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Journal of Pharmaceutical Policy and Practice

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/jppp20

Abstracts from the 5th PPRI conference 2024: ensuring access to affordable medicines through innovative policies, Vienna, Austria, 25–26 April 2024

To cite this article: (2024) Abstracts from the 5th PPRI conference 2024: ensuring access to affordable medicines through innovative policies, Vienna, Austria, 25–26 April 2024, Journal of Pharmaceutical Policy and Practice, 17:sup1, 2331920, DOI: 10.1080/20523211.2024.2331920

To link to this article: https://doi.org/10.1080/20523211.2024.2331920

Published online: 12 Apr 2024.

JOURNAL OF PHARMACEUTICAL POLICY AND PRACTICE
2024, VOL. 17, NO. S1, 2331920
https://doi.org/10.1080/20523211.2024.2331920

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ABSTRACT

Abstracts from the 5th PPRI conference 2024: ensuring access to affordable medicines through innovative policies, Vienna, Austria, 25–26 April 2024

KEYNOTE SPEAKER PRESENTATIONS

K1

How to make medicines more accessible and affordable – from evidence to policy to practice

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Global spending on pharmaceuticals is forecast to exceed pre-pandemic outlook to $1.2 trillion by 2028 (IQVIA, 2024). Health systems across the world face increasing calls for access to highly innovative, and often very expensive, medicines for patients with significant unmet need. Exciting new developments in science and technology give rise to ever more personalised medicines, pushing the boundaries of existing regulatory, pricing and reimbursement systems. Apart from high prices, the challenges for countries are wide ranging. From a lack of generic competition, disparities in access, inadequate health insurance coverage, supply chain disruptions, to policy and regulatory challenges. Strategies to overcome these challenges require the adoption of multi-faceted approaches. Different approaches are needed in high, middle, and low-income countries. The question of affordability could be a relatively straightforward one if there was a high degree of certainty about the benefits of expensive medicines. However, regulators are speeding up evaluation, taking the advantage of new approaches to evidence collection and analysis, including real-world evidence. Fewer medicines are coming to market with an open and shut case for value, leaving payors and commissioners with significant (financial) risks to manage. In

the United Kingdom, the government uses the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth as a vehicle to promote innovation and access to cost-effective medicines, commensurate to their value to patients and the NHS, while also supporting sustainability of NHS finances (UK Government, 2024). Other mechanisms such as the Cancer Drugs Fund and Innovative Medicines Fund are being used to manage access and collect further evidence to support the assessment of value for the NHS (NHS England, 2024). Several provisions in the Inflation Reduction Act address drug pricing, including allowing the Secretary of HHS to negotiate prices in Medicare Parts B and D for selected medications and introducing Medicare rebates for drug prices that rise faster than inflation (U.S. Department of Health & Human Services, 2024). Stakeholders across the spectrum of research, development, regulatory approval, and market access should act, together, to ensure valuable novel medicines are getting to patients fast, and at a reasonable cost to the (tax)payer. Starting with ensuring the evidence base for assessment of value is comprehensive, at an early stage of development. Health Technology Assessment is well placed to manage this process, taking a life-cycle approach to appraising the value of innovative technologies (Trowman et al., 2023).

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K2

Can people afford to pay for health care? Evidence on financial protection in 40 countries in Europe

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Financial protection – affordable access to health care – is undermined when out-of-pocket payments for health care lead to financial hardship

(impoverishing and catastrophic health spending) or create a barrier to access, resulting in unmet need for health care. This talk summarizes the findings of a new study of financial protection in 40 countries in Europe in 2019 or the latest available year before COVID-19 (Thomson et al., 2024; WHO Regional Office for Europe, 2023, 2024).

Health systems need to reduce their reliance on out-of-pocket payments: Out-of-pocket payments lead to financial hardship and unmet need in every country in the study – but country averages conceal major differences in impact. Financial hardship and unmet need are consistently most likely to affect households in the poorest fifth of the population.

Financial hardship is driven by gaps in the coverage of primary care: Catastrophic health spending is largely driven by out-of-pocket payments for outpatient medicines, medical products and dental care – services that are commonly delivered or managed in primary care settings – indicating significant gaps in the coverage of primary care in many countries. In countries with a higher incidence of catastrophic health spending, financial hardship is overwhelmingly driven by household spending on outpatient medicines.

'Addiction' to bad ideas – the coverage policy choices that undermine financial protection and slow progress towards UHC: A country's reliance on out-of-pocket payments is heavily influenced by coverage policy – the way in which health coverage is designed and implemented. The study highlights five coverage policy choices that countries should avoid:

(1) Avoid linking entitlement to payment of contributions
(2) Avoid excluding people from coverage
(3) Avoid applying user charges without effective protection mechanisms
(4) Avoid failing to cover treatment in primary care settings
(5) Avoid thinking VHI is the answer

Focusing on (3), the talk notes how countries that give greater protection from user charges to people with low incomes have lower levels of catastrophic health spending. This suggests that user charges should be applied sparingly and carefully designed so that people with low incomes or chronic conditions are automatically exempt from all co-payments; there is an annual income-based cap on all co-payments, which works automatically; there are no percentage co-payments; there is no balance billing or extra billing for medical services; and any co-payments in place are low and fixed and people know in advance exactly how much they have to pay when they see a doctor, undergo a diagnostic test, collect a prescription or are admitted to hospital.

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K3

Update on competition enforcement in the pharmaceutical sector (2018–2022): European competition authorities working together for affordable and innovative medicines: report from the Commission to the Council and the European Parliament

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The European Commission has published a report providing an overview of the (European Competition Network, 2021) enforcement of EU antitrust and merger rules by the Commission and the national competition authorities ('NCAs') in the pharmaceutical sector between 2018 and 2022. This report (European Commission, Directorate-Generate for Competition, 2024) shows that active enforcement of antitrust and merger rules continues to play an important role in delivering European patients' access to a wider choice of affordable and innovative medicines.

The Commission drafted the report in cooperation with the NCAs of the 27 EU Member States, with which the Commission works in the European Competition Network ('ECN'). It follows a previous report covering the years 2009–2017, published in 2019 (European Commission, Directorate-Generial for Competition, 2019).

With respect to anti-competitive agreements and cases of abuse of a dominant position, since 2018 the Commission and NCA's have adopted 26 decisions against anti-competitive practices in the supply of medicines, imposing fines totalling over €780 million or making legally binding commitments offered by companies to remedy their anti-competitive behaviour.

The anti-competitive practices concerned harmed innovation and prices, and ranged from: (i) the misuse of the patent system and abusive litigation to prolong patent exclusivity; (ii) the disparagement of a competitor's products to protect the dominant company's sales; (iii) pay for-delay agreements, where originator and generic companies colluded to keep generics off the market and share the originator's profits from doing so; and (iv) excessive prices charged for off-patent medicines.

The Commission also reviewed more than 30 mergers in the pharmaceutical sector and found concerns in five cases, where mergers could have led to price increases, patients and national health systems being deprived of some medicines, or a reduction in innovative efforts to develop new medicines. The Commission cleared four of these mergers only after the companies offered remedies to address the Commission's concerns and preserve the existing degree of competition. One merger was abandoned after the Commission raised competition concerns.

The competition authorities undertook 60 market monitoring and advocacy activities that (i) offered insight into the functioning of the markets; (ii) informed a more pro-competitive design of regulation and legislation; and (iii) provided guidance to market participants, and even triggered antitrust investigations in certain cases.

The report also describes the guidance and coordination initiatives undertaken by the ECN to respond to the coronavirus pandemic, in particular the joint Statement on the application of the EU antitrust rules in the context of the coronavirus outbreak.

The report is available in all official EU languages on the Commission's competition website.

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K4

Action needed: Rediscovering Solidarity in Europe and beyond

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Now that the world is seemingly, for good or bad, returning to 'normal' after the pandemic it might be time to revisit our concept of solidarity. In time of major crises the best and worst comes out in mankind, not just at the individual level but also at the societal and global level.

What have we learned, and will we do better next time? We have seen that solidarity is a fragile concept, there has been a lot of criticism that the pandemic has shown that scarce resources are not always distributed based on the biggest medical need or the biggest expected health gains. Rather economical interest has convoluted decisions but also discussions all along the way.

Now that we are back to normal (whatever normal might be), we might assume these lessons learned will shape our, hopefully better, future. Yet, we see the same conflicting interests still lingering in societal, global and national discussions. How much solidarity is needed, should solidarity be driven by altruistic motives or have we emerged as a new, less altruistic but more pragmatic mankind?

The obvious inequality in access to drugs globally, the conflicting interests of the need to have sustainable health care systems versus the economic interests that indirectly contribute to the financial ability to support our complex social systems and the individual perspective of patients, collide constantly and have led to heated discussions and increasing tension.

