# Estimating Real Prices of Medicines used in Hospitals

Study protocol

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



# Estimating Real Prices of Medicines used in Hospitals

Modelling Discounts and Rebates based on experts' estimates

Study protocol

Authors:

Sabine Vogler Peter Schneider Nina Zimmermann

Project assistant:

Ingrid Freiberger

The views expressed in this publication are those of the authors and not necessarily of the commissioning institution.

Vienna, October 2019 Commissioned by the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection



How to cite: Vogler, Sabine; Schneider, Peter; Zimmermann, Nina (2019): Estimating Real Prices of Medicines used in Hospitals – Modelling Discounts and Rebates based on experts' estimates. Gesundheit Österreich GmbH (GÖG / Austrian Public Health Institute), Vienna

Zl. P4/33/5121

Owner, editor and publisher: Gesundheit Österreich GmbH (Austrian Public Health Institute), Stubenring 6, 1010 Vienna, tel. +43 1 515 61, websites: www.goeg.at and http://ppri.goeg.at

For the environment: This report is produced on recycled paper without optical brighteners.

## Summary

Gesundheit Österreich GmbH (GÖG) was commissioned by the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMASGK) to conduct a European price comparison of medicines used in hospitals that takes "real prices" into account.

The present study protocol describes the methods for this study. Data collection is based on a survey among procurement experts about their opinion what discounts would be attainable for selected medicines used in hospitals. Their estimates will be used as input to model real prices in hospitals.

#### Key words

Medicine prices, hospital, European price comparison, discount, transparency, confidentiality

## Acknowledgments

In January 2019, key elements of the methodology were presented to the GÖG Scientific Advisory Board. Some members agreed to review the proposed methodology according to scientific standards. Elements of the methodology were presented in meetings with members of the Informal Advisory Group (January 2019) and the "Sounding Board" (hospital owners representatives, March 2019), This study protocol is a revised version of a first draft on the planned methods published in April/May 2019. It has taken into consideration the comments from the GÖG Scientific Advisory Board, international researchers, the Informal Advisory Group of Hospital Pharmacists, the "Sounding Board" and the Association of the Pharmaceutical in Austria which GÖG has received during the consultation phase.

## Content

Summ	nary			
Ackno	wledgm	ients III		
Figure	es and T	ablesV		
Abbre	viations	VI		
1	Backgro	ound7		
2	Objectives of the study8			
3	Project organisation9			
4	Methoc 4.1 4.2	lology		
5	Time-line13			
6	Appendix			
7	References			

# Figures and Tables

igure 5.1: Time schedule for the study1	4
	~
able 3.1: Key actors in the context of the study	9
able 6.1: Proposal for the selection of medicines for this price study: 30 active substances with 52 medicines ranked according to medicine groups (high, medium, low) and	' -
alphabetically according to the active substance hame.	1

## Abbreviations

AMNOG	Gesetz zur Neuordnung des Arzneimittelmarktes / Act on the Reform of the Market for Medicinal Products (Cermany)				
	the Market for Medicinal Products (Germany)				
BMASGK	Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumen-				
	tenschutz / Federal Ministry of Labour, Social Affairs, Health and Con-				
	sumer Protection (Austria)				
BMGF	Bundesministerium für Gesundheit und Frauen / Federal Ministry of Health				
	and Women's Affairs (Austria, previous name of the Federal Ministry of La-				
	bour, Social Affairs, Health and Consumer Protection)				
ECB	European Central Bank				
EU	European Union				
GÖG	Gesundheit Österreich GmbH / Austrian Public Health Institute				
HAI	Health Action International				
MEA	Managed Entry Agreement				
PHIS	Pharmaceutical Health Information System				
PPI	Pharma Price Information (medicine price information service provided by				
	GÖG)				
PPRI	Pharmaceutical Pricing and Reimbursement Information				
PPP	Pharmacy purchasing price				
PRP	Pharmacy retail price				
UK	United Kingdom				
VAT	Value added tax				
WHO	World Health Organization				

### 1 Background

The continuous monitoring and regular analysis of medicine prices support policy-makers in the development of pharmaceutical pricing policies. As one of its legally defined tasks, Gesundheit Österreich GmbH (GÖG / Austrian Public Health Institute) is mandated to perform medicine price analyses.

