PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: Cyprus 2021

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

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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.

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About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in Cyprus is part of the series of PPRI Pharma Briefs launched by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Secretariat in 2019.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of more than 52 – mostly European – countries (as of May 2021) as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of this network is to facilitate exchange between public officials, supported by scientific evidence and a common understanding of pharmaceutical policy issues. Under the framework of PPRI, further regional PPRI networks (e.g. in Central Asia) and thematic PPRI networks (e.g. on medical devices) have been established. PPRI networks are coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG).

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI contributes to the international scientific evidence base, in particular in the areas of (comparative) **pharmaceutical systems research** and **pharmaceutical policy analysis**, by providing country information that is usually not published in other literature. This is of interest for policy-makers who want to cross-learn and benchmark as well as for researchers who perform policy analyses and require contextual information on national pharmaceutical systems.

PPRI country information

Well-established publications that offer pharmaceutical pricing and reimbursement information on a single PPRI country are the **PPRI Pharma Profiles** that are available as in-depth reports as well as short reports, see https://ppri.goeg.at/ppri_pharma_profiles. Furthermore, one-page graphical abstracts are provided in the **PPRI Posters**, see https://ppri.goeg.at/ppri_posters.

The series **PPRI Pharma Briefs** responds to the interest and needs expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of the pharmaceutical policies in other countries.

The PPRI Pharma Briefs draw upon the information and data that have been provided by the PPRI network members, in addition to literature and relevant documents, such as legal provisions.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data[1]

Population (2018)	0.876 million
Country size (2020)	5,896 km²
Gross domestic product / GDP (2019)	GDP per capita: USD PPP 41,318 (provisional value)
Health expenditure / HE (2018)	HE per capita: € 1,644.67 HE in % of GDP: 6.77% Public HE as % of total HE: 43%
Pharmaceutical expenditure / PE (2018)	PE per capita: € 305.56 PE in % of HE: 19% Public PE as % of total PE: 17%

GDP = gross domestic product, HE = health expenditure, PE = pharmaceutical expenditure, PPP = Purchasing Power Parties, USD = United States dollars
Pharmaceutical expenditure data relate to the outpatient sector only (Position HC51 in SHA_11)

Sources: Population data: Republic of Cyprus - Statistical Service (2019); GDP: _ENREF_1OECD (2020); Expenditure data: Eurostat (2020)

Provision of pharmaceuticals

Community pharmacies (07 Oct.2020)	523 (with a contract with the Health Insurance Organisation); 506 private pharmacies and 17 public pharmacies2
Dispensing doctors	No dispensing doctors
Wholesale (2020)	Number of wholesale companies: 96 licensed wholesalers (2020)
Pharmaceutical industry (2015)	Number of companies: 6 pharmaceutical manufacturers

Sources: Community pharmacies: Health Insurance Organisation (2020b); private pharmacies: Ministry of Health (2020a); pharmaceutical industry – unpublished presentation WHO CC training Cyprus 2015

Pharmaceutical market

Pharmaceutical market (2020)	€ 227 million
Medicines (2020)	5,896 medicines authorised (counted including different pharmaceutical forms and dosages) 1,733 medicines (counted including different pharmaceutical forms and dosages) included in the outpatient reimbursement list (December 2020)
Generic market shares (2013/2014)	45.7% – Generic market share in value in total pharmaceutical market sales 49.5% (public sector)/16.1 (private sector) – Generic market share in volume in percent of the total outpatient market

Sources: Generic market shares: Vogler et al. (2019) taking data of IFPMA 2017, PPRI Network Query 2016 (unpublished)

1
excluding the Turkish Republic of Northern Cyprus (TRNC)

2
Public pharmacies are located in the public hospitals. They dispense only specialty/expensive products, in addition their inpatient activities. On the other hand, private pharmacies are located in the community and they dispense products for primary health care. In addition, their working hours vary, along with the products that each one can dispense. Their dispensing formulary is complementary and not overlapping.

Pharmaceutical pricing (2020)

Price regulation	Yes, for prescription-only medicines in the out- and inpatient sectors
Pricing authorities	Ministry of Health - Department of Pharmaceutical Services / For reimbursable medicines: Health Insurance Organisation
Key pricing policies	**External price referencing (EPR)**: Yes, for prescription-only medicines in the out- and inpatient sectors **Value-based pricing**: not applicable **Price negotiations**: Yes, for reimbursable medicines in the out- and inpatient sectors **Managed-entry agreements**: Recently implemented for reimbursable medicines **Tendering**: in the former public healthcare sector (prior to the reform in June 2019) for reimbursable medicines; after the reform, tendering in the inpatient sector is used but no tendering in the outpatient sector (except for existing tenders which are still used during the transition period) **Cost-plus pricing**: not applicable **Generic price link**: Yes, for prescription-only medicines in the out- and inpatient sectors **Biosimilar price link**: Not in place. Biosimilars are priced as per EPR
Pricing in the supply chain	**Wholesale**: ERP defines the wholesale price; wholesale mark-ups are not regulated **Pharmacy**: pharmacy remuneration is regulated: for reimbursable medicines - based on a fixed fee and a global budget, which includes a 4% mark-up profit for stock-keeping of expensive medicines; for non-reimbursable medicines - regressive mark-up scheme **Value-added tax**: 5% for medicines (and 19% standard VAT)

Source: Ministry of Health; Health Insurance Organisation

Pharmaceutical reimbursement (2020)

Reimbursement authorities	**Outpatient:** Health Insurance Organisation (HIO) **Inpatient:** Health Insurance Organisation (HIO)
Reimbursement lists	**Outpatient:** positive reimbursement list **Inpatient:** Catalogue Z
Reimbursement criteria	**Outpatient**: (a) documented clinical practice, (b) documented scientific literature, (c) pharmacoeconomic studies, (d) results of internationally recognized scientific health technology assessments, (e) the marketing authorisation / licensing status, (f) the therapeutic position of the product concerned in international guidelines, (g) alternative medicines included in the reimbursement list for this indication, (h) the epidemiological evidence of the disease, (i) the safety of the beneficiaries, (j) cost-effectiveness, (k) the rational use of these medicines, (l) the optimal management of the HIO's available resources, (m) the existence of alternative non-pharmacological treatments **Inpatient:** the same as for outpatient
Co-payments for medicines	**Outpatient:** co-payment fee of 1 euro per prescription, 100% reimbursement of products listed in the positive list based on the lowest reference price in the reference price system; patients may opt to pay a personal contribution and choose another interchangeable product, due to the reference price system For prescriptions of non-reimbursable medicines a prescription fee of 1 euro applies **Inpatient:** no co-payment
Demand-side measures to enhance the uptake of off-patent medicines	**Reference price system:** yes **Prescribing by International Non-Proprietary Name (INN):** allowed but not supported by the IT system. **Generic substitution:** allowed at the level of the cheapest medicine of the same active substance and pharmaceutical form

Source: Ministry of Health; Health Insurance Organisation

Key technical terms are defined in the glossary in Annex 2.

