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ISPOR Special Interest Group

Access to Medicines in Low- and Middle-Income Countries: What is Being Done? What More Can be Done? What Can ISPOR Do?

Monday, 18 November, 2024 11:45AM – 12:45PM

Discussion Topics

	Topic	Presenter(s)
1	Welcome and Introductions	Mikkel Oestergaard
2	Access to medicine in Latin America	Silvana Lay
3	Access to medicine in Europe	Marlene Gyldmark
4	Access to medicines in Estonia	Kärt Veliste
5	Q & A	

1

Introductions

Today's Panel

Mikkel Oestergaard, PhD

- Executive Director, HTA Statistics, MSD

Silvana Lay

- Director, Access and Public Affairs, FIFARMA

Marlene Gyldmark, Mphil

- EU HTA Lead, Beigene

Kärt Veliste, MSc

- Policy Lead, Medicines and Medical Devices, Estonian Ministry of Social Affairs

ISPOR EU 2024 session, Monday 18th November, 11:45-12:45 CET

Access to Medicines in Low- and Middle-Income Countries:
What is Being Done? What More Can be Done? What Can ISPOR Do?

Global differential pricing: 3 different perspectives (covering Why, What, How, ..& more)

Silvana Lay
FIFARMA perspective
Director, Access and Public Affairs
at FIFARMA

Marlene Gyldmark
EFPIA perspective
VP, Access Evidence
at Idorsia Pharmaceuticals

Kart Veliste
Estonian perspective
Policy Lead for Medicines and Medical Devices
at the Estonian Ministry of Social Affairs

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Author's Disclosure

Marlene Gyldmark - this presentation represents the views of the speaker and not those of Beigene

Kärt Veliste - this presentation represents the views of the speaker and not necessarily those of Estonian Ministry of Social Affairs

The ISPOR Global Differential Pricing Working Group (GDP-WG)

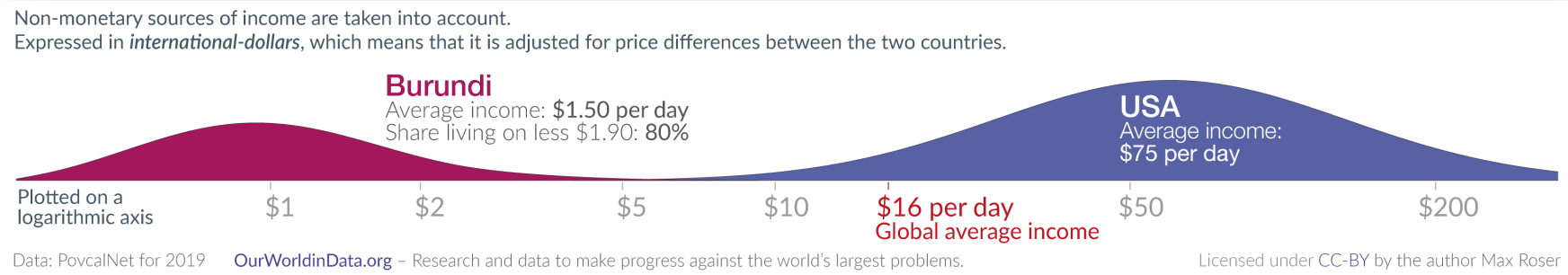
Mikkel Oestergaard, on behalf of the GDP-WG
Co-Chair of the GDP-WG
Executive Director of HTA Statistics in MSD
Barcelona, November 2024, ISPOR EU 24 conference

Disclaimers

- **Financial**: employee and owner of stocks in Merck & Co., Inc., Rahway, NJ, USA

- **Any perspective or opinion in this presentation…**
  - …are presented on behalf of the ISPOR Global Differential Pricing Working Group (GDP-WG)
  - …do not represent opinions by individual companies nor of industry

The price of a medicine in Burundi vs. the price in the USA?
Same price?/ Different price? / Why?

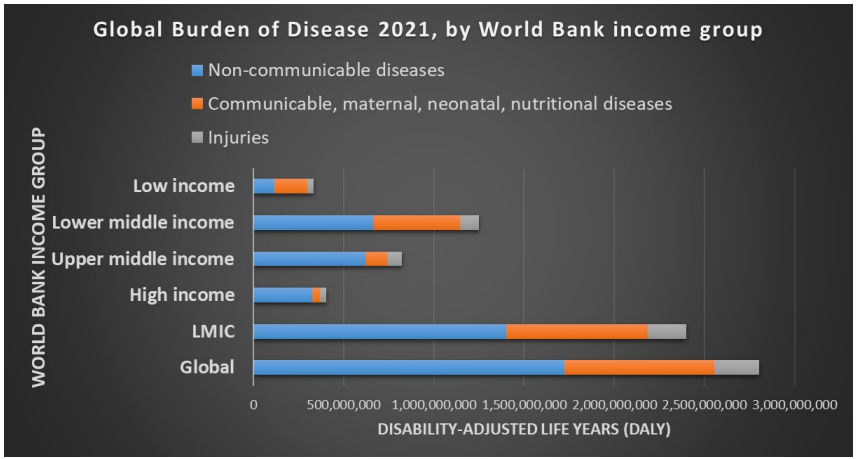


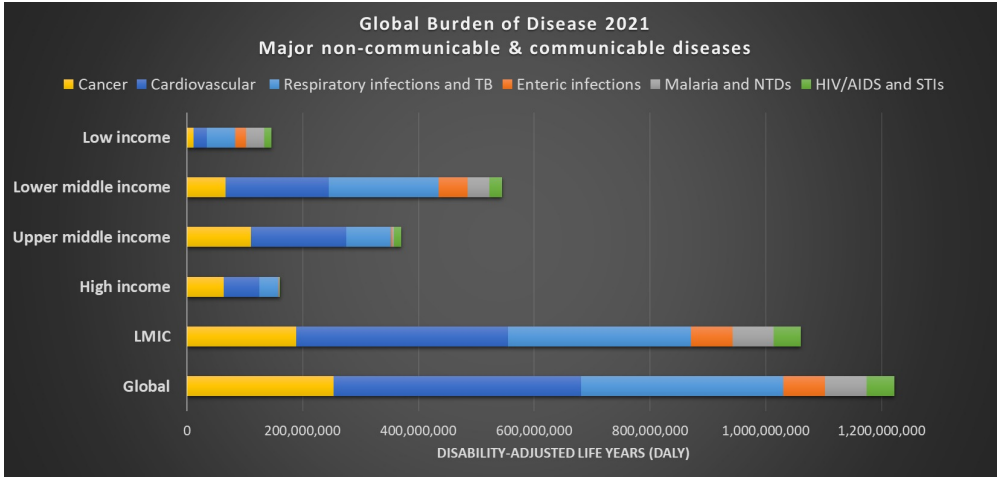
Context: the global burden of disease

81% of the global burden of disease from non-communicable diseases (NCDs) fall in LMIC

Many of the major causes of death and disability in the world are affecting most countries, independent of economic development

- 95% of the global burden from communicable, maternal, neonatal and nutritional diseases fall in LMIC
- 62% of the global burden of disease is from NCDs (81% in HIC, 58% across LMIC, 53% in lower middle income)
- Low and lower middle income countries are “double-hit”: large burden from NCDs, and from communicable diseases





Figures developed for this presentation based on most recent Global Burden of Disease (GBD) data from Data from IHME GBD (2024). Data accessed from OurWorldinData.org/burden-of-disease.