There is need for estimating real prices in the **inpatient sector**:

- » Many of the **high-priced medicines** that have increasingly entered the market in recent years are used either exclusively or **primarily in hospitals** (Vogler et al. 2018).
- Medicine procurement in the inpatient sector differs from that of the outpatient sector in many countries, including Austria. While outpatient medicine prices are the same throughout Austria, given the application of statutory (maximum) price regulation (Bundesministerium für Gesundheit und Frauen (BMGF) 2019) and price negotiation of the Main Association of Social Insurance Institutions, procurement of medicines in the inpatient sector is decentralised, performed by hospitals or owners of the hospitals (usually provinces). In most cases, those responsible for the procurement of medicines are in direct contact with the manufacturers and negotiate the prices for the hospital or hospitals of the same owner (Jommi 2018; Klemp et al. 2011; Morel et al. 2013; Pauwels et al. 2017; Stemar 2015; van Harten, Wim H et al. 2019).
- » A large number of discounts and similar agreements (so-called managed entry agreements / MEA, such as price-volume agreements, risk-sharing agreements, capping) are applied in the inpatient sector (Ferrario/Kanavos 2013; Ferrario/Kanavos 2015). Due to the confidential nature of these discounts, the validity of international price comparisons based on list prices is limited.

A decade ago, commissioned by the European Commission and the Austrian Federal Ministry of Health, the research project "Pharmaceutical Health Information System" (PHIS) was conducted in order to gain knowledge about pharmaceutical provision and procurement in hospitals in Europe. For selected medicines in Austria and four other European countries, the real prices (in comparison to the published list prices) were collected and analysed as of September 2009. The PHIS study showed differences in the extent of discounts granted between studied countries and, in particular, between medicines: Whereas no discounts were granted for monopoly pharmaceuticals, medicines which, after hospitalisation, continued to be prescribed in the outpatient sector (as long-term therapy) achieved high discounts or were offered free of charge in some countries (Austria) (Vogler et al. 2010; Vogler et al. 2013a; Vogler et al. 2013b). Ten years later, the PHIS study is still one of the few research projects internationally that has investigated real prices and discounts in hospitals (see Appendix 1 for further information and results of the PHIS study and other relevant studies in this field).

Against this background, GÖG was commissioned to carry out a European price comparison of medicines used in hospitals in 2019, which considers "real prices" of medicines. This would add to previous price studies that were based on list prices (Schneider et al. 2018; Vogler et al. 2014;

Vogler et al. 2016). Following discussions with experts, a study protocol was developed and shared for peer and stakeholder review in April 2019. The comments GÖG received during the review pointed to some feasibility limitations of the originally planned methodology that had been in-formed by the data collection methods employed during the PHIS study. As a result, the methodology was adapted, and the study protocol has been accordingly revised.

### 2 Objectives of the study

The general objective of the study is to estimate "real prices" for medicines used in hospitals and to develop a model which considers discounts, rebates and similar price agreements without violating existing confidentiality agreements. The estimator aims to adjust for structural information e.g. countries, experience with procurement mechanisms. The inputs for the model will be collected from opinions of procurement experts in Austria and some other EU Member States.

The specific objectives of the study are:

- Definition of the concept of "price" (list price versus "real price" in the light of application of MEA) for medicines used in hospitals and an assessment as to whether and in what form these prices can be collected, calculated (ex-post) and analysed<sup>1</sup>
- » Survey among experts about their opinion which size of discounts they would expect in the next year for (selected) medicines in their respective country.
- » Analysis of estimated "real prices" against the backdrop of the national pharmaceutical system

It is not an objective of this study to evaluate different procurement models in the inpatient sector with regard to their impact on medicine prices or access to medicines.

In addition, this study do not aim to collect and evaluate information on real prices, but to develop a statistical model of real prices based on expert inputs.

<sup>1</sup> 

Regardless of the question about confidentiality, the design of a pricing model can be complex, making it difficult to determine the actual price.

