Vortal” and interviews

Aquisições centralizadas (AC): centralised purchases via open procedure

The procurement agency SPMS performs centralised purchases (AC) for **defined active ingredients** (indicated on a list) through open procedure.

In preparation of the call, users (hospitals and ARS) are obliged to announce their forecasted needs (**needs assessment**) for these medicines around June of the previous year. The procurement procedures are then initiated by SPMS in autumn upon confirmation of the availability of the funds by the users.

One **bidder** (for on-patent medicines) is awarded a contract for the duration of the respective calendar year. Where possible, the “winner-takes-it-all” rule is no longer applied, and from 2020, two suppliers are given contracts.

The winning tenderer (or tenderers in the case of two suppliers) are expected to supply the whole country, and the users are expected to procure the amounts as indicated in the needs assessment.

Although the **Public Procurement Code (PPC)**, which translated EU legislation into the national framework, allows the application of MEAT (Most Economically Advantageous Tender) criterion (which may consider further aspects beyond price), in practice the price is applied as the sole criterion.

SPMS is allowed to also centrally purchase further medicines not listed for AC. This is done following requests of several hospitals to organise AC as a voluntary process to which SPMS has responded.

Acordos Quadros (AQ): procurement through e-catalogue / framework agreements

An e-catalogue resulting from framework agreements is a common procurement tool for medicines in a competitive area. It sets a frame in a first stage (price range for a product offered by several interested suppliers considered eligible) and allows individual call-offs for defined (smaller) amounts by individual contracting authorities. Framework agreements are typically used for off-patent medicines. While AQ are mainly targeted at off-patent medicines in Portugal, AQ have also been created for some on-patent medicines.

In the **first stage**, SPMS concludes a framework agreement for the period of up to four years with several suppliers of medicines of the same active substance (or for therapeutically equivalent medicines). Eligible suppliers are pre-qualified by SPMS. A price range defining a minimum and a maximum price for the product constitutes a key part of the AQ.

In the **second stage**, users can individually launch call-offs under the established framework agreement with the pre-qualified suppliers. This call-off phase is characterised by the following procedural steps:

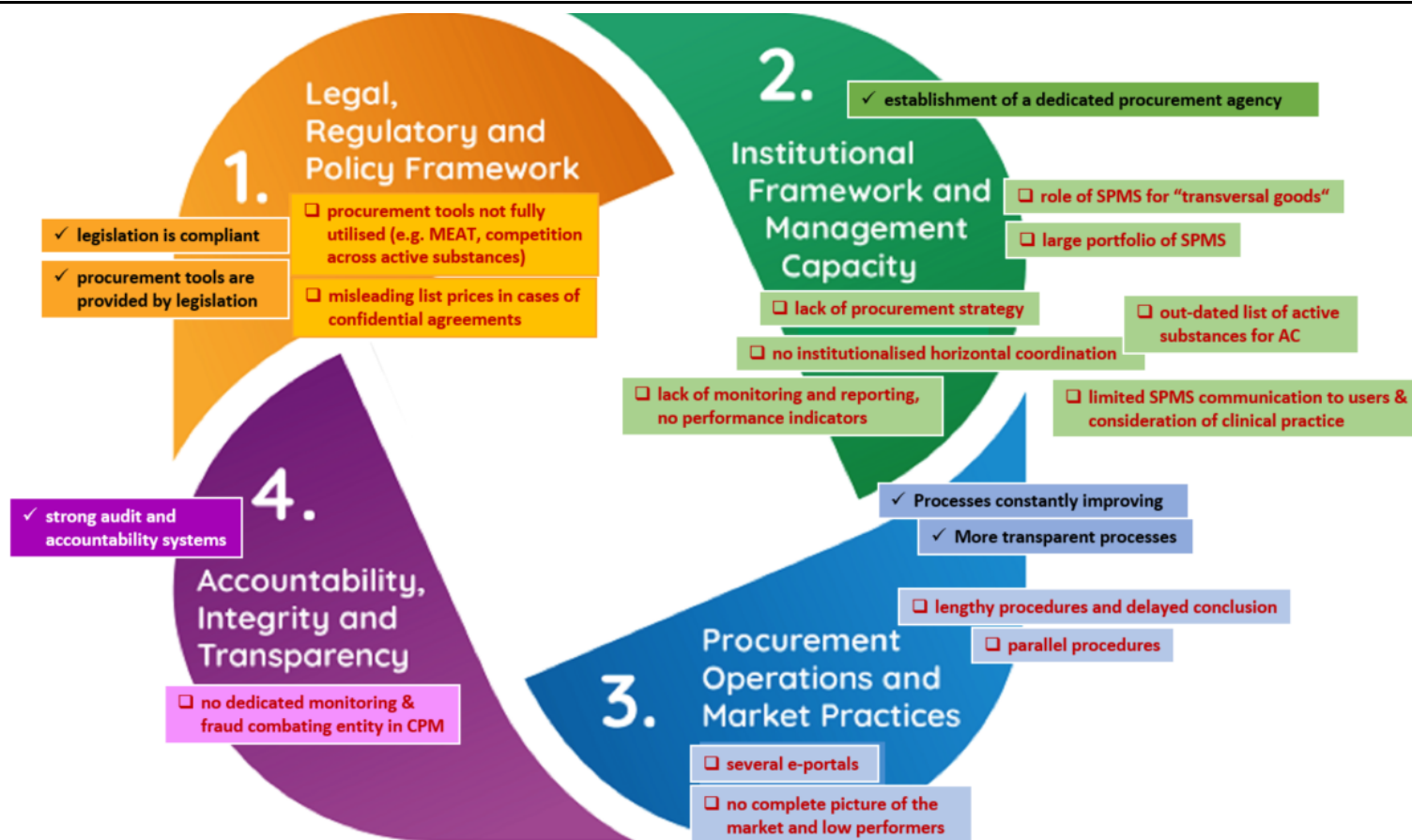
- » For the medicine they aim to procure, users send an invitation to all suppliers listed.
- » The suppliers listed are invited to submit a new proposal within the price range defined in the first stage. It is possible for the suppliers to not respond to the call.
- » The bidder offering the lowest price within the price range (bids above and below are excluded) is awarded the contract.

3.2 MAPS-based assessment

Based on information gained through literature review, analysis of procurement documents and in particular interviews, major indicators proposed by the MAPS framework were investigated. The focus in this chapter is on qualitative indicators. Figure 3.3 provides a summary of the assessment and identified gaps for the qualitative indicators (for the detailed list of indicators see chapter 7.1.2 and for the results in further detail in chapter 7.7 in the Annex). The subsequent chapter 3.3 on the bids analysis will focus more on quantitative indicators.

Figure 3.3:

Assessment of CPM – Summary of the assessment of CPM in Portugal based on the MAPS taxonomy, 2020



Source and presentation: the authors based on literature review, analysis of procurement documents and mainly interviews

3.2.1 Legal, regulatory and policy framework

As far as the authors could assess based on the study of the PPC and the expert opinions of the interviewees, the legal and regulatory framework of CPM is **compliant** with national and international standards. Translating the EU legislation into national law, the Portuguese law offers a **range of procurement tools** but they appear **not** to be **fully utilised**.

As the PPC addresses public procurement in general, it does **not take into account the specificities of the health sector**, and so medicines should be purchased like any other supply. Specific procedures would be needed to ensure consideration of the special circumstances of health care and pharmaceutical system.

Limited use of procurement tools

Several users remarked that CPM would **not sufficiently account for changes in treatment protocols and changes in the market**. There were mixed perspectives on the award criteria. The PPC asks to select the most economically advantageous tender (MEAT). MEAT allows taking into account other factors than the price. In practice, SPMS opted for the “lowest price” as the sole award criterion (cf. also chapter 3.3.1 in the bids analysis). Some interviewees, including hospital pharmacists, would prefer considering further award criteria (e.g. quality-related aspects).

Another example for limited utilisation of procurement tools concerns the competition between active ingredients of similar clinical effects (“**analogue competition**”) which was reported not to be done by SPMS. This could contribute to higher savings. But analogue competition was reported from earlier procedures of direct procurement of hospitals.

Biologicals (and thus biosimilars) were mentioned as a specific group which would require more attention. Marketing authorisation holders of biosimilar medicines expressed concern that call-offs would be mainly made for the originator medicines. Currently, a switch is only allowed after six months, which might have the effect that biosimilar competitors who were awarded the Portuguese market could lose attractiveness. If biosimilar companies withdrew from the market, this could contribute to shortages.

Misleading list prices in cases of confidential discounts

Interpretation of the current legal framework is very strict on confidentiality issues in a way that **discounted medicines prices** negotiated between INFARMED and the marketing authorisation holder are **not shared with SPMS**. So SPMS has limited information for the preparation of procurement procedures and uses the official list prices as a starting point (base price) for the procedure (cf. chapter 3.3 on consequences on prices and savings).

3.2.2 Institutional framework and management capacity

A major asset of the CPM system is the **establishment of a dedicated procurement agency**. This was officialised in 2010 with the establishment of SPMS. However, interviewees raised doubts with regard to the **large portfolio of SPMS** (which has other tasks in addition to CPM, cf. chapter 7.6) as this may incentivise cross-financing from CPM to other activities in SPMS. In addition, in the area of public procurement beyond medicines (for “transversal goods”), possible redundancies between SPMS (in charge of procurement of goods and services for SNS entities) and eSPap (in charge of procuring goods and services for the public sector except health and defence) may arise. In an interview, it was questioned whether or not there is a need for **two procurement agencies for “transversal goods”**, i.e. homogenous goods and services e.g. electricity, that was procured by different public entities, in particular as SPMS was perceived rather as “middleman” for the services of eSPap related to “transversal goods”.

With regard to CPM, the three key **public authorities** at management and operational levels are:

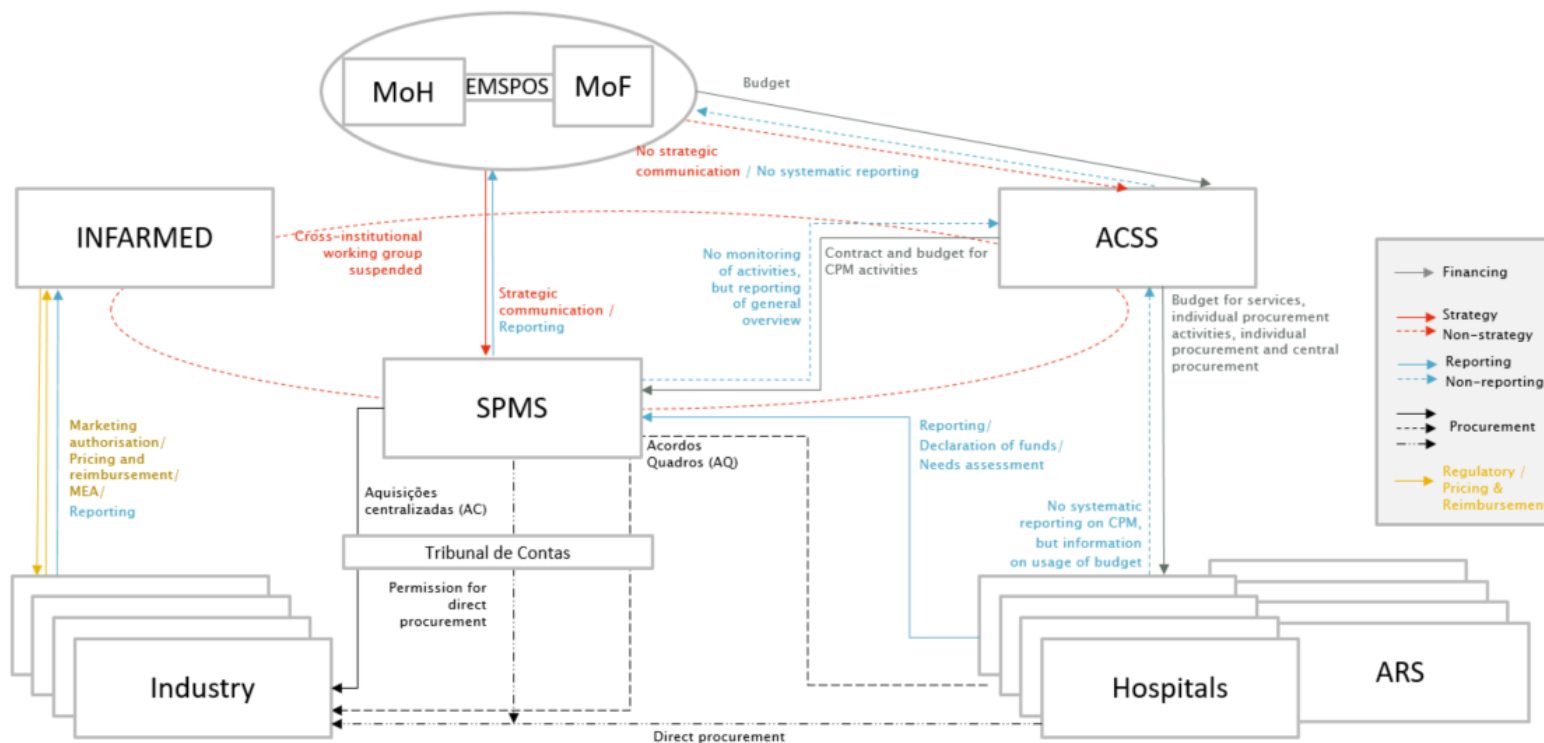
- » **SPMS** as the procurement agency, thus the key institution in charge of purchasing medicines, as a service provider to the users (hospitals and ARS) and as key contact to the suppliers (**operational** function),
- » **ACSS** as the public payer and contractor of SPMS, thus the key institution for commissioning SPMS and funding their activities (**coordinating** function); in addition, ACSS also defines the financing schemes for hospitals and primary care, sets budgets and makes payments,
- » the Medicines Agency **INFARMED** is not directly involved in CPM; however, due to its responsibilities for marketing authorisation, pharmacovigilance, reimbursement (i.e. selection of medicines eligible for funding), pricing (including conclusion of managed-entry agreements / MEA) and consumption monitoring it has valuable expertise on medicines and their suppliers (**expert** function).

At the **strategic level, guardianship** for the above-mentioned authorities lies with:

- » the Ministry of Health (MoH / Ministério da Saúde) which is in charge of regulation, planning and management of the SNS and
- » the Ministry of Finance (MoF / Ministério das Finanças) which is responsible for the national budget and its monitoring and control.

For an effective functioning of CPM, clarity of the role, mandate and responsibilities of each of these institutions is needed. Institutions at strategic level are responsible for vision and strategic guidance, while the other institutions are responsible for management and activities at operational levels. The assessment of the institutional framework for CPM visualized in Figure 3.4 points to gaps related to the clarity on the roles and responsibilities of the institutions, lack of strategy and, also as a result, lack of coordination, collaboration, reporting and monitoring.

Figure 3.4:
Assessment of CPM – Institutional framework of CPM in Portugal, 2020



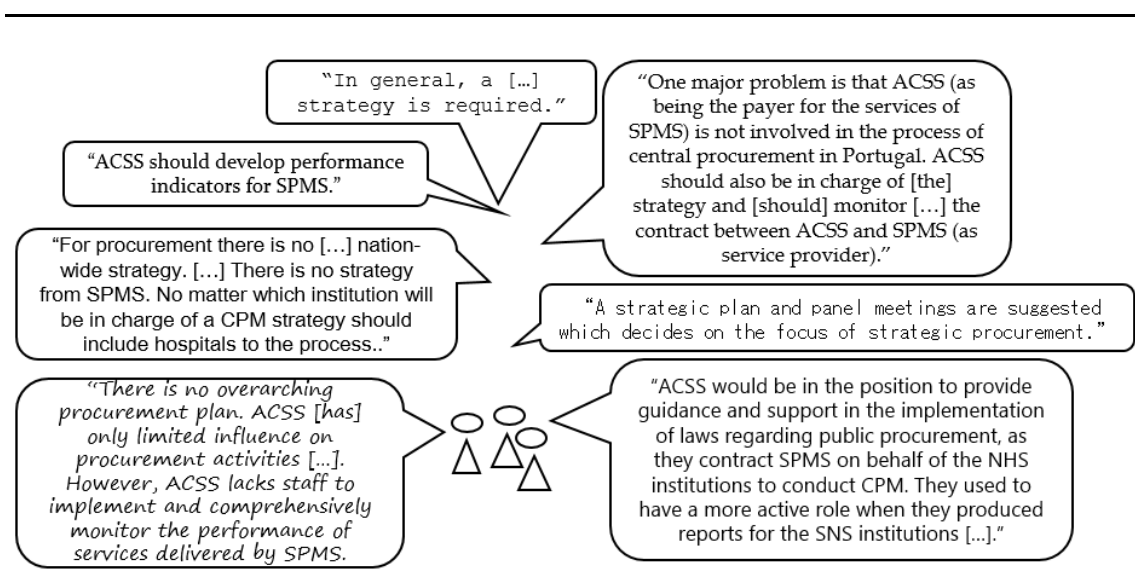
This simplified illustration focussed on public procurement of medicines. Other, more general relations between institutions (e.g. accountability of INFARMED to the MoH) are not displayed when they were considered of minor relevance for CPM in Portugal. For abbreviations please refer to the list of abbreviations.

Source and presentation: the authors based on literature review and interviews

Lack of overarching procurement strategy

Several interviewees raised the topic of a **missing procurement strategy**, including missing mechanisms for strategic procurement (see selected quotations in Figure 3.5). In this sense, it was pointed to “missing links” between MoH and MoF (as key public authorities at a strategic level) and ACSS (as the institution commissioning procurement) as well as between ACSS and SPMS. The necessity to **strengthen the (strategic) role of ACSS as a contractor** was highlighted by different stakeholders.

Figure 3.5:
Assessment of CPM – Quotations of interviewees on the procurement strategy, January / February 2020



Source and presentation: the authors based on information gathered in interviews

Lack of institutionalised coordination of public authorities (horizontal communication)

Several interviewees, including representatives of the three public authorities, expressed the need for an improved coordination between public authorities involved in CPM and/or pharmaceutical policies, thus **SPMS, ACSS and INFARMED**. Improved coordination was considered as a key element in a procurement strategy.

A **working group** of ACSS, INFARMED and SPMS existed with the aim to optimise procedures. Representatives of the three institutions reported to have appreciated the collaboration in this working group and the improved exchange of information. However, the working group had been established as an initiative of committed staff (cf. also interviewees’ quotations on coordination and collaboration in Figure 3.6), and its activities discontinued in 2019. This points to a gap in institutionalised communication and coordination between SPMS, ACSS and INFARMED.

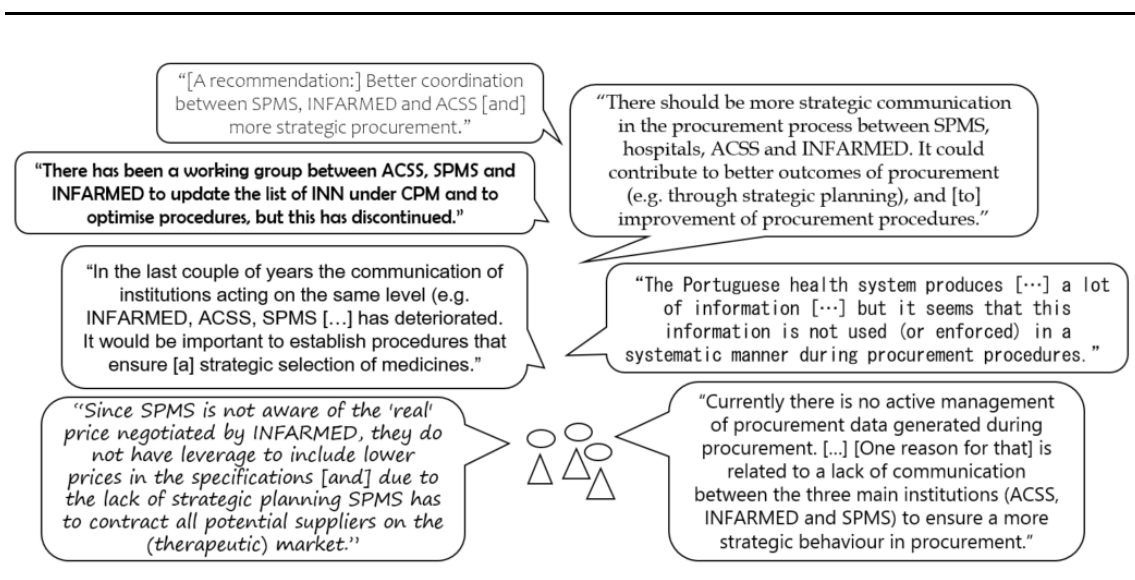
Outdated list of active substances for AC

The working group would have also been in charge of updating the list of active ingredients which are subject to AC.

Users urged an **update of the list of active ingredients under AC** since it was last revised in 2016. This list would require adjustments to account for clinical changes. Overall, it was suggested to **extend the number of active ingredients under AC**. One interviewee proposed including all medicines, except for therapeutic exceptions, into AC.

Figure 3.6:

Assessment of CPM – Quotations of interviewees on coordination and collaboration, January / February 2020



Source and presentation: the authors based on information gathered in interviews

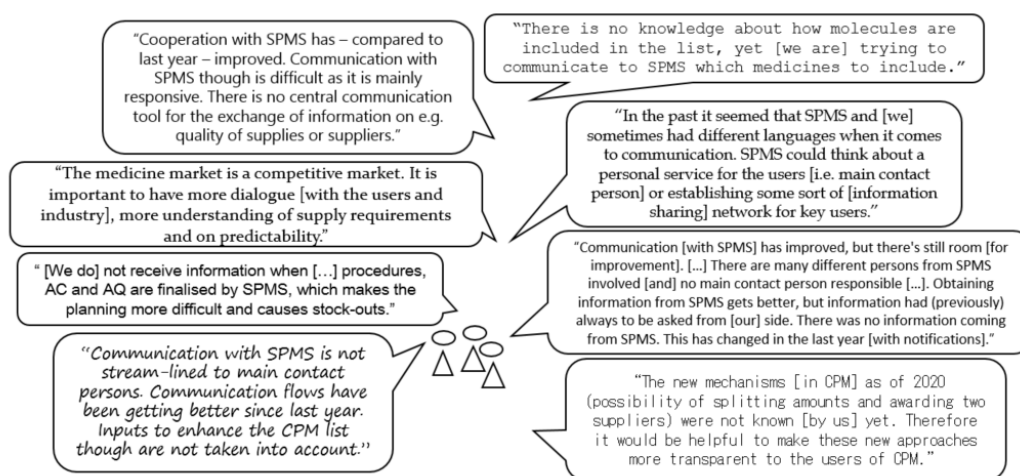
Limited communication of SPMS to users and limited consideration of clinical practice

Communication with SPMS was reported to mostly **rely on the initiative of users**. In some interviews, a lack of direct information on relevant changes in the system was mentioned, while it was stressed that the situation has considerably improved in recent years. Though it was reported that SPMS usually responded (normally in a course of a few days), SPMS communication was, in general, **not perceived as particularly service-oriented**.

Some interviewees suggested establishing a main focal point (some reported that they had **several contacts**) for each user and/or to create a network for the exchange of information between users e.g. on the quality of suppliers. Users requested **active information** from SPMS on changes in the AC list (and the rationale behind the changes) as well as on any new mechanisms to the system (cf. also Figure 3.7).

Some interviewees working in hospitals were critical about the capacity of SPMS staff who, normally, do not have clinical experience. It was argued that exposure to practice would be needed to optimise CPM. Users (mainly hospital pharmacists) did not request clinical expertise of SPMS staff but they **called for the involvement of experts from the field** (e.g. in the development of procedures), and they highly acknowledged that in recent months SPMS consulted some of them in the development of new framework agreements.

Figure 3.7:
Assessment of CPM – Quotations of interviewees on communication with SPMS, January / February 2020



Source and presentation: the authors based on information gathered in interviews

Lack of monitoring and reporting

The above-mentioned “missing links” between institutions as well as the lack of institutionalised communication are possible reasons for the **lack of monitoring and reporting mechanisms** related to CPM. While SPMS does some reporting to the MoH (and also MoF), ACSS appears not to be in the loop despite being the commissioning authority for SPMS. A possible cause may be the **lack of (budgetary and staff) capacity of ACSS** to fulfil its oversight role.

Procurement systems are usually measured by key **performance indicators (KPI)**. These performance indicators are lacking for the Portuguese CPM, and high-level data for quantitative indicators required for this study were not readily available. Overall, there appears to be a lack of quantitative data collection and its sharing (e.g. for research and evaluation purposes).

3.2.3 Procurement operations and market practices

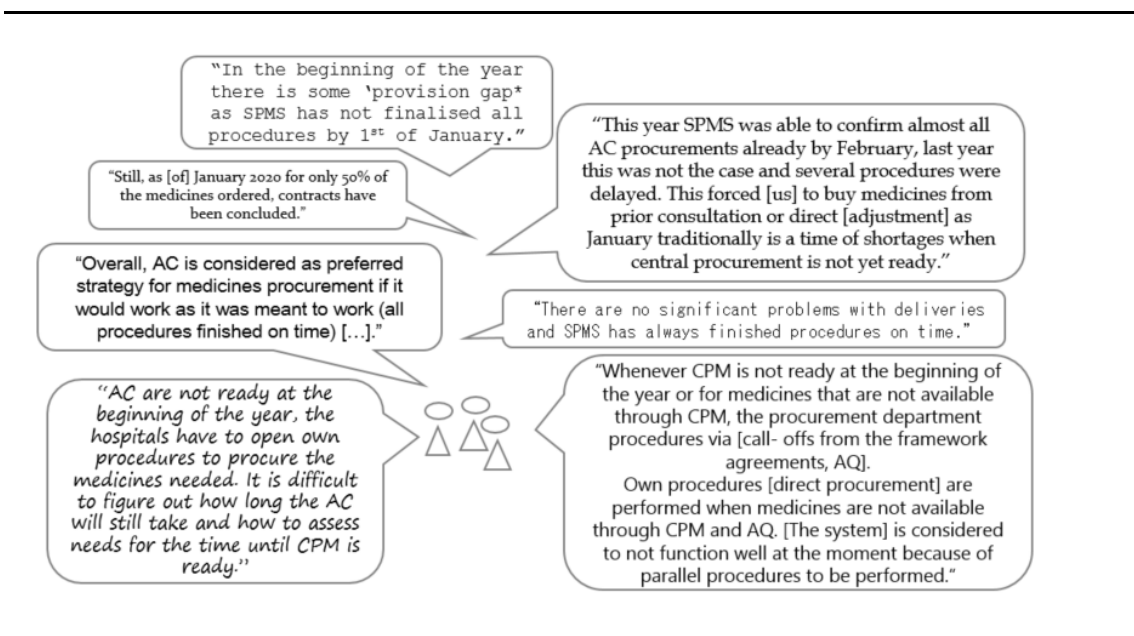
This MAPS “pillar” was the area in which most gaps and weaknesses were identified. It reflected the relative novelty of CPM in Portugal, with lessons learned in the starting phase. While progress over time was reported, there is potential for improvement in this area.

Lengthy processes and delays in the conclusion of procedures

Despite acknowledged improvements, AC procedures were still perceived as **lengthy and bureaucratic processes**.

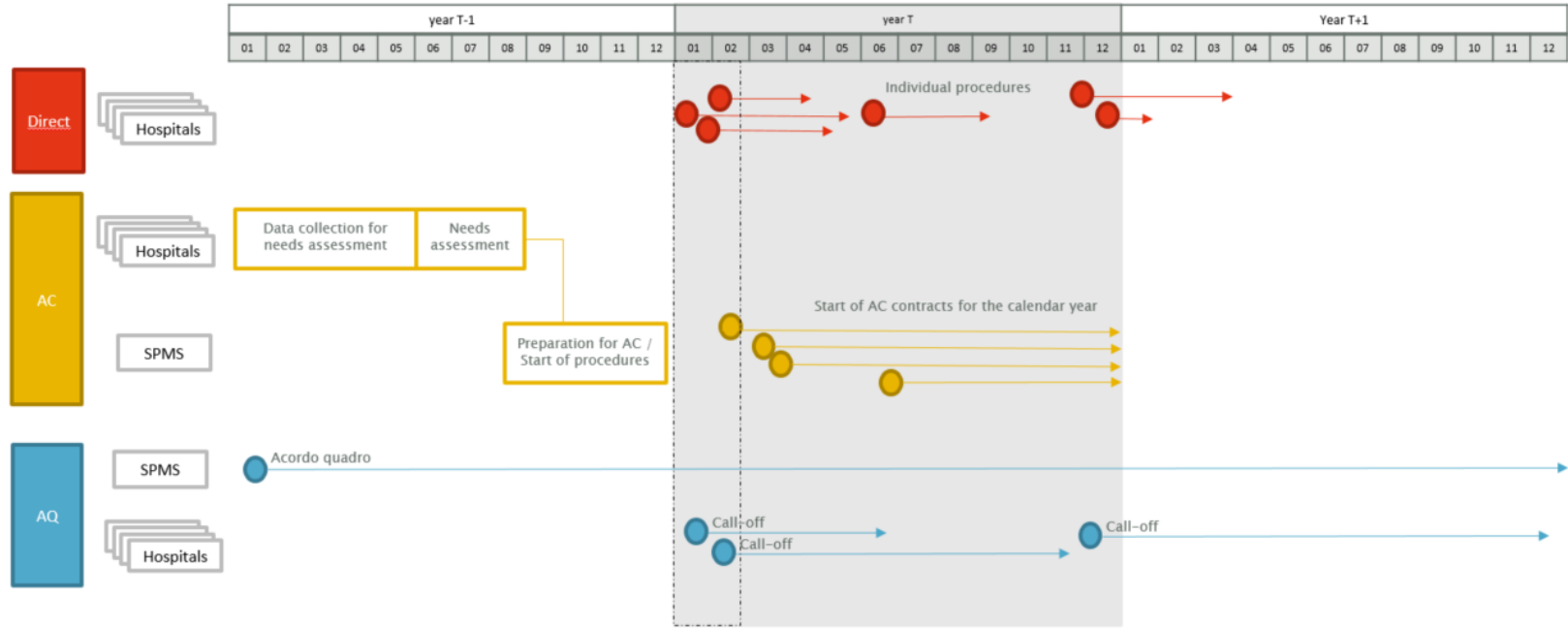
AC procedures start more than six months in advance. Major efforts are put on the **needs assessment** from the users which is done annually, as a two-step approach: First, the needs assessment is done internally in the hospitals / ARS (involvement of pharmacy and procurement units) around June, and filled files are submitted to SPMS by the end of August. The needs assessment sent to SPMS must be accompanied by the procurement mandate and a confirmation of funds. In several cases, procedures and contracts were reported to **not have been concluded on time**. As one of the coping strategies, direct procurements are launched by the users in parallel to bridge the gap in medicines supply at the beginning of the year (cf. Figure 3.8 on selected quotations and Figure 3.9 on parallel processes).