Solidarity as a concept is tested, the complexity of the social systems makes it very tempting to play interests against each other. Be that at the national level when negotiation and purchasing power is (ab)used or at the individual level when patient populations are weighted against each other.

The legislation framework in Europe reflects these conflicting interests and can be seen as a show-case for the larger problem. The complexity of drug development, regulatory approval and reimbursement (as the prerequisite for patient access) has been acknowledged by the new legislation's (HTAR and Pharma Legislation) put forward by the European Commission. Yet, both leave the reader with the impression that also here solidarity is used in many different meanings. Are we supposed to show solidarity with

patients, balance national or global interests or are we supposed to ensure economic growth no matter what? The verdict is still out whether these legislations will support solidarity and if, which kind.

ORAL PRESENTATIONS – STRAND 1
O1

Finland as a trailblazer in the uptake of less expensive biologic medicines – measures introduced in 2023 and 2024

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Background: Biologic medicines significantly contribute to pharmaceutical expenditure and the uptake of less expensive alternatives is encouraged globally. In Finland in 2022, seven out of ten medicines with highest reimbursement expenditure were biologic, accounting for 12% (218M€) of medicine reimbursements. Finland introduced steering of prescribing of biologics in 2023 and will gradually implement pharmacist-led substitution of all biologic medicines except for short-acting insulins during 2024–2026.
Objectives: We study (1) the effects of steering of prescribing; (2) the effects of pharmacist-led substitution of biologic medicines; and (3) the pharmaceutical landscape and market of biologic medicines after the introduction of measures described above. The study is part of a large consortium study with a total of eight national research organizations and universities and two patient organizations involved, executed during 2023–2028.
Methodology: Retrospective register study by using the statistics of the Social Insurance Institution of Finland. The study addresses the outpatient care sector and examines both public and private sectors prescribing, as medicines prescribed from public and private sectors are reimbursed similarly in Finland.

Region covered: The study is carried out in Finland in both national and regional levels. However, lessons learned can be utilized by other countries as well.

Time period: The study is executed during 2023–2028. The supervision task of Kela was introduced in the beginning of 2023 and the pharmacist-led substitution will be introduced from 2024 onwards in stages.

Results: Steering of prescribing started in 2023. To give an example: a total of 1 090 physicians that prescribed one or more of three selected biologic medicines for which price differences between products existed, were observed from April to November 2023. 520 physicians (48%) received a guidance letter to support rational prescribing. During the observation period, around 6 000 prescriptions were written and in 3 100 prescriptions (52%), physicians had selected the least inexpensive biologic product. The share of the least inexpensive product out of all prescribed products rose in 2023: in one active ingredient, for example, from 8% in March-May to 54% in July. The effects of pharmacist-led substitution and the effects on the pharmaceutical landscape, availability and markets will be reported after the introduction of the pharmacist-led substitution from 2024 onwards. Savings of 20M€ annually for the reimbursement expenditure are expected from the pharmacist-led substitution.

Conclusions and lessons learned: Steering appears to have an effect on the share of the least inexpensive product prescribed at least in some active ingredients. This study will contribute by providing insight on the effects of introduced measures and whether expected savings are met.

Keywords: Biologic medicine; biosimilar; pharmacist-led substitution; steering of prescribing; register study

Funding source: The study is funded by the Social Insurance Institution of Finland.

O2

Alignment in the registration, selection, procurement and reimbursement of essential medicines for childhood cancers in South Africa

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Background: South Africa's childhood cancer survival rates (52%) lag behind better-resourced countries. Improving outcomes requires access to chemotherapeutics and supportive medicines. The effectiveness of a health

system in providing access to medicines, including childhood cancer medicines, is in part determined by the alignment of several core pharmaceutical processes. In South Africa's public health these processes include the registration of medicines, selection based on National Essential Medicines Lists (NEMLs) and subsequent procurement of these medicines through national tenders. Alignment between registration, selection in reference formularies and positive reimbursement lists is key in the private sector.

Objectives: This study assessed the alignment of forementioned processes for essential paediatric oncology medicines in the South African context.

Methodology: A selection of 25 priority chemotherapeutics and 19 antiemetics and analgesics (including therapeutic alternatives) in the treatment of five prevalent childhood cancers in South Africa was compared to those listed in (1) the World Health Organization Essential Medicines List for Children (WHO EMLc) 2021, (2) the registered health products database of South Africa, (3) the relevant South African NEMLs, (4) bid packs and awarded tenders for oncology medicines for 2020 and 2022, and (5) oncology formularies from the leading Independent Clinical Oncology Network (ICON) and two private sector medical aid schemes (Figure 1). Consistency between these sources was assessed descriptively.

Region covered: This study was conducted at the South African national level (AFRO), covering both the public and private sector.

Results: There was full alignment for all 25 priority chemotherapeutics for children between the NEML, the products registered in South Africa and those included on tender, indicating good operationalization of pharmaceutical policies and processes in the public sector (Joose et al., 2023). However, due to unsuccessful procurement, access to seven chemotherapeutics was potentially constrained. Nine out of 19 supportive medicines were listed on the WHO EMLc, of which eight (89%) were also registered in South Africa and on its NEML. An exploratory assessment of private sector formularies showed various gaps in ICON's formulary and two medical scheme positive reimbursement lists, listing 33% and 24% of the chemotherapeutics, respectively. This indicates potential access constraints in the private sector due to unaffordability.

Conclusions and lessons learned: The alignment within South Africa's public sector processes presents an example for other low- and middle-income countries. Nonetheless, access constraints stemming from unsuccessful tenders highlight a need for alternative procurement approaches. The limited number of essential childhood cancer medicines on private sector formularies demand further study regarding their impact on patient access.

Keywords: alignment; descriptive analysis; policy analysis; South Africa; childhood cancer

Funding source: NA

Reference

This study, and adapted version of this abstract, was published in:

Joosse, I. R., van den Ham, H. A., Mantel-Teeuwisse, A. K., & Suleman, F. (2023). Alignment in the registration, selection, procurement and reimbursement of essential medicines for childhood cancers in South Africa. *BMJ Global Health*, 8(9), e012309. https://doi.org/10.1136/bmjgh-2023-012309.

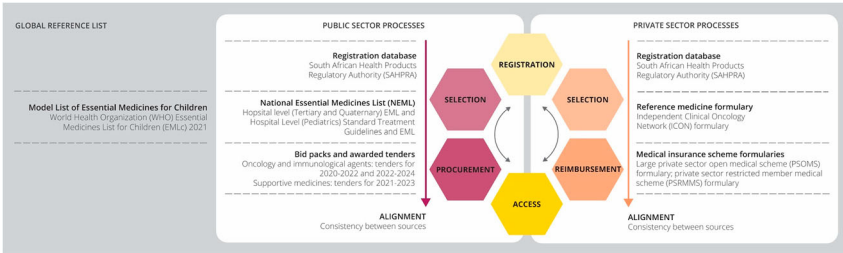

Figure 1. Ideal access pathways through alignment of core pharmaceutical processes, and respective resources compared. Comment: This figure does not capture loophole arrangement for unregistered access. Core domains distribution and use not shown.

O3

Cardiovascular Medicines on Pharmaceutical Market in Armenia

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Background: Cardiovascular diseases are the leading cause of death in Armenia; and access to appropriate medicines is thus vital for patients. However, the previous studies demonstrated certain problems with access to cardiovascular and other medicines in the country. Price regulation is still not introduced; and shortage of medicines is observed.

Objectives: The objective of this work was to study the situation with availability and affordability of cardiovascular medicines in Armenia.