# 3 Project organisation

Relevant actors of the study are summarised in Table 3.1.

#### Table 3.1:

Key actors in the context of the study

Actor	Role / Task
Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection	Commissioning party
Project team at GÖG	Implementation of the study
"Sounding Board": representatives of all key hospital owners (provinces, orders) in Aus- tria, represented by the management, the central procurement department or hospital pharmacy	Feedback on the draft methodology, receipt of the study protocol, sup- port through contacts to respondents, receipt of the study prior to pub- lication (possibility to provide feedback) Presentation of the study and its methodology (study protocol) at a meeting in March 2019 and, if needed, another meeting in autumn 2019 to present the preliminary results
Informal expert group: selected hospital pharmacists in Austria	Informal exchange on the study methodology, in particular on product selection, feedback on the study protocol, advance receipt of the study before publication (possibility to provide feedback) Information exchange at meetings in January and March 2019
Scientific Advisory Board of GÖG: individual members	Informal exchange on the study methodology, feedback on the study protocol, receipt of the study before publication (possibility to provide feedback) Information exchange at a meeting in January 2019
Procurement experts, hospital pharmacists and other people affiliated with procurement in Austria and other countries	Possible experts for estimates for the selected countries (depending on the selected method, possibly different for the countries of the study)
Researchers of other countries, international organisations, stakeholders	Reviewers who were invited to provide comment on the study protocol (available in German and English version)

## 4 Methodology

### 4.1 Survey method

#### Type of price comparison:

» Survey among experts about their personal opinion which price reductions they would consider as attainable given their experience in their respective country and to develop an estimator for real prices

<u>Justification</u>: Due to contractual obligations hospitals or procurement organisations are not allowed to share information on real prices of specific medicines. Therefore procurement experts will be asked about their personal opinion what size of discount they would consider as attainable for defined medicines / medicine groups. Experts must not share real prices or existing discounts but their estimation what size of discounts they would expect to achieve in the next year.

#### Country and hospital selection:

- » Austria and around 3-5 further European countries. The selection of countries will be finalised after having explored the availability of procurement experts in the countries (discussion with collaboration partners in the countries).
- » It is aimed to survey experts in five hospitals per country (caveat: Denmark and Norway have one hospital price country-wide; in other countries prices of the hospitals of one owner can be the same as well. The selection of hospitals to be surveyed will be guided by the respective country contacts.

<u>Justification</u>: The selection criteria for this survey are (1) European countries with similar economic strength, (2) countries which had already been investigated in the 2009 PHIS study, and (3) differences in the characteristics of the organisation of the pharmaceutical system and medicine procurement in the inpatient sector. Eventually, the willingness of experts to participate and provide estimates is a pragmatic guiding principle.

#### Selection of products:

- » Six medicines groups (on-patent biological medicines to treat cancer, on-patent medicines to treat orphan diseases, on-patent biological medicines to treat other diseases, on-patent chemical medicines, off-patent biological medicines, off-patent chemical medicines) with a representative selection of 5-6 medicines based on defined criteria (see below)
- » guided by technical advice provided by an informal expert group
- » provisional list of the 36 active ingredients; for further information see appendix 2 in chapter 6.2

<u>Justification</u>: Inclusion criteria for this study were (1) medicines with a high budget impact for the inpatient sector, (2) medicines of different indication groups, and (3) medicines which also account for high public expenditure in the outpatient sector (due to their price or quantity, e.g. long-term prescribing for outpatients following a first prescription in the hospital sector).

#### Date of survey:

- » Expert input will be surveyed in in Q4/2019
- » Estimates on discounts for the next year (2020)
- » Reference date of price data is 31 September 2019

<u>Justification</u>: If experts are asked about their opinion for attainable discounts there is a need for a benchmark to put their estimates in perspective. Therefore price data and estimates should be as updated as possible.

#### Scope of the survey:

- » Data for the descriptive and quantitative analysis of reported expected value within the different group of medicines and over the whole sample
- » Supplementary information e.g. on background of the surveyed or the country characteristics in which the procurement experience is embedded – will be surveyed in order to adjust for in the regression.