Figure 3.8:
Assessment of CPM – Quotations of interviewees on delays in the conclusion of procedures
January / February 2020



Source and presentation: the authors based on information gathered in interviews

Figure 3.9:
 Assessment of CPM – Parallel procurement processes for medicines in Portugal, 2020



Source and presentation: the authors based on literature review and interviews

Delays in AC procedures may also pose a **budgetary problem** for hospitals (funding challenges and issues of budgetary circles), as they have to reserve a certain amount of the budget according to their needs assessment, and are not flexible for other purchases.

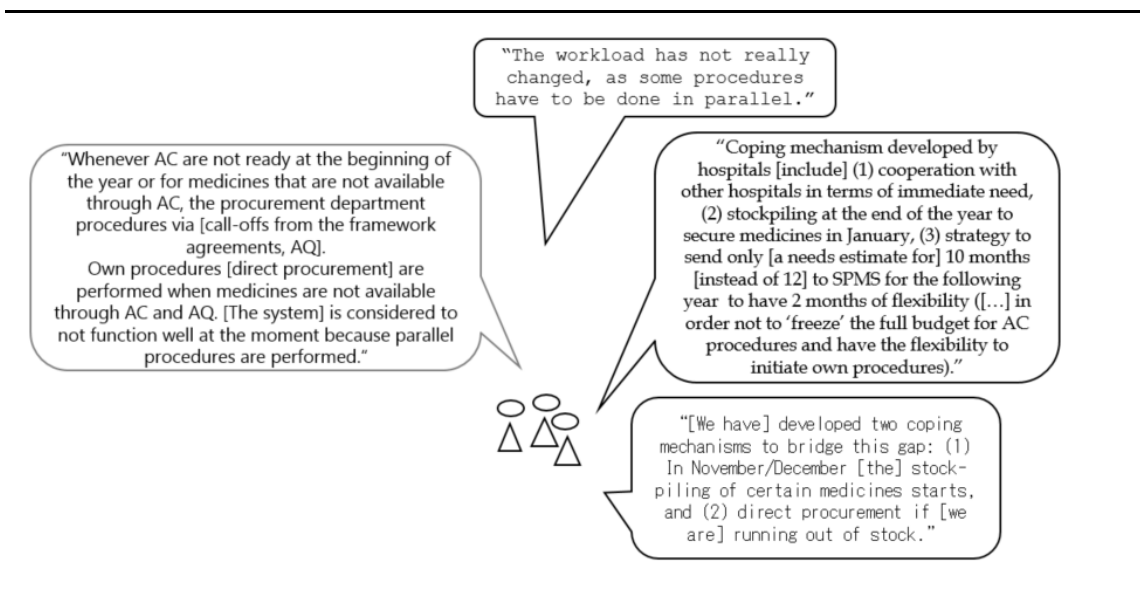
Parallel procedures as one response to delays

In response to the delays in AC, users developed different **coping strategies**, in particular to handle the time gap at the beginning of the year. Parallel procedures by using AQ (if possible) or launching **direct procurements** (more frequently) are the major mechanisms to bridge the gap. **Stockpiling**, **cooperation** with other users and **underreporting** to the needs assessment for AC are further options that some hospitals reported to apply (cf. Figure 3.10).

Some users reported increased **workload** because of the parallel procedures, which can undermine possible reductions in workload due to CPM in general (see also chapter 3.4 on interviewees' perceptions on workload).

Figure 3.10:

Assessment of CPM – Quotations of interviewees on users' reactions to delays in the conclusion of procedures, January / February 2020



Source and presentation: the authors based on information gathered in interviews

e-Procurement via several platforms

In principle, e-procurement is highly **appreciated** by users and industry. However, a major gap is the existence of **several e-procurement platforms** to manage CPM (five major portals, with "Vortal"

used by SPMS being the most relevant one). As a result, users have to register three times (on their own platform, on base.gov for contracts and with SPMS).

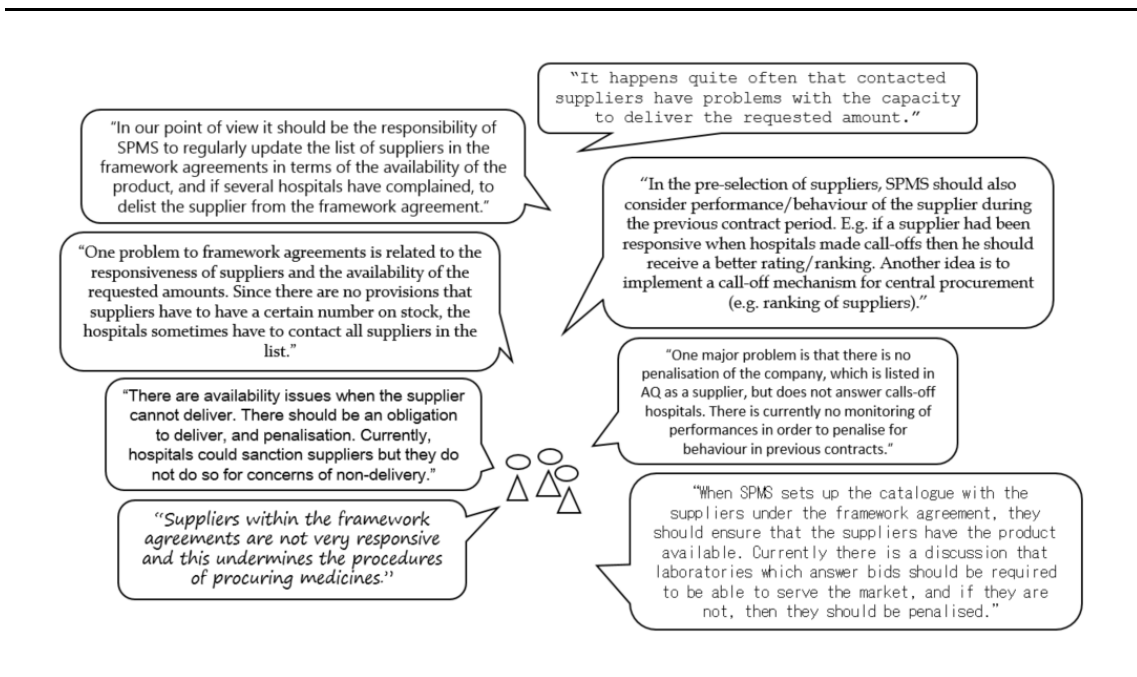
Also, some **features** of the procurement / contract platforms **could be improved**; for instance, tenderers are asked to provide attachments several times.

No full picture of the market and low performers

SPMS has not yet introduced a formal procedure for **market consultations**. Suppliers indicated that SPMS were conducting the inquiries before procedures were launched, but they were rather informal and mainly for the purpose of having the input for the technical specifications. Therefore, market research may benefit from a more institutionalised approach.

Users missed a rating or certification of suppliers and also the enforcement of sanctions of low performers (cf. Figure 3.11). The latter are those suppliers who do not have the capacity to deliver, and/or who do not respond (e.g. to call-offs). It would be appreciated if SPMS shared information on performance of suppliers with users and also regularly excluded **low performance suppliers**. Overall, the qualification criteria for bidders were considered easy to meet (IRS declaration and social insurance declaration).

Figure 3.11:
Assessment of CPM – Quotations of interviewees on possible strategies for addressing low performance of suppliers, January / February 2020



Source and presentation: the authors based on information gathered in interviews

In some cases, successful tenderers were **small businesses** and they were not able to supply the whole Portuguese market.

3.2.4 Accountability, integrity and transparency of the public procurement system

Overall, principles of accountability, integrity and transparency of the public procurement system in Portugal, including CPM, were reported to be in place and were found in legislation. Pressure from doctors was shifted from the hospital (pharmacy and procurement departments) to a centralised level.

More targeted monitoring and combating of fraud

Systems for fraud and corruption prevention, monitoring and combating are in place. However, it needs to be analysed whether or not these need to be more aligned to the specificities of CPM, as suggested by some (e.g. granting a specific mandate for fraud monitoring of CPM to an independent institution).

3.3 Bids analysis

3.3.1 Assessment of efficiency, competitiveness and prices

Selected bids were analysed in four areas (cf. Figure 2.4 in Methods chapter 2.2.3):

- » appeals by tenderers,
- » rejection of bids,
- » competition and
- » medicines prices and savings.

Appeals by tenderers

Inefficacy in procurement procedures can be assessed through the indicator “appeals by tenderers”. Numerous appeals that are presented by tenderers before a bid is awarded may significantly prolong procurement processes. Appeals also increase the risk of delayed signature of the contracts. These delays challenge delivery schedules, and stocks may not be available when needed. Additionally, appeals contribute to increased workload for procurement specialists and lawyers since a justification of the contracting authority’s position is required or new procedures have to be initiated.

For the selected bids (both AC and AQ) three different causes for appealing bids were identified:

- » **Technical error:** A competitor has not properly signed the bid documents. The appealing party requested to exclude the competitor from the procedure.
- » **Incorrect base price:** It was argued that SPMS had not calculated correctly the base price (expected contract value). The appealing party requested to consider their input and feedback in the next procedures.
- » **Patent issues:** SPMS launched a procedure open for competition although one indication had still been on-patent. The appealing party requested more transparency in the procedure and a division of the volumes into two lots, with one lot being open for competition and another one solely for the indication under data exclusivity.

Appeals caused by technical errors point to the need to explore possibilities to simplify the bid submission and possible amendments in legal grounds to avoid similar situations in the future. Appeals caused by incorrect base price calculations or patent issues indicate the need for more transparency and dialogue with suppliers. Before launching the procurement procedures, it should be ensured that there are no issues regarding the calculation of the base price and related to patents.

Rejection of bids

For procurement procedures reaching the stage of the contract award, the rejection of bids was found to have been applied legally correctly in the samples analysed. Nonetheless, for the three selected open procedures, 10 bids out of a total of 27 bids were rejected (no information available for the two AQ).

While acknowledging the small sample size, the rejection of one third of all bids points to a potential issue. The main reasons and potential consequences for the rejection of the bids are:

- » **The offered price of the bid exceeds the base price:** In the analysed sample, six out of the ten rejected bids were rejected because the offered price was too high (i.e. exceeding the base price). While a procurement system can deal with a few rejections, a rather high share – as in this case – points to issues related to the calculation of the base price (i.e. possibly incorrect calculation of the list price). This may lead to (excessive) price pressure. As a result, the participation rate in the procurement procedures is likely to decrease over time and therefore competition decreases.
- » **No proof (validation) of stock availability** in accordance with the terms of the procurement: Four of the ten rejections in the sample of AC were attributable to this. In cases of lack of stock availability as a reason for rejection, it could be beneficial to analyse the reason(s) for the absence of a proof (e.g. more time needed by marketing authorisation holders to prepare deliveries, especially in cases of higher volumes). A mutual understanding of the central procurement body and the suppliers operating in the market would be required in terms of minimum time needed between the signature of the contract and the deadline for first deliv-

eries. Unsuccessful tenderers having built up “preparedness stock” may contribute to a decline in price levels as they need to sell quickly. This could incentivise parallel procedures at users’ level or impact the base price of the next procurement period.

Competition

The indicator “degree of competition” can be assessed by the **participation rate**. It is defined by the number of marketing authorisations (MA) in the country in comparison to the number of bids comprising these MA.

Box 3.1:

Assessment of CPM – Examples of different participation rates in the studied bids

Example 1: Lots containing the active ingredient “entecavir”

While eight MAH had been registered for each presentation of 0.5 mg and 1 mg entecavir, respective lots for this active ingredient (0.5 mg presentation in AC and 1 mg presentation in AQ) showed differences in the participation rates: Seven MAH participated in AQ while only four participated in the AC procedures.

As an open procedure (AC) aims to find one contractor (supplier) for the whole country’s needs, it may be assumed that not all MAH are prepared to deliver volumes in this magnitude. Therefore, it could be beneficial to consult the market and explore the reasons for the hesitancy of the MAH to participate in the AC.

Despite the higher participation rate for AQ than AC in this illustrative example, AC prices were approximately 24% lower than for AQ (based on 1 mg unit price). In addition, if the bidders with the lowest prices in AQ will eventually not participate in the second stage (call-off), hospitals risk to purchase the medicine at a six times higher price (originator) than in the open procedure. This highlights the importance of studying the indicator “participation rate” in connection with other indicators.

Example 2: AC for bortezomib 3.5 mg

In the AC for bortezomib 3.5 mg, only 3 out of 15 registered MAH participated. This tender had a price for the winning bid, which was nearly half of the price of the base price. Despite this successful outcome from the contracting authority’s perspective, the underlying reasons of the low participation rate should be investigated. The low prices point to possible pressure on prices, which could over time reduce competition in the market and negatively impact access.

It should be noted that even if a medicine is not marketed in Portugal, MAH may still be willing to participate in a procurement procedure. In this respect, procurement specialists would benefit from learning about the reasons for the decision of companies as to whether they aim to market, or not, because this allows for better forecasting on the participation rate and thus the degree of competition.

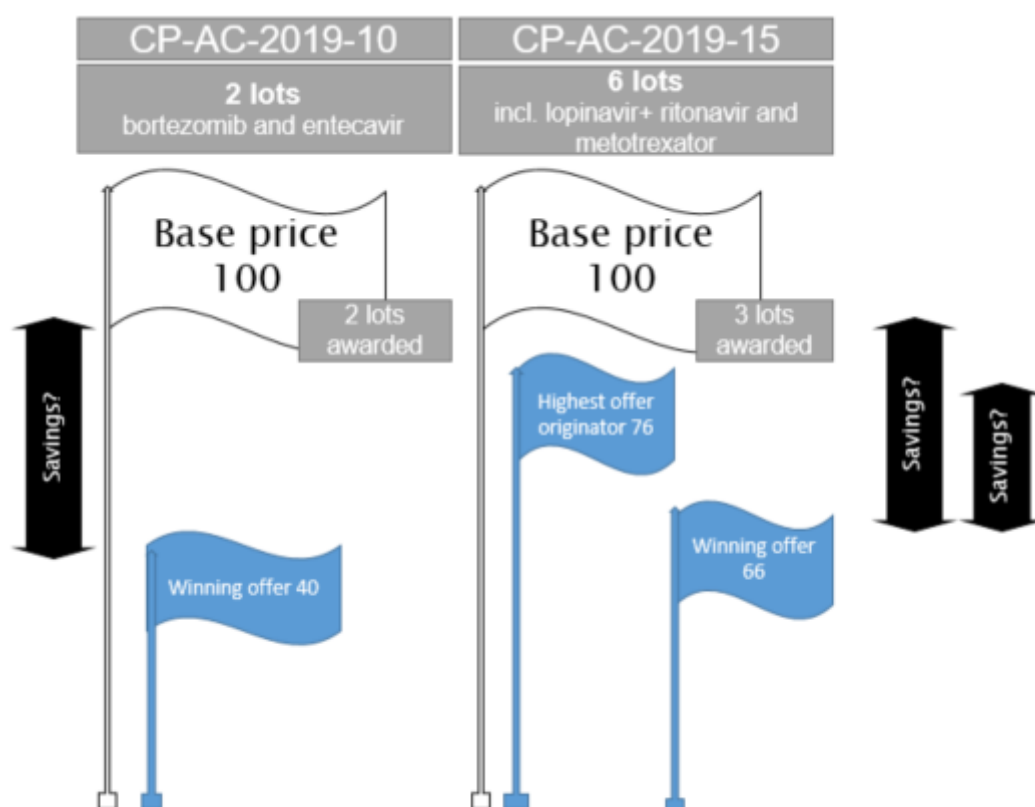
In the analysed bids, the **participation rate** was **between 50 to 90%**. However, it was considerably lower for AC procedures than for AQ.

Medicines prices and savings

In centralised procurement procedures in Portugal, the price is used as the sole award criterion – this information, shared with the authors in the interviews, was also confirmed by the sample of analysed bids (no other award criteria identified).

Figure 3.12:

Assessment of CPM – Impact on prices and savings illustrated by two AC procedures



Assumed base price instead of actual indicated base prices is taken in this example.

Source and presentation: the authors based on the selected AC procedures

Since the second half of 2019, procurement decision documents have included a paragraph on savings that were calculated by comparing the base price² to the price of the successful bid³.

² In the example, the base price corresponds to either the lowest price that had been previously paid by the SNS institutions, or it is calculated by applying a 30% reduction on the lowest price that had been previously paid by the SNS institutions.

³ Different methods to calculate the base price (e.g. different "base" market prices, price of the previous period, price identified in the market consultation, confidential price, AC price, QQ price,...) will result in different figures on the savings.

Figure 3.12 summarises the achieved prices in the selected AC bids and their impact on savings.

The three selected AC were also compared to the two selected AQ, selecting highly competitive lots (CP 2019/40, lot “emtricitabina + tenofovir 200 + 245 mg”) and CP 2019/61, lot “entecavir 1 mg”).

Table 3.2:

Assessment of CPM – Findings on key quantitative performance indicators for the analysed bids

Types of contract	AC			AQ	
Contract notice	CP-AC-2019-10 (bortezomib and entecavir)	CP-AC-2019-15 (incl. lopinavir+ ritonavir and metotrexato)	CP-AC-2019-18 (dasatinib)	CP 2019-40 (ARV medicines)	CP 2019-61 (miscellaneous medicines)
Number of lots in total & awarded¹	2 (2)	6 (3)	3 (3)	60	366
Efficiency indicators					
Appeals/oppositions² (total)	1	1	1	–	1
Technical error	1	–	–	–	–
Incorrect base price	–	1	–	–	–
Patent issues	–	–	1	–	–
Rejections (total)	1	3	6	n.a.	n.a.
Offered price above base price	1	2	3	n.a.	n.a.
Lack of proof of availability	–	1	3	n.a.	n.a.
Competitiveness					
Participation rate ³	23/7 (both lots available)	3/2 (only for 1 lot available: lopinavir + ritonavir 200mg+50mg)	6/4 (only for 1 lot available: dasatinib 100mg)	14/10 (data based for only 2 lots available)	9/8 (data for only 2 lots available)

AC = aquisições centralizadas (open procedure), AQ = acordos quadros (framework agreements), ARV = antiretroviral, n.a. = no data available given the high number of lots and bids submitted

¹ Data in bracket relate to lots awarded

² 2 of the 4 cases started as oppositions and continued as appeals

³ First figure: total number of MAH, second figure: number of submitted bids of different MAH. These pieces of information were provided by SPMS in response to requests of the authors.

No information on medicine prices or savings is provided due to confidentiality issues.

Source and presentation: the authors based on the bids analysed and the responses provided by SPMS to authors' requests

For both lots, the bids with the lowest prices (first stage) had prices three times lower than the base price. Although the final price will be determined in the call-off contracts (second stage), this indicates considerable variations between base price calculations and the actual bids prices.

The rather large differences between base prices and prices of actual bids points to the existence of possible paybacks or other similar financial arrangements (“managed entry agreements”). If price information is not fully transparent between SPMS and other SNS institutions, the savings calculations risk not reflecting the actual (lower) savings.

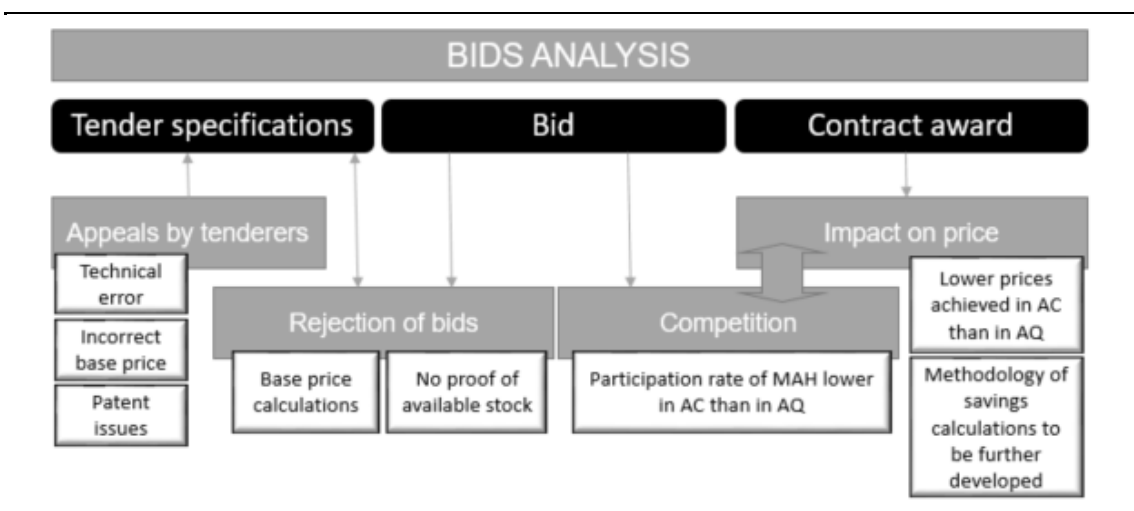
3.3.2 Key findings of possible gaps and weaknesses

The summary of the analysis performed in the previous chapter 3.3.1 is provided in Table 3.2, and Figure 3.13 summarizes main insights gathered through the analysis of the five bids (three AC and two AQ).

Difficulties and issues may be experienced at **several stages** during the procurement procedure:

- » At the beginning of a procurement procedure, errors in the tender specifications such as technical errors, an incorrect calculation of the base price or patent issues may lead to appeals by tenderers.
- » In the assessment of the bids, bids may be rejected from being awarded a contract when they do not correspond to the tender specifications. This is, for example, the case when the offered price exceeds the base price calculated in the tender specifications or when no proof of availability of necessary stock is provided.
- » During the procurement procedure, competition has a major impact on the price. For the bids analysed, the participation rate of tenderers was, as a trend, lower in AC than in AQ. Still, in international comparison (personal experience of the procurement expert among the study authors), the participation rate in the analysed bids appeared to be relatively high. Low participation rates risk not generating the potential savings.
- » The calculation of savings likely does not reflect a realistic picture as a result of non-transparent price calculations. The methodology for the savings calculations could be further developed. It could be more accurate and transparent to determine the savings for these AQ by using other calculation methods, e.g. comparing the treatment costs between different periods.

Figure 3.13:
Assessment of CPM – Conclusions from the bids analysis



Source and presentation: the authors based on an analysis of procurement documents for selected examples

Approaches to minimise the risk for oppositions / appeals and bid exclusions include:

- » an **improved dialogue with the market** (market actors),
- » possible **amendments** in the standard conditions to avoid common types of oppositions and
- » identifying **“red flag” lots** and implementing corresponding measures to minimise the risks in subsequent procurement procedures. “Red flag” lots include the following:
 - lots that have been appealed,
 - lots which contain a high number of excluded bids due to having exceeded base price,
 - lots for which no evidence (validation) of stock availability is provided, as this indicates discrepancies in procurement conditions and the willingness of MAH to ensure supply,
 - lots for which the base price varies significantly from the average, and it is not known or not transparent under what exact conditions this price was obtained by the SNS institutions in the previous period,
 - lots for which the participation rate is very low or where it is considerably lower in comparison to other procurement procedures.

3.4 National stakeholders’ perceptions

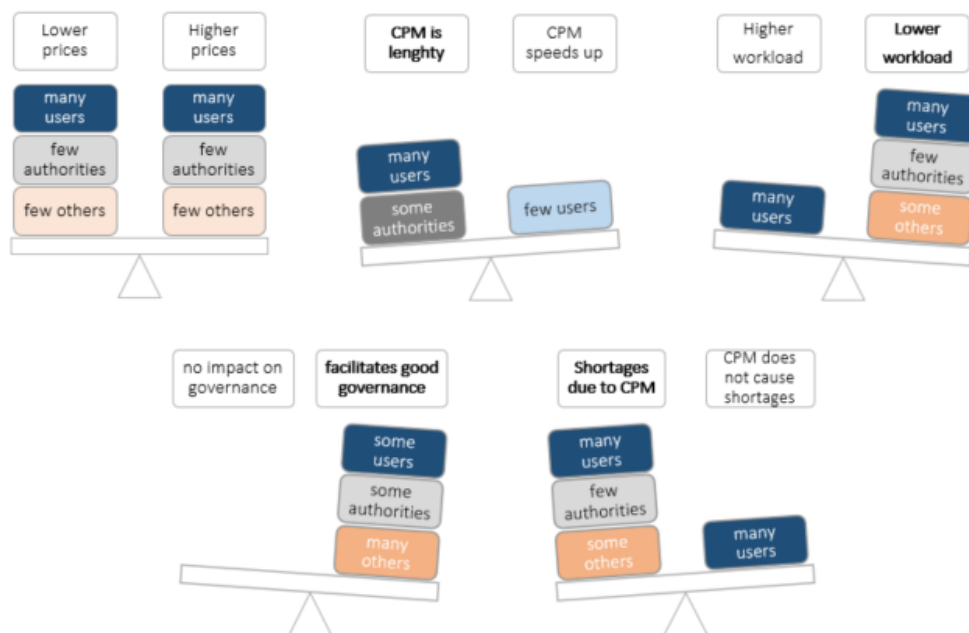
In the on-site interviews in January / February 2020 (cf. chapter 2.2.2), Portuguese stakeholders representing different groups (public authorities; hospital management, pharmacy and procurement; ARS; patients and industry) provided their perceptions on impacts of CPM in Portugal and offered suggestions for change.

3.4.1 Perceptions on effects of CPM

The authors are not aware of a strategic procurement policy document, which lists the objectives that CPM aims to achieve in Portugal. In the literature [3, 21–29], pooled procurement such as regional purchasing, CPM or other forms of intra-country or cross-country joint procurement is linked to several expectations: It aims to achieve financial objectives, in particular savings for public budgets, since possibly lower prices are anticipated as a result of stronger purchasing power as a single purchaser who aggregates larger volumes. In addition, pooled procurement of goods and services, including medicines and medical devices, is expected to result in improvements in efficiency (e.g. faster supplies), transparency, governance and accountability as well as equity in prices and thus in access to medicines across a country. However, there is concern that efficient procurement systems, such as a CPM, may contribute to shortages of medicines.

In the interviews, stakeholders were asked about their perceptions related to the impact of CPM on medicines prices, efficiency, their workload, governance and availability of medicines (shortages).

Figure 3.14:
 Assessment of CPM – Effects of CPM on medicines prices, efficiency, workload, governance and availability as perceived by interviewees,
 January / February 2020



How to read this figure: Statements from authorities, users and further stakeholders (patients and industry) were counted and categorised by frequency (e.g. few, some or many). Overall, more users than authorities and other stakeholders were interviewed, thus the classification "many" is mainly relevant for the stakeholder group of "users".

Source and presentation: the authors based on information gathered during interviews

Figure 3.14 summarises the perceptions of the interviewees:

- » **Prices:** For some medicines, prices under AC and particularly AQ have **decreased** compared to direct procurement, **but** this was **not** the case **for all medicines and all users**. In particular, large hospitals reported that due to arrangements with pharmaceutical companies, they would be able to secure better prices in direct procurements compared to AC.
- » **Efficiency:** The majority of the interviewees commenting on this issue (authorities and users) considered the **processes** to be lengthy and bureaucratic.
- » **Workload:** Despite the continuing administrative burden and some inefficient processes, CPM was perceived by many to have contributed to **reduced workload**. However, the need for coping strategies (e.g. direct procurements in parallel) to bridge gaps in the availability of medicines in the cases of delayed conclusion of procedures would lead again to a higher workload.
- » **Governance:** There was unanimity that CPM has contributed to **progresses in good governance and transparency**.
- » **Availability** of medicines: In recent years an increasing number of **shortages** has been experienced. While several interviewees raised their concern that public procurement aiming at lower prices could contribute to shortages, others stressed that shortages have multi-faceted reasons (e.g. production problems, quality issues, disruptions in the supply chain, dependency on few production sites) and that they are a global problem.

A more detailed description of the findings of the interviews related to the stakeholders' perceptions on the potential of CPM to reach certain objectives is provided in chapter 7.8 in the Annex.

3.4.2 Stakeholders' proposals

In the interviews, national stakeholders made suggestions on how to address perceived gaps in CPM in Portugal. Chapter 7.9.1 in the Annex provides a detailed listing of the proposals made, categorised per gap aligned to the MAPS taxonomy.

As for the assessment in general, the comments on proposals for optimisation also reflected that the Portuguese CPM system was perceived to offer several strengths. As a result, stakeholders welcomed recent changes (e.g. move away from the "winner-takes-it-all" approach at the beginning of the year 2020) and appreciated existing features of the system, such as e-procurement and collaboration initiatives of SPMS. Table 3.3 presents proposals for change clustered per status of implementation and urgency. A clear **definition of roles and responsibilities of the public institutions** with competences related to procurement or pricing (i.e. ACSS, INFARMED and SPMS), also as part of an updated **procurement strategy**, was mentioned as a measure of key importance. The **update of the list of active ingredients under CPM** was also considered to be urgent.

Table 3.3:

Assessment of CPM – List of proposals for improvement expressed by Portuguese stakeholders in interviews, clustered by urgency and novelty of measure

Measures already implemented:	
	<ul style="list-style-type: none"> - Implementation of the “two-winners” principle in 2020: highly appreciated by all stakeholders (background: there had been concern that the “winner-takes-it-all” principle could have contributed to limited availability of medicines since suppliers might not have been incentivised to supply the whole Portuguese market) - Increase in funding for hospitals in 2020: this announcement to do so was highly welcome by the interviewees
Required updates:	
	<ul style="list-style-type: none"> - Establishment of a clear definition of the roles and responsibilities of the key institutions in medicines policies and procurement (ACSS, INFARMED and SPMS) - Urgent update of the list of active substances under the CPM (last update: 2016)
Good practice and/or started initiatives but suggestions to optimise:	
	<ul style="list-style-type: none"> - Strengthening the e-procurement architecture (e.g. to reduce the number of platforms and interfaces) - Institutionalisation of the collaboration between ACSS, INFARMED and SPMS (e.g. the working group mandated to update the list of medicines under CPM) instead of current ad-hoc cooperation based on the initiative of committed staff) - SPMS to extend their collaboration with users (based on recent good practice examples such as the involvement of hospital pharmacists in the development of framework agreements; SPMS to organise meetings not only with procurement experts in hospitals and ARS but also with hospital pharmacists)
Approaches to change or improve existing practices:	
	<ul style="list-style-type: none"> - Application of the MEAT (Most Economically Advantageous Tender) criterion for awarding tenders, as foreseen in the Public Procurement Code (PPC), instead of the lowest price - Reconsideration of the division of tasks between public procurement institutions - Speeding up / changing schedule of procurement procedures at all levels (in hospitals, with SPMS), including the suggestion of an earlier start of procedures and of staggered starting times, as well as more attentiveness to planning - Optimisation of technical specifications in order to incentivise more competition
Approaches to introduce new features in the CPM in Portugal:	
	<ul style="list-style-type: none"> - Development of a procurement strategy¹ and provision of strategic guidance to institutions working at operational levels - Introduction of an entity to monitor and combat fraud in CPM - Strengthening local production (as an approach to address limited availability) - Introduction of a systematic market consultation before the launch of procurement procedures

For abbreviations not explained in the table, consult the list of abbreviations

¹ This proposal was made by the stakeholders based on their perception of a missing procurement strategy. Other interviewees pointed to a strategy – however unpublished –, which needs to be revisited, updated and disseminated.