[1]see most recent global health data at https://ourworldindata.org/health-meta

Presentation at ISPOR EU on behalf of the ISPOR Global Differential Pricing Working Group, Nov 2024

HIC: high income countries
LMIC: low and middle income countries
NCD: non-communicable diseases

Polling question

Which of the following statements is the most accurate one in your opinion?

Global differential pricing…

A. … allows prices to differ across countries based on countries **willingness-to-pay**
B. … allows prices to differ across countries based on countries **ability-to-pay**
C. …and **tiered pricing** can be used interchangeably
D. …and **value-based pricing** can be used interchangeably

Premise

For the work of the ISPOR Global Differential Pricing Working Group

Global differential pricing

- …allows prices to differ across countries **ability and willingness to pay**
- **…won't solve patient access by itself, but we need to solve for it to improve patient access**[1]
- …has long been argued for by economists to improve global health equity[2]
- …for pharmaceutical products is a broadly shared aspiration, but best-practice is not well understood, particularly for medicines for non-communicable diseases with high disease burden across the world

[1]Rockers et al. *Effect of Novartis Access on availability and price of non-communicable disease medicines in Kenya: a cluster-randomised controlled trial*, Lancet Global Health 2019
[2]e.g., see Danzon PM. Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues. Pharmacoeconomics. 2018 Dec;36(12):1395-1405.

Context: global income inequality

"Where a person lives is the most important factor of their income"

"The country where a person lives explains 2/3 of the variation of income differences between all people in the world"

"The vast majority of the world is very poor"

"Almost 4 billion people live on less than $6.70 a day"

"If you live on $30 a day, you are part of the richest 15% of the world"

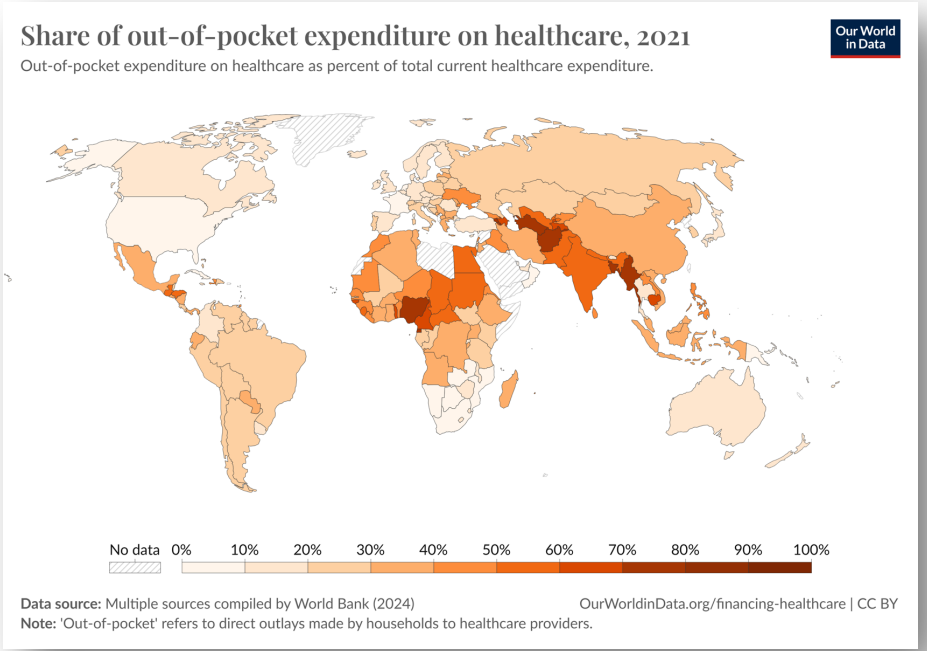
Quotes above are from: Max Roser (2021) - "Global economic inequality: what matters most for your living conditions is not who you are, but where you are" Published online at OurWorldinData.org. Retrieved from: 'https://ourworldindata.org/global-economic-inequality-introduction'

See also Branko Milanovic (2015) – "Global Inequality of Opportunity: How Much of Our Income Is Determined By Where We Live?", The Review of Economics and Statistics 97(2): 452-460

Some key challenges for global differential pricing

Skewed income distributions in many LMIC: risk of price setting that targets the richest rather than the average per capita income[1]

Healthcare financing in LMIC: high share of out-of-pocket expenditure on healthcare in some LMIC



* Prashant Yadav, "Differential Pricing for Pharmaceuticals, Review of current knowledge, new findings and ideas for action". http://www.dfid.gov.uk/Documents/publications1/prd/diffpcing-pharma.pdf.

What the ISPOR Global Differential Pricing Working Group has heard so far (by Oct 2024)*

- **Allow for** value-based country negotiations
- **Ensure dynamic efficiency**, i.e., global revenues to ensure sustainable future R&D and innovation
- **Keep it Simple,** e.g., small number of tiers, and focus on country-level price and not on potential in-market markups
- **Focus on the goal** of expanding access to medicines in LMIC rather than pre-supposing tiered-pricing is the answer
- **Make sure it is Validated:** "peer-reviewed" solution that stakeholders can reference and use as a starting point
- **Solidarity & partnership required:** ERP to countries in lower tiers risks compromising access for patients in these lower tiers
- **Consider challenge and impact from product arbitrage**
- **Take Perspective**: "what would it take for stakeholders to…"
- **Necessary, but not sufficient**: global differential pricing won't solve patient access, but needs to be solved to improve access
- **"Solving" global differential pricing can motivate** partnerships to find solutions for other patient access dependencies

* Informal guiding thoughts from stakeholders across industry. It does not represent opinions or positions by individual companies nor of pharma industry

ERP: external referring pricing
LMIC: low- and middle-income countries

Thought experiment by the ISPOR GDP-WG to stimulate discussion and insight:
what if we simply used the established **World Bank income groups**
to split countries into 4 pricing tiers

Tiering then based on gross-national-income (GNI) per capita
to reflect countries' level of development and economic capacity,
and "maintained" by the World Bank (annual update)

….and then simply apply the **pricing principles** proposed by EFPIA for EU countries
(EFPIA's Equity-Based Tiered Pricing proposal*)

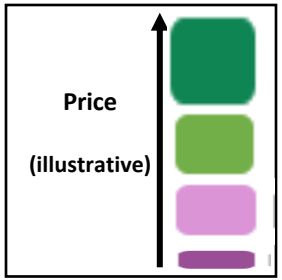
We could call it ***"Global Equity-Based Tiered Pricing"*** (GEBTP)

*www.efpia.eu/news-events/the-efpia-view/efpia-news/new-proposals-from-the-research-based-industry-can-reduce-inequalities-in-patient-access-to-medicines

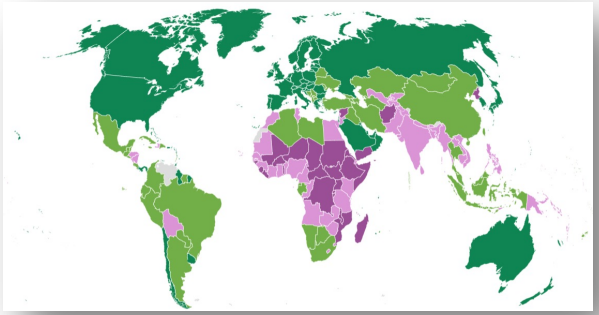
Global Equity-Based Tiered Pricing (GEBTP)[1]

A thought experiment by the ISPOR GDP-WG to stimulate discussion and insight
To improve access to medical innovation in low- and middle-income countries

- **What do you think** about GEBTP?
- What is missing from the GEBTP model? Why?
- What would it take to implement GEBBTP?