Summary

The Ministry of Health (Department of Pharmaceutical Services) is the competent authority for the implementation of legislation on medicines, cosmetics and the pharmacist's profession. The Ministry of Health (Department of Pharmaceutical Services), also acts as the Medicines Agency for Cyprus supported by the Drug Council and is in charge of marketing authorisation.

With regards to pricing and reimbursement of medicines, key institutions are the Ministry of Health (Department of Pharmaceutical Services), which, advised by the Drug Price Control Committee, is in charge of regulating prices for medicines on the Cypriot market, and the Health Insurance Organisation (HIO). The latter reimburses reimbursable medicines for the outpatient and inpatient sectors and decides on the inclusion of outpatient medicines into the reimbursement list (Catalogue of Medicinal Products) following relevant scientific committee's recommendations. For the inpatient sector, a formulary of medicines (positive list) was maintained by the Ministry of Health advised by the Medicines Committee until 31 of August 2020. From 1st of September 2020 onwards, HIO is the competent authority having its own Advisory Committee on Medicines.

Prices of medicines at manufacturer level are not regulated in Cyprus. At wholesale price level, prices of prescription-only medicines for both out- and inpatient sectors are regulated by using external price referencing (EPR) and are updated annually. Cyprus applies a generic price link policy for prescription-only medicines in the out- and inpatient sectors, with the first generic entering the Cypriot market being priced at 80% of the originator maximum wholesale price (derived by using EPR). Managed-entry agreements have recently been implemented in Cyprus. In the public sector, predominantly two procedures for the centralised procurement of medicines are applied, namely the open invitation to tender procedure for mostly off-patent medicines with increased competition, and the negotiation procedure for on-patent and innovative medicines without competition.

Wholesale mark-ups are not regulated in Cyprus. Instead, there are different models of business operation in the country with distribution margins ranging between 4-15%. For reimbursed medicines, pharmacy fees for dispensing medicines outpatients are paid per package (box) provided by the pharmacists to patients. A monthly budget is allocated to contracted pharmacies and at the end of the month is divided by the total number of dispensed packages. Therefore, in the context of a global budget, the fee for each outpatient service provided, is readjusted on a monthly basis depending on the volume of services/cases, so that the actual cost does not exceed the budgeted cost for that specific group of services. An extra 4% of the maximum wholesale price is provided as compensation for stocking and storing expensive medication. Currently, this percentage is incorporated in the fee (the monthly budget). The aim is to disentangle the percentage from the fee since this 4% regulation was introduced in order to compensate pharmacists for stock keeping of expensive products.

For non-reimbursable medicines, a different mark-ups scheme applies. For private prescriptions, an additional one euro charge per prescription as a professional fee is applicable. The VAT on medicines is 5% in comparison to a standard VAT of 19% in Cyprus.

The General Healthcare System (GHS) compensates for the necessary medicines, which are included in the Catalogue of Medicinal Products (positive list) and can only be dispensed with a doctor's prescription. The Advisory Committee on Medicines evaluates applications for inclusion or removal from the positive list and gives recommendations to the Board of which takes the decision based, among others, on documented clinical practice and scientific literature, alternative medicines included in the reimbursement list for this indication, safety and cost-effectiveness. There is 100% reimbursement of medicines listed in the positive list based on the lowest reference price. For each prescribed pharmaceutical item (regardless of quantity), a co-payment fee of 1 euro has to be paid by the patient. Patient co-payments amount to a maximum of 75 euro for the recipients of the Guaranteed Minimum Income, the low- income pensioners and children up to the age of 21, and 150 euro for the rest of the population. This ceiling incorporates all co-payments payable in any health care sector (not only pharmaceuticals).

Cyprus applies a reference price system and products with generic alternatives listed in the positive list are clustered into reference groups. For each reference group (either on an ATC 4 or 5 basis), the lowest-priced product is defined as reference medicine whose costs are 100% reimbursed by the HIO. Patients opting for a more expensive product are required to pay the difference between the price of the medicine and the price of the medicine covered by the GHS. Prescribing by International Non-proprietary Name (INN) and generic substitution at pharmacy level is allowed in Cyprus with the cheapest medicine of the same active substance and pharmaceutical form.

Since the establishment of the General Health System in 2019 many of the implemented pharmaceutical policies (e.g. introduction of a positive list) are still under evaluation or need to be evaluated regarding their impact on access to medicines in Cyprus. However the reform of the health care sector represents a major step towards universal health coverage as it is expected to reduce unmet need and financial hardship (Kontemeniotis 2021).

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, Cyprus

Περίληψη στα Ελληνικά

Το Υπουργείο Υγείας (Φαρμακευτικές Υπηρεσίες) είναι η υπεύθυνη Αρμόδια Αρχή για την εφαρμογή των νομοθεσιών σχετικά με τα φαρμακευτικά προϊόντα, τα καλλυντικά και το φαρμακευτικό επάγγελμα. Το Υπουργείο Υγείας (Φαρμακευτικές Υπηρεσίες), με την υποστήριξη του Συμβουλίου Φαρμάκων είναι η αρμόδια αρχή για τις άδειες κυκλοφορίας φαρμακευτικών προϊόντων.