Source and presentation: the authors based on interviews with stakeholders in January / February 2020

3.5 SWOT analysis

Based on the assessment, the authors summarised the learnings in a strengths, weaknesses, opportunities, and threats (SWOT) matrix (cf. Figure 3.15).

Figure 3.15:

Assessment of CPM – Strengths, weaknesses, opportunities and threats (SWOT) of CPM in Portugal, 2020

<p>Strengths</p> <ul style="list-style-type: none"> » Procurement legislation in line with international standards and publicly accessible » Dedicated procurement agency for CPM was set up » CPM has overall contributed to increased transparency of processes and improved governance » Lower workload for most (but not all) users » Shifting of pressure (e.g. by doctors asking for specific medicines) from the hospital to the central level » Lower prices and thus savings for public expenditure for some medicines (e.g. generics) – but not for all medicines » Lower risk of appeals for users » e-Procurement contributes to transparent and smooth processes » Several procurement documents are publicly accessible » High learning curve and improvements in recent times » Strong audit and control systems for public procurement in general 	<p>Weaknesses</p> <ul style="list-style-type: none"> » Procedures are bureaucratic and inefficient » Lengthy processes; procedures have not been concluded on time at the beginning of the year » Lack of strategy and prioritisation, including rules for announcing new procedures and procedures for exceptions » Lack of clarity of the roles of the involved institutions » Lack of coordination and cooperation between the public institutions » Several procurement management and data / information sharing platforms » Limitations in the active involvement of and communication to users, limited involvement of civil society » Critical under-budgeting of public hospitals over years » Higher prices and thus higher public expenditure in certain situation (e.g. larger hospitals) » Rather low number of bidders, limited competition » Limited flexibility in technical specifications » Lack of (performance) indicators to evaluate CPM and the performance of SPMS in this field » Lack of easy-at-hand high-level data for measuring and assessing CPM » No systematic market consultations
<p>Opportunities</p> <ul style="list-style-type: none"> » Positive attitude of all stakeholders towards CPM in principle; the rationale is well understood » Commitment of staff in SPMS and other public authorities to learn and improve » High interest and willingness of all stakeholders to collaborate and improve » A few recent positive experiences of involvement of users in the preparation of AQ to build on » Good collaboration between hospital pharmacy and procurement departments at user level » Progresses and improvements of SPMS and perceived high willingness of SPMS to optimise » Increase in budget for 2020 (if still applicable in COVID-19 times) » Higher volumes due to CPM make the Portuguese market more attractive » Changes made in recent years highlight high potential and interest to learn and improve » The introduction of the “two-winners” approach in 2020 (substituting the “winner-takes-it-all”-principle”) may help limit availability issues » The centralised approach can contribute to equity across Portugal (access also for patients in smaller hospitals in less central areas) 	<p>Threats</p> <ul style="list-style-type: none"> » Lack of clarity of the roles of the institutions may lead to redundancies (inefficiencies) and gaps / under-performance » Lack of strategy may cause inefficiencies and poor governance and may demotivate staff and experts » Low prices due to CPM may reduce the attractiveness of the Portuguese market » Switch of biologicals only after 6 months may limit headroom for savings from biosimilar medicines » Delays in timely conclusion of procedures result in parallel processes (direct procurements): this leads to redundancies, higher prices, higher workload and possibly higher risk of fraud and corruption » CPM is one of several activities that SPMS is mandated to do: risk of co-financing other areas » Public budgets may be inadequately defined and allocated and may thus not incentivise further developments (e.g. performance indicators – by ACS5) » Confidentiality of discounts negotiated by INFARMED misinforms SPMS in the procurement management » Lowest price as sole award criterion (as it may limit competition)

Source and presentation: the authors based on a mixed methods assessment

4 Recommendations

4.1 International learnings

The procurement experts of five European countries (Cyprus, Denmark, Estonia, Italy and Norway) consulted in this study (cf. chapter 2.3.1) were unanimously positive towards CPM and considered it to be a tool to improve affordable and sustainable access to medicines. This attitude was based on their own country experience.

Nonetheless, they all stressed that CPM is very **challenging**. In their country contexts, they had experienced successes and failures. Specific actions are required to address challenges in public procurement of medicines in general and in CPM in particular (cf. chapter 7.9.2 in the Annex).

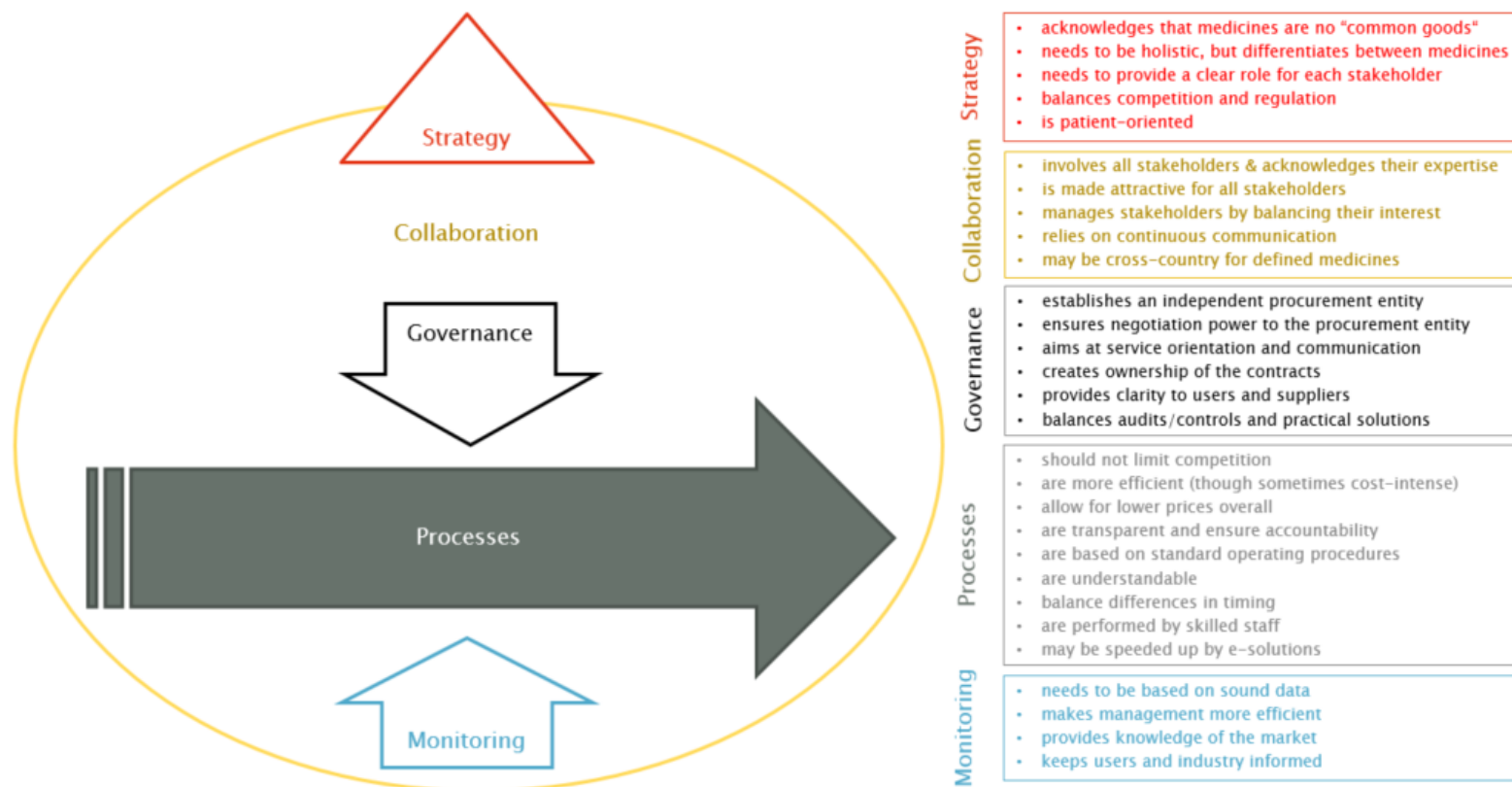
Overall, procurement experts of these countries considered the following **components key for a functioning and successful CPM** (cf. also Figure 4.1):

- » A patient-centred and holistic procurement **strategy** should be in place, accompanied by **political backing** for the CPM system. The strategy is expected to be specific regarding different types of medicines (e.g. on-patent versus off-patent medicines), and it should balance different objectives and approaches (e.g. competition versus regulation) as well as the different interests and different roles stakeholders.
- » The importance of **collaboration** with all relevant stakeholders was stressed.
- » With regard to **governance**, it was considered important to have a **dedicated entity in charge of CPM** (e.g. a procurement agency). This institution should have sufficient negotiation power, be service-oriented and ensure continuous communication.
- » It was urged to put sufficient attention into the design of the **processes**. They should be efficient and transparent and be based on standing operating procedures. Skilled staff should be responsible for handling the processes, and this should be supported by e-solutions.
- » **Monitoring** was mentioned to be a key component of an effective procurement system. It should be based on robust data.

Commenting on the assessment of the Portuguese CPM as presented to them by the authors, the procurement experts **appreciated** the establishment of a CPM system and the creation of a procurement agency in Portugal. The possibility for awarding two suppliers in an open procedure in 2020 was also welcome. However, some areas for optimisation were mentioned, such as the establishment of a **strong mandate of the procurement agency**, (more) involvement of **clinical expertise**, strengthening the **service-orientation** of the procurement agency, an earlier start of the **needs assessment** and/or a more efficient way of collecting data, improvements in terms and conditions (e.g. use of **standard operating procedures**) and more frequent **updates of the list** of active substances to be centrally purchased. They urged for developing an overarching **procurement strategy** and **performance indicators**, and for ensuring a **constant flow of information** (see also chapter 7.9.2 in the Annex).

Figure 4.1:

Recommendations – Comments made by procurement experts of other countries on key components of an effective CPM



A set of draft recommendations, which was also presented to the stakeholders attending the workshop in October 2020 (cf. chapter 2.3.2) and to the participants of the Delphi survey (cf. chapter 2.3.3), included 18 recommendations categorised into these five dimensions: strategy / political backing, collaboration, governance, processes and monitoring. The revision of the recommendations resulted in a lower number of recommendations due to streamlining. While the final set of recommendations was no longer explicitly clustered into the five above-mentioned dimensions, the key principles are still considered applicable.

Source and presentation: the authors based on information gathered in interviews with procurement interviews of other countries

4.2 List of recommendations

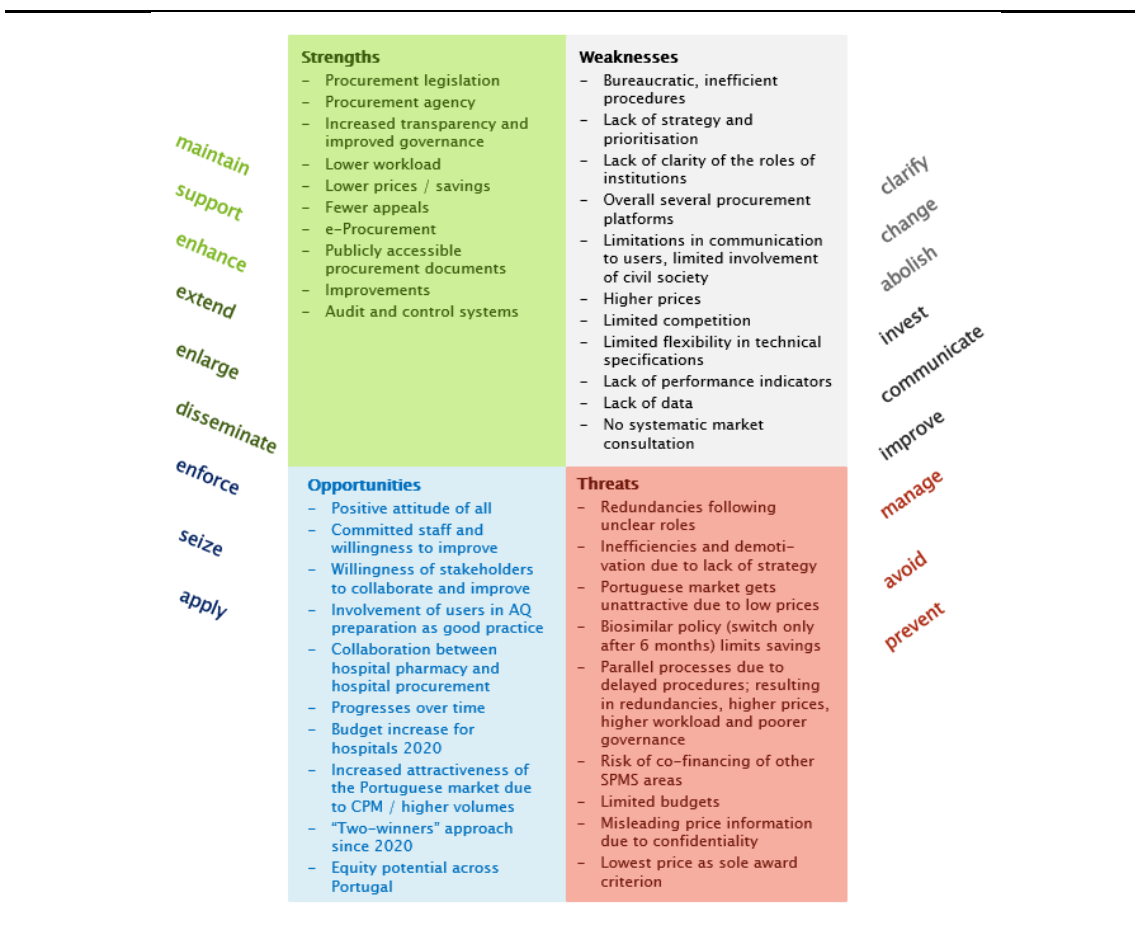
As described (cf. chapter 2.3), the development of the SMART recommendations was a multi-phased process, which included comments on a preliminary set of 18 draft recommendations by the members of the Advisory Board (cf. chapter 1.3) as well as by the participants of a stakeholder workshop (cf. chapter 2.3.2) and of a Delphi survey (cf. chapter 2.3.3). This chapter presents the updated final set of recommendations (for details on draft recommendations and development cf. chapter 7.10 in the Annex).

Use strengths, seize opportunities, address weaknesses and prevent threats

As an initial remark, it is reminded that the aim of the assessment of CPM in Portugal was to identify possible weaknesses and address these gaps.

Figure 4.2:

Recommendations – Addressing the findings of the SWOT analysis of CPM in Portugal



Source and presentation: the authors

The findings of the gaps analysis should not convey the message that CPM in Portugal is not now functional. Identified strengths should be used, maintained and extended and opportunities be seized (as a summary version of the SWOT analysis visualises in Figure 4.2; the more detailed SWOT analysis is presented in Figure 3.15 at the end of the Results chapter). In addition, good practice examples should be disseminated across Portugal and beyond in order to allow for lessons learning.

Policy recommendations to address gaps

Figure 4.3 summarises seven high-level recommendations that can improve CPM in Portugal.

The overarching recommendation is a call for strategic guidance. The **Ministry of Health and the Ministry of Finance** are urged **to develop**, if needed in consultation with other ministries (e.g. the Ministry of Economy), a **clearer and more consistent procurement strategy**.

Such a procurement strategy can only be developed and implemented if there is strong **political will** to move forward and take strategic decisions, accompanied by a clear focus on a few key actions and by the political commitment to invest wherever needed and considered appropriate (financial investment, e.g. to ensure appropriate funding for hospitals, as well as appropriate staff resources at SPMS and at users' levels).

Box: 4.1:

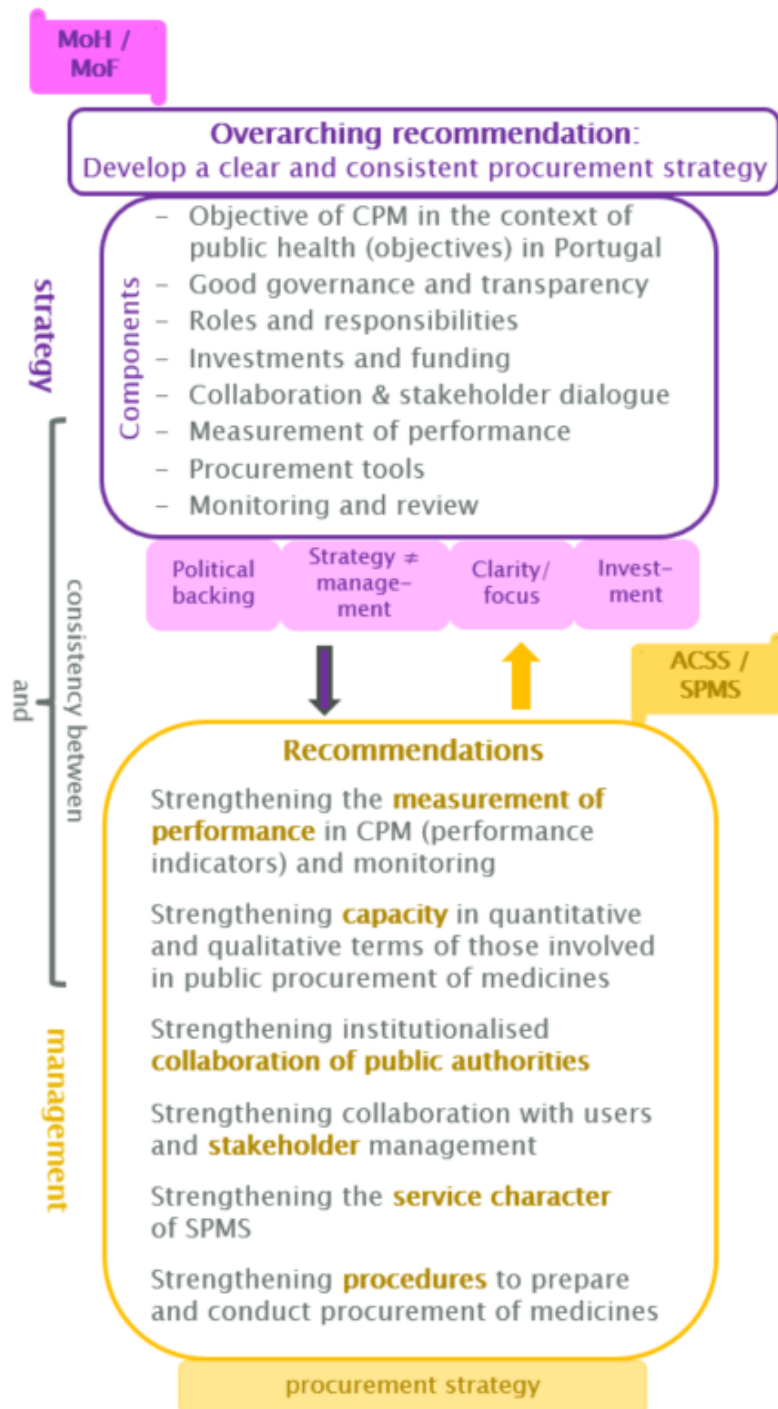
Recommendations – Reflections on possible lack of and need for a procurement strategy

Does Portugal lack a procurement strategy? Was CPM introduced without any strategic vision?

The answers are mixed. When CPM was introduced some years ago, its purpose and vision was apparently known and shared by those who had been involved in its establishment. However, over the years, founders of the CPM may have left their position, and new people may not have learned about the rather “implicit” objectives. In particular, new situations, challenges, procurement methodologies, tools and targets have emerged (both nationally and internationally), and thus an update of strategic guidance is needed. At the time of this study (2020), according to the knowledge of the authors, **no up-to-date high-level procurement strategy** (document) is available.

Why is there a need for a procurement strategy? Clarity on the strategic vision of the policy-makers with regard to short-term and, in particular, long-term objectives of CPM is needed to guide those involved in procurement or other pharmaceutical policies. This would be one mechanism in the policy framework to achieve affordable access to needed medicines at a cost that is affordable. Those responsible for the development of a management plan, i.e. the procurement agency SPMS and those for the oversight (ACSS) also require this guidance. If the strategic directions are lacking, operational decisions are more difficult to take. Limited clarity can negatively impact operational work. The lack of clarity and strategy was also mentioned by some users when they commented on SPMS's work.

Figure 4.3:
 Recommendations – Strategy and management action to address gaps and optimise CPM in Portugal



Source and presentation: the authors based on a multi-phase recommendations development process (see chapter 2.3)

The procurement strategy should provide directions to, at least, the following issues:

- » **Objective of CPM in the context of public health (objectives) in Portugal:** Which objectives should be primarily addressed with CPM? Savings for the public sector? If yes, at which cost? How are public health objectives and industry objectives balanced? Which role should procurers assign to availability and affordability issues (competitiveness) in cases of conflicts between these two objectives? How is CPM, with its two types of AQ and AC, aligned with other pharmaceutical (pricing) policies (e.g. the policies with regard to the uptake of biosimilar medicines)? Which importance do policy-makers assign to policy objectives such as equity (across Portugal), good governance and transparency, and efficiency? What is the understanding of the goods purchased in CPM (e.g. medicines, or parts of medicines, being “no normal commodities” which may require specific approaches)? Do policy-makers allow, and encourage the management to develop different procurement approaches for different types of medicines (e.g. on-patent / off-patent medicines)? Which characteristics do medicines (or active substances) subject to CPM have?
- » **Good governance and transparency:** How transparent should processes and outcomes be? Who should have access to which type of information? Which audit processes should be in place, and is there a need to strengthen governance structures? Which level of transparency (and exchange of information) should exist between the public institutions ACSS, INFARMED and SPMS, and which (confidential) data are they supposed to share? Which documents and areas of the e-procurement system should be kept confidential?
- » **Roles and responsibilities:** Which roles and competences are assigned to the procurement agency SPMS? This should be clarified also in comparison to other procurement entities for the public sector (e.g. eSPap) and to other public authorities with competences for medicines (e.g. INFARMED). Which decisions are to be taken by which public entities (alone and in consultation)?
- » **Investments and funding:** Is there a political commitment to ensure sufficient capacity (e.g. staff, appropriate professional training and experience) and funding (e.g. of the procurement agency, of users) in order to allow appropriate performance of CPM? Which investments are policy-makers willing to take to improve the reporting system and overcome inefficiencies (e.g. improvement in the e-procurement system, new and/or optimised data-bases)?
- » **Collaboration and stakeholder dialogue:** Which perspective do policy-makers have on the level and frequency of contacts and cooperation of SPMS with other public authorities, users and further stakeholders? Which role do policy-makers see for users (e.g. solely beneficiaries or, in addition, experts to be involved as advisors for the preparation of some procedures, establishment of advisory committees with representation of users and further stakeholders)? Which role do they see for patients and civil society related to CPM (e.g. consultation with specific patient groups before the purchase of defined medicines)?
- » **Measurement of performance:** In line with the overall strategic objectives that CPM should contribute to, for which domains should the performance of SPMS and of those responsible for good performance of CPM be measured (e.g. purely monetary performance indicators such as price decreases, savings, or quality aspects, or availability, or users' satisfaction)?

- » **Procurement tools:** Procurement legislation has further developed: meanwhile European legislation provides a toolbox of procurement mechanisms (e.g. use of the MEAT criterion, “more-than-one-winner” principle, “dynamic purchasing system” DPS, use of “mini-competitions”, “molecule-based competition”) which was integrated in the Portuguese procurement legislation. Which of these “new” procurement tools should be implemented? Under which circumstances (cases of “normal risks” such as delayed procedures or new unaffordable medicines versus “exceptional risks” such as a pandemic situation) may exceptional procurement procedures be implemented (how? who decides?)?
- » **Monitoring and review:** In addition to the evaluation through key performance indicators (KPI), which further monitoring and reviews processes (e.g. review and update of the procurement strategy after two years) do policy-makers aim to implement in an institutionalised manner?

All further action (both management action of the procurement agency SPMS and of its supervisory body ACSS) would ideally be derived from this procurement strategy.

While awaiting specifications through a procurement strategy, the authors have identified **six areas for optimisation at management level** (thus, the responsibility of SPMS and/or ACSS). These are listed below (no ranking), and improvements can be achieved through dedicated projects (actions) at operational level (examples for some areas are indicated in brackets, a visualisation is done in chapter 7.10.3):

- » **Measurement of performance** in CPM and monitoring (projects: development of key performance indicators and a review of the impact of the change from the “winner-takes-it-all” into the “two-winners” approach on the availability of medicines)
- » **Capacity** in quantitative and qualitative terms of those involved in public procurement of medicines
- » Institutionalised **collaboration of public authorities** (projects: establishment of an institutionalised working group of ACSS, INFARMED and SPMS, and the update of the list of active substances under CPM – an exercise to be jointly done by this working group)
- » **Collaboration with users and stakeholder management** (projects: SPMS to organise meetings with hospital pharmacists – in addition to existing meetings with procurement experts; systematic involvement of hospital pharmacists as “experts from the field” into the development of AC)
- » **Service character** of SPMS (project: optimisation of the e-procurement architecture)
- » **Procedures** to prepare and conduct procurement of medicines (projects: implementation of market consultation for AC; pilot project on changes in procedures such as earlier or staggered launch of the needs assessment)

Though the implementation of the above-mentioned high-level management recommendations requires guidance by a procurement strategy, action at management and even operational levels could also feed into the strategy.

While most projects (in terms of actions to implement the recommendations as presented in Figure 7.8 in the chapter 7.10.3 in the Annex) relate to management recommendations, two of them address rather strategic decisions: the review of the “toolbox” of procurement mechanisms, which current procurement legislation offers, and possible selection of some tools for implementation, and the measures to enhance transparency (see below the long-term projects in the following chapter 4.3).

4.3 Prioritisation and further actions

Next steps

It is urged to start some actions – at strategic as well as at management and operational level (cf. Table 4.1) as soon as possible.

Procurement strategy

The key action is to ensure the development (or update) of a **procurement strategy**, since further action at SPMS and other public institutions level depends on strategic guidance.

This should be started as soon as possible. If due to the current workload in the COVID-19 situation, no comprehensive procurement strategy can be produced in the coming year (2021), it is recommended to develop at least a **small-scale strategy** document. The latter should address, to the extent possible, the questions listed as components of a procurement strategy in the previous chapter 4.2. Further questions might be kept for later discussion; respective decisions could be postponed to a review process scheduled in one to three years’ time.

The authors consider the development of a **basic procurement strategy within six months feasible if there is political interest and will** and a well-designed process.

Operational collaborative projects

While waiting for strategic guidance, some **projects** at operational level can be started (or continued, respectively) immediately:

- » Setting up a **working group of ACSS, INFARMED and SPMS** and ensuring a working structure that allows continuity (initiative to be taken by ACSS or SPMS)
- » Updating the **list of active ingredients under CPM** by this working group
- » Organisation of a **meeting of SPMS with hospital pharmacists**

As far as resources allow, **SPMS** should start

- » performing **market consultations** for all centralised purchases (AC) and
- » inviting **hospital pharmacists** to support the preparation of AQ procedures.

Performance indicators

Finally, another task to be started as soon as possible is the **development of key performance indicators**. This would be the responsibility of **ACSS**, which, located between the strategic level of the ministries (Ministry of Health, Ministry of Finance) and the operational level of SPMS, is responsible for overseeing the performance of SPMS and providing appropriate funding.

The development of the indicators should take into consideration feasibility aspects. Thus, it is advised, at least in the beginning, to **limit the number of performance indicators** (max. 10 – 12 indicators) and to ensure that overall both data collection (SPMS) and validation of the indicators are not too time- and resource-intensive. A draft of such performance indicators could be shared, before piloting, with selected stakeholders for consultation (in particular with competent ministries as to whether, or not, their strategic objectives have been “translated” accordingly).

Table 4.1:
Recommendations – Top priority actions to improve CPM in Portugal

Measure	Responsible actor	Feasibility	Time-table
Procurement strategy	MoH / MoF / other ministries	Depends on strong political will	Major issues to be defined within 6 months (if political will)
Institutionalised working group of ACSS, INFARMED and SPMS	ACSS, INFARMED and SPMS at operational level (ACSS or SPMS to invite)	Middle – the existing high workload of institutions is a limiting factor; this action being mentioned in procurement strategy would be supportive	To be started immediately if time resources allow
Updated list of active ingredients under CPM	SPMS, in collaboration with ACSS and INFARMED	Middle – the existing high workload of institutions is a limiting factor; this action being mentioned in procurement strategy and the re-launch of the institutional working group would be a facilitating factor	4–6 months upon start
Regular meetings of SPMS with hospital pharmacists	SPMS	Middle	First meeting to be organised within 1–2 months
Systematic market consultations for all AC (alternative: development of criteria for which AC full market consultation is required)	SPMS	Extension of market consultation for use of some AC – middle Systematic market consultation for all AC – low	Systematic use: not before 2022 / 2023 Alternative approach: list of criteria for mandatory use of market consultation: Q4/2021
Involve hospital pharmacists and other experts from the field, as a standard, in the preparation of procedures	SPMS	High	To be started immediately
Development and application of performance indicators	ACSS	Middle – high workload being a limiting factor, whereas a procurement strategy demanding indicators and a focus on few high-level indicators would be supportive factors	Development In Q1/Q2/2021, application of a draft set for the performance measurement for the year 2021

Source and presentation: the authors

If developed on time, these indicators could be applied for measuring the performance in 2021.

It should be ensured that data for defined indicators are **routinely surveyed** and that they are considered and validated by ACSS. To improve transparency and accountability, it is recommended to communicate these indicators to the public, e.g. in a publication.

A mid-term review of the uptake, including challenges in the applicability, of these indicators should be planned from the beginning (e.g. after 2–3 years). This assessment should also consider the possibility to apply further indicators, which could not be included in the first set due to lack of data but for which a database will have been established in the meantime.

Actions for the future

Upon availability of a (draft) procurement strategy, the recommendations and derived projects (as presented in Figure 4.3 and in chapter 7.10.3) are to be reviewed. Additional projects might be proposed.