Pricing Tier	World Bank income group (2023)	#Countries[3]	Population (2023) in billions
Tier A	High income	86	1.26
Tier B	Upper middle income	54	2.81
Tier C	Lower middle income	51	3.25
Tier D	Low income	26	0.74



Pricing Principles for GEBTP

- **Allow for value-based price negotiation** at country level
- Mutually exclusive pricing tiers (no overlap between Tiers)
- No maximum absolute price prespecified in highest Tier (Tier A)
- Prices in a lower Tier lower than in any higher Tier
- No other pre-specification of price differences between Tiers
- **Allow for ERP to other countries within a Tier** (not between Tiers)
- **Prices implemented** through confidential net price agreements
- **Enables static & dynamic efficiency**: pricing in Tier A countries unaltered (all other things equal)
- **Voluntary** commitment by companies and by countries
- **Requires solidarity**: price negotiation without ERP to lower Tiers

Complement's EFPIA proposal for Equity-Based Tiered Pricing (EBTP) across EU countries[3]

EBTP is nested within GEBTP

Tier A of GEBTP contains all countries in the EU.

Companies could apply GEBTP globally and EBTP for EU countries

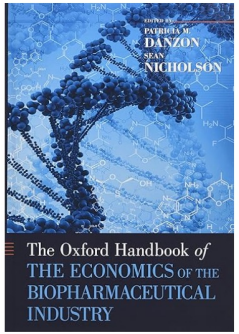
[1]Informal thought experiment. It does not represent opinions or positions by individual companies nor of pharma industry.
[2]World Bank income group data and map: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups
[3]Includes all World Bank countries (189) and all other economies with populations of more than 30,000
[4]www.efpia.eu/news-events/the-efpia-view/efpia-news/new-proposals-from-the-research-based-industry-can-reduce-inequalities-in-patient-access-to-medicines

EFPIA: European Federation of Pharmaceutical Industries and Associations
ERP: external reference pricing
GDP-WG: global differential pricing working group
GNI: gross national income

Lots of helpful literature (covering the last 3+ decades on global differential pricing for medicines)

including some that will likely move your current understanding and/or perspective

(list below is far from exhaustive)



PharmacoEconomics (2018) 36:1395–1405
https://doi.org/10.1007/s40273-018-0696-4

CURRENT OPINION

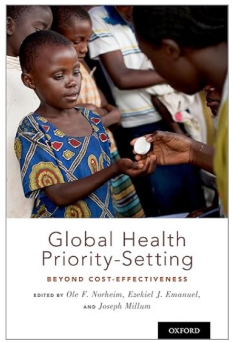
Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues

Patricia M. Danzon[1]

Published online: 30 July 2018

Chapter 4: Differential Pricing
(version 3, September 2021)

By Prof. William Fisher et al., IP Law, Harvard Law School
https://ipxcourses.org/AWNEW/Pricing.pdf



Moon et al. Globalization and Health 2011, 7:39
http://www.globalizationandhealth.com/content/7/1/39

GLOBALIZATION AND HEALTH

DEBATE Open Access

A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries

Suerie Moon[1*], Elodie Jambert[2], Michelle Childs[2] and Tido von Schoen-Angerer[2]

Defining the concept of fair pricing for medicines

Suerie Moon and colleagues consider what makes a fair price for both buyers and sellers

the bmj | BMJ 2020;368:l4726 | doi: 10.1136/bmj.l4726

Gates Open Research
Gates Open Research 2020, 4:16 Last updated: 13 NOV 2024

Check for updates

OPEN LETTER

REVISED **Value-based tiered pricing for universal health coverage: an idea worth revisiting**

[version 3; peer review: 3 approved]

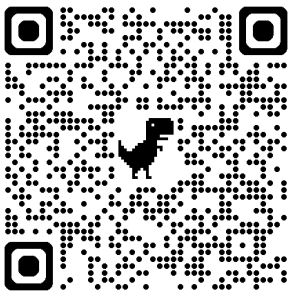
Kalipso Chalkidou[1,2], Karl Claxton[3], Rachel Silverman[1], Prashant Yadav[1,4]

[1]Global Health Policy, Center for Global Development, London, UK
[2]Medicine, School of Public Health, Imperial College London, London, UK
[3]Department of Economics, University of York, UK, York, UK
[4]Technology and Operations Management, INSEAD, Fontainebleau, France

The ISPOR Global Differential Pricing Working Group (GDP-WG)

Please reach out if you have interest, questions, and/or input

Maddie Shipley (GDP-WG coordinator): mshipley@ispor.org



The GDP-WG….

- seeks to generate insight & dialog to improve understanding & “best-practice” for global differential pricing
- functions as a Think Tank and doesn’t represent opinions by individual entities nor of industry
- is looking for a broader set of stakeholders to join, including assessors, payers, patients
- currently has 10 members from 10 different entities covering pharma, consultancies, venture capital, academia
- complements the work of other international collaborations to improve access to medical innovation
- is part of the ISPOR Special Interest Group on Global Access to Medical Innovation
- started in August 2024
- is Co-Chaired:
  - Mikkel Oestergaard (Executive Director, HTA Statistics, MSD)
  - Richard Willke (Principal, Scintegral Health Economics, former CSO of ISPOR)

2

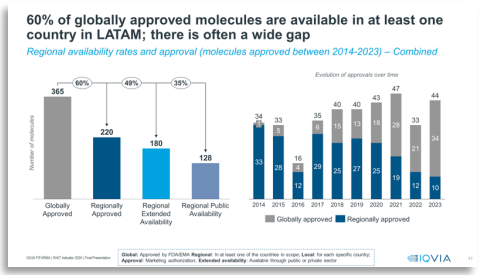
Access to Medicine in Latin America

An overview of access in Latin America

FIFARMA

10 Years

Covers globally approved molecules [FDA/EMA] between from 2014 to 2023 (n=365 molecules)