Οι αρμόδιες υπηρεσίες σχετικά με την τιμολόγηση και την αποζημίωση φαρμακευτικών προϊόντων, είναι το Υπουργείο Υγείας (Φαρμακευτικές Υπηρεσίες), το οποίο, με τη συμβολή της Επιτροπής Ελέγχου Τιμών, έχει την ευθύνη ρύθμισης των τιμών στην Κυπριακή αγορά, και ο Οργανισμός Ασφάλισης Υγείας (ΟΑΥ), ο οποίος έχει την ευθύνη αποζημίωσης των φαρμακευτικών προϊόντων ενδο-νοσοκομειακής και εξω-νοσοκομειακής φροντίδας, που περιλαμβάνονται στην λίστα αποζημίωσης (Κατάλογος Διαθέσιμων Φαρμακευτικών Προϊόντων) κατόπιν των αποφάσεων της σχετικής επιστημονικής επιτροπής. Μέχρι και την 31η Αυγούστου 2020, διατηρήθηκε κατάλογος ενδο-νοσοκομειακών φαρμάκων από το Υπουργείο Υγείας ενώ από την 1η Σεπτεμβρίου 2020 και μετά η ευθύνη μεταφέρθηκε στον ΟΑΥ ο οποίος δρα υπο την καθοδήγηση της Συμβουλευτικής Επιτροπής Φαρμάκων (ΣΕΦ) (στο Υπουργείο Υγείας υπήρχε ειδική Επιτροπή Φαρμάκων ενώ ο ΟΑΥ συμβουλεύεται από την Συμβουλευτική Επιτροπή Φαρμάκων).

Οι τιμές των φαρμακευτικών προϊόντων δεν ρυθμίζονται σε επίπεδο παρασκευαστή. Σε επίπεδο χονδρικής τιμής, οι τιμές των συνταγογραφούμενων φαρμάκων για την εξω-νοσοκομειακή και την ενδονοσοκομειακή φροντίδα ρυθμίζονται μέσω του external price referencing (EPR) και αναθεωρούνται ετησίως. Στην Κύπρο, εφαρμόζεται τιμολογιακή πολιτική generic price link στα συνταγογραφούμενα φάρμακα για την εξω-νοσοκομειακή και την ενδονοσοκομειακή φροντίδα. Το πρώτο γενόσημο φαρμακευτικό προϊόν που θα εισέλθει στην Κυπριακή αγορά, τιμολογείται στο 80% της μέγιστης χονδρικής τιμής του πρωτότυπου που έχει προκύψει από την εφαρμογή του EPR. Πρόσφατα, η Κύπρος εφάρμοσε συμφωνίες ελεγχόμενης εισόδου. Για την προμήθεια φαρμακευτικών προϊόντων στο δημόσιο τομέα, εφαρμόζονται δύο μέθοδοι, με κυρίαρχη να είναι η προκήρυξη ανοικτών διαγωνισμών. Η μέθοδος αυτή εφαρμόζεται κυρίως για την προμήθεια off-patent φαρμακευτικών προϊόντων ενώ για την προμήθεια on-patent και innovative φαρμακευτικών προϊόντων εφαρμόζονται συνήθως διαδικασίες διαπραγμάτευσης τιμής.

Οι προσαυξήσεις/ Τα περιθώρια κέρδους των εταιρειών χονδρικής πώλησης δεν ρυθμίζονται από κάποια αρχή. Αντ' αυτού, στη χώρα λειτουργούν διάφορα επιχειρησιακά μοντέλα με περιθώρια κέρδους μεταξύ 4-15%. Για τα φαρμακευτικά προϊόντα που αποζημιώνονται από το σύστημα υγείας ο φαρμακοποιός αμοίβεται ανά συσκευασία (κουτί) που χορηγεί. Στο ποσό αμοιβής του φαρμακοποιού προστίθεται ένα 4% της μέγιστης χονδρικής τιμής ως αντιστάθμιση του κόστους προμήθειας και διατήρησης αποθέματος ακριβών φαρμακευτικών προϊόντων. Τα ποσοστά κέρδους για τα φαρμακευτικά προϊόντα που δεν αποζημιώνονται από το σύστημα υγείας είναι διαφορετικά. Για τις συνταγές εκτός του συστήματος υγείας, οι φαρμακοποιοί έχουν την δυνατότητα χρέωσης 1,19 Ευρώ, ως επαγγελματικό τέλος.

Το Γενικό Σύστημα Υγείας (ΓεΣΥ) αποζημιώνει τα φαρμακευτικά προϊόντα που συμπεριλαμβάνονται στον Κατάλογο Διαθέσιμων Φαρμακευτικών Προϊόντων (positive list) και μπορούν να χορηγηθούν μόνο κατόπιν συνταγογράφησης από ιατρό ή οδοντίατρο. Η Συμβουλευτική Επιτροπή Φαρμάκων αξιολογεί αιτήσεις συμπερίληψης ή αφαίρεσης προϊόντων από τον κατάλογο αποζημίωσης βάσει της καταγεγραμμένης κλινικής πρακτικής, της επιστημονικής βιβλιογραφίας, των ήδη διαθέσιμων επιλογών στον κατάλογο αποζημίωσης, ασφάλειας, cost-effectiveness και άλλων. Ακολούθως, η Συμβουλευτική Επιτροπή Φαρμάκων δίνει τις εισηγήσεις της στο Διοικητικό Συμβούλιο του ΟΑΥ στο οποίο και έγκειται η τελική απόφαση συμπερίληψης φαρμακευτικών προϊόντων στον κατάλογο αποζημίωσης. Για τα προϊόντα που συμπεριλαμβάνονται στον κατάλογο αποζημίωσης, η αποζημίωση είναι στο 100% βάσει της φθηνότερης τιμής αναφοράς. Για κάθε είδος που χορηγείται από το φαρμακείο (ανεξαρτήτως ποσότητας), ο δικαιούχος καλείται να πληρώσει 1 Ευρώ. Το μέγιστο ύψος συμπληρωμής ανέρχεται στα 75 Ευρώ για τους λήπτες Ελάχιστου Εγγυημένου Εισοδήματος, τους χαμηλοσυνταξιούχους και τα παιδιά εώς και την ηλικία των 21, και στα 150 Ευρώ για τον υπόλοιπο πληθυσμό.