Methodology: The number of cardiovascular medicines and therapeutic equivalents listed in the WHO Model List of Essential Medicines (WHO EML) which are authorized in Armenia, was identified by analysing the List of

medicines registered in Armenia (2023). The number of registered generics for 12 selected (essential and some other often used) tracer medicines was identified. Data on availability and outlet prices of authorised essential medicines were received from information provided at the websites of two big pharmacy chains. Affordability of available in the country essential medicines was calculated using methodology adjusted from the method developed by World Health Organization (WHO) and Health Action International (cost of treatment is less than official national minimum wage calculated for 1 day).
Results: Only 24 of 37 cardiovascular medicines and therapeutic equivalents (active ingredients and combinations) listed in the WHO Model List of Essential Medicines (WHO EML) of 2021 were authorized in Armenia (2023). Essential medicines / equivalents, such as glyceryl trinitrate, dopamine, isosorbide dinitrate, hydralazine and others, are not registered in the country. Furthermore, some dosage forms and strengths of medicines included in WHO EML are also not in the List of Medicines registered in Armenia. The number of registered generic products for 8 of 12 selected tracer medicines decreased from 2018 to 2023 and only increased for one medicine (Amlodipine). Only 14 essential medicines / equivalents of 24 authorized and of 37 listed in WHO EML were available at 2 big pharmacy chains. Most of available essential cardiovascular medicines are affordable; some medicines are affordable if prescribed at low doses and would be unaffordable at higher doses; two medicines (clopidogrel, simvastatin) are unaffordable.
Conclusions and lessons learned: Only part of essential cardiovascular medicines and their dosage forms are authorized in Armenia that restricts their import to the country and leads to shortage. Low availability and unaffordability of some medicines can compromise access to treatment for patients with cardiovascular diseases. There is urgent need for developing and introducing strategies aimed to improve the situation with shortage of essential medicines as well as fair pricing.
Keywords: cardiovascular medicines, access to medicines
Funding source: No funding sources

ORAL PRESENTATIONS – STRAND 2
O4

Savings and Transparency: Comparing Publicly Reported Data on Managed Entry Agreements in Europe

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Background: Actual (net) prices of medicines often diverge from publicly listed prices. Confidential financial arrangements as part of managed entry agreements (MEAs) are a major driver of this discrepancy. Despite the existence of confidentiality agreements at medicinal product level, some countries opt to disclose aggregated information on MEAs in public reports.
Objectives: Our objective is to provide an overview of negotiation processes and publicly available financial data on MEAs across Europe.
Methodology: National flowcharts for selected European countries were created based on literature to map MEA negotiation processes and identify relevant stakeholders. Stakeholder websites were screened for MEA public reports in the years 2016–2023. Data analysis included the number of realized MEAs, estimated spending with and without MEAs, and calculated average discounts. Interviews were conducted to validate data completeness, analysis, and interpretation. Interviewees were national experts selected through purposing sampling via the networks of the Organisation of European Cancer Institutes (OECI), the European Cancer leagues (ECL), and the network of Pharmaceutical Pricing and Reimbursement Information (PPRI).
Results: Flowcharts depicting MEA processes were created for 15 European countries. Our preliminary results show varying complexities and stakeholder involvements among countries. Public data was mostly reported in local languages with differences in its accessibility (e.g. steps required to extract the data) and aggregation (e.g. product or indication level). National conditions and thresholds for MEA entry influenced prevalence and spending reductions across countries. Estimated spending reductions due to MEAs varied (e.g. 599 million euro in the Netherlands, 754 million euro in Belgium, and 144 million euro in Italy in 2020). Most countries exhibited increasing trends in the number of active MEAs and average discounts (20–

50%). Overall, we found strong variabilities in the availability and quality of reported data, which may affect the generalizability of our results.
Conclusions and lessons learned: MEAs have a considerable and increasing impact on pharmaceutical spending and the precision of list prices, contributing to the opacity of the pharmaceutical market. Our initial findings show substantial variations in information disclosure, conditions to enter a MEA, and the accessibility of reporting, posing challenges for cross-country assessments. Harmonizing and enhancing reporting practices across countries to publish aggregated information on MEAs, particularly in English and categorized per therapeutic class, could notably increase transparency and public accountability in the European pharmaceutical market, all while adhering to confidentiality provisions.
Keywords: Managed entry agreements, public reporting, information sharing, transparency, financial discounts
Funding source: The research is funded by the European Fair Pricing Network. The European Fair Pricing Network (EFPN) is funded by eleven Cancer charities in the European region. The network combines funds academic research with the expectation that scientifically sound outcomes may contribute to the policy debate and action to improve transparency, fair prices, and swiftly accessible medicines for patients living with cancer.

O5

Investigating the Nature and Scope of Innovative Payment and Pricing Schemes for Health Technologies

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Background: Innovative payment and pricing schemes have been proposed as solutions to the problems with the affordability of new health technologies and uncertainty about their long-term effectiveness. However, little is currently known about the nature and scope of these arrangements, or their impact in practice.
Objectives: As part of the Horizon Europe project HI-PRIX, an extensive mapping of the scientific and gray literature was performed with the

objective to investigate theoretical and applied pricing and payment schemes for innovative technologies in healthcare.

Methodology: We undertook a PRISMA-ScR-compliant review in PubMed, Web of Science and Scopus, from 2010 to 2023. We also searched health technology assessment (HTA) agency websites. The search strategy was structured around two blocks, 'pricing/payment schemes', and 'innovativeness'. Studies illustrating pricing/payment schemes with sufficient level of details to explain their functioning were selected, also through a nested evaluation of an artificial intelligence powered tool for systematic reviews. These schemes were classified according to several criteria, such as their purpose, nature, governance, product category, data collection needs, foreseen distribution of risk, and implementation challenges. The study protocol was published in PROSPERO (CRD42023444824).

Results: 'Innovative payment and pricing schemes' were defined as arrangements that go beyond price per unit of the technology, simple price/volume agreements or expenditure caps. Sixty-nine innovative schemes were identified, of which 22 were only illustrated theoretically, while 47 have been implemented in practice. So far, 170 real cases of implementation have been identified. The schemes target pharmaceuticals, vaccines, and/or medical devices. Whether designed to incorporate unique features of a given technology, or to address specific challenges, the schemes can be classified by different value drivers, including type of technology, therapeutic indication, or timeline of the agreement.

Conclusions and lessons learned: Available pricing and payment schemes have the potential to offer a comprehensive toolkit to policymakers facing reimbursement and access decisions, highlighting that it is not the scheme per se which is innovative, rather its application/use in a given context or for a given challenge. The schemes identified as part of this work, together with examples of real-world use, have populated the Pay-for-Innovation Observatory, an online catalogue of pricing and payment schemes for health innovations. The repository is publicly available and accessible here: https://p4i.hiprixhorizon.eu/.

Keywords: pricing scheme; payment scheme; reimbursement scheme; health innovations; observatory

Funding source: This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement number 101095593.

O6

European comparison of prices for off-patent medicines – findings for 16 countries and implications for methodological choices

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Background: Generic medicines, which enter the market after the patent of the originator product has expired, are considered as an important approach to ensure the financial sustainability of pharmaceutical systems. Therefore, generic medicines have been investigated in many price studies (Schneider & Vogler, 2019), which differ in methods used as comparisons for generic medicines, in particular between several countries, need to account for characteristics of the market structure (Vogler, Schneider, & Zimmermann, 2019).
Objectives: The aim of the study is to survey prices of selected medicines in the off-patent segment in 16 European countries and to explore different methodological approaches for analysing prices.
Methodology: The price comparison was conducted for eleven off-patent active pharmaceutical ingredients with high shares of public expenditure and/or prescriptions in Austria. Ex-factory prices of all medicines (generics and originator products) of the selected active ingredients which had the same (defined) dosage, pharmaceutical and dosage form, and pack size (so-called 'virtual pharmaceutical speciality', VPS) were surveyed for 16 European countries of comparable economic situation. Price data were collected via the Pharmaceutical Price Information System at Gesundheit Österreich GmbH.

Region covered: 16 countries of the WHO EURO region, i.e. Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom

Time period: Prices were collected as of July 2023 (Schneider, Fischer, & Heindl, 2021).
Results: The Austrian generic prices for the analysed sample of VPS tend to rank in the middle of the countries surveyed. Prices of originator products in Austria are among the lowest, which may be attributable to differences in the design of pricing policies between Austria and the surveyed European countries. Applying index-based approaches to international price comparisons highlighted the impact of methodological choices. Specifically, the choice of base country was shown to have an important impact on results, as the pharmaceutical system

characteristics and prescribing patterns in that country are implicitly transferred to comparator countries. In the case of Austria, it would mean a high relevance of originator products and comparatively low share of generics in the reimbursement market. As the generic price link in Austria also applies to originators, the Austrian price level seems comparatively lower when using Austria as base country for index calculation.

Conclusions and lessons learned: The application of different methods suggests that the loss of exclusivity seems to go along with product differentiation due to (1) fixed-dose combinations, (2) strength of active ingredient(s), (3) pharmaceutical forms or (4) therapeutic alternatives, which all seems to result in a greater variation in the metrics used in the analysis. This study of the price levels of generic medicines in selected European countries confirms that comparisons for off-patent active ingredients are challenging from a methodological perspective and that different methodological approaches may be necessary to better capture the price situation of off-patent markets.

Keywords: pharmaceutical prices, generic medicines, international comparison, price analysis, methods

Funding source: Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

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ORAL PRESENTATIONS STRAND 3
O7

Use of strategic approaches in public procurement of medicines: improving affordable patient access to medicines and protecting the environment in 32 European countries

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Background: Public procurement of medicines aims to improve affordable patient access to medicines. In addition, it may also address other policy objectives, including fostering more environmentally sustainable production, transport and use of medicines. A more strategic approach in public procurement may help achieve these objectives.