<u>Justification</u>: Since the survey asks experts about their personal opinion, no specific calculation methods are necessary. However, the questionnaire will provide a common definition, in order to ensure comparability of subjectively assessment data. In addition, further data and background information on the setting in which the expert opinion is based will be collected used for the regression and – if necessary – in the sensitivity analyses.

#### Survey method:

- » Questionnaire: For the expected price reduction of selected medicines: survey among procurement experts of the in-patient sector per country, by means of an online questionnaire).
- » For further background information e.g. setting in which experience is embedded to construct estimators: part of the online survey
- » Hospital list prices (ex-factory price or pharmacy purchasing price (PPP) in some countries) are not part of the primary data collection, but will be retrieved from the GÖG Pharma Price Information (PPI) service

<u>Justification</u>: There is some literature which aim to estimate possible discounts levels (Morgan et al. 2017). Since no Information on real prices is publicly available and, primary data collection

needs to take confidential issues into account, experts' estimates are considered as proxy input to run the regression.

#### Confidentiality:

- » Confidentiality will be ensured for all participating experts that share their personal expectations as input to the statistical model.
- » All results will be estimates on real prices and cannot be traced back to any individual institutions or countries. If deemed necessary, data presentation can be further aggregated over the defined medicines groups.

<u>Justification</u>: A method was developed that does not investigate specific hospitals as survey of discounts in real-world settings might be perceived in possible violation of contractual obligations.

#### Comparator product

- » no comparator product, but consideration of the active ingredient
- » consideration of generic and biosimilar medicines

<u>Justification</u>: The proposed method is not a medicine price comparison but aims to develop an estimator of possible "real" prices. Since it can be assumed that expectations on price reductions are uniformly over all authorised presentations of an active ingredient it is not necessary to define a comparator product. However, the definition of medicine groups including off-patent chemical and biological active ingredients allows to adjust the estimator for dynamics related to the off-patent life-cycle phase of medicines.

### 4.2 Methods related to analysis

#### Analysis parameters:

- » Unit of the analysis: Expected price reductions over an active ingredient; in contrast to price comparisons an analysis of unit prices of comparator products is not relevant,
- » Exchange rates: not relevant as, since the percentage size of discounts is applied to the respective price in national currency units and therefore translates into some form of Indexation:
- » Weighting of prices: the effect of a countries' income level is captured by the country fixed effects; economic indicators will be included in the regression to decompose the country effect

#### Evaluations and presentation of results:

» The descriptive analysis of the range of expected price reductions, adjusted for structural factors in which the experts' opinion is embedded in, for each medicine group will be presented as a boxplot (see example below) or in another appropriate form



» Construction of an estimator for real prices that includes structural and medicine-group specific variables which are included in the Vector  $(X_i)$ 

 $ListPrice_i = \alpha_i + \beta_i RealPrice_i + \gamma_i X_i + e$ 

 Following structural and medicine-group specific variables will be considered in the estimator: (1) Country effects, (2) Institutional background of the surveyee, (3) Therapeutic group effects, (4) Orphan designation,

### 5 Time-line

Figure 5.1 describes the time schedule and procedures for the study.





Source: Gesundheit Österreich GmbH (GÖG)

## 6 Appendix

### 6.1 Studies on real prices and discounts

In total, there are only a few studies on real prices of medicines used in hospitals. In the following the results of some of the major studies will be presented.

#### PHIS project - EU project on medicines management and prices in hospitals

One focus of the PHIS project (PHIS = Pharmaceutical Pricing and Reimbursement Information) commissioned by the European Commission was a survey of the organization of the inpatient pharmaceutical system in the countries of the network (36 European countries) and a survey of hospital prices in five case study countries (Austria, Netherlands, Norway, Portugal, Slovakia). Prices (list prices and "real prices") for twelve medicines as of September 2009 were collected from a total of 25 hospitals.