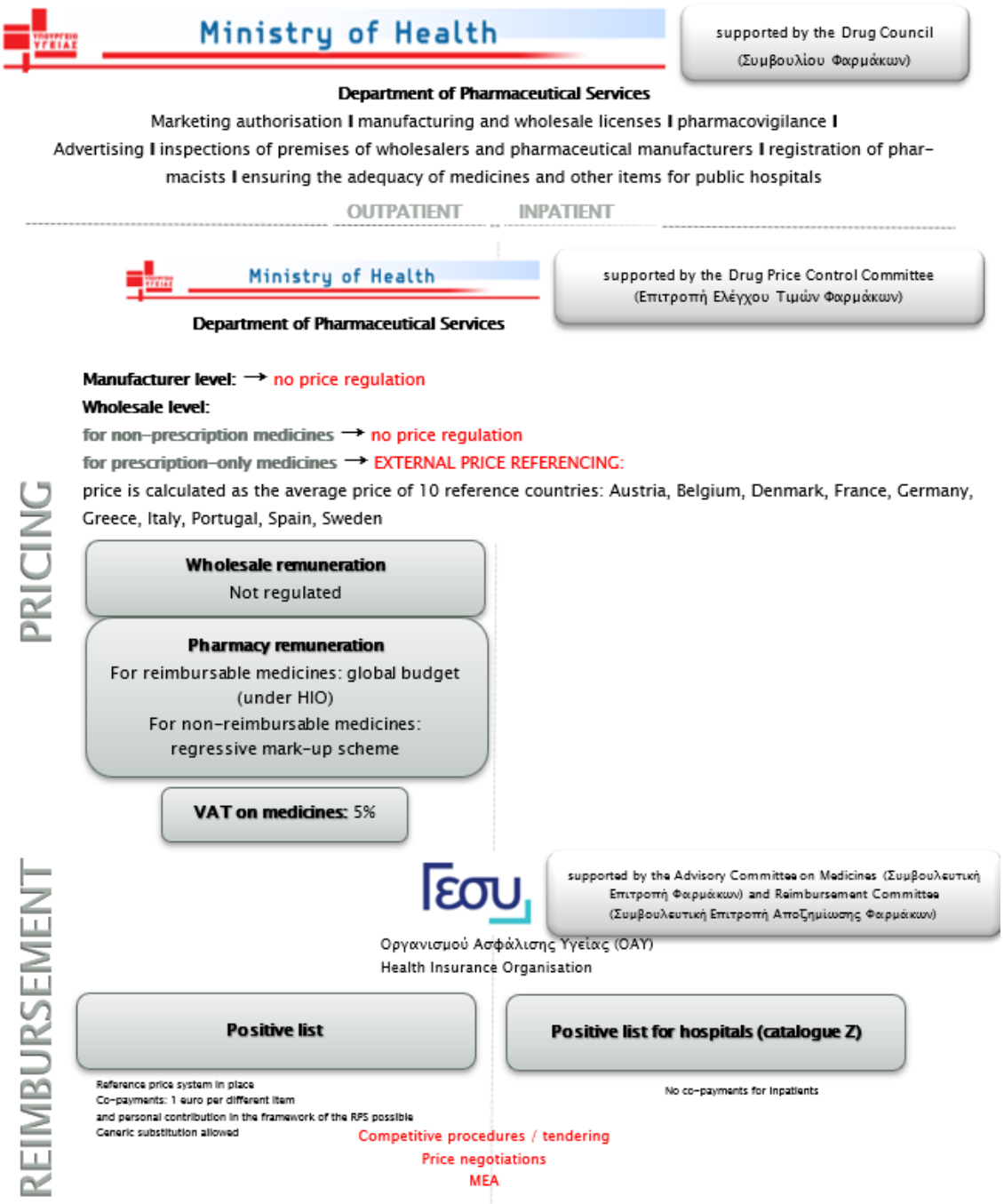
Στην Κύπρο εφαρμόζεται reference price system και τα φαρμακευτικά προϊόντα με διαθέσιμες επιλογές γενόσημων προϊόντων ομαδοποιούνται σε ομάδες αναφοράς. Για κάθε ομάδα αναφοράς καθορίζεται (σε επίπεδο ATC 4 ή 5) το προϊόν με την χαμηλότερη τιμή, το οποίο αποτελεί το προϊόν αναφοράς. Η αξία του προϊόντος αυτού, αποζημιώνεται από τον ΟΑΥ στο 100%. Οι δικαιούχοι έχουν την επιλογή ακριβότερου προϊόντος για το οποίο όμως θα πρέπει να καταβάλουν τη διαφορά στην τιμή μεταξύ αυτού και του συνταγογραφούμενου. Στην Κύπρο επιτρέπεται η συνταγογράφηση International Non-proprietary Name (INN) και η γενερική αντικατάσταση μόνο προς το φθηνότερο προϊόν.

Πολλές από τις φαρμακευτικές πολιτικές στην Κύπρο είναι υπο εξέταση λόγω του ότι η μεταρρύθμιση στον τομέα της υγείας είναι συνεχης, και κατ' επέκταση χρειάζεται αξιολόγηση της επίπτωσης των πολιτικών αυτών, όσον αφορά την πρόσβαση στη φαρμακευτική αγωγή.

Keywords

Τιμολόγηση, αποζημίωση, φαρμακευτική πολιτική, φαρμακευτικό σύστημα, Κύπρος

Graphical summary



1 Framework

Until 2019, there was no universal health system in Cyprus. Health care was provided by two uncoordinated subsystems (public and private sector), which led to inefficiencies (for a further description of the health care system before June 2019 – see box below). In June 2017, the General Health System (GHS) Law was enacted, amending the GHS Law of 2001 (Law 89 (I)/2001) to introduce **a National Health Insurance System (NHIS) in Cyprus by 2019** (WHO 2019). The amended law called for a system of **universal health coverage** to address inequalities in access to health care. The main features of the new **General Healthcare System (GHS)** are (Health Insurance Organisation 2020f):

» Universal coverage of the population
» Equal and equitable treatment of all beneficiaries
» Provision of a comprehensive package of healthcare services
» Freedom of choice of provider by the beneficiaries
» Social reciprocity