Actions considered important by the authors to be performed mid-term (in 2–3 years, i.e. to be finalised by end of 2023) are the following:

- » **Evaluating the impact of the implementation of the recommendations** and adapting, based on the findings, the procurement strategy and management recommendations, if needed
- » **Considering the learnings of COVID-19 pandemic management** in a future evaluation
- » Defining projects to **enhance transparency**, including price transparency (e.g. exploring the legal feasibility of INFARMED sharing “net” price data negotiated in a managed-entry agreement with SPMS)
- » Reviewing and further developing the **methodology to calculate savings** due to CPM
- » Contributing the experiences made in Portuguese CPM to **cross-country joint procurements** of medicines (e.g. in the “Valletta Declaration” to which Portugal is a member, or future initiatives at EU level).

5 Conclusions and outlook

CPM has been **gradually established** in Portugal with two milestones: the foundation of the procurement agency SPMS in 2010 which took over from ACSS the task of purchasing some medicines for hospitals, and the legal obligation for SNS institutions to use CPM (AC procedures) for defined medicines in 2016.

Any new initiative risks facing opposition. Changes in the institutional framework, which contribute to improved governance and transparency, and subsequent shifts in competences, are likely to be met with scepticism, as there will be **winners and losers**. In the case of CPM in Portugal, strong purchasers (large hospitals in more affluent regions) experienced a deterioration of their individual situation, since before CPM they had been granted “good” (lower) medicine prices by marketing authorisation holders. The disadvantages at the users’ level are balanced against the overall benefit of **improved equity in access to medicines across Portugal**. Before CPM, small hospitals had no or limited access to some medicines.

Opposition may also be fuelled by failures reported in the starting phase. Difficulties are common when new policies are implemented. In addition, public procurement of medicines is a particularly **sensitive area**, in which procurers in numerous countries have seen both **successes and failures**. This is especially the case for CPM.

Against this backdrop, difficulties related to CPM in Portugal are not a surprise. Based on reports gathered in interviews, the authors identified a **high learning curve** when interviewees stated that the performance of SPMS has constantly been improving. It was noted that the **concept of CPM** as a solidarity-based mechanism to improve equity was **understood and**, by and large, **supported**.

This offers an excellent basis to optimise CPM in Portugal. Improvements can build on the **strengths** and opportunities identified, which include the existence of a **dedicated procurement agency**, a **legal framework**, which offers further procurement tools to be utilised, and **e-procurement**. However, these positive features are undermined by several **gaps** including **bureaucratic and lengthy processes** and thus **delayed conclusion of procedures** (resulting in either non-availability of medicines or - to ensure availability - in direct procurements of users in parallel), an **outdated list of active substances** subject to AC, **no monitoring** based on key performance indicators, **limited coordination** between the public institutions, **deficits in the communication of SPMS with users** and in the agency’s **service character**, and **limited** activities of **market research** and consultation.

The study proposed some **technical projects** to address these gaps. Some are middle-term (e.g. better linkage between e-procurement platforms, develop a set of key performance indicators), whereas others could be “quick wins” (e.g. establish a working group of ACSS, INFARMED and SPMS, update of the list of active substances to be centrally procured, a first meeting of SPMS with hospital pharmacists).

In addition to these actions at management and operational levels, it is of uppermost importance to address the **limited clarity with regard to the mandate and responsibilities** of the procurement agency and to define its role as well as the role of other public institutions (particularly ACSS and INFARMED).

The study identified a clear need for a **procurement strategy**. This strategy would specify the role of public institutions and further stakeholders with regard to CPM and would define the objectives of CPM in the context of public health. A procurement strategy would **provide strategic vision** to ACSS (responsible for oversight of SPMS) and to SPMS. As one component, a clear **commitment for investment** (e.g. to ensure sufficient capacity) would be required.

The Portuguese Public Procurement Code, having translated EU legislation, provides for the use of **further procurement tools**, e.g. competition among therapeutically equivalent medicines, award criteria beyond price. Existing procurement tools which are legally possible have not been fully utilised in Portugal, and in a procurement strategy, policy-makers could advise exploring some of these tools.

From March 2020 on, Portugal has been hit by the global **COVID-19** pandemic. COVID-19 has been a major challenge for health care systems all over the world, including Portugal. It has been a “stress test” for public procurement of medicines and medical devices.

COVID-19 has highlighted in a dramatic manner the need for efficient procurement systems. The emergency situation due to the pandemic could also provide a **momentum to move forward** with optimising CPM in Portugal.

While the assessment in this report aims to be of interest for all involved in or targeted by CPM, the recommendations, in particular the call for a procurement strategy, primarily **address policy-makers**. They are urged to consider, endorse and launch implementation of the recommendations. **Political will** is an indispensable prerequisite. Once political commitment for the next steps is ensured, the authors believe the proposed actions for the optimisation of CPM feasible.

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7 Annex

7.1 Methodological approach for the assessment of CPM in Portugal

7.1.1 Selection of an appropriate assessment framework

Pharmaceutical policies, such as pricing policies and (centralised) procurement, aim to ensure affordable and equitable access of medicines while aiming to achieve other policy objectives (e.g. ensuring the long-term sustainability of the health care / pharmaceutical system, enhancing competition) or not compromising other policy objectives. Thus, such policies are embedded in the respective national multi-level policy frameworks defined by usually several, sometimes partially conflicting, policy objectives.

Centralised procurement of medicines has increasingly gained importance in high-income countries as a policy to improve access to medicines. A strategic use and design of procurement is vital to generate benefits associated with procurement of medicines and to achieve higher efficiency, e.g. through minimising of low-value repetitive purchases, increasing the benefits of economies of scale and reducing the transaction and transport costs [1].

An assessment of pharmaceutical policies, such as CPM as in the case of this assignment, requires the definition of indicators (of qualitative as well as quantitative nature) in order to determine if, and to which extent, defined policy objectives have been achieved, and if not, which were the barriers. Based on such an assessment, measures and actions that are able to 'correct' and thus achieve defined outcomes can be identified.

In recent times, some methodological frameworks to assess (aspects of) the performance of pharmaceutical policies have been developed, in particular by international institutions such as the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD). While an assessment framework for reviewing national medicines regulatory systems (e.g. marketing authorisation, pharmacovigilance) has been developed and implemented by the WHO [2, 3], no such assessment framework has yet been developed for evaluating the pricing and reimbursement policy framework. However, the OECD defined a methodological framework to assess public procurement [4]. Table 7.1 provides an overview of possibly relevant assessment frameworks and discusses their feasibility for the purpose of this project based on identified strengths and weaknesses.

Given the methodological approaches and thus identified benefits and weaknesses of the analysed assessment frameworks for the purpose of the project, the authors considered the OECD Methodology for Assessing Procurement Systems (MAPS) as the assessment tool that qualifies best. Still, it was considered as a basic and further developed for the purposes of this project.

Table 7.1:

Annex – Assessment frameworks with regard to public procurement and pharmaceutical policies

Assessment frameworks	Description	Strengths with regard to this project	Limitations with regard to this project
WHO Assessing national medicines regulatory systems [2, 3]	A review framework for existing legal frameworks, regulations and control activities with regard to medicines and medical devices to assess the national regulatory capacity against a set of predefined parameters.	A practical assessment tool that has been implemented in several countries. It ensures the involvement of national officials and contributes to identify gaps and develop strategies to address these gaps; and to identify specific areas and activities for WHO's technical input.	Focused on the 'regulatory framework' such as marketing authorisation and vigilance (safety and effectiveness of medicines) but not related to the policy such as procurement.
OECD Methodology for Assessing Procurement Systems (MAPS) [4, 5]	Assessment tool developed for public procurement, based on four pillars and a total of 14 indicators and 55 sub-indicators.	An assessment tool particularly developed for public procurement in high-income countries. It has been applied in several countries; there is experience (a focal point of the OECD MAPS Secretariat is available for requests). It includes several assessment criteria, also in areas that allow 'looking outside the box' of procurement (e.g. legal and policy framework). MAPS allows applying some flexibility in its further development.	It is a tool for public procurement in general, not related to medicines. A number of quantitative indicators defined is limited.
WHO Pharmaceutical System Transparency and Accountability Assessment Tool [6, 7]	An assessment tool to support the strengthening of governance by identifying areas for improvement in the pharmaceutical system.	The tool includes five cross-cutting themes (e.g. access to medicines, medicines policy) and cross-cutting areas as well as eight core functional areas of the pharmaceutical system. One of the functional areas is public procurement of medicines.	The focus of this tool is broader than just public procurement.
WHO Monitoring the components and predictors of access to medicines [8]	An 'access dashboard' that uses as reference an adaptation and simplification of a previously developed framework of 12 core functions and two cross-cutting enablers of the pharmaceutical system. It aims to focus on outcome instead of process indicators.	Procurement of medicines has been included as one component. A link to Sustainable Development Goal Indicator 3.b.3 exists. Includes suggestions for a few quantitative indicators related to procurement (and assessment of their feasibility)	Not a specific assessment tool for public procurement. Currently it is still work-in-progress, the development of indicators still needs to be finalised.

Source and presentation: sources of the identified frameworks indicated in the table; survey and analysis: the authors

7.1.2 OECD Methodology for Assessing Procurement Systems (MAPS)

The OECD Methodology for Assessing Procurement Systems (MAPS) framework was created by a joint initiative of the World Bank and the Development Assistance Committee (DAC) in 2003/2004. From 2015–2018, the MAPS methodology has been updated by the MAPS stakeholder group to match today’s public procurement challenges and to reflect the evolution of public procurement into a strategic function [5].

MAPS comprises 14 indicators attributable to four “pillars” To each of these indicators, sub-indicators (so-called “assessment criteria”) have been defined. Table 7.2 provides the full list of the 14 indicators and 55 sub-indicators of the OECD MAPS methodology, including qualitative indicators as well as suggestions (minimum requirements and recommendations) for quantitative indicators.

Table 7.2:
Annex – Indicators of the OECD MAPS methodology

Pillar I. Legal, Regulatory, and Policy Framework

1. The public procurement legal framework achieves the agreed principles and complies with applicable obligations.

Assessment criteria
(a) Is adequately recorded and organised hierarchically (laws, decrees, regulations, procedures), and precedence is clearly established.
(b) It covers goods, works and services, including consulting services for all procurement using public funds.
(c) PPPs, including concessions, are regulated.
(d) Current laws, regulations and policies are published and easily accessible to the public at no cost
1(a) Scope of application and coverage of the legal and regulatory framework. The legal and regulatory body of norms complies with the following conditions:
1(b) Procurement methods. The legal framework meets the following conditions:
Assessment criteria
(a) Procurement methods are established unambiguously at an appropriate hierarchical level, along with the associated conditions under which each method may be used.
(b) The procurement methods prescribed include competitive and less competitive procurement procedures and provide an appropriate range of options that ensure value for money, fairness, transparency, proportionality and integrity.
(c) Fractioning of contracts to limit competition is prohibited.
(d) Appropriate standards for competitive procedures are specified.
1(c) Advertising rules and time limits. The legal framework meets the following conditions:
Assessment criteria
(a) The legal framework requires that procurement opportunities are publicly advertised, unless the restriction of procurement opportunities is explicitly justified (refer to indicator 1(b)).
(b) Publication of opportunities provides sufficient time, consistent with the method, nature and complexity of procurement, for potential bidders to obtain documents and respond to the advertisement. The minimum time frames for submission of bids/proposals are defined for each procurement method, and these time frames are extended when international competition is solicited.
(c) Publication of open tenders is mandated in at least a newspaper of wide national circulation or on a unique internet official site where all public procurement opportunities are posted. This should be easily accessible at no cost and should not involve other barriers (e.g. technological barriers).
(d) The content published includes enough information to allow potential bidders to determine whether they are able to submit a bid and are interested in submitting one.
1(d) Rules on participation. The legal framework meets the following conditions:
Assessment criteria
(a) It establishes that participation of interested parties is fair and based on qualification and in accordance with rules on eligibility and exclusions.
(b) It ensures that there are no barriers to participation in the public procurement market.
(c) It details the eligibility requirements and provides for exclusions for criminal or corrupt activities, and for administrative debarment under the law, subject to due process or prohibition of commercial relations.
(d) It establishes rules for the participation of state-owned enterprises that promote fair competition.
(e) It details the procedures that can be used to determine a bidder's eligibility and ability to perform a specific contract.
1(e) Procurement documentation and specifications. The legal framework meets the following conditions:
Assessment criteria
(a) It establishes the minimum content of the procurement documents and requires that content is relevant and sufficient for suppliers to respond to the requirement.
(b) It requires the use of neutral specifications, citing international norms when possible, and provides for the use of functional specifications where appropriate.
(c) It requires recognition of standards that are equivalent, when neutral specifications are not available.
(d) Potential bidders are allowed to request a clarification of the procurement document, and the procuring entity is required to respond in a timely fashion and communicate the clarification to all potential bidders (in writing)
1(f) Evaluation and award criteria. The legal framework mandates that:
Assessment criteria
(a) The evaluation criteria are objective, relevant to the subject matter of the contract, and precisely specified in advance in the procurement documents, so that the award decision is made solely on the basis of the criteria stipulated in the documents.
(b) The use of price and non-price attributes and/or the consideration of life cycle cost is permitted as appropriate to ensure objective and value-for-money decisions.
(c) Quality is a major consideration in evaluating proposals for consulting services, and clear procedures and methodologies for assessment of technical capacity are defined.
(d) The way evaluation criteria are combined and their relative weight determined should be clearly defined in the procurement documents.
(e) During the period of the evaluation, information on the examination, clarification and evaluation of bids/proposals is not disclosed to participants or to others not officially involved in the evaluation process.
1(g) Submission, receipt, and opening of tenders. The legal framework provides for the following provisions:
Assessment criteria
(a) Opening of tenders in a defined and regulated proceeding, immediately following the closing date for bid submission.
(b) Records of proceedings for bid openings are retained and available for review.
(c) Security and confidentiality of bids is maintained prior to bid opening and until after the award of contracts.
(d) The disclosure of specific sensitive information is prohibited, as regulated in the legal framework.
(e) The modality of submitting tenders and receipt by the government is well defined, to avoid unnecessary rejection of tenders.
1(h) Right to challenge and appeal. The legal framework provides for the following:
Assessment criteria
(a) Participants in procurement proceedings have the right to challenge decisions or actions taken by the procuring entity.
(b) Provisions make it possible to respond to a challenge with administrative review by another body, independent of the procuring entity that has the authority to suspend the award decision and grant remedies, and also establish the right for judicial review.
(c) Rules establish the matters that are subject to review.
(d) Rules establish time frames for the submission of challenges and appeals and for issuance of decisions by the institution in charge of the review and the independent appeals body.
(e) Applications for appeal and decisions are published in easily accessible places and within specified time frames, in line with legislation protecting sensitive information.

(f) Decisions by the independent appeals body can be subject to higher-level review (judicial review).	
1(i) Contract management. The legal framework provides for the following:	Assessment criteria
(a) Functions for undertaking contract management are defined and responsibilities are clearly assigned.	
(b) Conditions for contract amendments are defined, ensure economy and do not arbitrarily limit competition.	
(c) There are efficient and fair processes to resolve disputes promptly during the performance of the contract.	
(d) The final outcome of a dispute resolution process is enforceable.	
1(j) Electronic Procurement (e-Procurement). The legal framework provides for the following:	Assessment criteria
(a) The legal framework allows or mandates e-Procurement solutions covering the public procurement cycle, whether entirely or partially.	
(b) The legal framework ensures the use of tools and standards that provide unrestricted and full access to the system, taking into consideration privacy, security of data and authentication.	
(c) The legal framework requires that interested parties be informed which parts of the processes will be managed electronically.	
1(k) Norms for safekeeping of records, documents and electronic data. The legal framework provides for the following:	Assessment criteria
(a) A comprehensive list is established of the procurement records and documents related to transactions including contract management. This should be kept at the operational level. It should outline what is available for public inspection including conditions for access.	
(b) There is a document retention policy that is both compatible with the statute of limitations in the country for investigating and prosecuting cases of fraud and corruption and compatible with the audit cycles.	
(c) There are established security protocols to protect records (physical and/or electronic).	
1(l) Public procurement principles in specialized legislation. The legal and regulatory body of norms complies with the following conditions:	Assessment criteria
(a) Public procurement principles and/or the legal framework apply in any specialised legislation that governs procurement by entities operating in specific sectors, as appropriate.	
(b) Public procurement principles and/or laws apply to the selection and contracting of public private partnerships (PPP), including concessions as appropriate.	
(c) Responsibilities for developing policies and supporting the implementation of PPPs, including concessions, are clearly assigned.	
2. Implementing regulations and tools support the legal framework.	
2(a) Implementing regulations to define processes and procedures	Assessment criteria
(a) There are regulations that supplement and detail the provisions of the procurement law, and do not contradict the law.	
(b) The regulations are clear, comprehensive and consolidated as a set of regulations readily available in a single accessible place.	
(c) Responsibility for maintenance of the regulations is clearly established, and the regulations are updated regularly.	
2(b) Model procurement documents for goods, works, and services	Assessment criteria
(a) There are model procurement documents provided for use for a wide range of goods, works and services, including consulting services procured by public entities.	
(b) At a minimum, there is a standard and mandatory set of clauses or templates that reflect the legal framework. These clauses can be used in documents prepared for competitive tendering/bidding.	
(c) The documents are kept up to date, with responsibility for preparation and updating clearly assigned.	
2 (c) Standard contract conditions	Assessment criteria
(a) There are standard contract conditions for the most common types of contracts, and their use is mandatory.	
(b) The content of the standard contract conditions is generally consistent with internationally accepted practice.	
(c) Standard contract conditions are an integral part of the procurement documents and made available to participants in procurement proceedings.	
2 (d) User's guide or manual for procuring entities	Assessment criteria
(a) There is (a) comprehensive procurement manual(s) detailing all procedures for the correct implementation of procurement regulations and laws.	
(b) Responsibility for maintenance of the manual is clearly established, and the manual is updated regularly.	
3. The legal and policy frameworks support the sustainable development of the country and the implementation of international obligations.	
3(a) Sustainable Public Procurement (SPP)	Assessment criteria
(a) The country has a policy/strategy in place to implement SPP in support of broader national policy objectives.	
(b) The SPP implementation plan is based on an in-depth assessment; systems and tools are in place to operationalise, facilitate and monitor the application of SPP.	
(c) The legal and regulatory frameworks allow for sustainability (i.e. economic, environmental and social criteria) to be incorporated at all stages of the procurement cycle.	
(d) The legal provisions require a well-balanced application of sustainability criteria to ensure value for money.	
3(b) Obligations deriving from international agreements. Public procurement-related obligations deriving from binding international agreements are:	Assessment criteria
(a) clearly established	
(b) consistently adopted in laws and regulations and reflected in procurement policies.	

Pillar II. Institutional Framework and Management Capacity

4. The public procurement system is mainstreamed and well integrated into the public financial management system

4(a) Procurement planning and the budget cycle. The legal and regulatory framework, financial procedures and systems provide for the following:

Assessment criteria
(a) Annual or multi-annual procurement plans are prepared, to facilitate the budget planning and formulation process and to contribute to multi-year planning.
(b) Budget funds are committed or appropriated in a timely manner and cover the full amount of the contract (or at least the amount necessary to cover the portion of the contract performed within the budget period).
(c) A feedback mechanism reporting on budget execution is in place, in particular regarding the completion of major contracts.

4(b) Financial procedures and the procurement cycle. The legal and regulatory framework, financial procedures and systems should ensure that:

Assessment criteria
(a) No solicitation of tenders/proposals takes place without certification of the availability of funds.
(b) The national regulations/procedures for processing of invoices and authorisation of payments are followed, publicly available and clear to potential bidders.*
// Minimum indicator // * Quantitative indicator to substantiate assessment of sub-indicator 4(b) Assessment criterion (b): - invoices for procurement of goods, works and services paid on time (in % of total number of invoices). Source: PFM systems.

5. The country has an institution in charge of the normative/regulatory function

5(a) Status and legal basis of the normative/regulatory institution function. The legal and regulatory framework, financial procedures and systems provide for the following:

Assessment criteria
(a) The legal and regulatory framework specifies the normative/regulatory function and assigns appropriate authorities formal powers to enable the institution to function effectively, or the normative/regulatory functions are clearly assigned to various units within the government.

5(b) Responsibilities of the normative/regulatory function. The following functions are clearly assigned to one or several agencies without creating gaps or overlaps in responsibility:

Assessment criteria
(a) providing advice to procuring entities
(b) drafting procurement policies
(c) proposing changes/drafting amendments to the legal and regulatory framework
(d) monitoring public procurement
(e) providing procurement information
(f) managing statistical databases
(g) preparing reports on procurement to other parts of government
(h) developing and supporting implementation of initiatives for improvements of the public procurement system
(i) providing tools and documents, including integrity training programmes, to support training and capacity development of the staff responsible for implementing procurement
(j) supporting the professionalisation of the procurement function (e.g. development of role descriptions, competency profiles and accreditation and certification schemes for the profession)
(k) designing and managing centralised online platforms and other e-Procurement systems, as appropriate

5(c) Organisation, funding, staffing, and level of independence and authority

Assessment criteria
(a) The normative/regulatory function (or the institutions entrusted with responsibilities for the regulatory function if there is not a single institution) and the head of the institution have a high-level and authoritative standing in government.
(b) Financing is secured by the legal/regulatory framework, to ensure the function's independence and proper staffing.
(c) The institution's internal organisation, authority and staffing are sufficient and consistent with its responsibilities.

5(d) Avoiding conflict of interest

Assessment criteria
(a) The normative/regulatory institution has a system in place to avoid conflicts of interest.*
* Recommended quantitative indicator to substantiate assessment of sub-indicator 5(d) Assessment criterion (a): - Perception that the normative/regulatory institution is free from conflicts of interest (in % of responses). Source: Survey.

6. Procuring entities and their mandates are clearly defined

6(a) Definition, responsibilities and formal powers of procuring entities. The legal framework provides for the following:

Assessment criteria
(a) Procuring entities are clearly defined.
(b) Responsibilities and competencies of procuring entities are clearly defined.
(c) Procuring entities are required to establish a designated, specialised procurement function with the necessary management structure, capacity and capability.*
// Minimum indicator // * Quantitative indicator to substantiate assessment of sub-indicator 6(a) Assessment criterion (c): - procuring entities with a designated, specialised procurement function (in % of total number of procuring entities). Source: Normative/regulatory function.
(d) Decision-making authority is delegated to the lowest competent levels consistent with the risks associated and the monetary sums involved.

(e) Accountability for decisions is precisely defined.

6(b) Centralized procurement body

Assessment criteria

(a) The country has considered the benefits of establishing a centralised procurement function in charge of consolidated procurement, framework agreements or specialised procurement.

(b) In case a centralised procurement body exists, the legal and regulatory framework provides for the following:

- Legal status, funding, responsibilities and decision-making powers are clearly defined.
- Accountability for decisions is precisely defined.
- The body and the head of the body have a high-level and authoritative standing in government.

(c) The centralised procurement body's internal organisation and staffing are sufficient and consistent with its responsibilities.

7. Public procurement is embedded in an effective information system

7(a) Publication of public procurement information supported by information technology. The country has a system that meets the following requirements:

Assessment criteria

(a) Information on procurement is easily accessible in media of wide circulation and availability. Information is relevant, timely and complete and helpful to interested parties to understand the procurement processes and requirements and to monitor outcomes, results and performance.

(b) There is an integrated information system (centralised online portal) that provides up-to-date information and is easily accessible to all interested parties at no cost.

(c) The information system provides for the publication of: *

- procurement plans
 - information related to specific procurements, at a minimum, advertisements or notices of procurement opportunities, procurement method, contract awards and contract implementation, including amendments, payments and appeals decisions
 - linkages to rules and regulations and other information relevant for promoting competition and transparency.
- // Minimum indicator // Quantitative indicators to substantiate assessment of sub-indicator 7(a) Assessment criterion (c):
- procurement plans published (in % of total number of required procurement plans)
 - key procurement information published along the procurement cycle (in % of total number of contracts):
 - invitation to bid (in % of total number of contracts)
 - contract awards (purpose, supplier, value, variations/amendments)
 - details related to contract implementation (milestones, completion and payment)
 - annual procurement statistics
 - appeals decisions posted within the time frames specified in the law (in %).
- Source: Centralised online portal.

(d) In support of the concept of open contracting, more comprehensive information is published on the online portal in each phase of the procurement process, including the full set of bidding documents, evaluation reports, full contract documents including technical specification and implementation details (in accordance with legal and regulatory framework).

(e) Information is published in an open and structured machine-readable format, using identifiers and classifications (open data format).*

* Recommended quantitative indicator to substantiate assessment of sub-indicator 7(a) Assessment criterion (e):

- Share of procurement information and data published in open data formats (in %).

Source: Centralised online portal.

(f) Responsibility for the management and operation of the system is clearly defined.

7(b) Use of e-Procurement

Assessment criteria

(a) E-Procurement is widely used or progressively implemented in the country at all levels of government.*

// Minimum indicator // * Quantitative indicators to substantiate assessment of sub-indicator 7(b) Assessment criterion (a):

uptake of e-Procurement

- number of e-Procurement procedures in % of total number of procedures

- value of e-Procurement procedures in % of total value of procedures

Source: e-Procurement system.

(b) Government officials have the capacity to plan, develop and manage e-Procurement systems.

(c) Procurement staff is adequately skilled to reliably and efficiently use e-Procurement systems.

(d) Suppliers (including micro, small and medium-sized enterprises) participate in a public procurement market increasingly dominated by digital technology.*

* Recommended quantitative indicators to substantiate assessment of sub-indicator 7(b) Assessment criterion (d):

- bids submitted online (in %)

- bids submitted online by micro, small and medium-sized enterprises (in %)

Source: e-Procurement system.

(e) If e-Procurement has not yet been introduced, the government has adopted an e-Procurement roadmap based on an e-Procurement readiness assessment.

7(c) Strategies to manage procurement data

Assessment criteria

(a) A system is in operation for collecting data on the procurement of goods, works and services, including consulting services, supported by e-Procurement or other information technology.

(b) The system manages data for the entire procurement process and allows for analysis of trends, levels of participation, efficiency and economy of procurement and compliance with requirements.

(c) The reliability of the information is high (verified by audits).

(d) Analysis of information is routinely carried out, published and fed back into the system. *

// Minimum indicator // * Quantitative indicators to substantiate assessment of sub-indicator 7(c) Assessment criterion (d):

• total number and value of contracts

• public procurement as a share of government expenditure and as share of GDP

* total value of contracts awarded through competitive methods in the most recent fiscal year.
Source: Normative/regulatory function/E-Procurement system.

8. The public procurement system has a strong capacity to develop and improve

8(a) Training, advice and assistance. There are systems in place that provide for:

Assessment criteria
(a) substantive permanent training programmes of suitable quality and content for the needs of the system.
(b) routine evaluation and periodic adjustment of training programmes based on feedback and need.
(c) advisory service or help desk function to resolve questions by procuring entities, suppliers and the public.
(d) a strategy well-integrated with other measures for developing the capacity of key actors involved in public procurement.

8(b) Recognition of procurement as a profession. The country's public service recognises procurement as a profession:

Assessment criteria
(a) Procurement is recognised as a specific function, with procurement positions defined at different professional levels, and job descriptions and the requisite qualifications and competencies specified.
(b) Appointments and promotion are competitive and based on qualifications and professional certification.
(c) Staff performance is evaluated on a regular and consistent basis, and staff development and adequate training is provided.

8(c) Monitoring performance to improve the system

Assessment criteria
(a) The country has established and consistently applies a performance measurement system that focuses on both quantitative and qualitative aspects.
(b) The information is used to support strategic policy making on procurement.
(c) Strategic plans, including results frameworks, are in place and used to improve the system.
(d) Responsibilities are clearly defined.

Pillar III. Public Procurement Operations and Market Practices

9. Public procurement practices achieve stated objectives

9(a) Planning

Assessment criteria
(a) Needs analysis and market research guide a proactive identification of optimal procurement strategies.
(b) The requirements and desired outcomes of contracts are clearly defined.
(c) Sustainability criteria, if any, are used in a balanced manner and in accordance with national priorities, to ensure value for money.

9(b) Selection and contracting

Assessment criteria
(a) Multi-stage procedures are used in complex procurements to ensure that only qualified and eligible participants are included in the competitive process.
(b) Clear and integrated procurement documents, standardised where possible and proportionate to the need, are used to encourage broad participation from potential competitors.
(c) Procurement methods are chosen, documented and justified in accordance with the purpose and in compliance with the legal framework.
(d) Procedures for bid submission, receipt and opening are clearly described in the procurement documents and complied with. This means, for instance, allowing bidders or their representatives to attend bid openings, and allowing civil society to monitor bid submission, receipt and opening, as prescribed.
(e) Throughout the bid evaluation and award process, confidentiality is ensured.
(f) Appropriate techniques are applied, to determine best value for money based on the criteria stated in the procurement documents and to award the contract.
(g) Contract awards are announced as prescribed.
(h) Contract clauses include sustainability considerations, where appropriate.
(i) Contract clauses provide incentives for exceeding defined performance levels and disincentives for poor performance.
(j) The selection and award process is carried out effectively, efficiently and in a transparent way. *
*Recommended quantitative indicators to substantiate assessment of sub-indicator 9(b) Assessment criterion (j):
- average time to procure goods, works and services
- number of days between advertisement/solicitation and contract signature (for each procurement method used)
- average number (and %) of bids that are responsive (for each procurement method used)
- share of processes that have been conducted in full compliance with publication requirements (in %)
- number (and %) of successful processes (successfully awarded; failed; cancelled; awarded within defined time frames)
Source for all: Sample of procurement cases.

9(c) Contract management

Assessment criteria
(a) Contracts are implemented in a timely manner.*
Recommended quantitative indicator to substantiate assessment criterion (a): time overruns (in %; and average delay in days)
(b) Inspection, quality control, supervision of work and final acceptance of products is carried out.*
Recommended quantitative indicator to substantiate assessment criterion (b): quality-control measures and final acceptance are carried out as stipulated in the contract (in %)

(c) Invoices are examined, time limits for payments comply with good international practices, and payments are processed as stipulated in the contract. Recommended quantitative indicator to substantiate assessment criterion (c): invoices for procurement of goods, works and services are paid on time (in % of total number of invoices).
(d) Contract amendments are reviewed, issued and published in a timely manner.* Recommended quantitative indicator to substantiate assessment criterion (d): contract amendments (in % of total number of contracts; average increase of contract value in %)
(e) Procurement statistics are available and a system is in place to measure and improve procurement practices.
(f) Opportunities for direct involvement of relevant external stakeholders in public procurement are utilised.* Recommended quantitative indicator to substantiate assessment criterion (f): percentage of contracts with direct involvement of civil society: planning phase; bid/proposal opening; evaluation and contract award, as permitted; contract implementation) Source for all: Sample of procurement cases.
(g) The records are complete and accurate, and easily accessible in a single file.* // Minimum indicator // * Quantitative indicators to substantiate assessment of sub-indicator 9(c) Assessment criterion (g): - share of contracts with complete and accurate records and databases (in %) Source: Sample of procurement cases*

10. The public procurement market is fully functional

10(a) Dialogue and partnerships between public and private sector

Assessment criteria
(a) The government encourages open dialogue with the private sector. Several established and formal mechanisms are available for open dialogue through associations or other means, including a transparent and consultative process when formulating changes to the public procurement system. The dialogue follows the applicable ethics and integrity rules of the government.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 10(a) Assessment criterion (a): - perception of openness and effectiveness in engaging with the private sector (in % of responses). Source: Survey.
(b) The government has programmes to help build capacity among private companies, including for small businesses and training to help new entries into the public procurement marketplace.