The price survey showed differences in "real prices" and the extent of discounts between the case study countries. The highest median discounts were found in Norway, followed by the Netherlands. Study results suggested that higher discounts could be obtained with centralised than with decentralised procurement. In all countries surveyed, the patent status of the medicines examined had an effect on the level of discounts: whereas hospitals were usually not granted discounts for patent-protected medicines – predominantly cancer medicines – and had to pay the list price, medicines used as long-term therapy after a hospital stay in the outpatient sector tended to have high discounts (Vogler et al. 2010; Vogler et al. 2013b). In Austria, a pattern of extreme values was evident – either hospitals bought the medicines at list prices or they received them for free from the pharmaceutical companies (Vogler et al. 2013a).

The PHIS project carried out methodology work to provide a definition of "real prices" in view of different price and financing models, e.g. discounts, price-volume agreements, bundling with the purchase of other medicines or other products, or cost- free products (Vogler et al. 2010).

#### Relevance of discount agreements and average amount of discounts

In its European overview for 27 countries, the PHIS project also surveyed the relevance of discount arrangements (in numerous countries) and cost-free medicines (only a few countries besides Aus-tria, e.g. Cyprus, Ireland, Slovakia) in the inpatient sector. Occasionally, countries also provided the average amount of discounts (Vogler et al. 2010).

A similar overview is provided by a study carried out in 2011 on the significance of discounts granted by the pharmaceutical industry to public payers, as well as their design and average amount. The study covered both the outpatient and the inpatient sectors; the information was provided by members of the PPRI (Pharmaceutical Pricing and Reimbursement Information) net-work (Vogler et al. 2012).

#### Real prices of cancer medicines

The study of van Harten, Wim H. et al. (2016) collected list and real prices of nine anti-cancer medicines in June/July 2015 using questionnaires in 21 hospitals in 15 countries. The study showed not only considerable differences in list prices (up to 92%) and real prices (58%) between countries, but also in the level of discounts. While Italy and Spain achieved discounts of 30 per cent and more for some medicines, Central and Eastern European countries paid the list price for a number of the medicines studied (van Harten, Wim H. et al. 2016).

For some medicines, however, no real price data could be collected, as some interviewees were concerned about (legal) consequences and were not willing to provide price information from confidential agreements on medicines. Furthermore, the Belgian government pointed out that the real price communicated for Belgium was de facto even lower (De Block 2016). Despite these weaknesses, this study by van Harten, Wim H. et al. (2016) is one of the few scientific papers that published real prices for hospital medicines.

#### Study on access to medicines used in hospitals, including hospital prices

A study by Health Action International (HAI) investigated access to patented medicines in hospitals in four European countries (Austria, France, Latvia and Spain). The prices of selected medicines were analysed and the authors came to the conclusion that hospital prices do not seem to be related to the economic power of the countries. However, official list prices were used in this study because the real prices were not accessible. The lack of transparency of real prices was highlighted as an important limitation, and the recommendation was made that EU Member States should be obliged to disclose confidential discounts in a publicly accessible database (Hawlik/Devalière 2016).

#### Anonymous surveys on discounts

Morgan et al. (2017) collected the average amount of discounts in eleven economically strong countries in America, Europe and Australasia, but only for medicines in the outpatient sector. The discounts for both primary care medicines and specialised medicines were usually between 20 and 29 percent of the list price, with one third of respondents stating that they could obtain discounts of more than 60 percent on one or more medicines (Morgan et al. 2017). It is worth mentioning that in this study the data was already submitted to the researcher anonymously.

#### Review of literature on real prices

A systematic literature search came to the conclusion that hardly any studies on real prices are available in the published literature (Mardetko et al. 2018): Only five studies were found on the subject of "discounts". In addition to the above-mentioned studies, these included a study on Germany in which an average price difference of approximately 22 percent (18 percent for medicines for rare diseases) was found between the price announced by the pharmaceutical manufacturer upon market authorisation and the price determined after price negotiations (Theidel/von

der Schulenburg 2016)<sup>2</sup>, and a study on off-patent medicines in the pharmacy market. In this study, an average discount of 39.3 percent of the reimbursement price was observed for 179 generics, which pharmacies were able to obtain at purchase – with the possibility of higher discounts with a higher number of suppliers (Puig-Junoy 2012).