10 Countries

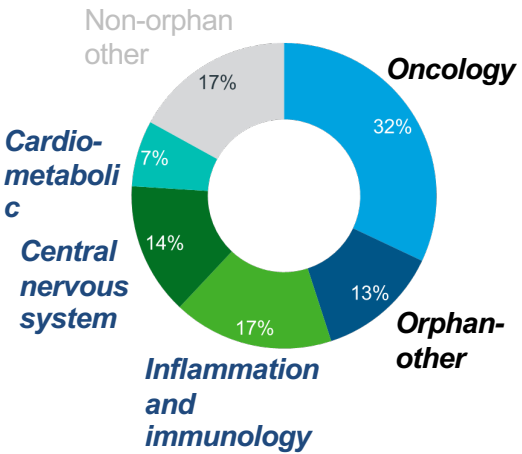
83%

Of total LATAM population

AR BR CL CO CR

DO EC MX PA PE

80% of new active substances



Approx. 80% of new active substances (NAS) launches in **5 Therapeutic Areas**

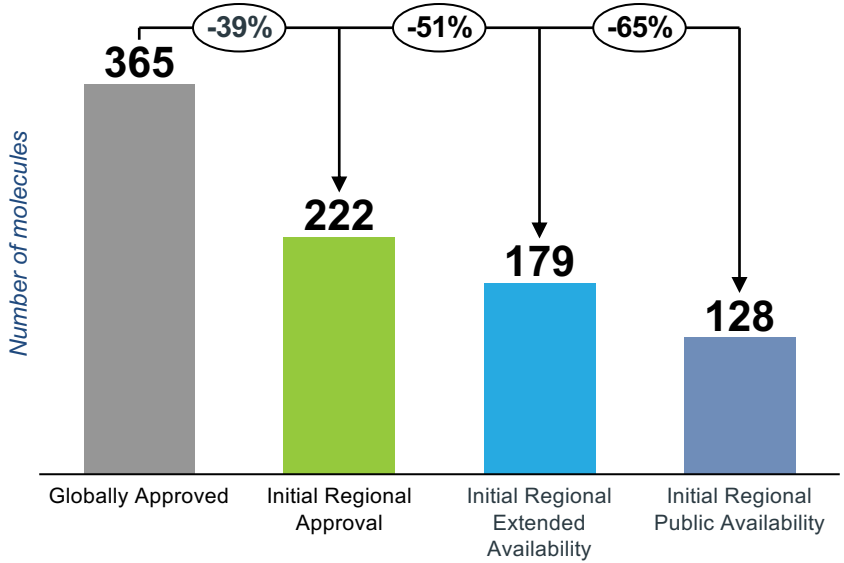
New inclusions Prior year inclusions Excluded

Note: Orphan-other are orphan designated molecules in TAs outside of those included specifically in the study e.g., respiratory

Acronyms: FDA: U.S. Food and Drug Administration; EMA: European Medical Agency; Fedefarma: Federación Centroamericana y del Caribe de Laboratorios Farmacéuticos; TA: Therapeutic Area; NAS: New Active Substance

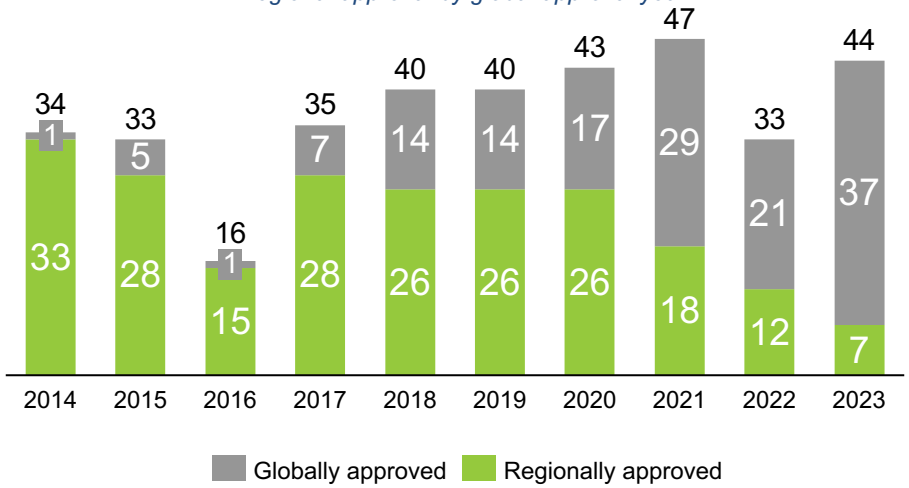
Latin America: Innovative medicines availability

Regional availability rates and approval (molecules approved between 2014-2023) 5TAs



Gaps in regional approvals and availability are comprised of predominantly molecules globally approved from 2018 onwards

Regional approval by global approval year

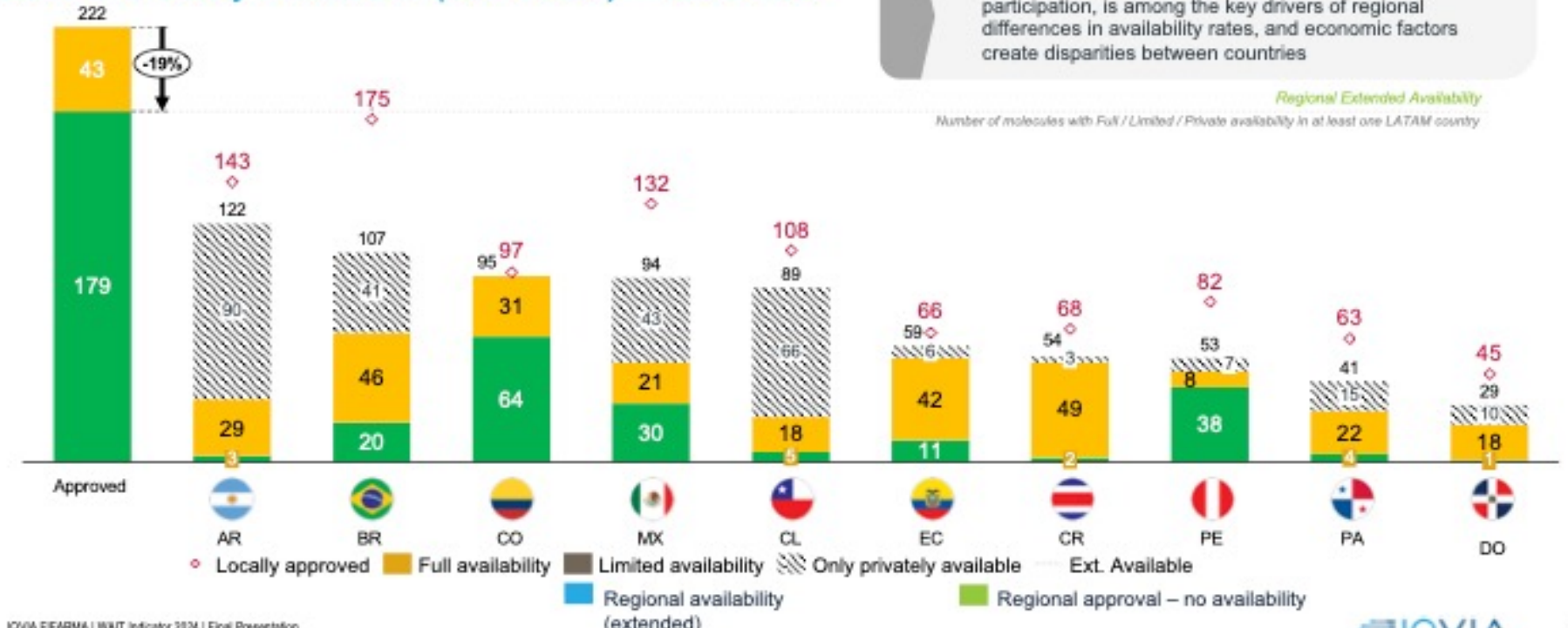


Global: Approved by FDA/EMA; **Regional**: In at least one of the countries in scope; **Local**: for each specific country; **Approval**: Marketing authorization; **Extended availability**: Available through public or private sector

Wide differences exist between countries in extended and public availability.