Objectives: The study aimed to survey public procurement for medicines in European countries, to identify use of strategic procurement practices and techniques, including environmental award criteria, and to assess their potential to help achieve affordable and sustainable access to effective medicines.

Methodology: We first conducted country-specific literature searches and produced 32 country fiches, which offered detailed information on procurement bodies, procedures, techniques, award criteria and supporting instruments (e.g., use of Health Technology Assessment) and accompanying tools (e.g., managed-entry agreements). Procurement experts of the studied countries were requested to validate the information in the country factsheets. Furthermore, we analysed data on pharmaceutical consumption (IQVIA) and public procurement information from Tenders Electronic Daily (TED). Views of different stakeholders (e.g., procurers, authorities, industry) were elicited through workshops and an online survey.

Region covered: 32 European countries from the WHO European Region: all 27 EU Member States, Iceland, Liechtenstein, Norway, Switzerland, the United Kingdom

Time period: Collected data relate to the year 2022.

Results: European countries apply a mix of different procurement practices and techniques across and even within countries. Overall, public procurement of medicines in European countries tends to be focused on achieving competitive prices. Strategic procurement practices and techniques such as Most Economically Advantageous Tender (MEAT) criteria considering award criteria beyond the price, granting contracts to more than one winner and joint procurement remain to be applied rather rarely. Environmental award criteria are considered by only a few countries in public tenders. The Nordic countries have gained experience with applying environmental award criteria, including climate-friendly packaging, transportation and production. Quantitative data analyses showed that countries which applied a mix of strategic procurement practices, supporting instruments and accompanying tools tend to contribute to better overall availability of medicines and generally lower unit prices of medicines.

Conclusions and lessons learned: The study showed some progress towards more strategic use of public procurement practices for medicines in European countries and an appetite of policymakers and procurers for moving forward on this path, with tailoring public procurement to contribute towards protection of the environment. However, overall use of strategic

procurement practices to improve patient access to medicines and managing the trade-off between different policy objectives remains limited.

Keywords: Public procurement, protection of the environment, award criteria

Funding source: European Commission, European Health and Digital Executive Agency

O8

Tendering of therapeutically equivalent, patented outpatient pharmaceuticals in Norway

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Background: Pharmaceuticals funded through the national reimbursement scheme have historically not been subject to price competition or tenders in Norway. In December 2021, the Norwegian Parliament adopted a proposal from the Ministry of Health to perform a pilot tender for PCSK9-inhibitors.

Objectives: The objective was to establish competence within procurement, and tenders, and find effective ways to cooperate between key governmental institutions and organisations.

Methodology: Repatha and Praluent are PCSK9-inhibitors and have been reimbursed in Norway on individual patient basis since 2017. Due to budget constraints, treatment was reserved only for selected patient groups. Confidential rebates were agreed between the health authorities and suppliers, and criteria (cholesterol levels) for eligible patient groups were set. A third PCSK9-inhibitor, Leqvio, was granted a reimbursement contract with similar terms in June 2022.

During 2022 the pilot tender was planned, and a three-party collaboration agreement between concerned health authorities was established, specifying duties and responsibilities between the participants. The Norwegian Medicines Agency (NoMA) conducts HTAs and appoints specialists, the Norwegian Hospital Procurement Association (Sykehusinnkjop) conducts the tender, and the Norwegian Directorate of Health is responsible for funding.

It was decided that only Repatha and Praluent should be eligible to fully compete in the national tender. If certain levels of rebates were obtained, the one PCSK9-inhibitor with the lowest price would gain general

reimbursement (instead of individual reimbursement), and access to a larger patient group where treatment would be cost-effective.

Results: The result of the PCSK9 tender was announced in November 2022. From January 1st, 2023, Praluent was made available on general reimbursement for new patients, while Repatha and Leqvio were made available on induvial patient basis for those unable to use Praluent. No patients were required to change existing treatment as result of the tender. In 2022, about 2,200 new patients (in addition to approximately 3,000 existing patients) were given access to PCSK9-inhibitors, only with a modest increase in overall public reimbursement costs. An evaluation of the tender process, preliminary results and a recommendation was published by the Norwegian Medicines Agency in the spring of 2023.

Conclusions and lessons learned: In December 2023 the Norwegian Parliament decided to go forward with tenders as a permanent method of procurement of outpatient pharmaceuticals.

Keywords: tender, reimbursement, outpatient pharmaceuticals, PCSK9-inhibitors.

Funding source: *no information provided*

O9

First Nordic Tender with Environmental Criteria

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Background: In recent years smaller markets like the Nordics, have seen a rise in medicine shortages. Simultaneously, there is increased focus on the environmental impact of pharmaceuticals. In 2022, Amgros (Denmark), Landspitali (Iceland), and Sykehusinnkjøp (Norway) conducted their first joint medicines tender with environmental criteria.

Objectives: The idea of conducting the first cross-national joint tender with environmental criteria was to: (1) Enhance experience in cross-border tenders (2) Create a larger and more attractive market for suppliers, thereby enhancing security of supply. (3) Acquiring experience in incorporating environmental criteria in a cross-border medicines tender.

Methodology: A comprehensive evaluation was conducted by examining the number of bidders, competition levels, tender prices, shortage instances, and adherence to environmental criteria by suppliers. The scope of the joint tender covered pharmaceuticals used in public hospitals which are supply critical.

Region covered: Region covered: Three of the five Nordic countries: Denmark, Norway and Iceland.

Time period: January 2022–December 2023

Results: The joint tender received bids for all included medicines and had multiple bidders for several of the substances. 11 out of 12 suppliers successfully met all environmental criteria, which included environmental certification, good environment practices (zero emissions and wastewater treatment). The criteria were selected through close collaboration between the Contracting Authorities and dialogue with suppliers.

Expectations were that environmental criteria could affect the number of bidders and prices. On the contrary, the prices remained relatively consistent compared to prices before the joint tender. Iceland even secured notably lower prices compared to its national tenders, and Norway experienced the same in specific cases. This suggests that small markets can potentially benefit from participating in joint tenders with other similarly sized markets. Additionally, Norway and Iceland gained access to molecules not previously available. Shortages occurred at a comparable rate to previous instances. However, some shortages were mitigated because there were multiple winners of the tenders, which enabled the other supplier to meet market demands for a temporary period.

Conclusions and lessons learned: The first joint Nordic tender with environmental criteria, stands as a pioneering effort with, to our knowledge, unprecedented results. The primary objective was to enhance security of supply while acquiring valuable experience in integrating environmental criteria into cross-border tenders, ultimately facilitating more sustainable access to medicines for patients. With bids received for all included medicines, competition in several substances, and 11 out of 12 suppliers meeting the environmental criteria, the intended goals were successfully achieved, marking the joint Nordic tender as a success.

Keywords: Nordic, joint tenders, environmental criteria

Funding source: none

O10

Using AIM's Fair Pricing Calculator for affordable and evidence-based pricing decisions, transitioning from policy concept to (inter-)national testing

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Background: The right to healthcare is recognized as a fundamental right and includes access to medicines. Yet, healthcare systems face affordability and access challenges due to escalating prices of new patented medicines without proper justification.
Objectives: The International Association of Mutual Benefit Societies (AIM) has developed a fair pricing model. The tool proposes a fair price for new medicines taking into account underlying costs, a reasonable profit and the considered therapeutic added value, in alignment with the WHO Fair Pricing Forum definition of a fair price. The model aims to enhance affordability and access to medicines to all Europeans by establishing improved purchasing conditions (International Association of Mutual Benefit Societies, 2021). The objectives of the research done by the German Techniker Krankenkasse (TK) (Muth et al., 2021) and the Belgian mutual fund Solidaris (Hendrickx et al., 2022), both non-for-profit healthcare insurers, are to apply the AIM tool to real-world examples of high-priced drugs in Germany and Belgium and to assess discrepancies between the prices calculated by the AIM tool and the real prices paid in Germany and Belgium.
Methodology: The algorithm was applied to seven medicines: Zolgensma®, Spinraza®, Entresto®, Jardiance®, Cosentyx®, Opdivo® and Lonsurf®. This selection reflects the diversity of new treatments recently reimbursed and the currently fastest-growing medicines classes in terms of expenditure both in the in-patient and the out-patient sector. The fair price per treatment was determined for each selected medicine and compared to the current net price per treatment in each country. A weighted average reduction percentage was estimated and applied to the expenses of all patented medicines in Germany and to new patented drugs reimbursed since 2015 for Belgium, in order to reach a potential saving figure for the health systems of Germany and Belgium.