The implementation of the GHS had been planned **in phases** and started with the **introduction of outpatient services** (family doctors, outpatient specialists, medicines, laboratories) **in June 2019** followed by the **implementation of inpatient services** (inpatient care, accident and emergency care, ambulance services, allied health professionals, nurses and midwives, dentists, rehabilitation care and palliative care) starting in **June 2020** (WHO 2019). The new NHIS is a single-payer system from which all payments to providers of healthcare services are made. For the implementation of the GHS, a **special fund** was established for the purpose of gathering the relevant contributions from the state, employers and employees, pensioners and the self-employed. The **Health Insurance Organization** (**HIO**, in Greek: Οργανισμός Ασφάλισης Υγείας, ΟΑΥ,) is the entity responsible for purchasing health services under the NHIS. Patients have the freedom to choose their health-care provider, including general practitioners (GPs) and specialists, from those providers registered with the HIO and access most of those services for free (Health Insurance Organisation 2020f).

The **Ministry of Health** (Department of Pharmaceutical Services) is still the competent authority for the implementation of legislation on medicines, cosmetics and the pharmacist's profession. The Ministry of Health also acts as **the Medicines Agency for Cyprus** supported by the **Drug Council** (Συμβούλίο Φαρμάκων) and is in charge of marketing authorisation, manufacturing and wholesale licenses, pharmacovigilance, advertising, setting of medicine prices, inspections of premises of wholesalers and pharmaceutical manufacturers, registration of pharmacists and ensuring the adequacy of medicines and other items for public hospitals (Ministry of Health 2020c).

The **Ministry of Health** (Department of Pharmaceutical Services) advised by the **Drug Price Control Committee** (Επιτροπή Ελέγχου Τιμών Φαρμάκων) is also in charge of regulating prices for medicines on the Cypriot market (Ministry of Health 2020b).

Since June 2019, medicines that are reimbursed within the new GHS in the **outpatient sector** are included in the **Catalogue of Medicinal Products** (positive list) which is compiled by the **Health**

Insurance Organisation following the relevant recommendations by the Advisory Committee on Medicines (Συμβουλευτική Επιτροπή Φαρμάκων) (Health Insurance Organisation 2020g).

For the inpatient sector, a **formulary of medicines used in public hospitals** was maintained by the **Ministry of Health** (Department of Pharmaceutical Services) advised by the Medicines Committee (Επιτροπής Φαρμάκων) till August 2020. Since September 2020, HIO is responsible for the inpatient medicines through the catalogue Z. Catalogue Z includes the formulary of medicines used in both private and public hospitals. Two scientific bodies regulate the inclusion of products: The Advisory Committee on Medicines decides on their inclusion and the Drug Reimbursement committee decides on the price and the use of managed entry agreements (MEA) (Health Insurance Organisation 2020d).

There is no separate HTA agency in Cyprus; however, some HTA evaluations were done within a special unit of the Department of Pharmaceutical Services at the Ministry of Health (Cairns et al. 2014; Panayiotopoulou et al. 2019; Petrou 2019). In the context of the introduction of the National Health Insurance System, this responsibility was transferred to HIO, jointly to its two committees – the Advisory Committee on Medicines (Συμβουλευτική Επιτροπή Φαρμάκων) and Drug Reimbursement Committee (Συμβουλευτική Επιτροπή Αποζημίωσης Φαρμάκων).

The pharmaceutical system in Cyprus before June 2019

Prior to 2019, the health system consisted of a **public and a private** sector, with no difference between the out- and inpatient sector. It was estimated that the public sector covered about 75–80% of the population – which had access to state-financed, public healthcare free of charge (or for a small fee); others had to pay a fee or rely on the private healthcare sector (Ministry of Health 2015; Petrou and Vandoros 2016). However, it is remarkable that the level of public spending on health in Cyprus was low (just under 3% of GDP in 2016, compared to an EU28 average of 6%). While the majority of the population was entitled to health care in public facilities financed by general taxation, many still opted for private health care and paid out-of-pocket. As a result, the rate of out-of-pocket expenditure in Cyprus was among the highest in the European Union (EU), exceeding 45% of total health spending, compared to an EU28 average of 22% in 2016 (WHO 2019). The dual system generated inefficiencies such as: duplication of health services since there were no links between public and private providers to ensure the continuity of care; high out-of-pocket payments; long waiting times; and weak primary health care. It also contributed to inequalities since better-off segments of the population were able to access health services privately to avoid long waiting lists in public facilities (WHO 2019).

2 Pricing

Pricing at manufacturer and wholesale price level

Prices at manufacturer level are not regulated in Cyprus. Free pricing by the pharmaceutical manufacturers or importers applies.

Prices of prescription-only medicines (both out- and inpatient) are regulated at **wholesale price level** using **external price referencing**: the maximum wholesale price is calculated as the average price of ten reference countries:

» Countries with high prices (group 1): Germany, Denmark, Austria
» Countries with medium prices (group 2): Italy, Belgium, Sweden, Spain
» Countries with low prices (group 3): Greece, Portugal, France

For the calculation of the reference value, the wholesale prices in all ten reference countries are taken into account based on the following algorithm: the average of the lowest price from the group of expensive countries (group 1), the two lowest prices from the group with medium prices (group 2) and the lowest price from the group of countries with relatively low prices (group 3) is calculated. If applicable, the prices of the reference countries are converted in euro using the average annual exchange rates. The maximum wholesale selling price of imported prescription-only medicines is fixed by using the reference value, **adding 3% for import cost**. This procedure leads to the official listed maximum wholesale prices for Cyprus ("Price to Pharmacy"). The price list is updated every year. Companies are invited by the Ministry of Health to submit wholesale prices of the reference countries to the Ministry of Health. The price review process starts every year on September 15th and the updated price list is announced on December 15th of the same year. Price reviews during the year resulting in updated price lists are possible. A re-calibration of the pricing method is performed on a biennial basis (Ministry of Health 2019b).

Special rules apply for imported prescription-only medicines at a wholesale price equal to or less of 6 euro and an annual sales volume of less than 25,000 euro.