### 6.2 Proposal for medicines to be selected in the study

#### Table 6.1:

Proposal for the selection of medicines for this price study: 30 active substances with 52 medicines ranked according to medicine groups (high, medium, low)<sup>3</sup> and alphabetically according to the active substance name.

Active ingredient	ATC code	No. of authorised presentations	Further information on authorised presentations / Possible Names of Biosimilars	
On-Patent biologi	cal medicines	to treat cancer		
Bevacizumab	L01XC07	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/avastin-epar-all-authorised-presenta- tions_en.pdf	
Daratumumab	L01XC24	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/darzalex-epar-all-authorised-presenta- tions_en.pdf	
lpilimumab	L01XC11	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/yervoy-epar-all-authorised-presenta- tions_en.pdf	
Nivolumab	L01XC17	3	https://www.ema.europa.eu/en/documents/all-authorised- presentations/opdivo-epar-all-authorised-presentati- ons_en.pdf	
Pembrolizumab	L01XC18	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/keytruda-epar-all-authorised-presentati- ons_en.pdf	
Pertuzumab	L01XC13	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/perjeta-epar-all-authorised-presenta- tions_en.pdf	
On-Patent biological medicines to treat other diseases				
Alemtuzumab	L03AA34	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/lemtrada-epar-all-authorised-presenta- tions_en.pdf	

2

However, the study did not take into account further individual discounts between companies and individual health insurance funds ("selective discount contracts") or hospitals or hospital associations.

3

The development of medicines groups is based on the WHO/HAI methodology to survey medicine prices (WHO/HAI 2008) which recommends to establish medicines groups of different relevance ("core list" and further groups). Medicines included in the medicines group 1 should have high data availability.

Active ingredient	ATC code	No. of authorised presentations	Further information on authorised presentations / Possible Names of Biosimilars
Belimumab	L04AA26	7	https://www.ema.europa.eu/en/documents/all-authorised- presentations/benlysta-epar-all-authorised-presenta- tions_en.pdf
Denosumab	M05BX04	3	https://www.ema.europa.eu/en/documents/all-authorised- presentations/xgeva-epar-all-authorised-presentations_en.pdf
Ixekizumab	L04AC13	6	https://www.ema.europa.eu/en/documents/all-authorised- presentations/taltz-epar-all-authorised-presentations_en.pdf
Lipefilgrastim	L03AA14	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/lonquex-epar-all-authorised-presenta- tions_en.pdf
Omalizumab	R03DX05	11	https://www.ema.europa.eu/en/documents/all-authorised- presentations/xolair-epar-all-authorised-presentations_en.pdf

#### On-Patent Medicines to treat Orphan diseases

Alglucosidase Alfa	A16AB04	3	https://www.ema.europa.eu/en/documents/all-authorised- presentations/myozyme-epar-all-authorised-presenta- tions_en.pdf
Defibrotide	B01AX01	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/defitelio-epar-all-authorised-presenta- tions_en.pdf
Eculizumab	L04AA25	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/soliris-epar-all-authorised-presentations_en.pdf
ldursulfase	A16AB09	3	https://www.ema.europa.eu/en/documents/all-authorised- presentations/replagal-epar-all-authorised-presenta- tions_en.pdf
Nusinersen	M09AX07	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/spinraza-epar-all-authorised-presenta- tions_en.pdf
Pasireotide	C02KX04	19	https://www.ema.europa.eu/en/documents/all-authorised- presentations/signifor-epar-all-authorised-presentati- ons_en.pdf

#### On-Patent chemical medicines

Abirateronacetat	L02BX03	3	https://www.ema.europa.eu/en/documents/all-authorised- presentations/zytiga-epar-all-authorised-presentations_en.pdf
Aflibercept	S01LA05	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/eylea-epar-all-authorised-presentations_en.pdf
Anidulafungin	J02AX06	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/ecalta-epar-all-authorised-presentations_en.pdf
Apixaban	B01AF02	15	https://www.ema.europa.eu/en/documents/all-authorised- presentations/eliquis-epar-all-authorised-presentati- ons_en.pdf
Azacitidine	L01BC07	1	https://www.ema.europa.eu/en/documents/all-authorised- presentations/vidaza-epar-all-authorised-presenta- tions_en.pdf
Micafungin	J02AX05	2	https://www.ema.europa.eu/en/documents/all-authorised- presentations/mycamine-epar-all-authorised-presenta- tions_en.pdf
Off-Patent biological medicines			