10(b) Private sector's organisation and access to the public procurement market

Assessment criteria
(a) The private sector is competitive, well-organised, willing and able to participate in the competition for public procurement contracts.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 10(b) Assessment criterion (a): • number of registered suppliers as a share of total number of suppliers in the country (in %) • share of registered suppliers that are participants and awarded contracts (in % of total number of registered suppliers) • total number and value of contracts awarded to domestic/foreign firms (and in % of total) Source: E-Procurement system/Supplier Database.
(b) There are no major systemic constraints inhibiting private sector access to the public procurement market. * Recommended quantitative indicator to substantiate assessment of sub-indicator 10(b) Assessment criterion (b): - perception of firms on the appropriateness of conditions in the public procurement market (in % of responses). Source: Survey.

10(c) Key sectors and sector strategies

Assessment criteria
(a) Key sectors associated with the public procurement market are identified by the government.
(b) Risks associated with certain sectors and opportunities to influence sector markets are assessed by the government, and sector market participants are engaged in support of procurement policy objectives.

Pillar IV. Accountability, Integrity and Transparency of the Public Procurement System

11. Transparency and civil society engagement foster integrity in public procurement

11(a) Enabling environment for public consultation and monitoring

Assessment criteria
(a) A transparent and consultative process is followed when formulating changes to the public procurement system.
(b) Programmes are in place to build the capacity of relevant stakeholders to understand, monitor and improve public procurement.
(c) There is ample evidence that the government takes into account the input, comments and feedback received from civil society.

11(b) Adequate and timely access to information by the public

Assessment criteria
(a) Requirements in combination with actual practices ensure that all stakeholders have adequate and timely access to information as a precondition for effective participation.

11(c) Direct engagement of civil society

Assessment criteria
(a) The legal/regulatory and policy framework allows citizens to participate in the following phases of a procurement process, as appropriate: • the planning phase (consultation) • bid/proposal opening (observation) • evaluation and contract award (observation), when appropriate, according to local law • contract management and completion (monitoring).

(b) There is ample evidence for direct participation of citizens in procurement processes through consultation, observation and monitoring.

12. The country has effective control audit systems

12(a) Legal framework, organisation and procedures of the control system

The system in the country provides for:

Assessment criteria
(a) laws and regulations that establish a comprehensive control framework, including internal controls, internal audits, external audits and oversight by legal bodies
(b) internal control/audit mechanisms and functions that ensure appropriate oversight of procurement, including reporting to management on compliance, effectiveness and efficiency of procurement operations
(c) internal control mechanisms that ensure a proper balance between timely and efficient decision-making and adequate risk mitigation
(d) independent external audits provided by the country's Supreme Audit Institution (SAI) that ensure appropriate oversight of the procurement function based on periodic risk assessments and controls tailored to risk management
(e) review of audit reports provided by the SAI and determination of appropriate actions by the legislature (or other body responsible for public finance governance)
(f) clear mechanisms to ensure that there is follow-up on the respective findings.

12(b) Coordination of controls and audits of public procurement

Assessment criteria
(a) There are written procedures that state requirements for internal controls, ideally in an internal control manual.
(b) There are written standards and procedures (e.g. a manual) for conducting procurement audits (both on compliance and performance) to facilitate co-ordinated and mutually reinforcing auditing.
(c) There is evidence that internal or external audits are carried out at least annually and that other established written standards are complied with.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 12(b) Assessment criterion (c): - number of specialised procurement audits carried out compared to total number of audits (in %). - share of procurement performance audits carried out (in % of total number of procurement audits). Source: Ministry of Finance/Supreme Audit Institution.
(d) Clear and reliable reporting lines to relevant oversight bodies exist.

12(c) Enforcement and follow-up on findings and recommendations

Assessment criteria
(a) Recommendations are responded to and implemented within the time frames established in the law.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 12(c) Assessment criterion (a): - Share of internal and external audit recommendations implemented within the time frames established in the law (in %). Source: Ministry of Finance/Supreme Audit Institution.
(b) There are systems in place to follow up on the implementation/enforcement of the audit recommendations.

12(d) Qualification and training to conduct procurement audits

Assessment criteria
(a) There is an established programme to train internal and external auditors to ensure that they are qualified to conduct high-quality procurement audits, including performance audits.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 12(d) Assessment criterion (a): - number of training courses conducted to train internal and external auditors in public procurement audits. Source: Ministry of Finance/Supreme Audit Institution. * Recommended quantitative indicator to substantiate assessment of sub-indicator 12(d) Assessment criterion (a): - share of auditors trained in public procurement (as % of total number of auditors). Source: Ministry of Finance/Supreme Audit Institution.
(b) The selection of auditors requires that they have adequate knowledge of the subject as a condition for carrying out procurement audits; if auditors lack procurement knowledge, they are routinely supported by procurement specialists or consultants.
(c) Auditors are selected in a fair and transparent way and are fully independent.

13. Procurement appeals mechanisms are effective and efficient

13(a) Process for challenges and appeals

Assessment criteria
(a) Decisions are rendered on the basis of available evidence submitted by the parties.
(b) The first review of the evidence is carried out by the entity specified in the law.
(c) The body or authority (appeals body) in charge of reviewing decisions of the specified first review body issues final, enforceable decisions.* // Minimum indicator // * Quantitative indicator to substantiate assessment of sub-indicator 13(a) Assessment criterion (c): - number of appeals. Source: Appeals body. * Recommended quantitative indicator to substantiate assessment of sub-indicator 13(a) Assessment criterion (c): number (and percentage) of enforced decisions. Source: Appeals body.
(d) The time frames specified for the submission and review of challenges and for appeals and issuing of decisions do not unduly delay the procurement process or make an appeal unrealistic.

13(b) Independence and capacity of the appeals body. The appeals body:

Assessment criteria
(a) is not involved in any capacity in procurement transactions or in the process leading to contract award decisions
(b) does not charge fees that inhibit access by concerned parties

(c) follows procedures for submission and resolution of complaints that are clearly defined and publicly available // Minimum indicator // * Quantitative indicator to substantiate assessment of sub-indicator 13(b) Assessment criterion (c): - appeals resolved within the time frame specified in the law/exceeding this time frame/unresolved (Total number and in %). Source: Appeals body.
(d) exercises its legal authority to suspend proceedings and impose remedies
(e) issues decisions within the time frame specified in the law/regulations*
(f) issues decisions that are binding on all parties
(g) is adequately resourced and staffed to fulfil its functions.
13(c) Decisions of the appeals body. Procedures governing the decision making process of the appeals body provide that decisions are:
Assessment criteria
(a) based on information relevant to the case.
(b) balanced and unbiased in consideration of the relevant information.* Recommended quantitative indicator to substantiate assessment of sub-indicator 13(c) Assessment criterion (b): - share of suppliers that perceive the challenge and appeals system as trustworthy (in % of responses). Source: Survey. - share of suppliers that perceive appeals decisions as consistent (in % of responses). Source: Survey.
(c) result in remedies, if required, that are necessary to correcting the implementation of the process or procedures.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 13(c) Assessment criterion (c): - outcome of appeals (dismissed; decision in favour of procuring entity; decision in favour of applicant) (in %). Source: Appeals body.
(d) decisions are published on the centralised government online portal within specified timelines and as stipulated in the law.* // Minimum indicator // *Quantitative indicator to substantiate assessment of sub-indicator 13(c) Assessment criterion (d): - share of appeals decisions posted on a central online platform within timelines specified in the law (in %). Source: Centralised online portal.*

14. The country has ethics and anticorruption measures in place

14(a) Legal definition of prohibited practices, conflict of interest, and associated responsibilities, accountabilities, and penalties: The legal/regulatory framework provides for the following:

Assessment criteria
(a) definitions of fraud, corruption and other prohibited practices in procurement, consistent with obligations deriving from legally binding international anti-corruption agreements.
(b) definitions of the individual responsibilities, accountability and penalties for government employees and private firms or individuals found guilty of fraud, corruption or other prohibited practices in procurement, without prejudice of other provisions in the criminal law.
(c) definitions and provisions concerning conflict of interest, including a cooling-off period for former public officials.

14(b) Provisions on prohibited practices in procurement documents

Assessment criteria
(a) The legal/regulatory framework specifies this mandatory requirement and gives precise instructions on how to incorporate the matter in procurement and contract documents.
(b) Procurement and contract documents include provisions on fraud, corruption and other prohibited practices, as specified in the legal/regulatory framework.

14(c) Effective sanctions and enforcement systems

Assessment criteria
(a) Procuring entities are required to report allegations of fraud, corruption and other prohibited practices to law enforcement authorities, and there is a clear procedure in place for doing this.
(b) There is evidence that this system is systematically applied and reports are consistently followed up by law enforcement authorities.
(c) There is a system for suspension/debarment that ensures due process and is consistently applied.
(d) There is evidence that the laws on fraud, corruption and other prohibited practices are being enforced in the country by application of stated penalties.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 14(c) Assessment criterion (d): - Firms/individuals found guilty of fraud and corruption in procurement: number of firms/individuals prosecuted/convicted; prohibited from participation in future procurements (suspended/debarred). Source: Normative/regulatory function/anti-corruption body. - Government officials found guilty of fraud and corruption in public procurement: number of officials prosecuted/convicted. Source: Normative/regulatory function/anti-corruption body. - Gifts to secure public contracts: number of firms admitting to unethical practices, including making gifts in (in %). Source: Survey.

14(d) Anti-corruption framework and integrity training

Assessment criteria
(a) The country has in place a comprehensive anti-corruption framework to prevent, detect and penalise corruption in government that involves the appropriate agencies of government with a level of responsibility and capacity to enable its responsibilities to be carried out.* * Recommended quantitative indicator to substantiate assessment of sub-indicator 14(d) Assessment criterion (a): - percentage of favourable opinions by the public on the effectiveness of anti-corruption measures (in % of responses). Source: Survey.
(b) As part of the anti-corruption framework, a mechanism is in place and is used for systematically identifying corruption risks and for mitigating these risks in the public procurement cycle.
(c) As part of the anti-corruption framework, statistics on corruption-related legal proceedings and convictions are compiled and reports are published annually.
(d) Special measures are in place for the detection and prevention of corruption associated with procurement.
(e) Special integrity training programmes are offered and the procurement workforce regularly participates in this training.

14(e) Stakeholder support to strengthen integrity in procurement

Assessment criteria
(a) There are strong and credible civil society organisations that exercise social audit and control.

(b) There is an enabling environment for civil society organisations to have a meaningful role as third-party monitors, including clear channels for engagement and feedback that are promoted by the government.	
(c) There is evidence that civil society contributes to shape and improve integrity of public procurement.*	
* Recommended quantitative indicator to substantiate assessment of sub-indicator 14(e) Assessment criterion (c): - number of domestic civil society organisations (CSOs), including national offices of international CSOs actively providing oversight and social control in public procurement.	
Source: Survey/interviews.	
(d) Suppliers and business associations actively support integrity and ethical behaviour in public procurement, e.g. through internal compliance measures.*	
* Recommended quantitative indicator to substantiate assessment of sub-indicator 14(e) Assessment criterion (d): - number of suppliers that have internal compliance measures in place (in %).	
Source: Supplier database.	
14(f) Secure mechanism for reporting prohibited practices or unethical behaviour	
Assessment criteria	
(a) There are secure, accessible and confidential channels for reporting cases of fraud, corruption or other prohibited practices or unethical behaviour.	
(b) There are legal provisions to protect whistle-blowers, and these are considered effective.	
(c) There is a functioning system that serves to follow up on disclosures.	
14(g) Codes of conduct/codes of ethics and financial disclosure rules	
Assessment criteria	
(a) There is a code of conduct or ethics for government officials, with particular provisions for those involved in public financial management, including procurement.*	
* Recommended quantitative indicator to substantiate assessment of sub-indicator 14(g) Assessment criterion (a): - share of procurement entities that have a mandatory code of conduct or ethics, with particular provisions for those involved in public financial management, including procurement (in % of total number of procuring entities).	
Source: Normative/regulatory function.	
(b) The code defines accountability for decision making, and subjects decision makers to specific financial disclosure requirements.*	
* Recommended quantitative indicator to substantiate assessment of sub-indicator 14(g) Assessment criterion (b): - officials involved in public procurement that have filed financial disclosure forms (in % of total required by law).	
Source: Normative/regulatory function.	
(c) The code is of mandatory, and the consequences of any failure to comply are administrative or criminal.	
(d) Regular training programmes are offered to ensure sustained awareness and implementation of measures.	
(e) Conflict of interest statements, financial disclosure forms and information on beneficial ownership are systematically filed, accessible and utilised by decision makers to prevent corruption risks throughout the public procurement cycle.	

Source: OECD Methodology for Assessing Procurement Systems (MAPS) [4]

7.2 Methodological aspects related to the interviews with Portuguese stakeholders

7.2.1 Informed consent form

Avaliação da compra centralizada de medicamentos em Portugal

FORMULÁRIO PARA CONSENTIMENTO INFORMADO

O formulário seguinte deve ser preenchido pelo entrevistador antes da entrevista. É necessário preencher um formulário por cada entrevistado. |

Informação sobre o entrevistado

Nome e apelido	
Afilição (instituição)	
Contactos	Morada: Telf: Email:
Grupo de <i>stakeholder</i> (se aplicável)	

Data da entrevista	
Nome do entrevistador	

Consentimento informado

Na tabela seguinte, assinale em que casos o entrevistado dá o seu consentimento.

<input type="checkbox"/>	Para participar no estudo O entrevistado manifesta verbalmente a sua vontade de participar no estudo, dizendo: "Fui informado sobre este estudo e compreendo os seus objetivos. Concordo em participar neste estudo, de forma voluntária, fornecendo informações e perspetivas sob o ponto de vista do <i>stakeholder</i> /instituição que represento. Compreendo que a minha participação no estudo não é remunerada."
<input type="checkbox"/>	Para recolha e validação da informação Os entrevistadores vão tomar notas durante a entrevista, que não será gravada. Em tempo útil, os pontos chave da entrevista serão resumidos e as minutas serão partilhadas para validação. O entrevistado está interessado em receber e validar as minutas que resultem da sua entrevista. O entrevistado foi informado de que os comentários às minutas deverão ser enviados no prazo de 2 semanas a contar da data em que as receber, caso contrário as minutas serão consideradas validadas. O entrevistado pode pedir a extensão do prazo para validar as minutas.
<input type="checkbox"/>	Para que o nome do entrevistado conste da lista de agradecimentos A informação que os entrevistados fornecerem será tratada com o devido zelo. O estudo não discriminará quem, em concreto, forneceu determinada informação. Contudo, a informação pode ser atribuída a uma instituição ou <i>stakeholder</i> (por exemplo: farmacêutico hospitalar, agência que faz a compra). Para podermos agradecer a participação do entrevistado, vamos precisar de mencionar o seu nome e afiliação na lista de agradecimentos do estudo. O entrevistado aceita que o seu nome e afiliação sejam listados nos agradecimentos.

7.2.2 Interview guides

More than 20 interview guides for the different groups were developed. The generic interview guides for three main groups addressed in the on-site in-depth interviews are presented below.

Generic interview guide for public authorities

Role of the Institution *(may be skipped for authorities that participated in the exploratory interviews)*

- » Please describe briefly the role of your institution within the structure of the Portuguese health system.
- » Please describe briefly the role of your institution against the backdrop of public procurement in general and procurement of medicines in particular.

Legal, regulatory and policy framework

- » Please describe the scope of application and coverage of the legal and regulatory framework regarding centralised public procurement of medicines.
- » Is it legally required that procurement opportunities are publicly announced?
 - » How many procurement platforms are there in Portugal? State owned or private companies?
- » Does legislation define a minimum content of procurement and requires that content is relevant and sufficient for suppliers to respond to the requirement?
 - » Are there any requirements for bidders that require specific registrations/licenses?
- » Does legislation define requirements for participation of interested parties? Are there any exclusion criteria?
 - » Are the exclusion grounds/qualification criteria for bidders generally the same in CPM for medicines?
 - » What could be the main reasons to set different types of qualification criteria in the procurements for medicines?
- » Are there any obligations emerging from the “Valletta Group” is there a partnership agreement?

Centralised public procurement (of medicines)

- » Please describe the process of public procurement (of medicines) from your perspective.
 - » Is there a policy framework or strategy in place to implement strategic public procurement?
 - » Is sustainability (i.e. economic, environmental and social criteria) considered in the procurement procedure and how?
- » What is the range of procurement methods used for medicines?
 - » If open procedures are the most common choice, in which situation other procedures (direct award) are used?
 - » Is fractioning of contracts to limit competition prohibited? Are there legal terminology / explanations for “fractioning of contracts” versus “dividing procurement into lots”?
 - » What are the standards for competitive procedures? Are there any restrictions for using less competitive procedures?
- » What are the evaluation criteria for public procurement in general, and for medicines in particular?
 - » Other than price criteria, what are the most common quality criteria used in the procurements for medicines?
 - » Are they precisely specified in advance e.g. in law, in the procurement documents?

Implementing regulations and tools to support the legal framework

- » Are there regulations that supplement and detail the provisions of procurement law?
- » Which types of tools to support the legal framework on CPM for medicines in Portugal exist?
 - » Are there standard contract conditions for the procurement of medicines and is their use mandatory?
 - » Are there any model procurement documents related to the procurement of medicines?
 - » What is the status of e-procurement in Portugal?
 - » Are there any procurement manuals detailing the procedures related to procurement of medicines?

Concluding & further information to share

- » Any other issues / challenges, developments and observations (positive or negative) that you wish to share with us?
- » Any documents that you suggest us to consider (they can be in Portuguese)?
- » Any further people that we should talk to?

Generic interview guide for users (hospitals and ARS)

Process of procurement of medicines, including CPM – Description

- » Which processes of procuring medicines do you apply (CPM, direct procurement by the hospital or a group of hospitals you are involved in)?
 - » How many medicines under which procedure?
 - » Which types of medicines under which procedure?
- » Could you describe the procedure of CPM?
 - » Who is involved? Who decides on the needs' estimate? Who reports to SPMS?
 - » How do you assess the need for the medicines under CPM? Are the estimates always correct? What do you do if you require more centrally procured medicines during a year? What if fewer medicines are consumed?
- » Could you describe other procedures of procuring medicines in your hospital? What are the main differences?

Assessment of CPM

- » What have been major changes due to the introduction of CPM?
 - » E.g. with regard to processes, time-lines, planning security?
 - » E.g. with regard to workload (if possible, to be specified by the interviewee through concrete figures)
 - » E.g. with regard to medicine prices (concrete examples to be listed)
- » How do you assess the CPM processes? (*unless already covered by answers to the previous question*)
 - » E.g. with regard to efficiency?
 - » E.g. with regard to availability and accessibility of medicines needed?
 - » E.g. with regard to economic outcomes such as savings (concrete examples to be listed)
- » Are you aware of the list of INN under CPM?
 - » Do you consider them sufficient?
 - » Any suggestions for change?
 - » Are you aware of the rules which are applied to include INN in this CPM list? If yes, do you agree with them, or would you have any suggestions for improvement?
- » How do you consider the cooperation with relevant institutions related to CPM, such as SPMS?
 - » Do you receive all the information you require?
 - » Time of response?
 - » Is all your input appropriately taken into consideration?
 - » Any suggestions for improvement?
 - » Which other public institutions besides SPMS are also of relevance for you?
- » Has the introduction of CPM changed the communication (and how?)?
 - » within the hospital (e.g. with the doctors, the Pharmaceutical Therapeutic Committee)?
 - » With pharmaceutical companies and wholesale?
 - » With patients?
 - » Others?

Challenges and solutions for the future

- » How high is the relevance of shortages in your hospital? (*unless already covered before, e.g. on the question related to availability*)
 - » Do shortages affect equally medicines under CPM as well as those not procured under CPM?
 - » Would you see a relationship between the introduction of CPM and (the increase in) shortages? Why (not)?
 - » Which instruments (e.g. supply obligations, mandatory registers) could be used to minimise the risk of shortages? Could they be built into the CPM procedure?

Concluding & further information to share

- » Any other issues / challenges, developments and observations (positive or negative) that you wish to share with us?
- » Any documents that you suggest us to consider (they can be in Portuguese)?
- » Any further people that we should talk to?

Generic interview guide for other stakeholders (patients, industry)

Involvement in CPM

- » Are you directly or indirectly involved in or affected by CPM?
 - » Could you describe the role of your association/organisation?
 - » Do you estimate the possibilities for participation of your institution/association as sufficient?
- » In which stages of the procurement process do you have the opportunity to get involved?
 - » with regard to following stages: (1) planning, (2) proposal opening, (3) evaluation and contract award.
 - » How much are you involved in activities preceding public procurement, such as implementation and development of strategies and processes?
- » How would you consider the conditions for participating in public procurement for medicines?
 - » With regard to following dimensions: (1) access to financing, (2) procurement methods, (3) contracting provisions, (4) payment provisions, (5) appeal mechanisms, and (6) division of contracts into lots.
 - » What conditions are met, and which should be improved, and how?

Capacity and processes of CPM

- » Do you consider the legal framework of CPM sufficient for its purpose? If not, what would have to be changed?
- » Is it clear to you, which institutions take which responsibilities for CPM in Portugal?
 - » Do you estimate that these institutions are competent and accountable?
 - » How do you perceive the procedure of public procurement conducted by SPMS?
- » Are the public procurement processes transparent to you?
 - » How would you consider the accessibility and availability of information (data, analysis, information, monitoring, results, guidelines) about procurement?
- » Do existent procurement methods meet the needs (choice and documentation of procurement methods, differences between contract awards and invitations of tenders, defined criteria in public procurement used, level of confidentiality)?
- » Do you estimate the CPM has a strong capacity to develop and improve?
 - » Are there any programmes to help build capacity of relevant stakeholders to understand, monitor and improve public procurement?
- » Have you ever challenged a decision of CPM?
 - » Are there concerns regarding the opportunities to appeal to the administrative court?
 - » Are there concerns regarding the consideration of evidence submitted to the appeals body?
 - » How large are the fees for filling complaints, do they constitute an obstacle?
 - » Do you have the impression that all pieces of information relevant to the appeal are considered?
- » Are the ethics and anti-corruption measures in place suitable, are you aware of them?
 - » Do you think governmental anti-corruption agencies do have sufficient responsibility and capacity to carry out effective anti-corruption measures? Do you think that the current legal provisions to protect whistle blowers in the field of public procurement are effective?
 - » Have you developed a code of conduct for your members including provisions on ethical behaviour in public procurement?
- » How would you consider the Portuguese market for public procurement of medicines in terms of competitiveness?

Assessment of changes

- » What would you consider as the most important changes due to CPM?
 - » With regard to (1) availability of medicines, (2) processes (decision-making), governance, accountability, (3) efficiency and effectiveness, (4) prices (concrete examples)?
- » What were the key successes and less successful developments due to the introduction of CPM?
 - » Which would be your proposals for improvement?

Further information to share

- » Would you like to share any further information, data or documents?

7.2.3 Overview of interviews by geography and stakeholder group

Table 7.3:

Annex – Participants of the on-site interviews in Portugal in January / February 2020

Stakeholder	Federal level	Regional level					Total
		Porto and North	Centre	Lisbon & Tagus Valley	Alentejo	Algarve	
Public authorities	10 interviews: MoF, MoH, INFARMED, ACSS, DGS, esPap, IGAS, SPMS, AdC, TdC	–	–	–	–	–	10
Hospitals	–	5 interviews: CHUP, CHUSJ, CHVNG, Hospital Pedro Hispano	4 interviews: IPO de Coimbra, CHUC	4 interviews: IPO de Lisboa, HGO, CHULC	2 interviews: HESE	2 interviews: CHUA	17
ARS	–	1 interview: ARS Norte	1 interview: ARS Centro	1 interview: ARS LVT	2 interviews: ARS Alentejo, ULSNA	–	5
Patients	2 interviews: APDI, GAT	–	–	–	–	–	2
Industry	3 interviews: Generic company, APIFARMA, Health expert whose affiliation should not be disclosed	–	–	–	–	–	3
Total	15	6	5	5	4	2	37

ACSS = Administração central do Sistema de Saúde / Central Administration of the Health System, AdC = Autoridade da Concorrência / Competition Authority, ADPI = Associação Portuguesa da Doença Inflamatória do Intestino / Portuguese Association of Inflammatory Bowel Disease, APIFARMA = Associação Portuguesa da Indústria Farmacêutica / Portuguese Association of Hospital Pharmacists, ARS = Administração Regional de Saúde / Regional Health Authority, CHUC = Centro Hospitalar e Universitário de Coimbra, CHUP = Centro Hospitalar Universitário do Porto, CHUSJ = Centro Hospitalar Universitário de São João, CHVNG = Centro Hospitalar de Vila Nova de Gaia, DGS = Direção-Geral da Saúde / Directorate-General of Health, esPap = Entidade de Serviços Partilhados da Administração Pública / Government Shared Services Entity, GAT = Grupo de Ativistas em Tratamento, IGAS = Inspeção-Geral das Atividades em Saúde / Central State Direct Administration Service, INFARMED = Autoridade Nacional do Medicamento e Produtos de Saúde / National Authority of Medicines and Health Products, IPO = Instituto Português de Oncologia / Portuguese Oncology Institute, MoF = Ministry of Finance, MoH = Ministry of Health, SPMS = Serviços Partilhados do Ministério da Saúde, TdC = Tribunal de Contas / Court of Auditors

Note: The number of interviews is higher than the number of institutions because in some institutions two interviews were held. Some interviewees also represented further associations, e.g. Pharmacists' association (OF), Portuguese Association of Hospital Pharmacists (APFH), Portuguese Association of Hospital Managers (APAH)

Source and presentation: the authors

7.3 Methodological aspects related to the interviews with procurement experts of other countries

Semi-structured interviews were held with procurement experts from **Cyprus, Denmark, Italy and Norway**. An interview guide was developed which was shared in advance together with the informed consent form (see below). The interviews surveyed learnings from the national procurement experience, and the interviewees were invited to suggest possible approaches for improvements for Portugal. Informed consent was taken orally. The researchers took notes and documented the findings in minutes that were sent to the interviewees for information and possible validation. It was agreed with the interviewees that the minutes were considered to be accepted in cases of no responses within two weeks (or a requested extended period of time).

In the case of **Estonia** and also the **Baltic Procurement Initiative**, no separate interview was held but project team member Eveli Bauer of the Estonia Health Insurance Fund (EHIF) provided this information.

The Baltic Procurement Initiative and the **Nordic Pharmaceutical Forum** were the sole cross-country collaborations included in this investigation of international procurement expertise, since they are the only ones with experience in joint procurement. Other collaborations such as “Valletta Declaration” (to which Portugal is a member) have not yet started to perform joint procurement or they conduct joint price and reimbursement negotiations but no procurement, such as the Beneluxa initiative [9]).

An international procurement expert of UNICEF was also invited for an interview but declined, given her intensive involvement in the global COVID-19 crisis management.

Informed consent form

Evaluating the centralised public procurement of medicines in Portugal

INFORMED CONSENT FORM

Informed consent has to be taken by the interviewer before each interview.

The interviewer is responsible for filling the table below.

Information about the interviewee (to be filled for each interviewee)	
Name and surname	
Affiliation (institution)	
Contact details	Address: Tel: Email:
Stakeholder group (if applicable)	
Interview date	
Interviewer	
Informed consent (tick if there is consent)	
<input type="radio"/>	Consent to participate in the study The interviewee accepts orally to participate in the study: <i>"I was informed about the study, and I understand its aims. I agree in participating, on a voluntary basis, in this study by providing information and perspectives from the point of view of the stakeholder/institution that I represent. I understand that there is no remuneration for my participation in the study."</i>
<input type="radio"/>	Collection and validation of information The interviewer(s) will take notes during the interview (no recording). In due time, the key findings of the interview will be summarized, and the minutes can be shared for validation. The interviewee is interested in receiving the minutes of the interview for information and validation. The interviewee was informed that comments on the minutes are to be provided within 2 weeks upon receipt, otherwise the minutes are considered to be accepted. The interviewee can ask for an extension of the time period for validation of the minutes.
<input type="radio"/>	To be listed in the acknowledgements The information received will be dealt with the highest possible level of diligence. It will not be disclosed who said what. However, information might be attributable to an institution and stakeholder group (e.g. hospital pharmacist, procurement agency). In order to acknowledge for the participation in the study, the interviewee's name and affiliation will be mentioned in the acknowledgements of the study, if there is no objection. The interviewee agrees to be listed in the acknowledgements.

Interview guide

1) Personal experience on public (centralised) procurement of medicines

Briefly explain your role and expertise with regard to public (centralised) procurement of medicines in your country / in the international context.

What have been your key learnings that you would like to share, with regard to

- difficulties and challenges that you were confronted with – and how you managed them,
- opportunities – and how you used (and could not use) them,
- necessary prerequisites,
- achievements and benefits,
- continuing and new barriers and hurdles,
- others

2) Discussion on possible approaches on how to address gaps in CPM in Portugal – optional *(kindly do not share the findings at this point of time)*

Portugal's procurement agency is SPMS ("Shared Services of the Ministry of Health"), a public entity under the Ministry of Health which offers other public services (e.g. IT services) for NHS entities and does the procurement of all goods and services, including medicines and medical devices, for NHS institutions (i.e. public hospitals and regional health administrations). SPMS is commissioned and funded for its services by ACSS ("Central Administration of the Health System", payer in the NHS) to perform CPM and to further develop procedures.

There are two major procedures:

- » CPM in the narrower sense: SPMS to procure centrally for NHS institutions for a period of one year, based on the need assessment submitted by the users and their proof of availability of funds. There is a list of INN subject to CPM (last updated in 2016).
- » Framework agreements (Acordos Quadros / AQ): SPMS to list qualified suitable suppliers within an acceptable price range in an e-catalogue for several years, and the NHS institutions can then make call-offs.