Medicines whose wholesale price is less than 3 euro may apply for a price increase up to 20%, given that no other interchangeable product with the same active ingredient is authorized in Cyprus

Medicines whose wholesale price is between 3.01-6 euro can apply for a price increase up to 10% provided that no other interchangeable product, with the same active ingredient, is authorized in Cyprus.

The price lists containing the official maximum wholesale prices are published at the website of the Ministry of Health: https://www.moh.gov.cy/Moh/phs/phs.nsf/home_en/home_en?open-form.

In the case of non-prescription medicines, the setting and / or increase of the maximum wholesale price is determined by the marketing authorization holder indicated in the relevant application, without the need to submit other information (Ministry of Health 2019b).

The Ministry of Health is advised by the Drug Price Control Committee (Επιτροπή Ελέγχου Τιμών Φαρμάκων) on any matter concerning medicine prices.

The price list with the maximum wholesale prices is the basis for further pricing mechanisms at the time of inclusion in the positive lists.

A price link policy is in place with the first generic entering the Cypriot market being priced at 80% of the originator maximum wholesale price (derived by using EPR). If no originator is on the market, EPR is used to calculate generic prices (Ministry of Health 2019b).

Managed-entry agreements (MEA) have recently been applied in Cyprus, after the introduction of the second phase of NHS in September 2020.

Value-based pricing is not applied in Cyprus.

Procurement

Prior to the implementation of the new health care system in June 2019, all medicines for the public sector were centrally procured by the Ministry of Health through public tendering. Over the past three decades, Cyprus had been considerably successful in the **centralised procurement of medicines as a key strategy for cost containment** (Panayiotopoulou et al. 2020; Petrou and Talias 2015).

Until June 2019, Cyprus mainly applied two procedures for the procurement of medicines for the public sector:

1. **Open invitation to tender procedure**: suppliers were invited to submit their tender among which the **lowest-priced offer** was awarded provided it complied with all required terms and specifications; this procedure was generally used for **off-patent medicines** due to the increased competition, as well as for biosimilar medicines (tendering was commonly performed at the ATC 5 level or sometimes at the ATC 4 level).
2. **Negotiation procedure**: for **on-patent and innovative** medicines without competition central procurement could not be applied. Instead, other procedures were used, performed through a negotiation process).

Both procedures provided the winning tenderer with the right to supply the public sector usually for a period of **two years** with the government procuring the total volume in instalments and the supplier being reimbursed upon delivery of the medicines at public pharmacies.

Before launching a tendering procedure, an **HTA was conducted** to evaluate and compare the medicine in question with alternative products for the same condition and to assess their epidemiological and economic impact. Based on the results of the HTA, the tender was announced either for a specific medicine ("**INN sole**"), an **INN group**, or **INN alternative**. For the INN sole tender, only one specific product was eligible to participate in the tender and thus no competition possible. However, the medicine's committee of the Ministry of Health could reject the product if it considered its price too high. For the INN group tender, usually more than three products were invited to compete, with the lowest-priced product being chosen as first line therapy, and the second lowest priced product as second line therapy, provided that products were interchangeable. For the third option, INN alternative, only one among several interchangeable products were selected (usually between three and six products compete).

Public procurement procedures follow strict **Standard Operating Procedures** (SOP) and the primary principles of **transparency and equal treatment**. Tendering documents require to set precise terms and conditions at the beginning of the procurement process, including defined timelines for e.g. call for tender, evaluation of tender, issuing the contract, and the delivery of the goods, as well as about instalment regulation, termination rights of the contract, and shelf life of the medicine. A tender which is expected to exceed the amount of 133,000 euro is required to be **published** in the Tenders Electronic Daily (TED) Europe; tenders of lower value are published in the official journal of the Cyprus Government.

The tender procedure achieved additional price reductions on wholesale prices which are published in the official pharmaceutical price list (see above). Through the open invitations to tender procedure, **significant discounts** were achieved in particular for off-patent medicines (up to 80% lower than the lowest wholesale prices in the private sector). The **tendering agreement was legally binding** and the outcomes of the tendering procedure were published including final price and contract value.

Public tendering procedure started approximately **one year prior to the expected date** of product delivery. All necessary calculations regarding the product's stocks were made before announcement of the tender (possible issues were considered i.e. the possibility of the introduction of a new medicine for a specific indication in the health system and the impact this may have for the currently administered medicine for the same indication, seasonal effects, or changes in prescribing habits etc.) to prevent stock-out or overstock of the medicine. The average time needed from the first day of the publication of the invitation for tenders until the day of the product's delivery is 273 days in Cyprus.

Overall, Cyprus states it greatly **benefits from centralised procurement of medicines** and its potential to lead to

» **reduced prices** provided there is enough competition,
» larger **competition** due to increased participation (especially for generics),
» enhanced **transparency** through clear procedures and consistency of method and
» **no discrimination** between suppliers (Vogler et al. 2020).

However, it was observed that in Cyprus **centralised procurement of medicines** does **not perform well for new medicines** considered to be innovative due to the weak negotiation power of national authorities (small market) and the monopoly situation of the industry (Petrou 2014; Petrou and Talias 2014).

The lessons learned through decades of practice of using public procurement including tendering which has delivered significant benefits for the health system should also be used for the new GHS. The Ministry of Health in Cyprus has accumulated considerable experience in the use and administration of tenders through the open invitation procedure for off-patent and generic medicines. Tenders could be seen as an additional tool for the new reimbursement system to select cost-effective medicines (Panayiotopoulou et al. 2020; Petrou and Talias 2015).

With the introduction of the National Health Insurance System (NHIS), the reimbursement shifted to an ATC-4 and ATC-5 reimbursement. The lowest-priced medicine is fully reimbursed, while

patients that opt for another medicine, in the given category, must pay the out-of-pocket price difference. This comprises a strong motive for the industry to lower prices.

Pricing in the supply chain

Wholesalers

Wholesale mark-ups are not regulated in Cyprus. There are different models of business operation in the country and the following assumptions can be made:

» There are companies with an affiliate status in Cyprus with distribution margins of around 4 - 6%
» There are companies with expanded agreements and apart from storage and distribution with local distributors other services are also included (e.g. regulatory affairs, pharmacovigilance, etc.). In such cases the margins are higher - between 7-10%.
» There are also agents which handle everything from regulatory affairs, marketing and distribution. In these cases, the margins are expected to be higher and probably around 15% or higher.