Enoxaparin	B01AB05	101	Lovenox/Clexane, Enoxaparin Becat, Enoxaparin Rovi, Hepa- xane, Inhixa, Neoparin

Active ingredient	ATC code	No. of authorised presentations	Further information on authorised presentations / Possible Names of Biosimilars	
Filgrastim	L03AA02	122	Accofil, Filgrastim HEXAL, Grastofil, Neupogen, Nivestim, Ratio- grastim, Tevegrastim, Zarzio	
Infliximab	L04AB02	5 <sup>2</sup>	Flixabi, Inflectra, Remicade Remsima, Zessly	
Rituximab	L01XC02	42	Blitzima, Mabthera, Ritemvia, Rixathon, Riximyo, Truxima	
Pegfilgrastim	L03AA13	42	Fulphila, Neulasta, Pelgraz, Pelmeg, Ziextenzo	
Trastuzumab	L01XC03	22	Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera	
Off-Patent chemical medicines				
Amlodipin	C08CA01	6 <sup>3</sup>		
Clopidogrel	B01AC04	33		
Imatinib	L01XE01	16²	https://www.ema.europa.eu/en/documents/all-authorised- presentations/glivec-epar-all-authorised-presentations_en.pdf	
Paclitaxel	L01CD01	22	https://www.ema.europa.eu/en/documents/all-authorised- presentations/abraxane-epar-all-authorised-presenta- tions_en.pdf	
Pantoprazole	A02BC02	23		

ATC = Anatomical Therapeutic Chemical

Rosuvastatin

C10AA07

<sup>1</sup> The number of authorised presentations refers to different strengths of the reference product according to the product monography

**6**³

<sup>2</sup> The number of authorised presentations refer to the reference product
<sup>3</sup> The number of authorised presentations refer to different strengths of the active ingredient available on the market

Source: Gesundheit Österreich GmbH, advised by hospital pharmacists, Presentation: Gesundheit Österreich GmbH

### 7 References

- Bundesministerium für Gesundheit und Frauen (BMGF) (2019): Regelung für die Vorgehensweise der Preiskommission für die Ermittlung des EU Durchschnittspreises gemäß §§ 351c Abs. 6 und Abs. 9a ASVG, Fassung vom 21. 01. 2019
- De Block, Maggie (2016): The difficulty of comparing drug prices between countries. In: The Lancet Oncology 17/4:e125
- Ferrario, Alessandra; Kanavos, Panos (2013): Managed entry agreements for pharmaceuticals: The European experience. London School of Economics (LSE), London
- Ferrario, Alessandra; Kanavos, Panos (2015): Dealing with uncertainty and high prices of new medicines: a comparative analysis of the use of managed entry agreements in Belgium, England, the Netherlands and Sweden. In: Social Science & Medicine 124/:39-47
- Hawlik, K; Devalière, A (2016): Access to High-priced Medicines in Hospital Settings in Europe: A Study in Four European Countries. Amsterdam: Health Action International
- Jommi, Claudio (2018): Managed Entry Agreements and High Cost Medicines (European Perspective). In: Equitable Access to High-Cost Pharmaceuticals. Elsevier 35-49
- Klemp, Marianne; Frønsdal, Katrine B; Facey, Karen (2011): What principles should govern the use of managed entry agreements? In: International Journal of Technology Assessment in Health Care 27/01:77-83
- Mardetko, Nika; Kos, Mitja; Vogler, Sabine (2018): Review of studies reporting actual prices for medicines. In: Expert Review of Pharmacoeconomics & Outcomes Research:1-21
- Morel, Thomas; Arickx, F; Befrits, G; Siviero, PD; van der Meijden, CMJ; Xoxi, E; Simoens, Steven (2013): Managed Entry Agreements and Orphan Drugs: A European Comparative Study (2006–2012). In: Value in Health 16/7:A391–A391
- Morgan, Steven G; Vogler, Sabine; Wagner, Anita K (2017): Payers' experiences with confidential pharmaceutical price discounts: A survey of public and statutory health systems in North America, Europe, and Australasia. In: Health Policy 121/4:354-362
- Pauwels, Kim; Huys, Isabelle; Vogler, Sabine; Casteels, Minne; Simoens, Steven (2017): Managed Entry Agreements for oncology drugs: lessons from the European experience to inform the future. In: Frontiers in pharmacology 171/8:
- Puig-Junoy, Jaume (2012): Do Higher-Priced Generic Medicines Enjoy a Competitive Advantage under Reference Pricing? In: Applied Health Economics and Health Policy 10/6:441-451
- Schneider, Peter; Vogler, Sabine; Zimmermann, Nina; Zuba, Martin (2018): Preisvergleich ausgabenstarker Arzneispezialitäten 2017. Hg. v. (BMASGK), Bundesministerium für Arbeit Soziales Gesundheit und Konsumentenschutz, Wien