Region covered: The study concerns the EURO region, with preliminary results in Belgium and Germany and the intention to wider the scope to more European countries.

Time period: In the TK study, price differences were factored in with actual spending in 2019. In the Solidaris study, the data for the public compulsory health insurance for 2020 have been used.

Results: AIM's fair pricing model indicates a fair price up to 13 times lower than the currently paid net prices for Germany and up to 18 times for Belgium. Orphan medicines and oncology treatments showed the largest gaps. The German study estimates a potential average reduction of 63,3 % for patented medicines (€13,071 bn yearly savings for the German healthcare budget) (Table 1). Solidaris calculated an average reduction of 76,7 % for all innovative medicines since 2015 (€1,059 bn yearly potential Ungs for the Belgian medicines budget) (Table 2).

Conclusions and lessons learned: Using AIM's model demonstrates that current prices paid for new medicines are not justified by their underlying costs of research, or their therapeutic performance. Additionally, introducing cost and price transparency could improve negotiating positions for buyers in pricing and reimbursement discussions.

Keywords: fair pricing, transparency, affordability, access

Funding source: International Association of Mutual Benefit Societies Solidaris Techniker Krankenkasse

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Table 1. Potential GKV savings for innovative substances using *the* AIM *fair price calculator* on selected examples at the current ex-factory price [Lauer-Taxe as of 15.07.2021].

INN	Brand name	Net Statutory Health Insurance spending 2019	Net Statutory Health Insurance spending, AIM Price, 2019	Statutory Health Insurance savings potential 15.07.2021	Statutory Health Insurance savings potential [%]
Onasemnogen-Abeparvovec	Zolgensma	NN		NN	
Nusinersen	Spinraza	13.729.200,00 €	1.571.137,22 €	12.158.062,78 €	88,56%
Sacubitril-Valsartan	Entresto	186.611.500,00 €	86.421.551,23 €	100.189.948,77 €	53,69%
Empagliflozin	Jardiance	198.084.200,00 €	221.467.133,15 €	-23.382.933,15 €	-11,80%
Secukinumab	Cosentyx	336.341.700,00 €	51.255.204,19 €	285.086.495,81 €	84,76%
Nivolumab	Opdivo	453.619.400,00 €	82.197.306,85 €	371.422.093,15 €	81,88%
Trifluridin/ Tipiracil	Lonsurf	23.807.800,00 €	1.497.110,79 €	22.310.689,21 €	93,71%
		1.212.193.800,00 €	444.409.443,43 €	767.784.356,57 €	63,34%
Net costs for patent drugs in the German federal health insurance		20.637.000.000,00 €		13.071.148.991,59 €	63,34%

Source: Techniker Krankenkasse, 2021.

Table 2. Actual expenditures and potential savings with fair price.

Expenditure 2020	Amount (euros)
Patented medicines reimbursed from 2015 onwards	1.949.245.638
Of which with managed entry agreement	1.379.426.580
Average refund of 41.19%.	(568.185.808)
Net Actual Expenditures	1.381.059.830
Calculating the fair price	
Average percentage of savings	-76,67%
Fair price	322.201.258,32
Savings if the fair price was applied	1.058.858.572

Source: Solidaris calculation (NIHDI 2020 expenditures).

O11

Disaggregation of the costs of pharmaceutical research and development

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Background: Costs for pharmaceutical products are increasing. Pharmaceutical companies claim that high Research and Development (R&D) costs are the reason for the steep price increase of new products. However, there exists little data to support such claims. There is a lack of transparency in R&D cost reporting.

Objectives: This paper wants to analyse and disaggregate the costs of pharmaceutical R&D. The following research questions (RQ) led this analysis: RQ1: What is the R&D cost of bringing a new drug to the market? RQ2: Which factors influence these costs of R&D for pharmaceuticals? We want to find out how expensive pharmaceutical R&D is, so at a later stage we can analyse public contributions in relation to total pharmaceutical R&D costs.

Methodology: Studies on the costs of introducing new medications to the market can differ substantially in their methodology, their origin of data and their results. A scoping review (on the basis of a systematic review by Schlander et al., 2021) was conducted on costs of R&D for pharmaceutical products using PubMed and Google Scholar, using a combination of the terms 'drug research and development' and 'costs' or 'drug research and development' and 'expenditure'. Additionally, semi-structured interviews with 17 experts from non-governmental organizations (NGOs), pharmaceutical companies, academic researchers and not-for-profit pharmaceutical companies were conducted to identify the main driving factors for rising costs of new drugs. Once identified targeted searches were conducted.

Regions covered: Pharmaceutical development for multinational pharmaceutical companies. Focus on most relevant drug developers for European market which mostly are European and US American pharmaceutical companies.

Time period: Started with first publication of average capitalized cost estimates for pharmaceutical products which was 1979 and to the latest publication in this field 2023.

Results: There is no standardized reporting of R&D activity or a standardized definition of R&D. Out of 24 identified studies that analysed mixed therapeutic fields the five highest cost estimates had affiliations with industry or received funding from pharmaceutical companies (see Figure 1 'Capitalised Cost Estimates for mixed therapeutic fields'). The interviewees emphasised that driving factors that influence costs for pharmaceutical R&D are therapeutic indication, drug complexity, number of patients in clinical trials, length of the development process and attrition rates. For each of the factors the reported margins vary dramatically between studies.

Conclusions and lessons learned: Due to the diverse nature of drug development and the confidential information held by pharmaceutical companies, it is challenging to provide an exact assessment of the average costs of pharmaceutical R&D. Non-affiliated researchers are unable to reproduce studies that use confidential data and therefore cannot check the validity of the results. Additionally, different definitions for R&D make analysing costs increasingly difficult. Existing literature reports huge margins of their cost estimations. Therefore, transparency policies with well-defined definitions for R&D are necessary to level the information asymmetries (pharmaceutical companies know the R&D costs, production costs and expected return on investment while public negotiators lack that knowledge) between the private and the public at price negotiations.

Keywords: pharmaceutical R&D, costs, disaggregation, attrition rates

Funding source: This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement number 101095593.

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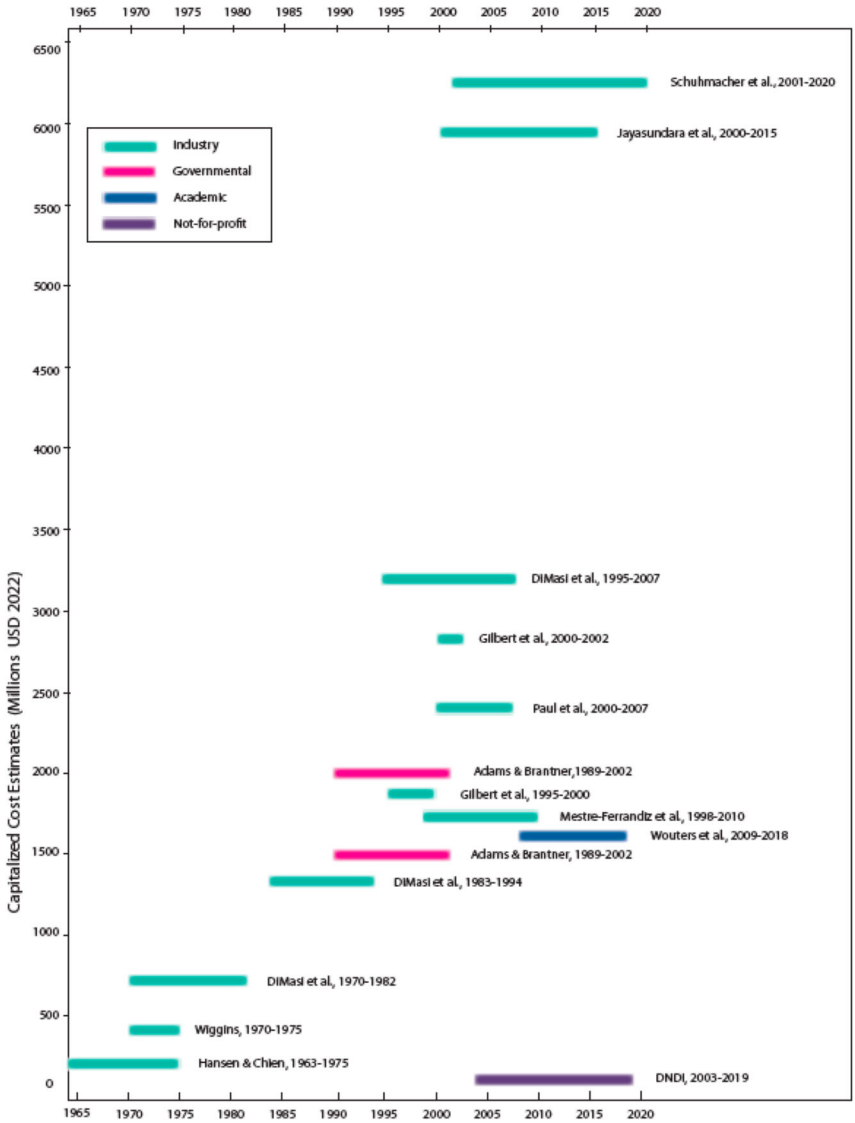

Figure 1. Capitalised cost estimates for mixed therapeutic fields.