Local availability breakdown (2014-2023) – Combined

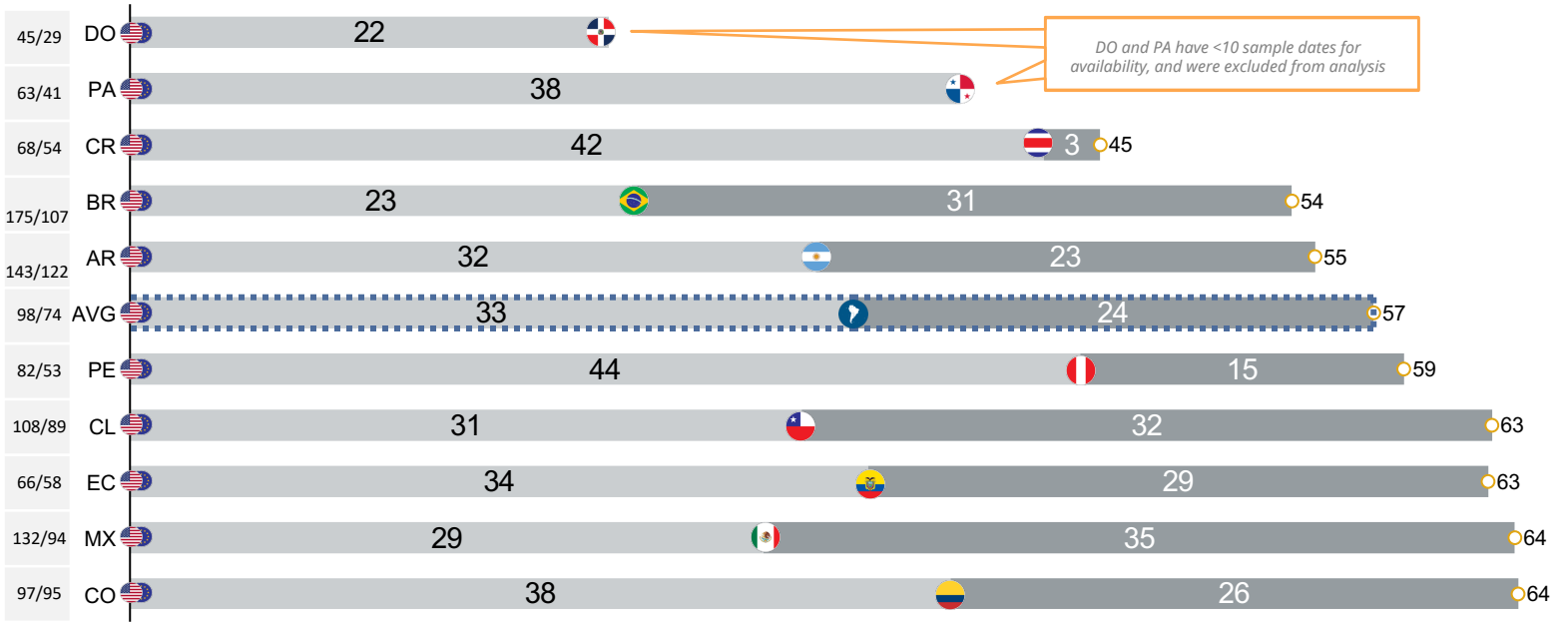
Healthcare system design, esp. private market participation, is among the key drivers of regional differences in availability rates, and economic factors create disparities between countries



Time to availability is 4.8 yrs on average, with average time to local regulatory approval at 2.8 yrs, and availability at 2 yrs

Average time to approval and availability by country (from FDA/EMA approval) – Combined

- DO, BR, MX, CL and AR have the shortest times to regulatory approval, all below the average (<2.8yrs)
- CR, AR, and PE have the shortest times to availability, all below the average (<2yrs)



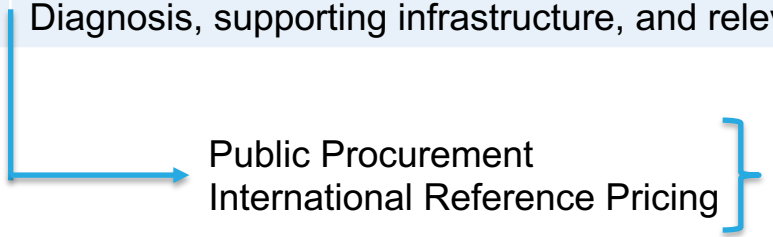
Comparison with 2023	App	Reimb.	Tot.
DO	-	-	-
PA	-	-	-
CR	+34%	-48%	+19%
BR	+0%	+5%	+2%
AR	+20%	+211%	+51%
AVG	+9%	+6%	+7%
PE	+21%	-22%	-8%
CL	+6%	-2%	-2%
EC	-2%	-5%	-1%
MX	+6%	-5%	+1%
CO	-2%	+61%	+18%

Global approval (FDA / EMA)[1] | Local approval | Local availability[2]

[1] *Global approval date: the earliest date between FDA or EMA*
[2] *Considering molecules with Full and / or Limited Availability*

Potential Causes

Category	Potential causes
Time before marketing authorization	The speed of the regulatory process The speed of the dossier's submissions
Price & reimbursement process	Initiation of the process National timelines
Value assessment process	Misalignment on evidence requirements Misalignment on value and price
Health system constraints & resources	**Insufficient budget (managed by delay access)** Diagnosis, supporting infrastructure, and relevance to patients