- Stemar, Gunar (2015): Managed entry agreements für Arzneimittel Auswirkungen auf und Möglichkeiten für den intramuralen Versorgungsbereich in Österreich. MBA für Health Care Management, Vienna: Business University Vienna
- Theidel, Ulrike; von der Schulenburg, J-Matthias Graf (2016): Benefit assessment in Germany: implications for price discounts. In: Health Economics Review 6/1:33
- van Harten, Wim H; Ots, Riin; Retèl, Valesca P (2019): The Tip of the Iceberg? Budget Restrictions and Patient Perspectives on Cancer Drug Costs: An international survey in 29 hospitals and 56 patient organizations. In: Journal of Cancer Policy:100195
- van Harten, Wim H.; Wind, Anke; de Paoli, Paolo; Saghatchian, Mahasti; Oberst, Simon (2016): Actual costs of cancer drugs in 15 European countries. In: The Lancet Oncology 17/1:18-20
- Vogler, Sabine; Habl, Claudia; Leopold, Christine; Mazag, Jan; Morak, Simone; Zimmermann, Nina (2010): PHIS Hospital Pharma Report. Pharmaceutical Health Information System (PHIS), Vienna
- Vogler, Sabine; Paris, Valérie; Panteli, Dimitra (2018): Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? Policy Brief and Summaries. Hg. v. Systems, European Observatory on Health Care. WHO Regional Office for Europe, Copenhagen
- Vogler, Sabine; Schneider, Peter; Zimmermann, Nina (2016): Preisvergleich kostenintensiver Arzneimittel 2015 (Wissenschaftlicher Endbericht). Gesundheit Österreich GmbH, Wien
- Vogler, Sabine; Zimmermann, Nina; Habl, Claudia (2014): Kostenintensive Arzneispezialitäten im europäischen Preisvergleich. Gesundheit Österreich GmbH im Auftrag des Bundesministeriums für Gesundheit, Wien
- Vogler, Sabine; Zimmermann, Nina; Habl, Claudia; Mazag, Jan (2013a): The role of discounts and loss leaders in medicine procurement in Austrian hospitals – a primary survey of official and actual medicine prices. In: Cost Effectiveness and Resource Allocation 11/1:15
- Vogler, Sabine; Zimmermann, Nina; Habl, Claudia; Piessnegger, Jutta; Bucsics, Anna (2012): Discounts and rebates granted to public payers for medicines in European countries. In: Southern Med Review 5/1:38-46
- Vogler, Sabine; Zimmermann, Nina; Leopold, Christine; Habl, Claudia; Mazag, Jan (2013b): Discounts and Rebates Granted for Medicines for Hospital Use in Five European Countries. In: The Open Pharmacoeconomics & Health Economics Journal 5/:1-10
- WHO; HAI (2008): Measuring medicine prices, availability, affordability and price components. 2nd edition. World Health Organization / Health Action International, Geneva