Based on the indications above, an average wholesale margin of 9.25% is assumed (BMSGPK 2020).

Pharmacies

Reimbursed medicines

Pharmacists wishing to provide health care services within the context of GHS must comply with the provisions of the GHS Law and the regulations and decisions issued under it. Beneficiaries will receive their medication from **all pharmacies contracted with HIO** by submitting a prescription of a physician or a dentist also contracted with HIO. (Health Insurance Organisation 2020a) The provision of pharmaceutical healthcare services by pharmacists within the GHS context involves dispensing of prescriptions, the provision of information and advice on the correct, safe and responsible use of medicines and the possibility of substitution with the cheapest medicine of the same active substance and pharmaceutical form (generic substitution) (Health Insurance Organisation 2020g).

Pharmacy fees for dispensing medicines to outpatients are paid per package (box) provided by the pharmacists to beneficiaries. A monthly budget is allocated and, at the end of the month, divided by the total number of dispensed packages. Therefore in the context of a **Global Budget, the fee for each outpatient service provided, is readjusted on a monthly basis** depending on the volume of services/cases, so that the actual cost does not exceed the budgeted cost for that specific group of services.

According to the relevant law (Κ.Δ.Π. 195/2019, No. 5165, 7 June 2019), an extra 4 % of the maximum wholesale price is provided as compensation for stocking and storing expensive medication. This remuneration is incorporated in the fee. The aim is to disentangle the percentage from the fee since this 4% regulation was introduced in order to compensate pharmacists for stock keeping of expensive medicines (Health Insurance Organisation 2019b).

Non-reimbursed medicines

For non-reimbursable medicines the following mark-ups apply (since 1 June 2018):

1. For medicines with a wholesale price up to 10 euro, a pharmacy mark-up of is 37% added on wholesale price
2. For medicines with a wholesale price between 10 – 50 euro, a pharmacy mark-up of 35% is added on wholesale price
3. For medicines with a wholesale price between 50 – 250 euro, a pharmacy mark-up of 3% is added on wholesale price
4. For medicines with a wholesale price between 250 – 1,500 euro, the pharmacy gets a fix amount of to 83 euro.
5. For medicines with a wholesale price higher than 1,500 euro, the pharmacy gets a fix amount equal to 100 euro.

In addition to the above, pharmacists charge one euro per prescription as professional fee (incl. VAT = 19% = 1,19 euro) (Ministry of Health 2018).

VAT

The VAT on medicines is 5% in comparison to a standard VAT of 19% in Cyprus.

Pricing before July 2019

Medicines in the public sector were procured centrally by the Ministry of Health (Pharmaceutical Services) through **tendering procedures** to achieve additional discounts on the wholesale prices as they were noted in the **official pharmaceutical price list**. The individual prices of the medicines were not published.

Medicine prices in the private sector were set by the Ministry of Health, based on the recommendations of the Drugs Price Committee. The Committee applied an EPR Scheme to obtain the official price, i.e. the wholesale price for the Cypriot pharmaceutical market (Panayiotopoulou et al. 2020; Petrou and Vandoros 2016). Pharmacy mark-ups were regulated on the basis of a regressive scheme (see section on non-reimbursed medicines above).

3 Reimbursement

Reimbursement for outpatient medicines

The GHS compensates for the necessary medicines, which on a legal basis can only be dispensed with a doctor's prescription and which are included in the Catalogue of Medicinal Products which serves as the reimbursement list in the format of a positive list (Health Insurance Organisation 2020a).

The Catalogue of Medicinal Products is compiled by the HIO following the relevant scientific committee's recommendations. (Health Insurance Organisation 2020g)

The rules for the inclusion of medicines are laid down in the internal regulations of the General Health System (Advisory Committee on Medicines, Subcommittees, compilation of a list of medicines) of 2019 (Health Insurance Organisation 2019a). The Advisory Committee on Medicines evaluates applications for inclusion or removal from the positive list and gives recommendations to the Board of Directors of HIO (Συμβούλιο) which takes the decision. The following criteria are evaluated by the Advisory Committee:

(a) documented clinical practice
(b) documented scientific literature
(c) pharmacoeconomic studies
(d) results of internationally recognized scientific health technology assessments
(e) the marketing authorisation / licensing status
(f) the therapeutic position of the product concerned in international guidelines
(g) alternative medicines included in the reimbursement list for this indication
(h) the epidemiological evidence of the disease
(i) the safety of the beneficiaries
(j) cost-effectiveness
(k) the rational use of these medicines
(l) the optimal management of the HIO's available resources
(m) the existence of alternative non-pharmacological treatments.

The GHS Catalogue of Medicinal Products (ΚΑΤΑΛΟΓΟΣ ΔΙΑΘΕΣΙΜΩΝ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΓεΣΥ) includes originator, generic, biological and biosimilar medicines (Health Insurance Organisation 2020d).

An appeal procedure for marketing authorisation holders is currently prepared.

The medicines included in the positive list are grouped into reference groups. For each reference group, at least one product is defined as reference product whose costs are covered 100% by the Health Insurance Organisation. If the beneficiary chooses a more expensive product than the one HIO fully compensates for, he / she pays the so-called "Personal Contribution II" (Συνεισφορά ΙΙ) which equals the difference between the price of the medicine covered by the GHS and the price

of the medicines that the beneficiary chose. In addition, for each pharmaceutical package (regardless of the quantity dispensed), a co-payment of 1 euro has to be paid by the patient (Health Insurance Organisation 2020g).

The maximum annual amount of co-payments is 75 euro for recipients of the Guaranteed Minimum Income, the low-income pensioners and children up to the age of 21, and 150 euro for the rest of the population. This ceiling incorporates all co-payments payable in any health care sector (not only pharmaceuticals) (Health Insurance Organisation 2020c).