3

Access to Medicine in Europe
Marlene Gyldmark

Low- and Middle-Income Countries in Europe

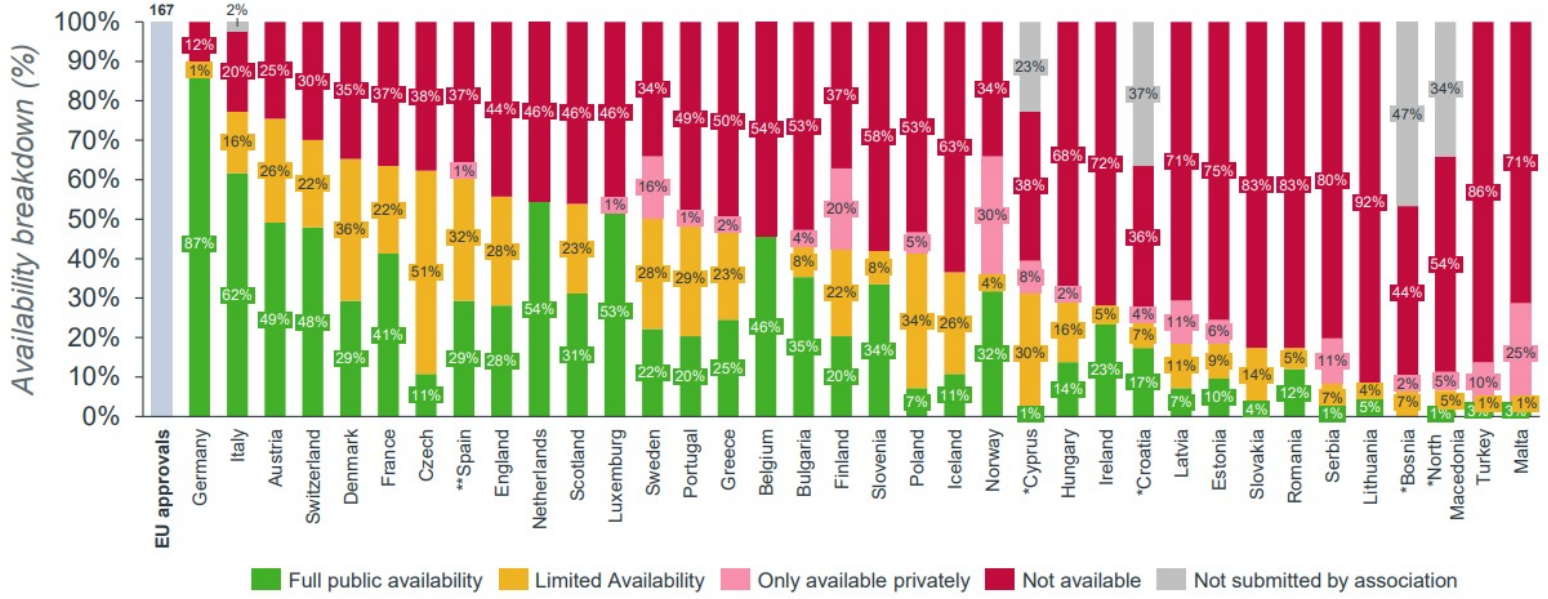
- 44 countries in Europe (UN world report, 2024)
- 8 LMICs in Europe (datahelpdesk.worldbank.org 2024):
  - Eastern Europe: Belarus, Republic of Moldovia, Ukraine
  - Southern Europe: Albania, Bosnia and Herzegovina, Montenegro, North Macedonia, Serbia
- 27 countries in the European Union (EU)
- 0 LMICs in the EU (datahelpdesk.worldbank.org, 2024)

Availability of medicine in Europe

- The W.A.I.T indicator was established 2004 by EFPIA
- The W.A.I.T indicator includes 36 countries (27 EU and 9 non-EU)
- Non-included countries: Russia, Ukraine, Moldova, Albania, Belarus, Kazakhstan (Holy See, San Marino)
- The Access Portal was established 2020 by EFPIA to better understand the root causes of time to availability.

Availability of medicines (2019-2022), per Jan 5th, 2024

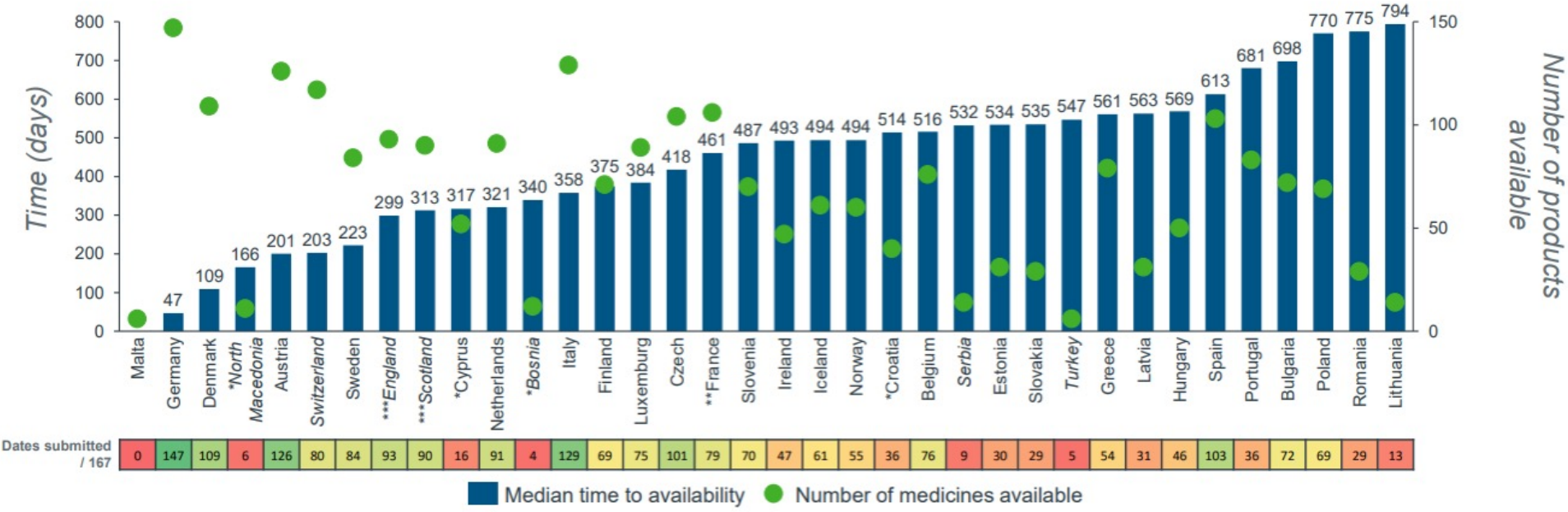
- Definition of availability : Time from central approval (with exceptions) to national reimbursement
- Average availability is 43% across Europe
- Average time to availability is 126 days (Germany) – 531 days (Poland)



Median time to availability and number of products (2019-2022), Jan 5th, 2024

- Median time to availability shows large variation across countries
- Caution with high waiting time and low number of submissions
- Within country time to availability shows high variation across products

(Italics indicate where local regulatory submissions is used instead of EU central submission)



Root causes leading to less availability and reduced access to medicine

- The manufacturer related causes:
  - Time to file for reimbursement makes up 29% of the delayed time to availability
  - Ability to file (no local presence, no resources to file)

- System related causes:
  - External referencing (HTA decisions in other countries)
  - National HTA systems capacities
  - Misalignment of evidence requirements
  - Misalignment on value and price
  - Health system readiness

Root causes from the Access Portal report EFPIA 2023

What can ISPOR do to improve availability and access to medicine?