O12

Unlocking global access to medicines for pandemics: the potential and limits of alternative innovation models

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Background: Recent infectious disease crises show that both development of, and equitable access to health technologies is critical for pandemic preparedness and response (PPR), but the current innovation system is unfit for this purpose.
Objectives: We conceptualised and examined a 'niche' focused on PPR that operates with alternative rules, norms, actors and resource flows within a broader complex, adaptive pharmaceutical innovation system. We inductively developed a typology of three alternative innovation models, and analysed their strengths and weaknesses for delivering both innovation and equitable access to pandemic products.
Methodology: We collected and analysed background information on 35 organisations operating in the niche, and conducted semi-structured interviews with 10 stakeholder organisations to describe both how the niche functions overall, and how these organisations operate within it

Region covered: Most interviewed organizations are located in the Region of the Americas (AMR) and European Region (EUR), including High-Income Countries (HICs) and Low- and Middle-Income Countries (LMICs).

Time period: Data was collected and analysed from 2020 to 2023, having curated a database of alternative initiatives for pharmaceutical R&D, conducted interviews, and synthesised results.
Results: First, the National Biosecurity model is the most established - driven and funded primarily by the public sector, with proven capacity to deliver innovation. This proliferating model might enhance national health security, but is likely to replicate the highly inequitable outcomes of the COVID-19 vaccine crisis. Second, the Cosmopolitan Public Private Partnership (PPP) model focuses on global access with demonstrated capacity to deliver innovation. It is represented by partnerships including not-for-profit funders such as the Coalition for Epidemic Preparedness Innovations (CEPI), who might ask grantees to implement access strategies. However, this model is vulnerable to the voluntary nature of partnerships, the challenges aligning public and private interests,

and the relatively uncertain availability of funds. Third, the Open Science Collaborative Network model is the most recent to emerge. In this model, scientific progress is accelerated through cooperation among researchers, while access is facilitated by working without intellectual property barriers. In practice, the development of Corbevax by the Baylor College of Medicine, or initiatives such as the Covid Moonshot embody these emerging efforts.

Conclusions and lessons learned: While the Cosmopolitan PPP and Open Science models prioritise global access alongside innovation, they require sustained political, financial and technical support to deliver on these joint goals. Understanding how all three models may compete with, or complement each other is critical for developing policies to deliver both rapid innovation and equitable access for future pandemics.

Keywords: pandemic preparedness and response, access to medicines, alternative innovation models, global health, covid-19

Funding source: Swiss National Science Foundation

POSTER PRESENTATIONS STRAND 1
P1

Early and compassionate access to medicines in France: two years after launch, what did and did not work?

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Background: In the 1980s, in France, early and compassionate access to medications originated with the AIDS epidemic. Since then, the legislation had evolved, proposing various systems for each situation, making the overall framework relatively complex to understand. Thus, in 2021, a comprehensive reform of the system was proposed.

Objectives: This system has been set up to ensure a better, faster access to innovative treatments, facilitate its understanding for healthcare professionals and companies, and offer guarantees of financial sustainability for our healthcare system. In order to be less complex, the new process proposes two types of exceptional accesses: (i) early access (EA) authorised by the French HTA body assessment for treatments destined to require access for reimbursement and (ii) compassionate access (CA) authorised by the national drug safety agency for medicines without marketing purpose. To promote access to innovative treatments and speed up their availability to patients, companies set their own price during the early and compassionate access period. In return, they must pay discounts to the health insurance scheme.

Methodology: Our study is both a description and analysis study of a policy evaluation, addresses the in-patient sector and examines both public and private sector. Data from the national health data system (SNDS), health agencies and the payer mainly are collected over a two-year period: from July 1, 2021 to July 1, 2023. We evaluate the reform results on some key parameters: number of applications, nature of the pathology concerned, number of French HTA body acceptance rate and their motives, number of patients treated, length of the approval, allowances claimed per therapeutic area, and so on.

Region covered: Study is located in France and carried out at national level.
Time period: From July 1, 2021 to July 1, 2023

Results: During the period of our study (HAS, 2023), around 280,000 patients have had access to treatments through this system, in 858 indications (87% of them through CA). Approximatively 78% of the EA evaluated by French HTA body were positive, and half of the first requests granted were in the oncology area.

Conclusions and lessons learned: Ministry of Health and Prevention is also currently working on an exclusive report on the assessment of this reform over the same period and results will be presented at the fifth PPRI conference.

Keywords: early access, compassionate access, HTA

Funding source: Direction de la sécurité sociale

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P2

Selection of novel medicines for acute conditions versus chronic conditions on National Essential Medicines Lists compared to the WHO Model List

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Background: The World Health Organization (WHO) developed and updates a Model List of Essential Medicines (MLEM) as guidance for countries' National Essential Medicines Lists (NEMLs). The NEML is an important tool for countries to enhance access to essential medicines, however this is still suboptimal especially for chronic conditions treated with novel, often high-cost medicines. This raises concerns about access to treatments for chronic conditions in low- and middle-income countries (LMICs) despite their growing disease burden in these countries.

Objectives: The aim of this study was to compare the WHO MLEM with NEMLs to determine the time between addition or deletion of essential medicines for several acute and chronic conditions in countries.

Methodology: A basket of medicines was compiled including novel medicines for diabetes, hepatitis C, HIV, oncology and tuberculosis that were added to or deleted from the WHO MLEM (2007–2021). This was compared with NEMLs from fourteen countries (Australia, Bhutan, Ethiopia, India, Ireland, Jordan, Lebanon, Malaysia, Nigeria, South Africa, Suriname, Uganda, Uruguay, Zambia) selected based on a variety of income group and geographic region. For high-income countries, reimbursement lists were used as an alternative to NEMLs. The time between addition to or deletion from the WHO MLEM and NEMLs was assessed descriptively.

Results: The basket of medicines consisted of 90 additions to and 15 deletions from the WHO MLEM. Overall, most medicines were added to NEMLs from the basket for HIV (54%), then for tuberculosis (50%), oncology (48%), hepatitis C (33%) and diabetes (29%). High-income countries included more medicines for diabetes (71%) and oncology (63%), while medicines for HIV (38 – 79%) and tuberculosis (45% – 64%) were included more by LMICs. High-income countries mostly selected medicines before their addition to the WHO MLEM (interquartile ranges (IQR): -13 years, 2 years). In contrast, LMICs mostly selected medicines after their addition to the WHO MLEM (IQR: -11 years, 10 years), especially for HIV (IQR: -2 years, 10 years) and tuberculosis (IQR: -3 years, 8 years). There was no trend in the deletion period of the basket of medicines.

Conclusions and lessons learned: Overall, more novel medicines were added to NEMLs for acute conditions (HIV and tuberculosis) than for chronic conditions (diabetes, hepatitis C and oncology). However, when looking at high-income countries, more medicines for chronic conditions (diabetes and oncology) were added, while LMICs included more medicines for acute conditions (HIV and tuberculosis). High-income countries selected medicines before their addition to the WHO MLEM in contrast to LMICs

Keywords: access to medicines, Essential Medicines List, National Essential Medicines List, high-cost medicines

Funding source: Utrecht University

P3

A hidden tragedy: Why do so many people still die from lack of insulin?

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Background: Wide-spread lack of insulin in low-and middle-income countries (LMIC) is a hidden tragedy. Over half the people in LMIC cannot get this life-saving medicine. Yet insulin expenditure is rapidly rising in many countries.
Objectives: To present practical lessons of different LMICs in promoting universal access to insulin.
Methodology: Key findings from papers and direct contacts with national diabetes programmes in five LMICs.
Region covered: Tanzania, Mali, Kyrgyzstan, Peru, Maldives
Time period: 2016–present
Results: The insulin market is strongly dominated by only three pharmaceutical companies without any meaningful competition; very few biosimilars enter the global market. In LMICs monthly prices for insulin and essential supplies for one person can be over half a month's minimum wage. Insulin analogues are 5–10x more expensive than human insulin, with limited clinical advantage. In some countries oral antidiabetics are marketed at very inflated prices.