Major relevant actors are the procurement agency SPMS, ACSS as commissioner and payer of SPMS's activities, the Medicines Agency INFARMED which is in charge of marketing authorisation and pharmacovigilance as well as pricing and reimbursement of medicines, including the conclusion of managed-entry agreements (but not directly involved in CPM), the Ministries of Health and of Finance, the Court of Auditors (which has to approve procurements of NHS institutions above a specific budget threshold) as well as public hospitals and regional health administrations.

Major gaps: *In the following, we list some weaknesses, gaps and characteristics identified in Portugal, and we would like to discuss with you some of them with a view on finding feasible solutions:*

Delays in conclusion of procedures of CPM (in narrower sense) by end of the year, resulting in parallel procedures launched by hospitals (direct procurements):

No procurement strategy:

No performance indicators to monitor:

Underfunding:

Lack of clinical expertise in procurement agency:

No institutionalised horizontal communication between key public authorities (procurement agency, Medicines Agency, public payers and commissioning entity for procurement agency):

“Winner-takes-it-all-principle” (until beginning of 2020):

3) Challenges and opportunities

Which are the key messages to share with Portugal (and any country that moves on with CPM)?

7.4 Stakeholder workshop

7.4.1 Methodology

Online “World Café” methodology

The stakeholder workshop had initially been designed as an on-site meeting in Lisbon, applying the “World Café” methodology. This is the format for hosting large group dialogue, in which people discuss in a small group (around a table facilitated by “table host”), and then move on after some time to a next table.

Given the COVID-19 pandemic situation, a face-to-face meeting was not possible. A virtual stakeholder workshop was held which integrated, in an adopted manner, elements of the “World Café” methodology.

Participations to the stakeholder meeting was upon invitation. All interviewees were invited, plus some further stakeholders representing public authorities, users, patients and industry. Upon registration, all participants received a background document (a 4-page paper which summarized key findings of the assessment and some preliminary proposals for action), including the agenda.

After an introductory input of the authors of this study, four breakout sessions were created. The assignment to the groups had been decided in advance, upon registration of the participants, in order to ensure a balance of different stakeholder groups (members of the Advisory Board did not participate in the breakout session; since an Advisory Board meeting was held in parallel).

Each group had a facilitator (usually a hospital administrator) to guide the discussion, and a rapporteur. Facilitators and rapporteurs had been briefed in writing and in a briefing meeting.

The discussion was aimed to address the following questions:

- » Do you consider the diagnosis of the CPM evaluation comprehensive and correct? (*reference of a visualisation provided in the background document shared in advance with the participants and presented by the authors in their input was made*)
 - Which parts do you explicitly agree to and would like to endorse?
 - Which parts do you not agree to? Why not?
 - What is missing?

- » Would you agree to the preliminary recommendations? (*reference of a visualisation provided in the background document shared in advance with the participants and presented by the authors in their input was made*)
 - Which recommendations would you agree to?
 - Which recommendations do you not agree to? Why not?
 - Which recommendations are missing?
 - Which recommendations do you consider not (very) feasible or realistic?

- » How would assign priorities to the preliminary recommendations? (*optional, if there is enough time to discuss*)
 - Which (reform) actions would you consider of highest priority?
Do you agree with the prioritisation made by the researchers (*reference of a visualisation provided in the background document shared in advance with the participants and presented by the authors in their input was made*)
 - How can you (your stakeholder group) contribute?
 - Which prerequisites would be needed for implementation?

The facilitators briefly reported back to the plenary at the end of the meeting.

The rapporteurs provided a written report in English about the discussions in their group, based on a template provided to them, to the authors in the report.

The stakeholder workshop was held in English, apart from the discussion in the breakout sessions (in Portuguese).

Meeting materials

The authors prepared the following documents for the stakeholder workshop:

- » Concept note on the organisation of a stakeholder workshop in times of Corona for the project “Evaluating CPM in Portugal” – for discussion with EMSPOS and DG REFORM
- » Agenda – shared with the participants of the stakeholder workshop in advance
- » “Evaluating the centralised public procurement of medicines in Portugal”. Background Document in preparation of the virtual Stakeholder Workshop, 8 October 2020 – shared with the participants of the stakeholder workshop in advance
- » Guidance document for facilitators and rapporteurs of the breakout sessions of the Stakeholder Workshop, 8 October 2020 – shared with the facilitators and rapporteurs in advance, explained in a briefing meeting on 6 October 2020
- » Template for the rapporteur’s reports – shared with the rapporteurs in advance

The agenda is presented below. The other documents are made available by the authors at request.

Agenda

Facilitator: Julian Perelman

- **10:30 – 10:45 Welcome**
 Antonieta Ávila, *Mission structure for the sustainability of the Portuguese National Health Service (EMSPOS)*
 Miguel Rodrigues, *Ministry of Health*
 Florin Popa, *Project Officer, DG REFORM, European Commission*
- **10:45 – 11:00 Setting the scene**
 Julian Perelman, *National School of Public Health*
- **11:00 – 11:30 Assessment of Centralised Procurement of Medicines in Portugal – Key findings of the evaluation and preliminary recommendations**
 Sabine Vogler and Katharina Habimana, *Pharmacoeconomics Department, GÖ FP (Gesundheit Österreich Forschungs- und Planungs GmbH / Austrian National Public Health Institute)*
- **11:30 – 12:45 Moderated breakout sessions**
 Small group discussion on the findings and recommendations of the assessment (supported by group facilitator)
- **12:45 – 13:15 Brief reporting back from the groups** (by group facilitator)
- **13:15 – 13:30 Closing of the meeting & outlook**
 Rui Rodrigues, *Ministry of Finance*

Working language: English (except for moderated breakout sessions: held in Portuguese)

7.4.2 Outcomes

Meeting Report

Gesundheit Österreich
Forschungs- und Planungs GmbH

Evaluating the centralised public procurement of medicines in Portugal

Meeting report of the virtual Stakeholder Workshop,
8 October 2020

Around 40 stakeholders of public authorities, hospitals, regional health administrations, patients and industry participated in a workshop in which findings of an evaluation of the centralised procurement of medicines and preliminary recommendations were presented and discussed.

Welcome

Antonieta Ávila from the Mission structure for the sustainability of the Portuguese National Health Service (EMSPoS), Miguel Rodrigues of the Ministry of Health and Florin Popa of the Directorate-General for Structural Reform Support (DG REFORM) of the European Commission welcomed the participants of the stakeholder workshop. The welcoming words emphasised that the high participation rate of stakeholders is a sign for the relevance of public procurement in Portugal and the commitment of the participants to this project.

Setting the scene

Julian Perelman from the National School of Public Health (previously affiliated to the Mission structure for the sustainability of the Portuguese National Health Service) gave an overview about the context of the project (i.e. relevance of public procurement, increasing pharmaceutical expenditures) and the cornerstones of the project. Julian highlighted that the project is not a scientific exercise, but rather a 'hands-on' project, based on experience of users and stakeholders of CPM in Portugal. Therefore it is expected that the results of this project will be feasible and implementable, and contribute to an improvement of CPM in Portugal that will serve as best-practice example for other EU countries.

Assessment of Centralised Procurement of Medicines in Portugal – Key findings of the evaluation and preliminary recommendations

Sabine Vogler and Katharina Habimana of GÖ FP (Austrian National Public Health institute) gave a presentation on the key findings from the evaluation of centralised public procurement of medicines (CPM) in Portugal. The assessment of CPM was based on (1) literature, (2) interviews (5 exploratory interviews with the Advisory Board and 37 on-site face-to-face interviews, in total 52 people in 11 municipalities in all 5 mainland regions of Portugal), and (3) analysis of the procurement portal 'Vortal' and of a sample of bids. The assessment was guided by the analytical framework of the "Methodology for Assessment Procurement Mechanisms" (MAPS) of the Organisation for Economic Co-operation and Development (OECD), see <http://www.mapsinitiative.org>. The information provided by interviewees was structured according to the MAPS taxonomy, and the following figure lists the gaps identified and mentioned in interviews.



Source: analysis of GÖ FP based on the OECD MAPS framework

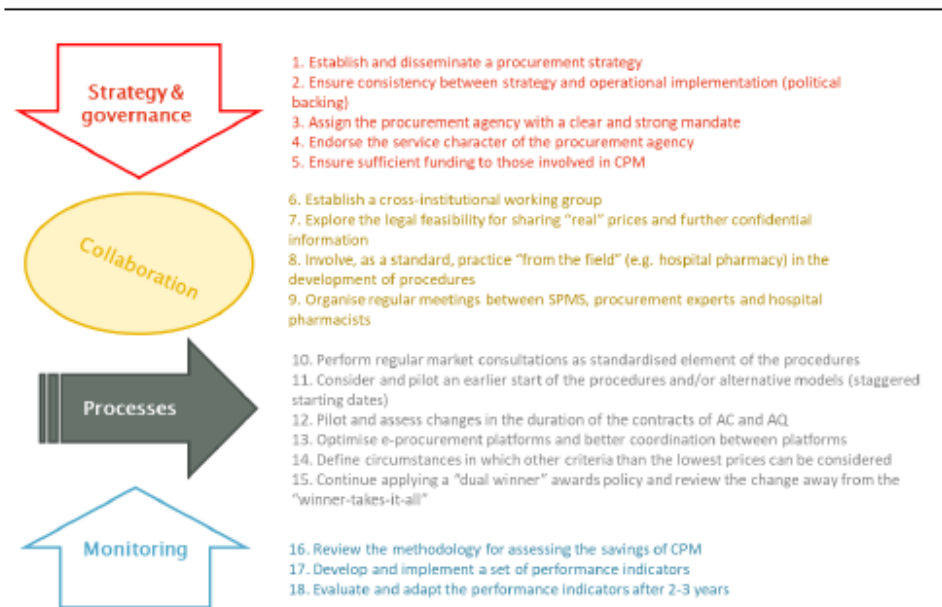
In addition to the gaps analysis, the researchers conducted a SWOT (strengths, weaknesses, opportunities and threats) analysis. In principle, interviewees representing different stakeholders (public authorities, users, patients and industry) were all supportive of the concept of CPM but pointed to some weaknesses and (possible) gaps that require further attention. Overall, both strengths and weaknesses of the CPM in Portugal were identified.

Strengths	Weaknesses
<ul style="list-style-type: none"> » Procurement legislation in line with international standards and publicly accessible » Specific procurement agency for CPM was set up » Overall, CPM has contributed to increased transparency of processes and governance » Lower workload for most (but not all) users » Shifting of pressure (e.g. by doctors asking for specific medicines) from the hospital to central level » Lower prices and thus savings for public expenditure for some medicines (e.g. generics) - but not for other medicines » Lower risk of appeals for users » e-Procurement contributes to transparent and smooth processes » Several procurement documents are publicly accessible » High learning curve and improvements in recent times » Strong audit and control systems for public procurement in general 	<ul style="list-style-type: none"> » Procedures are bureaucratic and inefficient » Lengthy processes; procedures have not been concluded on time at the beginning of the year » Lack in strategy and prioritisation, including related to rules for announcing new procedures and procedures for exceptions » Lack in clarity of the roles of the involved institutions » Lack in coordination and cooperation between the public institutions » Several procurement management and data / information sharing platforms to manage CPM » Limitations in the active involvement of and communication to users, limited involvement of civil society » Critical under-budgeting of public hospitals over years » Higher prices and thus higher public expenditure in certain situation (e.g. larger hospitals) » Rather low number of bidders, limited competition » Lack of flexibility in technical specifications » Lack of (performance) indicators to evaluate CPM and the tasks of SPMS in this field » Lack of easy-at-hand high-level data for measuring and assessing CPM » No systematic market consultations » Lowest price as sole evaluation criterion as it may limit competition

Opportunities	Threats
<ul style="list-style-type: none"> » Positive attitude of all stakeholders towards CPM in principle, rationale is well understood » Commitment of staff in SPMS and other public authorities to learn and improve » High interest and willingness of all stakeholders to collaborate and improve » A few recent positive experiences of involvement of users in the preparation of AQ to build on » Good collaboration between hospital pharmacy and procurement departments at user level » Improvements of SPMS and perceived high willingness of SPMS to optimise » Increase in budget for 2020 (if still applicable in COVID-19 times) » Higher volumes due to CPM make the Portuguese market more attractive » Changes made in recent years highlight high potential and interest to learn and improve » The introduction of the "two-winners" approach in 2020 (substituting the "winner-takes-it-all"-principle) may help limit availability issues » Centralised approach can contribute to equity across Portugal (access also for patients in smaller hospitals in less central areas) 	<ul style="list-style-type: none"> » Lack of clarity of the roles of the institutions may lead to redundancies (inefficiencies) and gaps / under-performance » Lack of strategy may cause inefficiencies and poor governance and may demotivate staff and experts » Low prices due to CPM may reduce the attractiveness of the Portuguese market » Switch of biologicals only after 6 months may limit headroom for savings from biosimilar medicines » Delays in timely conclusion of procedures result in parallel processes (direct procurements): this leads to redundancies, higher prices, higher workload and possibly higher risk of fraud and corruption » CPM is one of several activities that SPMS is mandated to do: risk of co-financing other areas » Public budgets may be inadequately defined and allocated and do not incentivise further developments (e.g. performance indicators – by ACSS) » Confidentiality of discounts negotiated by INFARMED misinforms SPMS in the tender management

Source and presentation: CÖ FP

The assessment of CPM in Portugal was the starting point for the development of recommendations. This process was also informed by interviews with procurement experts in Cyprus, Denmark, Estonia, Italy and Norway.



Source and presentation: CÖ FP

Moderated breakout sessions

Participants of the workshop (see Annex) were split into four groups to discuss the findings of the project's assessment exercise and the draft recommendations.

Brief reporting back from the groups

The facilitator of each group briefly summarised the key messages of the discussions in their groups. Following points were mentioned by the facilitators.

- » **Overall agreement with recommendations:** Discussions within the group showed overall agreement with the findings and recommendations of the project team. While it was remarked that most points are no novelty but have been known to the participants for a while, hope was expressed that the research conducted by a foreign institute might raise attention and could lead to change.
- » **Clinical and pharmaceutical expertise at procurement procedures:** It was noted that centralised procurement is mainly conducted by lawyers who are experts in legal provisions, but they may not have the necessary expertise when it comes to pharmaceuticals. Thus, the recommendation to involve more pharmacy expertise was supported.
- » **Increase transparency – decrease bureaucracy:** Increased transparency among entities involved in pharmaceutical regulation and procurement could result in a better allocation of resources (e.g. currently, however, information on MEAs concluded by INFARMED is not available to SPMS when preparing procurement of medicines). In addition, participants highlighted the need for streamlined procedures as the current administrative burden for centralised procurement is deemed too high.
- » **Performance indicators:** The definition of performance indicators for institutions involved in procurement could contribute to a better comparability of figures on savings. Furthermore, a set of indicators supports procurement units to identify headroom for improvement but also allows an evaluation of the impact of procurement in the next year.
- » **Broader focus than just prices:** It was critically discussed whether, or not, the price should be the sole award criterion. An emphasis on price is perceived as ‘secure’/‘defensive’ tendering, because quantitative elements of tendering (like prices) are hard criteria and less subject to appeals. However, this focus could have undesired – maybe not advantageous – effects on society (e.g. thinning of the market).
- » **More dialogue with stakeholders:** Along the procurement procedures several stakeholders are affected and it was recommended to better involve them. These include patients who do not have any active role in current procedures, pharmaceutical companies whose regular consultation prior to call for tenders was suggested, and users in hospitals or other health facilities.

The researchers were asked to elaborate better in the report how the findings of the gaps analysis, the SWOT analysis and the recommendations are linked.

Furthermore, it was recommended to look more closely at shortages. Since shortages are a major issue in Portugal – and also in all other EU member states – it was recommended to consider including them in the final recommendations.

Closing of the meeting & outlook

Rui Rodrigues from the Ministry of Finance closed the stakeholder workshop and gave an outlook on the next steps: The report will be finalised by the end of this year, and next year the implementation of recommendations will start.

Annex: List of Participants

Name	Institution
Carlos Alves	Centro Hospitalar Universitário de São. João Comissão Nacional de Farmácia e Terapêutica
Antonieta Avila	Mission structure for the sustainability of the Portuguese National Health Service
Paulo Barbosa	Centro Hospitalar Universitário do Porto
Eveli Bauer	Estonian Health Insurance Fund
Rafael Belchior	<i>Rapporteur</i>
José Antonio Carpinteiro	Tribunal de Contas
Catarina Coelho	Administração Regional de Saúde (ARS) do Centro
Heitor Costa	Associação Portuguesa da Indústria Farmacêutica (Apifarma)
Nuno Costa	Serviços Partilhados do Ministério da Saúde (SPMS)
Célia Cravo	Centro Hospitalar e Universitário de Coimbra
Ana Teresa Cruz	Centro Hospitalar Universitário de Lisboa Central
Ana Duarte	Hospital do Espírito Santo de Évora
Jessica Duvee	<i>Rapporteur</i>
Pedro Freitas	Associação Portuguesa da Indústria Farmacêutica (Apifarma)
Luis Filipe Fernandes	Administração Regional de Saúde (ARS) do Norte
Manuela Figueiredo	Centro Hospitalar Universitário do Algarve
Valter Fonseca	Direção-Geral da Saúde
Claudia Furtado	INFARMED
António Melo Gouveia	Instituto Português de Oncologia Francisco Gentil
Alexander Haasis	Austrian National Public Health Institute
Katharina Habimana	Austrian National Public Health Institute
Karla Leal	<i>Rapporteur</i>
Luis Almeida Lopes	Associação Portuguesa da Indústria Farmacêutica (Apifarma)
João Madeira	Associação Portuguesa de Medicamentos Genéricos e Biossimilares (APOGEN)

Luis Mendão	Grupo de Ativistas em Tratamentos
Sónia Moura	Autoridade da Concorrência
João Oliveira	Instituto Português de Oncologia Francisco Gentil
Andreia Túlia Oliveira	Serviços Partilhados do Ministério da Saúde (SPMS)
Julian Perelman	Mission structure for the sustainability of the Portuguese National Health Service
Luisa Pereira	Hospital do Espírito Santo de Évora
Julio Pedro	Instituto Português de Oncologia de Lisboa
César Pestana	Entidade de Serviços Partilhados da Administração Pública (eSPap)
Ana Quaresma	<i>Rapporteur</i>
Nadine Ribeiro	Administração Regional de Saúde (ARS) de Lisboa e Vale do Tejo
Ana Sofia Rodrigues	Autoridade da Concorrência
Miguel Rodrigues	Ministério da Saúde
Rui Rodrigues	Ministério das Finanças
Ana Sampaio	Associação Portuguesa Doença Inflamatória Intestino
Carla Reis Santos	Inspeção-Geral de Finanças
Carlos Santos	Centro Hospitalar e Universitário de Coimbra
Inês Louro dos Santos	Associação Portuguesa de Farmacêuticos Hospitalares (APFH)
Peter Schneider	Austrian National Public Health Institute
Sandra Sousa	Centro Hospitalar e Universitário de Coimbra
Ana Valente	Associação Portuguesa de Medicamentos Genéricos e Biossimilares (APOGEN)
Clementina Varela	Instituto Português De Oncologia De Coimbra
Isaura Vieira	Administração Central do Sistema de Saúde (ACSS)
Sabine Vogler	Austrian National Public Health Institute

Follow-up reports

Rapporteurs of the four moderated break-out session sent in a more detailed meeting report in writing within one week after the meeting.

Key additional findings of these reports included:

- » There were mixed opinions of participants with regard to the recommendation on exploring legal feasibility of sharing confidential price data. The recommendation was discussed rather generally, with addressing limited transparency of medicines prices in general. While some participants were supportive of the current situation (and beneficial for the public payer) and/or did not see a change feasible, others were in favour to move forward towards more price transparency.
- » Some participants (hospital administrators) had doubts whether, or not, the “two-winners-system” is sufficiently effective to address shortages. (*note*: from 2020 on, the “two-winners-principle” was – where possible – introduced in AC procedures, and the award is granted to the two best-bidding suppliers).
- » Some recommendations are considered as too broad. The authors were asked to further develop the recommendation in a way that they are more specific.
- » A point of discussion concerned the feasibility of the measures. Some measures were not considered to be very feasible, and a few suggested to focus the more feasible options.
- » The need for a procurement strategy was highlighted.
- » Users (hospitals) asked for a review of their payment plans (*note*: this topic concerns hospital funding / payment options which was not scope of this study).
- » Hospital representatives reported to feel pressured by patient associations and pharmaceutical industry in some cases.
- » In more than two break-out groups, the lack of human resources in CPM was stressed.

7.5 Delphi survey

Summary of the first round

Evaluating the centralised public procurement of medicines in Portugal

Delphi Survey 2nd round

Background

The centralised procurement of medicines (CPM), which had been introduced some years ago, was evaluated, with a view of identifying gaps and developing recommendations for improvement.

One activity of the planned validation process is a 2-round Delphi process (see Annex 1) for the respective section on the Delphi survey in the tender.

- » **1st round:** selected stakeholders to comment on the Draft Report with SMART recommendations – a template ("questionnaire") to be provided
- » **2nd round:** stakeholders to comment on the summary of the comments and the revised Draft Report with SMART recommendations – a template ("questionnaire") to be provided
- » **In case of no agreement:** different viewpoints to be documented

In the Status Update meeting on 1 September 2020, it was decided **not to aim for agreement** among the group of those participating in the Delphi survey, **but to benefit from their comments for improving** the (presentation of the) recommendations.

Participants in the Delphi survey

- » Jaime Espin, professor in health economics, Escuela Andaluza de Salud Pública (EASP), <https://www.easp.es/personal-easp/profesorado-y-equipo-tecnico/#20>
- » Helder Mota Filipe, professor of pharmacy at Lisbon university, former INFARMED vice-president, <https://imed.ulisboa.pt/cv/helder-mota-filipe/>
- » Francisco Ramos, professor in health economics, Escola Nacional de Saúde Pública, <https://www.ensp.unl.pt/docentes/francisco-ramos/>
- » Nuno Sousa Pereira, professor in economics at Porto university and specialist in drug market, <https://up-pt.academia.edu/NunoDeSousaPereira>

Summary of comments on the draft recommendations on the first round

- » Agreement to several recommendations, different perception of prioritisation in some cases
- » The main issues are (1) a clear mandate, (2) strategy, (3) involvement of users (hospital pharmacists, hospital managers, etc.), (4) improving of monitoring/evaluation/assessment tools, (5) importance of e-procurement and (6) market consultation
- » The mandate should be aligned with the general objective of procurement (improve competition, obtaining fair and affordable prices)
- » Ensure willingness to develop and establish monitoring/evaluation/assessment tools
- » Viability depends on the political will to change the process and provide technical conditions
- » Recommendations should separate 'technical' aspects of CPM from 'political' aspects

- » Consider potential extension of procurement to medical devices
- » Savings generated by better prices should be earmarked to improve resources of CPM

Legend for the "Heat-Map" below

Agreement on Yes / Agreement on priority/feasibility

Agreement on No / Agreement on or weak disagreement priority/Feasibility (strong vs. middle)

Weak disagreement (1 person) on recommendations / weak disagreement on priority/feasibility (middle vs. low)

Strong Disagreement (2 persons) on recommendations / strong disagreement on priority / feasibility (high vs. low)

Assessment has not been possible (e.g. due to missing answer)

Recommendations	Do you agree with proposing the recommendation?	Priority (High / Middle / Low)	Feasibility (High / Middle / Low) -	Required prerequisites (optional)	Any further comments (optional)
1. Establish and disseminate a procurement strategy	4 in favour	3 high / 1 middle	1 High / 2 middle	Development of a strategy and description (technical and scientific preparation) of how it fits in the overall health care strategy	Feasibility of all recommendations is affected by COVID-19 pandemic Dissemination not so important
2. Ensure consistency between strategy and operational implementation (political backing)	4 in favour Is this recommendations covered or interlinked with recommendation 3?	3 high / 1 middle	2 middle / 1 low	Political willing and strong leadership of the SPMS administration.	How to deal with changes in the management of entities e.g. SPMS management has changed in 2020
3. Assign the procurement agency with a clear and strong mandate	4 in favour	3 high / 1 middle	3 middle	Agreement between MoH and MoF Willingness to accept autonomy of the agency Strengthening of internal audit tools	
4. Endorse the service character of the procurement agency	2 in favour / 1 against / 1 not sure Is this recommendation covered or interlinked with recommendation 1B	1 high / 2 middle	2 high / 1 middle	Political will and strong leadership of the SPMS administration.	
5. Ensure sufficient funding to those involved in CPM	3 in favour / 1 against	2 high / 1 middle / 1 Low	3 low		
6. Establish a cross-institutional working group	4 in favour	4 high	4 high	Definition of goals and procedures Group should be responsible for implementation of the strategy	Consider involvement of stakeholders not directly involved in the process Consider difficulties on institutional relationships
7. Explore the legal feasibility for sharing "real" prices and further confidential information	4 in favour	3 middle / 1 low	2 middle / 2 low	Cooperation of pharmaceutical industry (opposition can be expected) Final price of tender should not be disclosed Transparency of procurement process promotes implementation of recommendations	For on patent medicines this situation is similar in all EU countries, therefore it could be an issue for an intervention from the European Commission Crucial step towards full transparency and accountability of the process

Recommendations	Do you agree with proposing the recommendation?	Priority (High / Middle / Low)	Feasibility (High / Middle / Low) -	Required prerequisites (optional)	Any further comments (optional)
8. Involve, as a standard, practice "from the field" (e.g. hospital pharmacy) in the development of procedures	3 in favour / 1 against	2 high / 1 middle	2 high / 1 middle		A clear mandate for these persons is essential. Unclarity with regard to rec. 6
9. Organise regular meetings between SPMS, procurement experts and hospital pharmacists	2 in favour / 1 against / 1 not sure Is this recommendation a separate recommendation or	2 high / 1 low	3 high	Implementation of recommendation # 6 --> could # 6 extended by #9	
10. Perform regular market consultations as standardised element of the procedures	4 in favour	2 high / 1 middle / 1 low	3 high / 1 middle		Main activity to ensure the success in the tender Could be covered through involvement of actors in the cross-institutional working group
11. Consider and pilot an earlier start of the procedures and/or alternative models (staggered starting dates)	2 in favour, 1 against	1 high / 1 low	2 middle		Not sure exactly what procedures are being mentioned that are not in place right now.
12. Pilot and assess changes in the duration of the contracts of AC and AQ	3 in favour, 1 against	2 high / 1 low	1 high / 2 middle		
13. Optimise e-procurement platforms and better coordination between platforms	4 in favour	3 High / 1 low	1 high / 1 middle / 2 low		
14. Define circumstances in which other criteria than the lowest prices can be considered	3 in favour / 1 against	2 high / 1 middle	3 middle		E.g. in order to ensure competition in the biosimilar market other criteria than prices need to be defined Should reflect choices made in recommendation 1

Recommendations	Do you agree with proposing the recommendation?	Priority (High / Middle / Low)	Feasibility (High / Middle / Low) -	Required prerequisites (optional)	Any further comments (optional)
15. Continue applying a "dual winner" awards policy and review the change away from the "winner-takes-it-all"	4 in favour	1 high / 2 middle / 1 low	2 high / 1 middle / 1 low		The "dual winner" principle should also depend on the number of competitors; for few competitors (e.g. biosimilars) dual winner is recommended, for many competitors (e.g. generics) single winner can be the best solution "dual winner" principle should be decided case-by-case
16. Review the methodology for assessing the savings of CPM	4 in favour	1 High / 1 middle / 1 low	2 High / 1 low		High importance in order to assess the impact of the strategy This is one of the most important aspects involved in the process of CPM.
17. Develop and implement a set of performance indicators	3 in favour / 1 against No need for a separate recommendations as it is covered by a previous recommendation.	2 high / 1 middle	2 High / 1 Low	Implementation of recommendation 1	This is a key issue to bring transparency and confidence to the process.
18. Evaluate and adapt the performance indicators after 2-3 years	3 in favour / 1 against	1 high / 2 middle	1 high / 1 Middle / 1 low		
List below any recommendations that you consider missing!					
Political decision makers should have their involvement mostly limited to the approval of the agency's strategy.					
There should be clear enforcement and accountability rules in the process.					
Align the list of products involved in the process with the priorities and strategy of the MS					

Evaluating the centralised procurement of medicines in Portugal – Recommendations

Delphi Survey 2nd round, 17 November 2020

Meeting Report

Participants

Delphi survey participants:

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Background

The centralised procurement of medicines (CPM) in Portugal had been evaluated by the study authors, and they had developed draft recommendations for improvement.

In a first round, the Delphi survey participants commented in writing on a draft report with 18 SMART recommendations. The second round took place in the form of a virtual meeting on 17 November 2020, in which the participants explained the rationale behind their choices, i.e. whether, or not, they agreed with the proposed recommendations and with the priority and feasibility assessments. As a preparation for the second round meeting, a summary document which compiled the responses of the four Delphi survey participants was shared with them.

Key messages

1. *Broadly overall agreement:* Overall, the Delphi survey participants agreed with most of the recommendations, and for several recommendations, they also agreed with each other.

2. *Different perceptions related to priorities and feasibility:* It was argued for a larger balance between low and high priority – not all recommendations should be high priority.
3. *Redundancy of recommendations:* Recommendations were considered to be too detailed for a high level policy document. Some of the recommendations seem to be duplicated, and they could be emerged into one strong overarching recommendation (i.e. on strategy)
4. *Different way of presenting the recommendations:* It was proposed to divide recommendations into two parts: into strategy and (high-level) management. In fact, the establishment of a procurement strategy was considered to be the key recommendation, on which all further action depends.
5. *Misunderstandings:* In some cases, some recommendations had been misunderstood in the way how they had been originally phrased --> the authors will rephrase and better explain.
6. *Further recommendations:* Some additional recommendations were suggested (e.g. strong internal auditing processes).