- Support the work to better understand availability barriers
  - To what extent is pricing the main barrier?
  - Is International Reference Pricing harming availability?
  - Are national HTA systems and diverse evidence requirements leading to delay in availability?
- Help explore how the barriers can be removed or remodeled
- Help move from **availability** to **access** to medicine
- Support research to promote efficient HTA and access systems

4

Access to Medicines in Estonia

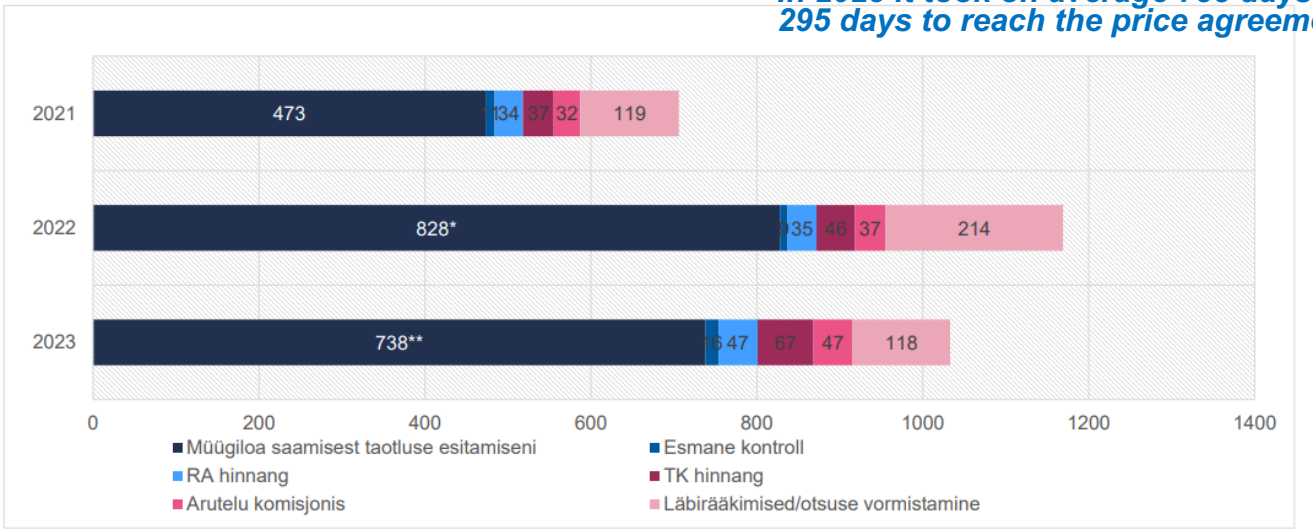
Estonia

Population size – **1,33 million** (stat.ee)
Member of **EU** since 2004
Official currency **€** since 01.01.2011
GDP per capita **29 824 USD** (2023), PPS **87%** in relation to EU average (Eurostat)
EHIF is the **single public payer**
Digital prescription since 2010
Health Care budget 2023: **2,13 billion €**
pharmaceuticals **339 million € (ca 16%)**

The time Estonia has to wait after MA for the submission of the P&R application is more than double the time it takes to negotiate and reach a price agreement

Taotluste menetlemise tähtajad

In 2023 it took on average 738 days for the submission vs 295 days to reach the price agreement!

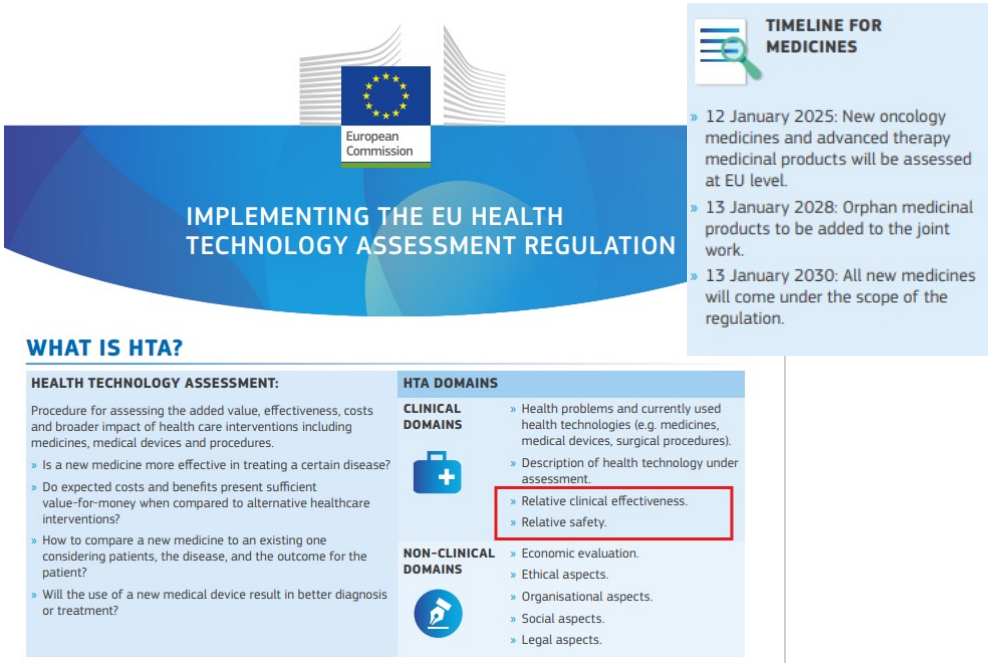


- Data from Estonian Health Insurance Fund

Current situation for medicines in Estonia, but this is not a national problem

PRO(mise)S	CON(sequence)S
Highest possible health gains	Uncertain health gains
Specific funds for specific type of diseases	Overspent budgets & access restrictions
Willingess to pay thresholds	What the market can bear
Incentives for innovation	Incentive for me-too´s
Evidence based	Emotion based

But things are changing in Europe



European Commission - Press release

European Health Union: Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines

Brussels, 26 April 2023

Today, the Commission is proposing to revise the EU's pharmaceutical legislation - the largest reform in over 20 years - to make it more agile, flexible, and adapted to the needs of citizens and businesses across the EU. The revision will make **medicines more available, accessible and affordable**. It will support innovation and boost the **competitiveness** and attractiveness of **the EU pharmaceutical industry**, while promoting higher environmental standards. In addition to this reform, the Commission proposes a Council Recommendation to step up the **fight against antimicrobial resistance** (AMR).

The **challenges** this reform addresses are fundamental. Medicines authorised in the EU are still **not reaching patients quickly enough** and are not equally accessible in all Member States. There are significant gaps in addressing **unmet medical needs**, rare diseases and antimicrobial resistance (AMR). **High prices** for innovative treatments and **shortages** of medicines remain an important concern for patients and healthcare systems. In addition, to ensure that the EU remains an attractive place for investment and a world leader in the development of medicines, it needs to adapt its rules to the **digital transformation** and **new technologies**, whilst cutting red tape and simplifying procedures. Finally, the new rules need to address the **environmental impact** of medicine production in line with the objectives of the European Green Deal.