Several LMIC, such as Mali, Kyrgyzstan, Peru and Tanzania, provide practical lessons for other countries (Abdraimova et al., 2022). For example, Tanzania made a successful transition from a donor-funded diabetes project to an integrated national NCD programme, moving towards universal health coverage (Hogerzeil, n.d.). In Peru pooled procurement has led to considerable price reduction and increased access. The Maldives has achieved equity in supply but at excessive cost through wide-spread use and reimbursement of non-essential expensive items.
Conclusions and lessons learned: Insulin and essential supplies (syringes, needles, glucose monitoring tools) should be included in social health insurance, and diabetes should be integrated with decentralized NCD programmes. Evidence-based selection of insulin and oral antidiabetics should guide and restrict public procurement and reimbursement.
Keywords: Universal access, essential medicines, diabetes, insulin, LMIC
Funding source: Health Action International, Amsterdam

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P4

Spillovers of Pharmaceutical Price Regulations: Strategic Response to External Reference Pricing

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Background: In years of growing pharmaceutical spending, regulators have exerted substantial effort in reducing the impact of this tendency. As part of their strategy, several countries have introduced External Reference Pricing (ERP). This is a mechanism through which the domestic price is linked to a benchmark price, based on publicly available pricing data from a number of foreign countries where a price has already been set. This creates potentially complex mechanisms of strategic interaction at the international level.
Objectives: The study aims to investigate the spillover effects, due to strategic responses, of the adoption of ERP by one country on countries that are included in the ERP reference set.
Methodology: We use a simple theoretical model to show that the introduction of ERP in one country may increase prices in those countries that adopt the new drug before that country and are included in its reference basket. Our empirical analysis uses a dataset of 65 cancer drugs in 21 countries and exploits the introduction of ERP in Germany in 2011 as part of the AMNOG bill in a difference-in-differences framework.
Results: The empirical results confirm our theoretical predictions, showing that the introduction of ERP in Germany led to increases, on average, between 6% and 8%. Also in line with the results from the theory, we find that the size of the impact may depend on the size of the market.
Conclusions and lessons learned: These results imply that the adoption of ERP policies in one country may have an impact on other countries due to strategic responses and that these responses may imply that the actual impact of ERP adoption on own prices may be lower than expected.
Keywords: -
Funding source: none

P5

High price treatments: characterization of requests in Mendoza- Argentine and implications for reimbursement- 2018–2022

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Background: High-price medicines (HPM) constitute a relevant problem due to their consequences for reimbursement. In Argentina, multiple financing mechanisms coexist that threaten the access to medicines. Treatments which generally address rare, usually chronic pathologies, put patients' lives at serious risk. They have been classified as 'high price' or 'high complexity'.

Objectives: Describe the health technologies requested in Mendoza, Argentina, by the Direct Assistance Program for Special Situations, a national organization) such as: type, indication, population, relevance of the request. Identify high-cost medications and know the expense and impact on the Mendoza health system.

Methodology: Descriptive study based on data from requests for health technology coverage. A database was created on medications, medical devices and procedures requested and selected among those that met the high price criterion. Regulatory aspects, evidence support such as inclusion in the WHO List of Essential Medicines (WHO, n.d.), and coverage recommendations based on clinical value made by HTA agencies and evidence-based medicine, were analysed. The indicator Treatment Cost Day (CTD) was estimated and the DDD of the main requested medications was used. The average number of requests per patient and annual budget estimate was obtained for each medication.

Region covered: PAHO - Argentina-Mendoza Study at local level, province of Mendoza Argentina

Time period**:** 2018–2022

Results: 787 requests were received, 50.6% (398) corresponded to medications, 46% (367) to medical products and 2.3% to procedures (transplants, hearing aids). The requests correspond to 787 people treated in highly complex hospitals, mostly from the state health coverage sector. 75.4% of medications requests meet the criteria of being a HPM: five (5) active ingredients. (Figure 1). The three most requested medications, health conditions were: for adalimumab (30.7% of requests), secukinumab (18.48%) and

omalizumab (8.33%). The resources destined to cover the three main requested medications would imply 70% of the resources necessary to deal with the treatments of diabetic patients who represent some 13,022 people with exclusive state coverage (Figures 2 and 3).

Conclusions and lessons learned: Evidence, affordability and the price-therapeutic value of HPMs do not follow a linearity, various factors converge in their dynamics. The mechanisms that exist to cover the needs of disadvantaged people, such as personalized subsidies, are usually framed in the exceptional nature and criteria of the organizations that pursue the care of vulnerable people. Our work shows that HPMs requested have direct impact in reimbursement and sometimes with insufficient evidence. The affordability is often at risk for health coverage.

Keywords: high price medications, reimbursement, rational use of medications

Funding source: Government fund

Reference

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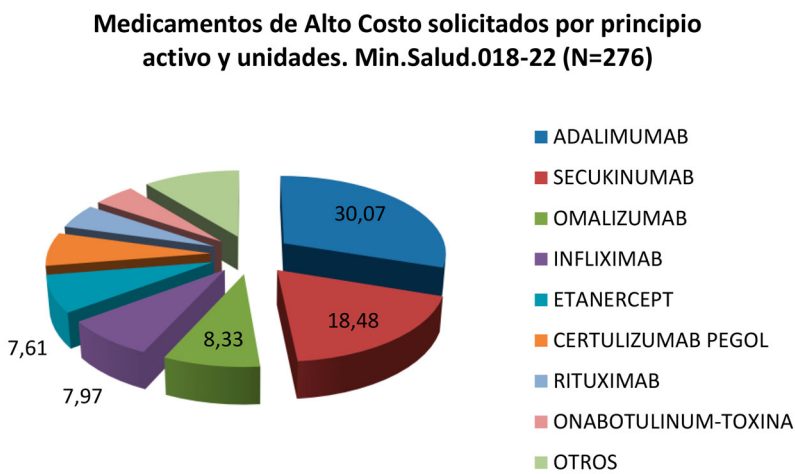

Figure 1. High Cost Medications requested by way of exception in Ministry of Health of Mendoza- Argentina.

Tabla N°1- Regulación y Evidencia para Adalimumab en las 3 principales indicaciones solicitadas			
TIPO DE EVIDENCIA/INDICACIÓN	Artritis Reumatoidea	Espondilitis Anquilosante	Artritis Psoriásica
REGULACIÓN	Si, ANMAT [13]	Si, ANMAT	Si, ANMAT
LISTADO M-ESENCIALES-OMS	Si, considerar alternativas	Si, considerar alternativas	Si
EVIDENCIA de EFECTIVIDAD	NICE no recomienda[14]	NICE, recomendación condicional	NICE, recomendación condicional
	EULAR 21 no recomienda [15]	EULAR 2016 recomend a favor	Cochrane Rev.Sist.. Baja efectividac
	COPTES no recomienda [16]	Cochrane Rev siste. evidencia alta calidad	

Figure 2. Approval and evidence of adalimumab in its main indications.

Tabla Nº 4- Estimación Costo de tratamiento anual y estimación presupuestaria de los 3 principales MAC solicitado-2018-22-						
Medicamento	Clasificación ATC	Costo Unitario *	DDD/u/vía adm	CostoTrat/ Dia	Costo Trat/ Año	Estimación Presupuestaria
ADALIMUMAB 40 mg/2 plumas precargada	L04AB04 (Inhibidores del factor de necrosis tumoral TNF alfa)	116.485,45	2.9/mg /parenteral	8.445,20	3.082.496,22	63.191.172,52
SECUKINUMAB 150 mg/2 plumas precargada	L04AC10 (Inhibidores de interleucina)	152.330,13	10/mg /parenteral	10.155,34	3.706.699,83	47.260.422,83
OMALIZUMAB 150mg/12 pluma precargada	R03DX05 (medicamentos sistémicos para enfermedades obstructivas de las vias respiratorias)	126378,22	16/mg /parenteral	13.480,34	4.920.325,37	28.291.870,85
*PVP-40%						

Figure 3. Annual treatment cost estimate and budget estimate of requested medicines 2018–2022.

P6

Evaluation of the external price referencing (EPR) policy for the National Essential Medicines List in Ukraine

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Background: In an effort to improve access to medicines, the Ministry of Health of Ukraine (MoHU) introduced in 2022 a price regulation for all medicines listed in the National Essential Medicines List (NEML). One central policy in this undertaking was external price referencing (EPR). In February 2023 the WHO Country Office in Ukraine commissioned the Austrian National Public Health Institute to conduct an evaluation of the EPR methodology and price calculation of the NEML in Ukraine.