Detailed comments on the draft recommendations

Recommendations	Comments of the Delphi survey participants in the 2 nd round
<p><u>Recommendations 1– 3:</u></p> <p>R1. Establish and disseminate a procurement strategy</p> <p>R2. Ensure consistency between strategy and operational implementation (political backing)</p> <p>R3. Assign the procurement agency with a clear and strong mandate</p>	<p>These recommendations are considered to be the basis for change and development of the current central (CPM) and are principle recommendations for following recommendations 4–18 to be implemented.</p> <p>It was pointed out that SPMS currently lacks strong mandate and clear strategy. Also, CPM should be more focused as centrally procured product list is very long and specificities of the medicines are not always considered. Therefore, substantial effort and work should be put on the procurement strategy together with the product list that needs to be aligned with the overall health strategy and priorities of the Ministry of Health and Ministry of Economics. There was also a suggestion to establish a high-level task force to implement the procurement strategy.</p>
<p>R4. Endorse the service character of the procurement agency</p>	<p>It was suggested that recommendation 4 could be interlinked to recommendations 1–3 as integral part of the strategy and operational implementation.</p>
<p>R5. Ensure sufficient funding to those involved in CPM</p>	<p>It was suggested that recommendation 5 could be interlinked to recommendations 1–3 as integral part of the strategy and operational implementation. It is not supported to raise the funding in general without substantiation for increased costs (e.g. an annual percentage of overall budget). However, it was noted that there must be sufficient funding to fulfil commitments. A key problem about funding is lack of transparency, especially in terms of savings. It should be clear for everyone how savings are distributed and what are the main principles to invest the earnings (e.g. either investments to hospitals or return to treasury, etc.). One suggestion was to use savings to fund CPM.</p> <p>In this context, the importance of capacity (of SPMS staff, for instance) was considered as key (both in quantitative as well as in qualitative terms).</p>

Recommendations	Comments of the Delphi survey participants in the 2 nd round
R6. Establish a cross-institutional working group	This recommendation was considered a high priority and was assessed high feasibility. It was emphasised several times that the cross-institutional working group is the key element for successful implementation of the procurement strategy. There is a need to update the INN list for CPM. However, it was noted that there must be clear understanding of the tasks and mandate of the working group to avoid establishing too many different (small) expert groups which essentially could experience problems in terms of responsibilities and collaboration. Furthermore, it should be avoided spending excessive resources and time on too many meetings without clear results and input to CPM. Working group(s) should have shared goals and clear understanding how each institution can contribute to achieve the predefined objectives. It was also suggested that the involvement of external institutions and agencies could be beneficial to implement procurement strategy. In addition, it was also suggested (as recommendation to the EC) to strengthen the health procurement collaboration at European level.
R7: Explore the legal feasibility for sharing "real" prices and further confidential information	This recommendation is linked to the transparency of the procedures and accountability of the processes. It was urged for a strong mandate for both internal and external auditing procedures and entities.
R8: Involve, as a standard, practice "from the field" (e.g. hospital pharmacy) in the development of procedures	The recommendation was considered important, but the involvement of the practise "from the field" should be foremost based on sharing know-how and expertise, not delegating decision-making processes. CPM has changed the procurement culture in hospitals and therefore regular information sharing and communication on pre-defined goals is mutually beneficial to avoid confrontations and negative feedback on CPM from the users. It was also suggested to consider using internal expertise for the off-patent and the on-patent markets separately since the situation in terms of competition and possible choice of the strategic procurement tools are different for these two market segments
R9. Organise regular meetings between SPMS, procurement experts and hospital pharmacists	It was suggested that recommendation 9 could be merged with other recommendations keeping in mind the comment made on recommendation 6 to avoid too many working groups/ meetings.
<p>Recommendations 10 –15:</p> <p>R10. Perform regular market consultations as standardised element of the procedures</p> <p>R11: Consider and pilot an earlier start of the procedures and/or alternative models (staggered starting dates)</p> <p>R12: Pilot and assess changes in the duration of the contracts of AC and AQ</p> <p>R13: Optimise e-procurement platforms and better coordination between platforms</p> <p>R14: Define circumstances in which other criteria than the lowest prices can be considered</p> <p>R15: Continue applying a "dual winner" awards policy and review the change away from the "winner-takes-it-all"</p>	These recommendations were considered good and valuable, but rather as recommendations at management/operational level and not as high priority at the policy level. Linking to other recommendations could be an option to shorten the overall list of recommendations. The recommendations could be listed as strategic procurement options which should be used only if they are justified. The aim should be to ensure the sustainability of the system by strengthening the procedures and focusing on long-term rather than short-term savings. Piloting new procurement procedures before a change was not favoured as it will lose valuable time, and the results could be difficult to assess based on the pilot.

Recommendations	Comments of the Delphi survey participants in the 2 nd round
<u>Recommendations 16 – 18:</u> R16: Review the methodology for assessing the savings of CPM R17: Develop and implement a set of performance indicators R18: Evaluate and adapt the performance indicators after 2–3 years	Recommendations 17 and 18 were considered to be part of one recommendation and they were also considered to be linked to the recommendation on developing a methodology to assess savings of the CPM (recommendation 7). It was considered as high priority to have transparency in terms of goals (performance indicators) and results (foremost savings). It was also noted that right incentives are important so that everyone who is involved understands how s/he can benefit. Developing and implementing performance indicators and assessing the results should be linked to the procurement strategy established in the recommendation 1.

Conclusions

The study authors thanked the Delphi survey participants for their valuable inputs. All Delphi survey participants agreed to be acknowledged in the report. No further action on their behalf is needed.

7.6 Framework for public procurement of medicines

The key document regulating public procurement in Portugal is the **Public Procurement Code (PPC)**, approved by Decree 18/2008 as of 29 January) that translates EU Directives 2004/17 and 2004/18 into national public procurement legislation. PPC was amended latest by Decree 111-B/2017 as of 31 August implementing the regulation foreseen in three EU directives as of 26 February 2014 (2014/23/EU (Concession Contracts Directive), 2014/24/EU (Public Procurement Directive) and 2014/25/EU (Utilities Directive)) and translating them into the Portuguese legal framework, which also provides for “transparency, non-discrimination and fair competition” [10].

In the most recent update of the PPC, Decree no. 33/2018 of 15 May, significant aspects of public procurement procedures and contracts were modified with the intention to simplify the PPC while adding on transparency measures and reducing bureaucracy in the decision-making processes. Moreover, the new PCC intends to increase the access to small- and medium-sized enterprises to the public contracts market, as it creates more flexible rules. Additionally, Decree Law no. 123/2018, of 28 December, which was approved in 2019, regulates an organisational model for the implementation of electronic invoicing in public procurement.

As functions and activities of public procurement are rather fragmented, updating the legal framework regarding public procurement is, in principle, a shared responsibility of several institutions. In reality, it is the Ministry of Finance that contributes most to changes in legislation.

The institution implemented as vehicle for the central procurement in health in Portugal is **SPMS**, established in 2010 under the Decree-Law no. 19/2010 as a public entity (Entidade Pública Empresarial / EPE). SPMS has three main areas of activities: (1) central procurement of goods including medicines for SNS institutions such as public hospitals and ARS, (2) the development of IT and (3) communication tasks. All legislation regarding establishing, rights and duties of SPMS is available under <https://www.spms.min-saude.pt/estatutos>.

Ordinance no. 55/2013, of 7 February defines the categories of products subject to central procurement by SPMS. According to Decree No. 1571B/2016 all SNS institutions are obliged to use SPMS for the procurement of their goods and services. The role of SPMS though goes beyond this, as the range of medicines purchased centrally has increased and exceeds the ones named on the central purchase list.

It should be noted that the central procurement by SPMS adds to the central procurement activities of the Government Shared Services Entity (Entidade de Serviços Partilhados da Administração Pública / **eSPap**). Among other activities, eSPap is responsible for the central purchase of all goods and services for public administration except for health and defence.

CPM in Portugal was implemented with a view to being compliant to the international framework. Portugal’s legal framework on public procurement incorporates, complements and details respective EU directives.

7.7 Summary of the MAPS–based findings

Table 7.4:
Annex – Summary of findings per MAPS indicator (qualitative indicators)

Indicator	Assessment	Identified gaps / concerns voiced by interviewees
Pillar I: Legal, Regulatory and Policy Framework		
1. The public procurement legal framework achieves the agreed principles and complies with applicable obligations.	<p>CPM in Portugal complies with the different legal and regulatory instruments and fulfils obligations deriving from international agreements and standards (e.g. EU). The Public Procurement Code (PPC) is the key legal provision in this area. The legal framework offers a clear definition of procurement methods, includes requirements to publish procurement opportunities and regulates participation and selection to ensure that they are non-discriminatory. It specifies the content of procurement documents, evaluation and award criteria, submission of tenders and e-procurement, the right to appeals and norms for safekeeping of records, documents and electronic data.</p> <p>At the level of the legal and regulatory framework, no issues were detected.</p> <p>It is to be noted that the PPC does not take into account the specificities of the health sector, and as such medicines would be acquired as any other supply.</p>	–
2. Implementing regulations and tools support the legal framework.	<p>The regulatory framework / legislation regarding public procurement is continuously updated.</p> <p>Procurement documentation for CPM appears to be standardized, and there are no or minor discrepancies between document clauses / conditions. Specifications (including contract terms) for CPM appear to be standardized.</p> <p>Procurement tools are provided for in the legislation but they appear not to be fully utilised. For instance, the PPC allows the use of the MEAT (Most Economically Advantageous Tender), but in practice the price is used as sole award criterion. There is no competition across active substances (if therapeutically equivalent).</p>	<ul style="list-style-type: none"> - Procurement tools are provided for in the legislation but they appear not to be fully utilised - Net prices (i.e. real prices that include confidential discounts negotiated in managed-entry agreements between INFARMED and a pharmaceutical companies) are not shared with SPMS.
3. The legal and policy frameworks support the sustainable development of the country and the implementation of international obligations.	<p>Public procurement-related obligations deriving from binding international agreements are consistently adopted in laws and regulations and reflected in procurement policies.</p> <p>While the law does not explicitly define sustainability aspects, it provides for the possibility that such aspects could be built either in the tender or could be used to define eligibility conditions.</p>	–
Pillar II: Institutional Framework & Management Capacity		
4. The public procurement system is mainstreamed and well integrated into the public	<p>In principle, planning, budgetary allocation and feedback mechanisms are in place and integrated.</p> <p>The funding of the procurement activities of SPMS by ACSS is seen as a major advantage, as it allows for an early start of CPM procedures.</p> <p>There are securities built in the system (e.g. proof of availability of funds for the solicitation of tenders and call-offs). As a result, funds at user level are blocked. This can be an issue</p>	<ul style="list-style-type: none"> - Concerns of cross-funding (from CPM to other SPMS activities) due to the large portfolio of SPMS (see below indicator 5 and also indicator 7 on monitoring)

Indicator	Assessment	Identified gaps / concerns voiced by interviewees
financial management system.	<p>when they would need funding for parallel procedures as contingency measure.</p> <p>One underlying problem is likely the very tight budgets of hospitals and SNS institutions. Due to limited budgets in recent years, several hospitals have arrears and appear to have developed practices which are not in line with rules (e.g. storing of goods and paying at the time of use).</p>	<ul style="list-style-type: none"> - Tight budgets of hospitals and further SNS institutions - Lack of a procurement strategy, which would, among others, define the role of CPM and the procurement agency as part of the financial management system
5: The country has an institution in charge of the normative / regulatory function.	<p>In 2010, SPMS was set up and was tasked to, among others, perform CPM (before done by ACSS which now commissions SPMS). Further legislation (e.g. obligation to SNS institutions to obligatorily use SPMS for defined active substances) strengthened the role of SPMS in CPM.</p> <p>The establishment of an explicit procurement agency for CPM offers a valuable basis.</p> <p>However, in the case of "transversal goods" (not health goods), the role of SPMS (responsible to procure the whole portfolio for SNS institutions) versus the eSPap (the procurement agency for the public sector except for health and defence) is not clear.</p> <p>Furthermore, the analysis showed an urgent need for more clarity on the role and responsibilities and roles of SPMS and other key institutions (ACSS and INFARMED), in particular with regard to strategic and operational roles: It should be ensured that SPMS can focus on the operational performance of CPM while other institutions (e.g. ACSS, MoH) are responsible for strategic guidance based on a procurement strategy.</p> <p>There is no overarching national procurement strategy related to medicines.</p> <p>Collaboration between ACSS, INFARMED and SPMS is done based on ad-hoc initiatives of committed staff.</p> <p>As a result, a working group of ACSS, INFARMED and SPMS which would be responsible for the update of the list of active substances under AC was discontinued.</p>	<ul style="list-style-type: none"> - Large portfolio of SPMS (procurement is only one among several tasks; concern of cross-funding, see above) - Limited clarity on the role of SPMS for "transversal goods" – in comparison to the procurement agency eSPap - Roles and responsibilities of SPMS, ACSS and INFARMED are not sufficiently well defined, in particular with regard to the division of competences between strategy and operational issues - Lack of a procurement strategy, which would, among others, define the role of SPMS and other public institutions involved - No institutional coordination between ACSS, INFARMED and SPMS, the key public institutions in the field - Outdated list of active substances under AC
6: Procuring entities and their mandates are clearly defined	<p>Parallel procedures (AC by SPMS and direct procurement of hospitals) are performed, in particular at the beginning of the year, when AC procedures have not been concluded on time and provisions are needed to bridge the gap.</p>	<ul style="list-style-type: none"> - Effects of CPM may be undermined by parallel processes (direct procurement of users)
7: Public procurement is embedded in an effective information system.	<p>Publication of public procurement information supported by information technology (IT), namely the platform "Vortal" whose content is partially publicly accessible.</p> <p>Due to lack of funding and staff and possible lack of clarity who is in fact in charge of strategy, electronically available data are not analysed. In addition, the data are not always easily retrievable.</p>	<ul style="list-style-type: none"> - Lack of capacity and resources to move forward with strategic procurement (including analysis of procurement data)

Indicator	Assessment	Identified gaps / concerns voiced by interviewees
8: The public procurement system has a strong capacity to develop and improve.	Data on key performance indicators (KPI) to describe procurement activities and efficiency are not be available . Key elements such as trainings, advice to users, collaboration between targeted institutions exist but they appear not to be institutionalised but rather happen based on ad-hoc initiatives of committed staff. Good practice examples include the recent involvement of hospital pharmacists in the preparation of AQ by SPMS and regular meetings of SPMS with procurement experts. However, regular meetings of SPMS with hospital pharmacists would be appreciated.	<ul style="list-style-type: none"> - No monitoring of performance of CPM (lack of performance indicators) - Room for improvement of SPMS communication to users and consideration of clinical practice
Pillar III: Public Procurement Operations & Market Practices		
9: Public procurement practices achieve stated objectives.	<p><i>Planning:</i></p> <p>Major efforts are put on the needs assessment reported by the users for AC procedures. This is done annually, as a two-step approach: First, there is the need assessment internally in the hospitals / ARS (involvement of pharmacy and procurement units) around June, and later filled files are submitted to SPMS by end of August. The need analysis sent to SPMS must be accompanied by the procurement mandate and a confirmation of funds.</p> <p>There is a risk of delay if SPMS does not receive the required documents from the users in time. Delays may also result from missing budget approval for the users.</p> <p><i>Selection and contracting:</i></p> <p>Procurement procedures ensure that only qualified suppliers are included in the competitive process. For both procedures, AC and AQ, only few qualification criteria need to be met by suppliers (usually IRS declaration and the social security declaration).</p> <p>There is no clear understanding when the award decisions are published and contracts signed. This lack in transparency on timelines of the tender lead to waste and mismanagement in the stock management.</p> <p>Delays in procedures are risks for access to medicines, and can lead to parallel procedures when hospitals start their own procurements to avoid stock-outs.</p> <p><i>Contract management:</i></p> <p>Procedures and contracts were reported to not have been implemented on time.</p> <p>Invoices were reported to not be examined and processed on time.</p>	<ul style="list-style-type: none"> - Lengthy procedures and delayed conclusion of procedures - Resulting in parallel procedures of users (direct procurements)
10: The public procurement market is fully functional.	<p>There are few mechanisms to establish dialogue between private sector and representatives of SPMS, and this is considered insufficient by pharmaceutical industry.</p> <p>Capacity building programmes for private companies are offered by SPMS ad-hoc at request: as they are not strategically structured in a continuous manner, this can result in overlooking needs of private companies, especially of small businesses.</p> <p>Before the procedures SPMS makes inquiries with possible suppliers, but there is no formal protocol for market consultation.</p>	<ul style="list-style-type: none"> - No complete picture of the market, no systematic market research and consultation - Limited knowledge of low performers - Several e-portals

Indicator	Assessment	Identified gaps / concerns voiced by interviewees
	<p>There are indications that the private sector competitiveness level in the procurement for medicines is decreasing. If not addressed appropriately, this may lead to more frequent shortages and stock-outs and higher prices for medicines.</p> <p>There are several procurement portals, with “Vortal” being the most important one for CPM. IT and electronic platforms to support e-procurement support CPM processes. However, it is not always used by users (e.g. in case of direct procurement). Thus, there are several procurement portals in place, and this is not coordinated. It is a challenge for possible bidder.</p>	
Pillar IV: Accountability, Integrity and Transparency of the Public Procurement System		
<p>11: Transparency and civil society engagement foster integrity in public procurement.</p>	<p>An environment that allows consultation of the public has been created through specific project (e.g. “Projeto Incluir” of INFARMED). Due to limited resources, patient involvement is not always possible (e.g. in guideline development). In CPM, an example of consultation and involvement was reported, but it appears to be rather rare cases.</p> <p>There appears to be no systematic involvement of patients and the public in CPM. However, overall, projects for patient involvement (e.g. in HTA processes) have been started.</p> <p>E-procurement allows easy and timely access to procurement documents (if not protected), but the parallel use of different procurement platform is considered as a potential barrier.</p>	<p>- Limited involvement of the civil society</p>
<p>12: The country has effective control and audit systems.</p>	<p>Portugal has strong audit systems and institutions, in particular Tribunal de Contas (TdC) and – less relevant for public procurement – audit. In addition, ACSS as payer and contracting body for SPMS is in charge of the performance of SPMS. Strategic performance indicators are yet to be developed by ACSS. Linked to limitations on the clarity of roles of public institutions involved in procurement, there appears to be a need for improvement in the coordination of monitoring. Application of a few selected indicators applied by ACSS to evaluate the performance of ACSS would be helpful to both ACSS and SPMS and also offer strategic guidance.</p>	<p>- No monitoring of performance of CPM (see indicator 8)</p>
<p>13: Procurement appeals mechanisms are effective and efficient.</p>	<p>While operational questions and complaints are dealt through the platform by SPMS, the administrative courts are responsible for handling procurement appeals.</p> <p>CPM shifted the risk to be confronted by an appeal from the users (hospital) to a more central level and thus freed resources for hospitals.</p>	<p>-</p>
<p>14: The country has ethics and anti-corruption measures in place.</p>	<p>Portugal has several ethic and anti-corruption measures for government staff and public procurement (not specifically targeted to CPM) in place. A milestone was the establishment of the Council for the Prevention of Corruption in 2008 as an independent administrative body to prevent corruption in public and private organisations that use public funds. The Court of Auditors (TdC) which presides this Council undertakes audits. The Competition Agency (AdC) launched a public campaign to improve awareness of unethical behaviour (e.g. bid rigging) and offer in-house training programmes for public entities. Code of conducts have been introduced at central, regional and likely also entity levels.</p> <p>Despite these progresses, it was commented that an institution for fraud monitoring in procurement of medicines that is independent from ACSS and SPMS is missing.</p>	<p>- Lack of a dedicated entity to monitor and combat fraud in CPM</p>

Indicator	Assessment	Identified gaps / concerns voiced by interviewees
	The authors cannot assess if this well-established package of measures for ensuring good governance is, in practice, always effective to avoid and combat fraud and corruption.	

Data compilation and analysis based on OECD MAPS [4] by the authors

7.8 Stakeholders' perceptions of effects of CPM

Perceptions on the implications and effects of CPM in Portugal by mainly users of CPM given in the on-site interviews in January / February 2020 were as follows.

7.8.1 Perceived effects of CPM on medicines prices

There was a **mixed assessment** related to the evolution of prices following CPM, as some interviewees of all stakeholder groups (users, authorities and others) reporting lower medicines prices due to CPM and others, again of all groups, noted price increases.

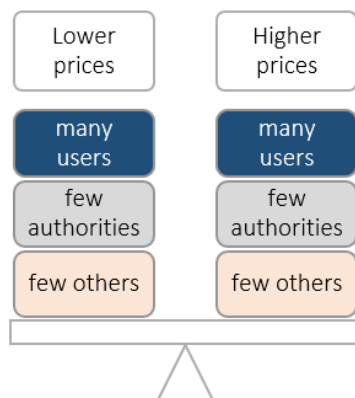
Interviewees who argued that CPM contributed to lower prices considered **economies of scale** as major reason. In particular for **low-volume medicines**, lower prices were said to have been achieved compared to direct procurement.

Generics were among the medicines that were reported to have shown lower prices. At the same time, it was argued that price reductions might be attributable to other causes (e.g. patent expiry, increased competition) than larger volumes.

Some users pointed to **different developments of prices dependent on the type of medicines**: prices for some medicines went down and prices of other medicines increased.

Figure 7.1:

Annex – Stakeholders’ perception of the effect of CPM on medicines prices



How to read this figures and following similar figures: Statements from users, authorities and other stakeholders on presented topics were counted and categorised by their frequency (e.g. few, some or many users who made this statement in the relevant context). It is to be noted that more users than authorities and other stakeholders were interviewed, resulting in the categorisation of "many" mainly relevant for the stakeholder group of users. In this Figure the statements were balanced, i.e. many users, few authorities and few other stakeholders perceived a decrease in prices, while many users, few authorities and few other stakeholders also observed higher prices compared to the situation before the introduction of CPM in Portugal. This may be attributable to the fact that prices for some medicines might have increased while others might have decreased.

Source and presentation: The authors based on information gathered during interviews

Several interviewees (mainly users, but also some public authorities), however, said that there was no proof that CPM has led to lower prices than compared to what single, in particular large hospitals were able to achieve. This was mainly due to the **discontinuation of confidential discounts** and rebates that hospitals had been granted by industry before introduction of CPM.

Finally, users and industry argued that with the delayed conclusion of procedures and non-availability of medicines at the beginning of the year, hospitals eventually had to **procure directly** from the pharmaceutical companies at possibly higher prices. It was also argued that due to the low price level (unattractive markets), suppliers had left the market, which required importing medicines at higher prices.

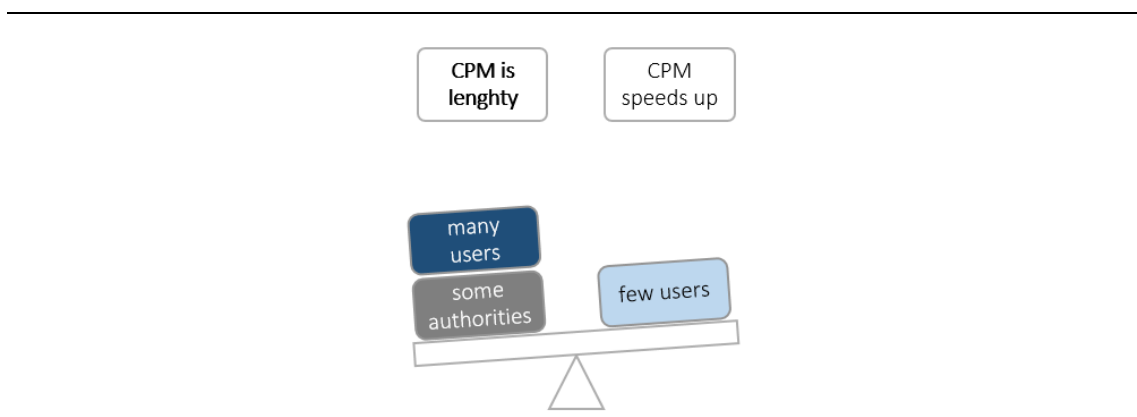
7.8.2 Perceived implications of CPM related to efficiency

Many users and some authorities mentioned in their interviews that CPM is a **lengthy process**. Few users felt that CPM would have the potential to speed up processes (cf. Table 7.2). Users mentioned the **duration of the needs assessments** as well as the **delayed conclusion of procedures** at the beginning of the year as major reasons why they considered CPM to be lengthy. Further mentioned shortcomings with regard to efficiency including **bureaucratic procedures**, **missing first contact points** with SPMS and slow responses as well as the **need to run direct procurements** as coping strategy. Though **e-procurement** was generally appreciated, improvements in the processes and in some features supported by the system would be appreciated (e.g. redundancies

due to multiple registering of buying notes, upload of attachments several times). The fact that there are **five large procurement platforms** in the medicines market is also a challenge for industry who has to be registered in all platforms in order not to miss out any call for tender.

Figure 7.2:

Annex – Stakeholders' perception on the effect of CPM on efficiency of CPM



Source and presentation: The authors based on information gathered during interviews

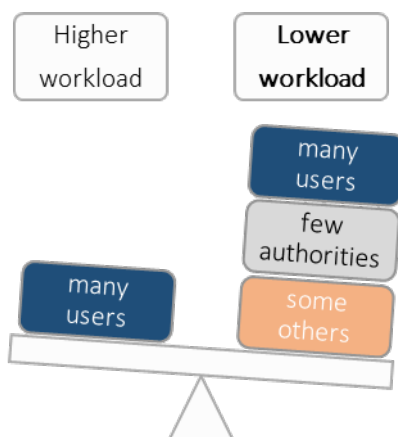
7.8.3 Perceived effects of CPM on workload

Overall, there was the perception that due to CPM the burden of work for users has considerably decreased, and it allowed pharmacists to **focus on other, more clinical, tasks**. There are **fewer procedures** that have to be done by the hospitals. Also, the work to handle **appeals** was shifted from the users to SPMS. The e-catalogue for the AQ was, in general, highly appreciated by users; **e-procurement** in general was welcomed but some efficiency gains were identified. From industry's perspective, it was also acknowledged that CPM has reduced the administrative burden and had led to some rationalisation.

However, the positive effect of the reduction in workload is compromised by **bureaucratic procedures** for the users (these statements were only made by users, cf. Figure 7.3). It was even argued by some that the workload due to the bureaucracy and requirements by SPMS has increased. In one interview, it was stated that the higher workload was attributable to the new procurement law, not to SPMS.

Figure 7.3:

Annex – Stakeholders' perception of the effect of CPM on workload



Source and presentation: The authors based on information gathered during interviews

7.8.4 Perceived effects of CPM on competition

Data to substantiate whether or not CPM has increased competition are yet to be analysed (e.g. average number of bidders per type of procurement and developments, data requests were made to SPMS). An interviewee (not from SPMS) indicated an average number of 1.7 bidders per open tender by SPMS. This figure is considered low as possible efficiency gains in the off-patent market are apparently not fully used. Another indication for limited use of competition is the **average number of competitors per procedure** which **decreased** over the years (analysis for the years 2014–2017). However, this figure provided by the Competition Authority relates to public procurement in general and not to CPM.

Some authorities and users raised the concern that CPM may bear the risk to contribute to **concentration** (monopolisation) in the market since **smaller suppliers may lack the capacity to supply the whole national market** and thus to participate in a national market. While some users pointed to difficulties of small businesses, there are no solid data to assess the effects of CPM in Portugal on competition (thus no figure for visualisation).

In this context, several users and industry expressed concern about a high degree of competition since this may risk to drive down prices to a level so that the market would become unattractive for suppliers. From 2020 on, the **“winner-takes-it-all” principle was replaced** by allocating the winning bid to two suppliers to ensure availability. The change in 2020 to share the award between two bidders was appreciated by de facto all interviewees.

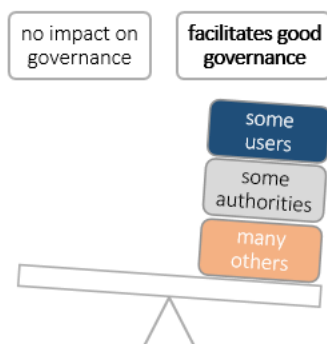
7.8.5 Perceived implications of CPM related to governance and transparency

Some users and industry representatives perceived a **positive impact of CPM on good governance and** also, in some cases, on **transparency** (cf. Figure 7.4). Compared to a decade ago, legal provisions and processes, including governance, were now considered clear and unambiguous. Timelines related to submission of bids are regulated and clear for industry. However, the **evaluation processes** can last between one week and several months, and the reasons for the clock-stops are not communicated to the bidders.

From a users' perspective, CPM was perceived as a **way to cut the link between industry and prescribers** of medicines as the pressure of prescribing doctors who asked for specific medication was shifted from the hospital to a central level. Though attributing a general positive impact on transparency in the procurement system, other users mentioned that procurement processes still **lack transparency as communication flows** from authorities and SPMS to the users were reported to not fully function. Furthermore, the effectiveness of CPM was considered to be flawed by the **confidential managed-entry agreements** that are concluded by INFARMED and the pharmaceutical companies, whose negotiated prices are kept confidential, even to SPMS.

Figure 7.4:

Annex – Stakeholders' perception of the effect of CPM on good governance



Source and presentation: The authors based on information gathered during interviews

7.8.6 Perceived implications and effects of CPM on availability of medicines

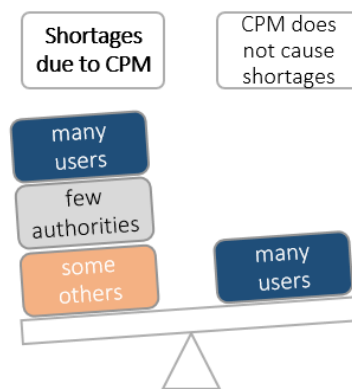
Availability issues noted by interviewees (cf. Figure 7.5) were perceived to mainly result from procedures that have not been concluded on time. Users mentioned that many **medicines were not available at the beginning of the year**, even if the situation has improved compared to last years.

Overall, the perception that shortages are attributable to CPM (or at least connected to CPM) was shared by many interviewees. However, many users did not argue that a causal link or correlation between shortages and CPM existed but simply stated that **shortages increased in the last years**.

Many users, few authorities and some other stakeholders (industry) commented that CPM could have contributed to this development of increasing shortages as a **result of low prices**. The “winner-takes-it-all” mechanism may have contributed to shortages, as it may drive competitors out of the market. **Other reasons mentioned for availability limitations** included a low number of suppliers on the market, insufficient stocks and products that are no longer offered.

Figure 7.5:

Annex – Stakeholders’ perception of the effect of CPM on availability



Source and presentation: The authors based on information gathered during interviews

7.9 Proposals of national and international interviewees

7.9.1 National stakeholders

Table 7.5 lists in detail suggestions made by national stakeholders during the on-site interviews held in Portugal in January / February 2020.

7.9.2 Procurement experts of other countries

Based on their country-specific expertise with CPM, procurement experts of Cyprus, Denmark, Estonia, Italy and Norway reported on challenges of CPM and necessary prerequisites to address these challenges (cf. Table 7.6).

They also reviewed a summary of the assessment of the CPM presented to them by the authors. Their comments, including recommendations, on the identified gaps is presented in Table 7.7.