The revision includes proposals for a new Directive and a new Regulation, which revise and replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases. It aims to achieve the following main **objectives**:

- Create a **Single Market for medicines** ensuring that all patients across the EU have **timely and equitable access to safe, effective, and affordable** medicines;
- Continue to offer an attractive and **innovation-friendly framework** for research, development, and production of medicines in Europe;
- Reduce drastically the **administrative burden** by speeding up procedures significantly, reducing authorisation times for medicines, so they reach patients faster;
- Enhance **availability** and ensure medicines can always be supplied to patients, regardless of where they live in the EU;
- Address **antimicrobial resistance** (AMR) and the presence of pharmaceuticals in the environment through a One Health approach;
- Make medicines more **environmentally sustainable.**

- Implementing the EU Health Technology Assessment Regulation
- EU pharmaceutical legislation

https://dx.doi.org/10.1787/8c1d16c4-en

Further development or expansion of this work beyond this pilot study would benefit from the following, while also recognising that there will be an inherent trade-off between accuracy, comprehensiveness and feasibility of any indicators produced moving forward:

- **Greater clarity around the objectives of monitoring and measurement of access**, and consideration of whether other approaches may be more appropriate. Most countries that responded to the survey do not systematically measure or monitor access to medicines on a national level; of those that do, some focus on the efficiency of processes, others on measures of overall consumption or expenditure. A **multistakeholder consultation** could be used to develop consensus around what should be measured routinely to inform policymakers, including whether measuring access to *treatment* as distinct from access to individual medicines may be more appropriate.
- **Agreement on the indicators that should be prioritised**. Some indicators are more suitable for routine collection than others, such as those with data in the public domain or in existing sharing platforms. Going forward, it will be important to develop some consensus on the indicators of highest priority, utilising criteria such as such as policy-relevance, accessibility, comparability etc.
- **Agreement on the scope of analysis for periodic assessment.** Analyses may need to distinguish between outpatient and inpatient products, or consider them separately, given the differences in country processes and data availability. Some indicators may be more appropriate for measuring access to a medicine archetype or therapeutic class, rather than an individual medicine. For example, an analysis of access to breakthrough therapies used in the treatment of rare diseases could be appropriate, given that these products may be subject to exceptional evaluation processes.
- **Development of agreed methods for collecting, exchanging, and interpreting data,** with consideration of individual country contexts. Taking into account the structure of the health care system, and the regulation, selection, coverage and pricing policies in place, can help in framing and interpreting the results. While it may not be possible to control for these factors, cross-country comparisons could be facilitated by grouping countries with common health system characteristics that could affect specific indicators.
- **Investment in improving the evidence base,** which involves the willingness of countries to systematically collect and share the necessary data. The lack of transparency in the area of pharmaceutical coverage, pricing, and utilisation not only hinders the routine analysis of data, but also the generation of reliable evidence to inform important policy questions. Where possible, priority indicators should draw on existing data sources, but where these are unavailable, they should be a priority for development.

Before the discussions about differentiated pricing we should agree on what is fair altogether for health sysems and industry

Fair Price - "one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines"

World Health Organization

European initiatives

AIM Healthcare and social benefits for all

EUROPEAN FAIR PRICE
Calculator
For Medicines

ET SI, ON PAYAIT
Le juste prix
DES MÉDICAMENTS

ASCERTAIN

WP4

Pricing methods for IHTs (GOEG)

This work package focuses on developing new approaches for pricing innovative technologies (elements, principles and algorithms of novel pricing policies that take the value and cost perspective into account). Crucial in these models is finding a balance between improving patient access and stimulating entrepreneurship. Partners from academia, patients, professional organisations, industry, and payers will engage to ensure a broad perspective on the pricing policies.

Discussion at Belgium Federal Parliament in April 2024 after Solidaris citizen initiative (50 000 signatures) for fair price for medicines

- https://fairpricingcalculator.eu/
- lejusteprixdesmedicaments.be
- https://www.access2meds.eu/
- https://www.deutsche-apotheker-zeitung.de/daz-az/2021/az-36-2021/13-milliarden-euro-einsparpotenzial

AIM Healthcare and social benefits for all

EUROPEAN FAIR PRICE Calculator For Medicines

Welcome to the International Association of Mutual Benefit Societies (AIM)'s fair price calculator for medicines. The calculator is the practical transl
pricing model (Ctrl + clik here), using the assumptions for the various parameters made in the model. The calculator is a tool designed to help healt
anybody interested in the matter calculate a FAIR price for new or existing medicines (without generic competition) and compare it to the price paid
More importantly, this is a hands-on tool with clear proposals for data components to contribute to European and international debates about fair pr
transparency of R&D costs of medicines.

DESCRIPTION OF THE MEDICINE AND THE PATIENT POPULATION

Type of disease
Select from the list below

Estimated total patient population (prevalence/incidence/n patients)
Enter number of patients /10 years period

Target population (automatic)
0 patients (10 year period)

Treated population (automatic)
50%

Global R&D cost for the drug developer
Select from the list below

Number of expected competitors (market share)
Select from the list below

Composition of the medicine/Production cost
Select from the list below

Average duration of treatment in months
Enter value between 1 and 120

Sales and medical information (automatic)
20% of R&D cost

Basic profit (automatic)
8% of total cost

LEVEL OF INNOVATION BASED ON THE THERAPEUTIC VALUE

Select one or more items :

FAIR PRICE COMPONENTS (per treatment per patient)

R&D cost	€801,12
Production cost	€1 800,00
Sales and medical information	€160,22
Basic profit	€220,91
Innovation bonus	€1 104,54

FAIR PRICE CALCULATION

Fair price per treatment per patient	€4 086,78
Fair price per month of treatment per patient	€340,57
Fair price per year of treatment	€4 086,78

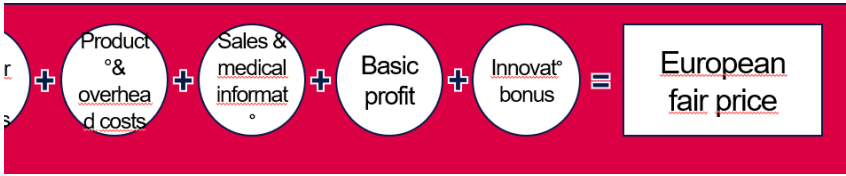
This calculation is a unique price for all EU 27 countries. Mechanisms could be put in place in order to adapt the price to the situation of each country. Purchasing power could be one of the calculation method. Expand data by countries to see the differentiated fair price per treatment per patient according to purchasing power for 2019.

Source: https://ec.europa.eu/eurostat/web/products-datasets/-/tec00114

Comments:

Collapse Data By Countries

Bulgaria	€2 166,00
Romania	€2 860,75
Croatia	€2 656,41
Latvia	€2 819,88
Poland	€2 983,35
Hungary	€2 983,35
Lithuania	€3 432,90
Estonia	€3 432,90



What can ISPOR do?

- **Provide platform for open and balanced discussion about access to medicines**
- **Bring societal view into the discussions –** it is not only the problem of HTA bodies, payers, industry, patients, health care professionals, but also our **citizens** who are financing the system with taxes
- **Bring forward ISPOR's vision** *„for a world where healthcare is accessible, effective, efficient, and affordable for all“* with gathering the best practises and transparent data to better understand the core of the problems and to find actionable solutions.

5

Q & A

Your thoughts?

- What are opportunities and challenges of global differential pricing for improving access?
- What are key requirements of a global differential pricing framework to improve access?
- What can ISPOR do?

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ISPOR
Special Interest Group

ISPOR Global Access to Medical Innovations (GAMI) Special Interest Group

Sign up to join our Special Interest Group

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peer-reviewed and MEDLINE-indexed publications, good practices guidance, education, collaboration, and tools/resources in the field.

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Improving healthcare decisions