Reimbursement for inpatient medicines

In phase 2 of the health system reform also hospitals and inpatients services were integrated in the Health Insurance System starting in September 2020. For the inatient sector, a national **formulary of medicines for public hospitals Catalogue Z** (ΚΑΤΑΛΟΓΟ Ζ) used to be maintained by the **Ministry of Health** (Department of Pharmaceutical Services) advised by the Medicines Committee (Επιτροπής Φαρμάκων) (Ministry of Health 2019a). The Board of Directors of the Health Insurance Organisation upon recommendation of the Advisory Committee on Medicines decided to adopt this list. Catalogue Z refers to hospital medicines or day care medicines and are not included in DRG fees. These medicines will be provided by HIO either through tenders or through agreements with the marketing authorization holders. All products included in Catalogue Z can participate in competitive procedures and/ or in negotiations, and will only be reimbursed after taking part in these procedure with HIO. (Health Insurance Organisation 2020e) Until the competitive procedures/negotiations are completed, only existing patients receive the medicines.

The Catalogue Z is available at this link: https://www.gesy.org.cy/sites/Sites?d=Desktop&locale=el_GR&lookuphost=/el-gr/&lookuppage=hiopharmacatalogues2020.

GHS participants do not need to pay anything for medicines administered while in hospital.

Agreements

Managed-entry agreements (MEA) were launched in September 2020 for a few medicines.

Generic substitution at community pharmacy level is allowed (indicative) in Cyprus with the cheapest medicine of the same active substance and pharmaceutical form.

INN prescribing is allowed, but the IT system, from a technically perspective, does not provide the option for INN prescribing.

Prescribing of certain medicines is subject to special regulations such as protocols / guidelines / prescription restrictions (only by certain specialists) or pre-approval by the HIO (Health Insurance Organisation 2020g).

4 Developments

The pharmaceutical landscape of Cyprus has been substantially reformed. The shift from a closed formulary to a positive list has been a fundamental reform. Moreover, the engagement of all community pharmacies has transformed their operational status. This led to several reforms, such as the introduction of generic substitution.

One of the most important changes is the introduction of MEA, in the wake of the positive list.

Due to the ongoing health reform many of the implemented new pharmaceutical policies are still under evaluation or need to be evaluated regarding their impact on access to medicines in Cyprus.

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6 Annex

Annex 1: Stakeholders

Role	Name in local language (in Greek)	Website(s)
Competent authority for marketing authorisation of medicines	Ministry of Health (Department of Pharmaceutical Services) / Φαρμακευτικών Υπηρεσιών του Υπουργείου Υγείας	https://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_gr/dmlindex_gr?opendocument
Competent authority for pricing of medicines	Ministry of Health (Department of Pharmaceutical Services) / Φαρμακευτικών Υπηρεσιών του Υπουργείου Υγείας	https://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_gr/dmlindex_gr?opendocument
Competent authority for reimbursement of medicines (outpatient)	Health Insurance Organisation (HIO) / Οργανισμού Ασφάλισης Υγείας (ΟΑΥ)	https://www.gesy.org.cy/sites/Sites?d=Desktop&locale=el_GR&lookuphost=/el-gr/&lookuppage=home
Public payer(s) for outpatient medicines	Health Insurance Organisation (HIO) / Οργανισμού Ασφάλισης Υγείας (ΟΑΥ)	https://www.gesy.org.cy/sites/Sites?d=Desktop&locale=el_GR&lookuphost=/el-gr/&lookuppage=home
Public payers for inpatient medicines	Health Insurance Organisation (HIO) / Οργανισμού Ασφάλισης Υγείας (ΟΑΥ)	https://www.gesy.org.cy/sites/Sites?d=Desktop&locale=el_GR&lookuphost=/el-gr/&lookuppage=home
Patients organisations	Pancyprian Federation of Patient Associations and Friends (PFPA)	-
Consumers organisations	Cyprus Consumers' Association / Κυπριακού Συνδέσμου Καταναλωτών (ΚΣΚ)	http://www.katanalotis.org.cy/
Pharmacy associations	Pancyprian Pharmaceutical Association / Παγκύπριος Φαρμακευτικός Σύλλογος (ΠΦΣ)	-
Industry associations	Cyprus Association of Pharmaceutical Companies (CAPC) / Σύνδεσμος Φαρμακευτικών Εταιρειών Κύπρου (ΣΦΕΚ)	http://capc.org.cy/

Source: Research by PPRI Secretariat

Annex 2: Glossary

Community pharmacies	Health care facilities which dispense medicines (prescription-only medicines and/or non-prescription medicines, reimbursable and/or non-reimbursable medicines) to outpatients.
Co-payment	Insured patient's contribution towards the cost of a medical service covered by the health insurance. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
Cost-plus pricing	Pricing policy that determines a medicine price by taking into account production costs, promotional expenses, research & development, administration costs, overheads and a profit that is considered 'reasonable'.
Discount	A price reduction granted to specified purchasers under specific conditions prior to purchase.
Dispensing fee	A fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up.
External price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Free pricing	Pricing policy, in which governments allow pharmaceutical companies to determine the price of the medicine they launch.
Generic substitution	Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s).
Health Technology Assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
INN prescribing	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its International Non-Proprietary Name (INN), i.e. the active ingredient name instead of the trade name.
Managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financially-based and performance-based MEA.
Marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
Mark-up	Percentage of the purchasing price added on to get the selling price.

Pharmaceutical expenditure	Total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives and other medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.
Policies	Instruments, tools and approaches that allow policy-makers to achieve defined objectives.
Price link policy	Practice of setting the price of a medicine (e.g. a generic or a biosimilar) in relationship to the price of another medicine (e.g. originator, biological reference medicine), usually at a certain percentage lower.
Pricing (price setting)	Act of determining the medicine price which is either taken by a pharmaceutical company (free pricing) or is the competence (responsibility) of a competent authority (price control).
Price negotiation	A pricing procedure, in which medicine prices are discussed and agreed (e.g. between manufacturer and third party payer).
Price regulation (price control)	Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement).
Procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
Reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments.
Reimbursable medicines	Medicines which are eligible for reimbursement. Expenses of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
Reimbursement	Coverage of the expenditure by a third party payer (e.g. social health insurance/National Health Service).
Reimbursement list	A list that contains medicines with regard to their reimbursement status. It may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).
Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.

Value-based pricing	Policy of authorities to set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
Wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Source: Glossary of Pharmaceutical Terms