Table 7.5:

Annex – Proposals made by national stakeholders on how to address gaps of CPM in Portugal

MAPS taxonomy	Gaps mentioned in the interviews	Approaches to address gaps
Pillar I: Legal, regulatory and policy framework		
1. The public procurement legal framework achieves the agreed principles and complies with applicable obligations.	a) The Public Procurement Code does not take into account the specificities of the health sector, and as such medicines would be acquired as any other supply	It was proposed to ensure that the mechanisms and procedures consider the specificities of medicines procurement and the pharmaceutical market, see also 8b)
	b) SPMS serves as “middleman” for eSPap in the case of “transversal goods” (not related to medicines)	It was suggested to reconsider the division of tasks between the procurement institutions and considering moving procurement of non-medicines to eSPap.
	c) The broad and mixed portfolio of SPMS	Given the assumption of possible cross-funding of procurement into other tasks of SPMS, a more rigid monitoring of its performance and enforcement of possible sanctions was proposed.
	d) Lack of monitoring of suppliers	It was proposed that low-performance suppliers would be delisted or at least labelled appropriately in the portals. SPMS to provide a ranking of the suppliers.
	e) Using of lowest price as key award criterion	According to the Public Procurement Code (PPC), the key awarding criterion is most economically advantageous tender (MEAT) which allows some flexibility. However, SPMS focuses on the lowest price. It was suggested to also consider – if appropriate – qualitative aspects.
	f) No sharing of discounted price data between public institutions	It was suggested to develop a legally robust way to share these data , as part of an improved collaboration between public institutions (in particular ACSS, INFARMED and SPMS). It was also noted that lack of clarity on the roles of these three institutions has led to a rather competitive setting which does not facilitate collaboration and sharing of data. See also 5a)
	g) Several platforms to manage CPM, with different interfaces	To continue improving the e-procurement architecture (overall, e-procurement is highly appreciated), with the aim to reduce redundancies in the system (so that possible suppliers do not have to register on several platforms and have to monitor all of them).
2. Implementing regulations and tools support the legal framework.	<i>No gaps in the interviews identified (an assessment of the procurement documents is still ongoing)</i>	-

MAPS taxonomy	Gaps mentioned in the interviews	Approaches to address gaps
3. The legal and policy frameworks support the sustainable development of the country and the implementation of international obligations.	<i>No gaps in the interviews identified (an assessment of the procurement documents is still ongoing)</i>	-
Pillar II: Institutional Framework and Management Capacity		
4. The public procurement system is mainstreamed and well integrated into the public financial management system.	a) No overarching procurement plan	It was urged by several interviewees to develop a national procurement strategy , which spells out the strategic objectives that are aimed to be achieved through CPM and the roles of entities involved. The strategy development should be done by a strategically acting institution, such as ACSS, and not by the procurement agency SPMS which is deemed to act operationally. It was also suggested to consider including users in the development of such a strategy. See also 8c)
	b) Chronic underfunding of the hospitals and SNS institutions	Several interviewees called for an increase in funding for hospitals , which was indeed planned for 2020 (it is not known to the authors how the Covid-19 pandemic impacted this plan, and if the actual increase in funding as a supplementary state budget due to COVID-19 would be able to cover increased expenditure resulting from the COVID-19 management). Increased funding would also help users to get rid of the arrears in their books and reduce dependency from their suppliers. It was also argued not to solely increase funding but to have more targeted funding in certain disease groups.
	c) Arrears in the accounts of hospitals and accounting practices that are considered dubious	
	d) Perceived limited capacity in accounting of hospitals and SNS institutions	Stricter monitoring of accounting in hospitals , and capacity-building activities for those in charge of accounting in hospitals
	e) SPMS plan of activities is considered to be repetitive and not innovative	More capacity (resources) needed in ACSS to critically review the SPMS plan of activity and monitor it. See also 8d)
	f) "Frozen budgets" of hospitals in case of delays in CPM procedures, no available funds left in summer period	Several interviewees opted for multi-annual contracts . It was also suggested to introduce mechanisms to delink procurement activities from the annual budgets in order to allow hospitals some flexibility of procuring alternatively in case of delayed procedures.

MAPS taxonomy	Gaps mentioned in the interviews	Approaches to address gaps
5. The country has an institution in charge of the normative/regulatory function.	a) Limited clarity of the roles of the three institutions related to CPM (SPMS, ACSS and INFARMED), in particular related to the definition of strategy	<ul style="list-style-type: none"> – As the lack of clarity regarding the roles is a result of historical developments (i.e. taking the procurement area out of ACSS and putting it in a newly set-up institution, SPMS), it was strongly recommended to define the roles (and non-responsibility) of the three institutions as well as of the Court of Auditors (TdC). – It was suggested to institutionalise the collaboration between the three institutions, following a definition of their roles. One way to do so could be the instalment of the yet informal working group as an institutionalised body.
	b) Lack of horizontal communication, of strategy and of clarity of roles and responsibilities	Regular meetings of SPMS with users were requested. The SPMS meetings with procurement experts were considered as good practice model and were suggested to be extended to SPMS meeting with hospital pharmacists. See also 8b)
6. Procuring entities and their mandates are clearly defined.	a) Effects of CPM may be undermined by parallel processes (direct procurement of users), and it is not clear whether, or not, direct procurements allow authorisation	See approaches proposed regarding 9a)
7. Public procurement is embedded in an effective information system.	a) Lack of capacity and resources to move forward with strategic procurement (including analysis of procurement data)	It was noted that ACSS should be better resourced and staffed to take the role of providing strategic guidance and oversight. Performance indicators should be applied to assess the work of SPMS. It was stressed that the performance monitoring should be focused and that thus only few indicators should be developed and monitored. The extent of savings can be included as an indicator but it should be accompanied by other indicators, also to shift the focus from the solely economic perspective to quality, performance and accessibility aspects. Possible indicators suggested include: keeping timelines, optimising procedures in terms of innovative procedures, participation rate of suppliers in tenders, satisfaction rate of users, share of complaints.
	b) No updated list of medicines subject to CPM	Users in particular asked for an update of the list of INN under CPM which is of 2016. There were mixed perceptions with regard to the content to be updated. While some argued for a broad extension (up to the inclusion of nearly all medicines, others aimed for a more focused adaptation that takes into account recent clinical changes. A more institutionalised approach to ensure regular updates of the list of medicines under CPM was suggested.
8. The public procurement system has a strong capacity to develop and improve.	a) Collaboration between ACSS, INFARMED and SPMS depended the initiative of committed staff	It was called upon to formalise and institutionalise procedures , including cross-institutional cooperation. See also 1f)
	b) Lack of knowledge on hospital pharmacy with SPMS staff	To ensure consideration of clinical knowledge and expertise, the involvement of hospital pharmacists working in the field into the development of framework agreements and further procedures was seen as a good practice example in recent times. This should be also applied in future.

MAPS taxonomy	Gaps mentioned in the interviews	Approaches to address gaps
	c) No strategic procurement / no procurement strategy	<p>Strategic institutions such as ACSS and the MoH were called upon to provide strategic guidance by deciding on key objectives of CPM and to communicate them to institutions working at operational levels (e.g. SPMS).</p> <p>In developing strategic planning, it was stressed that there is a need to investigate three layers: 1) The MoH should develop an overall strategy related to procurement (e.g. strategic goals), see also 4a. 2) The key institutions (SPMS, ACSS and INFARMED) were advised to improve planning, monitoring and providing guidance. 3) The users (hospitals) should improve their planning at institutional levels (by putting sufficient attention on planning). For the latter, more resources and funding would, among others, be required (cf. 4b).</p>
	d) No monitoring of performance of CPM	<p>It was urged to develop some basic performance indicators which allows assessing the performance of CPM (not solely of SPMS). This was seen to be linked to the needed procurement strategy, in order to have objectives which impact the operationalisation of the performance indicators (e.g. different indicators for the objectives of savings for public funding or equity in access to medicines for all hospitals). It was noted that probably no new information might be needed since the Portuguese health system has produced a lot of data that could be used. The importance of performing a defined monitoring exercise was stressed. See also 7a) for suggested indicators.</p>
III. Public Procurement Operations and Market Practices		
9. Public procurement practices achieve stated objectives.	a) Delayed (start and) conclusion of procedures	<ul style="list-style-type: none"> - It was recommended that SPMS should speed up the procedures by, among others, including less administrative work. - Users were urged to submit their need assessments on time. This requires improved planning processes at hospital levels, with possibly starting the planning earlier. A good intra-hospital collaboration between the hospital pharmacy and the procurement department and assignment of sufficient resources to planning in the hospitals were brought forward as key factors. - It was also recommended that SPMS should start procurement procedures for different medicines at different times. This would provide more flexibility to CPM, thus reducing the workload for the hospital pharmacy and giving more time to SPMS to finish procedures.
	b) Parallel procedures (hospital procuring on their own as a result of delayed procedures of CPM)	<p>The timely conclusion of procedures of SPMS was seen as the major solution to avoid parallel procedures.</p>

MAPS taxonomy	Gaps mentioned in the interviews	Approaches to address gaps
10. The public procurement market is fully functional.	a) Possibly decreasing number of competitors, low participation rate	<ul style="list-style-type: none"> - The move away from the “winner-takes-it-all” principle in 2020 was welcomed as a good step in the right direction. It was also suggested to divide procurement into lots, e.g. regional lots. - It was suggested to optimise the technical specifications, e.g. building in more competitive elements. - It was proposed to consider using analogue competition between active ingredients of similar clinical effects which may attract more bidders. - It was recommended giving small companies a chance to develop, so that they can also participate. - It was also proposed to strengthen local production. - It was recommended indicating not only maximum prices, but also minimum prices in the tender. - It was proposed to have a negotiation of the price in the second stage of a Framework Agreement.
	b) SPMS's limited picture of the market and of low-performing suppliers	<ul style="list-style-type: none"> - More comprehensive market consultation was considered to be helpful. - It was requested to have penalties for low performance (e.g. non-delivery) and to enforce them.
Pillar IV: Accountability, Integrity and Transparency of the Public Procurement System		
11. Transparency and civil society engagement foster integrity in public procurement.	a) Limited involvement	It was suggested to better engage with patients and to actively ask for their expertise related to specific medicines. It was recommended to consider patient involvement also in procurement (i.e. patient's expertise on a product), building on the experience of a successful patient involvement project of INFARMED. However, it was warned that sufficient resources are required to do it right.
12. The country has effective control and audit systems.	a) Lack of strategic performance indicators with ACSS to monitor the activities of SPMS	Cf. the recommendation under 7a).
13. Procurement appeals mechanisms are effective and efficient.	<i>No gaps in the interviews identified</i>	-
14. The country has ethics and anti-corruption measures in place.	a) Lack of a targeted monitoring and fraud combating in CPM	It was suggested to establish an entity which is dedicated to this task.

ACSS = Administração central do Sistema de Saúde / Central Administration of the Health System, CPM = Centralised procurement of medicines, INFARMED = Autoridade Nacional do Medicamento e Produtos de Saúde / National Authority of Medicines and Health Products, INN = International Non-Proprietary Name, MAPS = Methodology for Assessing Procurement Systems, MEAT = Most Economically Advantageous Tender, MoH = Ministry of Health, PPC = Public Procurement Code, SNS = Serviço Nacional de Saúde / National Health Service, SPMS = Serviços Partilhados do Ministério de Saúde / Shared services of the Ministry of Health, TdC = Tribunal de Contas / Court of Auditors

The presentation of gaps in this Table 7.5 as presented in the D4 Recommendations report [11] slightly differs from the one in Table 7.4, which is provided the most updated final version.

Source and presentation: the authors based on interviews with national stakeholders

Table 7.6:

Annex – Key learnings of CPM in their respective country contexts shared by procurement experts from other countries

Domain	Difficulties and challenges	Necessary prerequisites
Strategy & political backing	<ul style="list-style-type: none"> • Adjustment of the procurement strategy to the fact that medicines are no common goods • Not all CPM procedures are applicable to all medicines in the same way (difficulty in applicability for new / expensive medicines) • Trade-off between competition and regulation 	<ul style="list-style-type: none"> • Holistic procurement approach • Focus on the treatment of patients rather than reducing expenditure
Collaboration	<ul style="list-style-type: none"> • Involvement of different partners / stakeholders in the process of CPM • Opposition from industry 	<ul style="list-style-type: none"> • Active and balanced management of multiple stakeholders • Scientific encounter and continuous communication with the users of CPM • Creation of trust in the collaboration • Ensure interest of stakeholders, including users, to contribute (both to the procedures as well as to improve processes)
Governance	<ul style="list-style-type: none"> • Establishment of a CPM entity (e.g. procurement agency) as an independent organisation with a clear mandate • Ensuring that the procurement agency being a strong counterpart for the industry 	<ul style="list-style-type: none"> • Certainty for both users and industry from binding contracts • Clear communication and application of the service character of central procurement • Ownership of the contracts with well-defined terms and conditions • Well acknowledged leading person with strong back-up from the agency
Processes	<ul style="list-style-type: none"> • Low participation rates of suppliers in framework agreements • Little competition for short-term contracts • Services provided by procurement agency may be cost-intensive • Possibly higher prices for specific products 	<ul style="list-style-type: none"> • Standardisation of procedures, thus provision of standard operating procedures • Well-trained procurement staff • Sound and well-functioning e-procurement platform(s)
Monitoring	<ul style="list-style-type: none"> • Ensure enforcement • Provision of capacity and sufficient resources 	<ul style="list-style-type: none"> • Implementation of a monitoring system • Efficiency in the administrative and logistics management • Monitoring to be done based on the data gathered through CPM • Need to have identified a few essential data / indicators to allow monitoring

In bold: mentioned in more than one interview or emphasized more than once

Source: interviews with international procurement experts, presentation by the authors

Table 7.7:

Annex – Comments made by procurement experts of other countries on how to address gaps in CPM in Portugal

Gaps	Key messages	Recommendations
General (scope and procedures)	<ul style="list-style-type: none"> It is good that CPM is in place in Portugal. However, the list of INN should be updated. Framework agreements for medicines might turn out to be difficult as normally better used for other products than medicines, such as medical devices. 	<ul style="list-style-type: none"> <i>Update the INN list more often.</i> <i>Rethink applicability of framework agreements on medicines.</i>
Missing (horizontal/vertical) communication	<ul style="list-style-type: none"> A strong organisation is needed to balance the interests of all stakeholders. Communication with all different levels (horizontal and vertical) is a necessary prerequisite for central procurement. Trust has to be established in the system. 	<ul style="list-style-type: none"> <i>Consider the users of central procurement as your partners.</i> <i>Ensure that all regions and stakeholders are included in the process.</i> <i>Do not see the industry as an enemy but be strong in negotiations and contracts.</i>
Missing procurement strategy	<ul style="list-style-type: none"> Without a procurement strategy you lose the game. For a good procurement strategy it is key to differentiate between new medicines, medical devices, biosimilars/generics and other products. There needs to be an overarching strategy, combining potentially conflicting non-transparent but existing strategies from single players in the system. A strategy needs to include precise timelines, terms and specifications, qualification of the procurement staff and concrete roles of agencies. Flow-charts and illustrations help to understand a strategy and also to increase transparency within the system. It should be ensure that a strong procurement agency can balance the interests of all stakeholders. Collaboration with stakeholders at national level, but also other countries (for expensive/innovative medicines) is needed. It is important to be able to negotiate for expensive medicines and that there is a strong willingness to say “no”. Otherwise the industry will use their power. 	<ul style="list-style-type: none"> <i>Make sure that you have a (differentiated) procurement strategy.</i> <i>Make sure that your strategy is clear for all stakeholders and that their tasks and roles in the procurement system are defined.</i> <i>Make sure that your procurement strategy is precise, transparent and easy to understand.</i> <i>Provide a strong mandates to the acting institutions in the procurement system.</i> <i>Find areas to cooperate with other countries/partners, where applicable.</i> <i>Share tasks with your partners.</i> <i>Look into the product life-cycle to develop strategic procurement for different products.</i> <i>Make sure that you know the real price [at marketing authorisation] but keep it confidential.</i>
Lack of clinical expertise in procurement agency	<ul style="list-style-type: none"> It is important to have enough clinical expertise in the procurement agency. Pharmacists, knowing how to handle the medicines, are definitely an added value when consulted or working in the procurement procedures. The procurement agency should focus on what they know best (conducting a tender). The procurement agency should provide the “machinery” (framework of procedures, IT platform). 	<ul style="list-style-type: none"> <i>Ensure that your procurement agency has the knowledge and the skills.</i> <i>Alternatively: Involve people from the field with skills needed.</i> <i>Make your tendering documents precise and create strong contracts.</i>
Delays in conclusion of procedures, parallel procedures	<ul style="list-style-type: none"> An earlier start of the needs assessment is needed. It is necessary that information is not only transmitted to the procurement agency once a year. 	<ul style="list-style-type: none"> <i>Plan enough time (around 250 days from needs assessment to procurement).</i> <i>Let the information on needs flow more than once a year.</i> <i>Keep going at least for five years and learn from the process.</i>

	<ul style="list-style-type: none"> • Mid of September of the year before the contract starts, the contract is already awarded to allow for any corrections by the industry if it is not able to deliver anymore. • One year contracts in CPM could be too short, and could be made for two years with the right terms regarding the management of the stock. • Tendering documents should contain precise terms and conditions. • Standard Operating Procedures (SOP) including timelines have to be provided and followed in a very strict way. 	<ul style="list-style-type: none"> • <i>Provide clear SOP.</i> • <i>If you do contracts for one year, then start to prepare in April.</i> • <i>Include terms and conditions to the tendering documents.</i> • <i>Make strong contracts.</i> • <i>Provide good and attractive methods.</i> • <i>Have the needs aggregation done by users.</i> (one interviewee)
“The winner takes it all” (until 2020)	<ul style="list-style-type: none"> • The applicability of such a principle depends on the market and the treatment. • Suppliers want to be in the contract, when they are the only supplier. Yet, the opportunity to contract more than one supplier is good to help avoid delivery delays from the awarded industry. • To have more than one contract is time-consuming though. • Ensure that multi-award contracts are granted, otherwise there is the risk that – after some time of low prices granted by one supplier – the others leave the market and due to dependency prices get up. 	<ul style="list-style-type: none"> • <i>Balance bureaucracy and availability of supplies when choosing more than one supplier.</i> • <i>Aim to grant multi-award contracts.</i>
Lack of performance indicators to monitor	<ul style="list-style-type: none"> • It is important for the procurement agency to be able to decide based on historical data and monitoring the market. • Strengthening of the contracts by implementation of a monitoring and horizon scanning system is needed. • In order to be the contract owner it is necessary to monitor the contract. • You need to evaluate the tenders. • It is important that doctors, pharmacists, nurses and procurement entities work together. 	<ul style="list-style-type: none"> • <i>Ensure that you get the data.</i> • <i>Monitor your contracts and evaluate your tenders and learn from experience.</i> • <i>Ensure coalition with doctors and nurses; do not see them as competitors.</i>
Underfunding	<ul style="list-style-type: none"> • Funding is a fundamental issue, the authority needs to have the funds for the publication of the tendering. It is a prerequisite in the tendering documents. 	<ul style="list-style-type: none"> • <i>Make sure you have the funding for the fulfilment of a contract from both sides.</i>

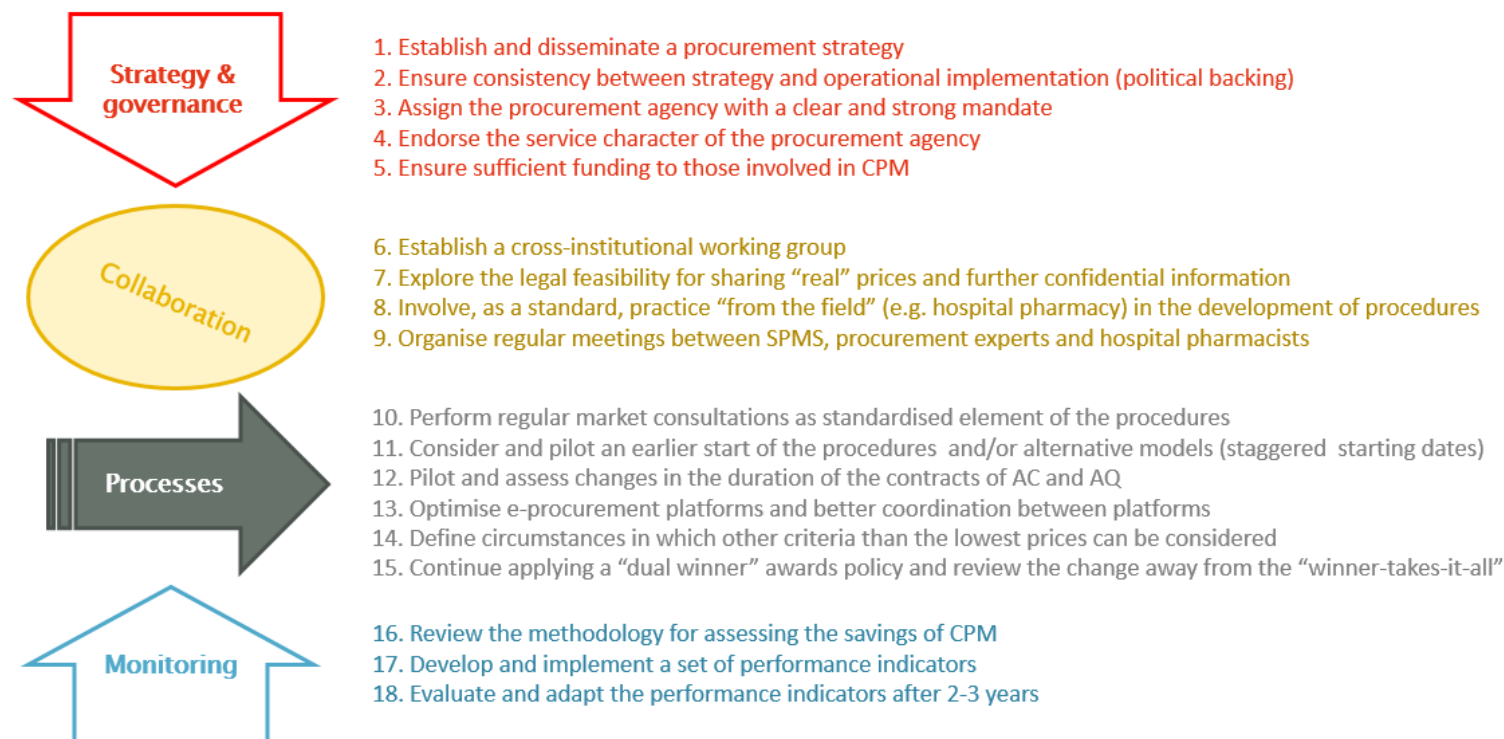
Source and presentation: the authors based on interviews with procurement experts in other countries

7.10 Recommendations

7.10.1 Draft recommendations

Figure 7.6:

Annex – Preliminary list of draft recommendations to address gaps in CPM in Portugal



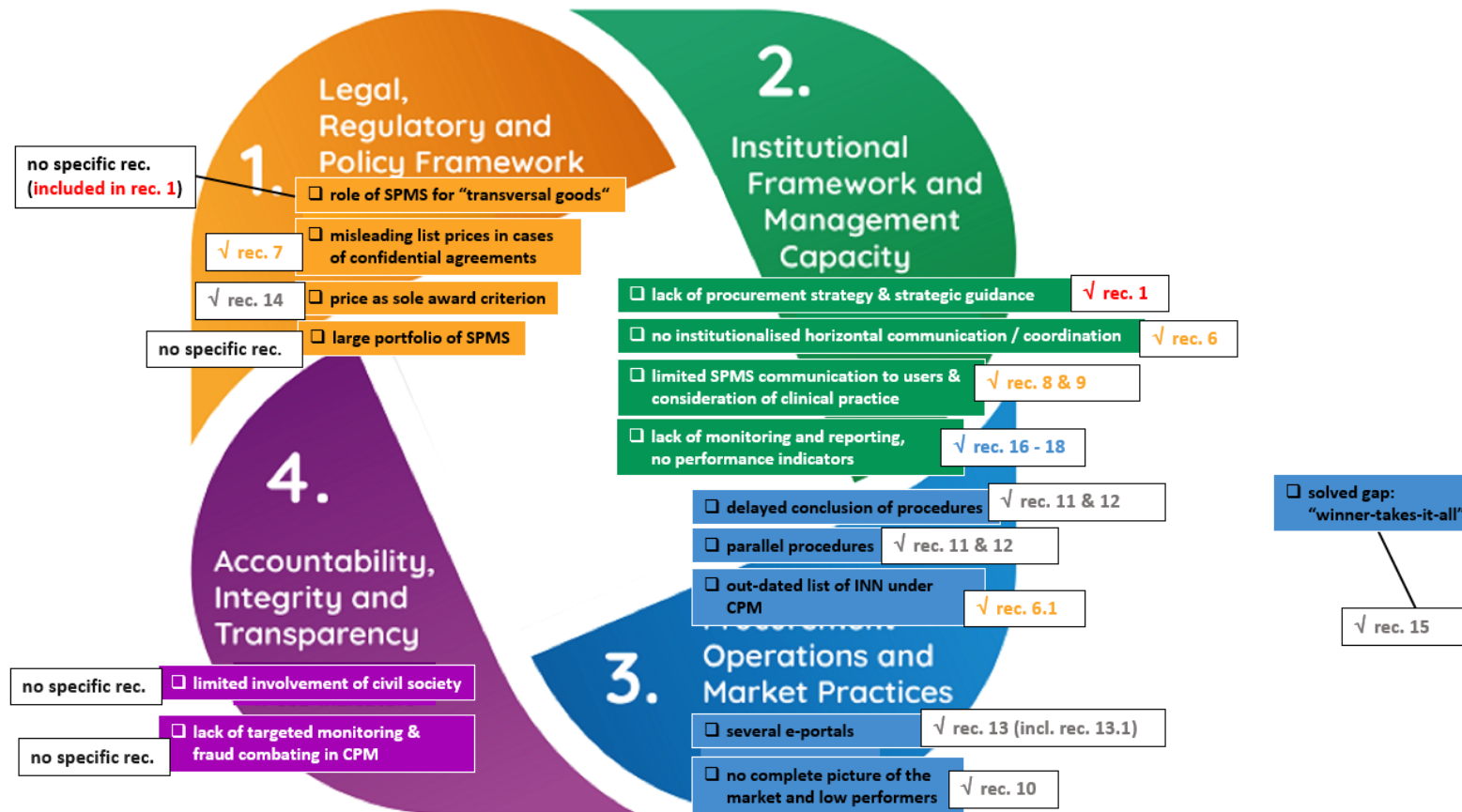
AC = Aquisição centralizada / centralised purchases (open tenders), AQ = Acordos Quadros / Framework Agreements, CPM = centralised procurement of medicines, SPMS = Serviços Partilhados do Ministério de Saúde / Shared services of the Ministry of Health

Source: The authors based on their assessment of CPM in Portugal, informed by input of Portuguese stakeholders and international procurement experts

7.10.2 Linkage between findings of the assessment and draft recommendations

Figure 7.7:

Annex – Gaps identified in CPM and respective recommendations (draft version)

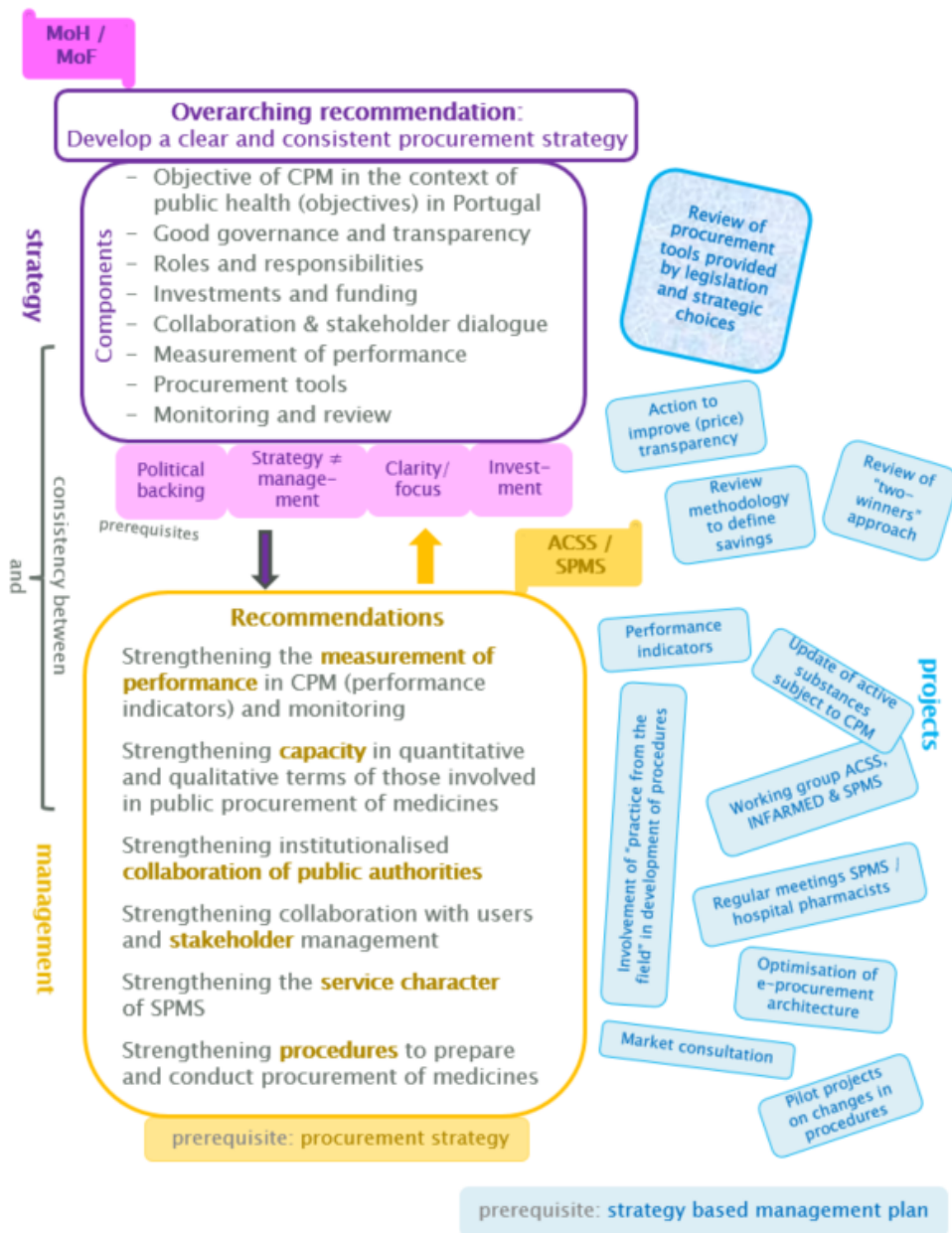


Source: the authors

7.10.3 Final recommendations (strategy, management and projects)

Figure 7.8:

Annex – Final recommendations on strategy and management and suggestions for projects to optimise CPM



Source and presentation: the authors based on a multi-phase recommendations development process

References of the Annex

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