Objectives: The main objective of the study was to analyse a sample of maximum wholesale prices for the NEML published in February 2023 to determine whether or not the prices determined by EPR were calculated correctly (maximum wholesale prices based on the prices for medicines published in the Czech Republic, Hungary, Latvia, Poland, and Slovakia). Other objectives of the study were to analyse the EPR methodology with regard to feasibility and adherence to international guidelines and recommendations (Habl, Schneider, Sebesta, & Nemeth, 2018; Vogler & Schneider, 2019; World Health Organization, 2020), and to propose changes to the EPR methodology, if needed.

Methodology: Price data for medicines of 21 active ingredients (15% of all international non-proprietary names INNs on the NEML) was collected from the five reference countries, standardised and computed based on the EPR methodology defined by the MoHU for NEML medicines. Results were compared to the prices included in the official price list as of February 2023. In order to evaluate the Ukrainian methodology for calculating EPR prices for the NEML, the algorithms were compared against common methodologies applied in other European countries and approaches mentioned in (scientific) literature.

Region covered: WHO EURO: Ukraine

Time period: February 2023–April 2023

Results: For almost all price calculations, the same reference price as listed in the Ukrainian price list were reached. For a few of the price calculations, discrepancies were observed e.g. due to lack of clarity in the EPR methodology. While the EPR methodology is generally consistent with standard practice, its complexity and labour-intensive nature due to manual calculations and predominance of generics pose challenges for the Ukrainian context. Hence implementing a simplified approach to generic drug price regulation under NEML is of paramount importance.

Conclusions and lessons learned: Some suggestions for policy modification were identified. These include: - Simplify EPR methodology and streamline with other programmes in Ukraine - Apply EPR only for on-patent products and explore alternative pricing mechanisms for generics such as generic price links, tendering etc. - Introduce an IT tool (instead of manual calculation) It is highly recommended to monitor the impacts on prices, affordability and access to medicines in Ukraine.

Keywords: pharmaceutical prices, external price referencing (EPR), price regulation, evaluation, Ukraine

Funding source: WHO Country Office Ukraine

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P7

Community pharmacy in Austria, England, Estonia and Portugal: Has the COVID-19 pandemic changed the range of pharmacy services offered?

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Background: Community pharmacies form an essential part for access to medicines for patients. Over the decades, the role of community pharmacy has changed and new services, which go beyond dispensing medicines and counselling, are being offered. The COVID-19 pandemic may have contributed to an expanded role for community pharmacies and provision of additional services.
Objectives: To survey community pharmacy services in selected European countries and to identify similarities and differences in service provision and potential root causes for change.
Methodology: Four European countries, with different scope of community pharmacy services offered, were selected as case-study examples. Data on services provided by community pharmacies were collected based on a review of peer-reviewed and grey literature and through an interview with a national pharmacy representative.

Region covered: Four countries in the WHO European Region: Austria, England, Estonia and Portugal.

Time period**:** Year 2023
Results: In addition to dispensing and counselling, community pharmacies in all four studied countries also offer information on general health topics, signposting to other health care providers, disposal of returned medicines and needle-exchange programmes. Point-of-care testing by community pharmacies is also provided in the four countries but the type of the tests and the

extent of pharmacies providing this service varies. Testing for COVID-19 is a new service which emerged during the pandemic. Provision of other pharmacy services was found to vary across the studied countries: Medication use review has a long tradition in England and is also offered by some community pharmacies in Portugal. In Estonia, the service has been piloted and awaited roll-out, while in Austria a law to provide the legal framework for its implementation was tabled in 2023. Generic substitution is a standard service in Estonia and Portugal, while it is not permitted in Austria and England. Defined vaccinations (e.g., influenza) by community pharmacists are offered in England and Portugal, whereas this service is not allowed in Austria. In Estonia, some vaccinations (including for COVID-19) are provided in community pharmacies, but they have to be administered by other health professionals than pharmacists.

Conclusions and lessons learned: The study found that despite cross-country differences rooted in legal and organisational frameworks, the range of services offered by community pharmacies has overall expanded, as community pharmacists aim to play a stronger role in primary health care. While a few pharmacy services had been piloted or implemented some years ago, the COVID-19 pandemic has indeed triggered introduction of additional services on short notice.

Keywords: community pharmacy, pharmacy service, cross-country analysis
Funding source: Austrian Chamber of Pharmacists

P8

Impact of health benefit package policy interventions on utilization under Government-funded health insurance: Evidence from India's Ayushman Bharat Pradhan Mantri Jan Arogya Yojana

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Background: Design of health benefits package (HBP), and its associated payment and pricing system, is central to the performance of government funded health insurance programs aimed to achieve Universal Health Coverage.

Objectives: We evaluated the impact of revision in HBP within Ayushman Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) on provider behaviour, manifesting in terms of utilization of services (National Health Authority, 2021).
Methodology: The present analysis is a policy evaluation wherein we analysed the data on 1.35 million hospitalization claims submitted by all the 886 (222 government and 664 private) empanelled hospitals in Punjab state, from August 2019 to December 2022, to assess the change in utilization from HBP 1.0 to HBP 2.0 (National Health Authority, 2020). The packages were stratified based on the nature of revision introduced in HBP 2.0, i.e. change in nomenclature, construct, price, or a combination of these. Data from National Health System Cost Database on cost of these packages was used to determine the cost-price differential for each package during HBP 1.0 and 2.0 respectively. A dose-response relationship was also evaluated, based on the multiplicity of revision type undertaken, or based on extent of price correction done. Change in the number of monthly claims, and the number of monthly claims per package was computed for each package category using an appropriate seasonal autoregressive integrated moving average (SARIMA) time series model (Ramsay et al., 2003).

Region covered: SEARO Country: India Level of analysis: Provincial/regional level - Punjab State, India

Time period: We used the data on 1.35 million claims over a period of 28 months (August 2019 and December 2022) from Punjab state of India to determine the impact of change from HBP 1.0 to HBP 2.0 on the utilization of surgical care services.
Results: Overall, we found that the HBP revision led to a positive impact on utilization of services [Table 1]. While changes in HBP nomenclature and construct had a positive effect, incorporating price corrections further accentuated the impact. Secondly, pricing reforms led to a significantly higher impact on those packages which were originally significantly under-priced. However, we did not find significant dose-response relationship based on extent of price correction. Thirdly, the overall impact of HBP revision was similar in public and private hospitals [Table 2].
Conclusions and lessons learned: The findings hold significance in the context of achieving the best outcomes of government funded health insurance programs. Improving the description of the package, i.e. nomenclature and construct improves its uptake, implying that it is advisable to keep the package updated with recent medical knowledge and practice. Our findings also imply that the price levels are the most important aspect of the HBP revision, which is likely to have the largest impact on its utilization. Further, pricing reforms led to a significantly higher impact on packages which were originally significantly underpriced. No dose-response relationship with the correction in extent of pricing implies that the price signals operate at an overall level, rather than package by package.

Keywords: health benefit packages, reimbursement rates, health insurance, behavioural economics, universal health coverage, supplier-induced demand
Funding source: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)

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Table 1. Impact of redesigning of health benefit packages (HBPs) in terms of change in package nomenclature, construct and price on utilization of claims in Punjab state.

Scenario	Price change	Sample size	Pre slope*	Change in slope*	Post slope*	p- value*
Change in Package nomenclature and construct	Change in price	186	−1889.81 (− 10.25)	1071.31 (5.77)	− 818.50 (− 4.48)	<0.0001 (0.001)
	No change	11	− 15.89 (− 1.82)	0.03 (0.26)	− 15.86 (− 1.56)	0.997 (0.823)
	Total	197	− 1933.66 (− 9.74)	1143.63 (5.74)	− 790.03 (− 4.00)	0.003 (0.001)
Change in Package nomenclature	Change in price	209	3.69 (− 1.46)	365.54 (2.24)	369.23 (0.78)	0.006 (0.002)
	No change	60	− 72.58 (− 0.95)	96.01 (1.48)	23.43 (0.53)	0.001 (0.003)
	Total	269	− 68.17 (− 0.35)	461.54 (1.79)	393.37 (1.44)	0.003 (0.005)
Change in Package construct	Change in price	25	1.78 (− 0.24)	10.31 (0.43)	8.53 (0.19)	0.033 (0.036)
	No change	19	− 6.80 (− 0.45)	4.34 (0.23)	− 2.46 (− 0.22)	0.031 (0.017)
	Total	44	− 8.33 (− 0.17)	14.75 (0.34)	6.42 (0.17)	0.006 (0.032)
No change in package nomenclature and construct	Change in price	177	− 20.59 (− 0.09)	6.88 (0.07)	− 13.71 (− 0.02)	0.911 (0.85)
	No change	188	− 193.33 (− 0.89)	170.43 (0.84)	− 22.90 (− 0.05)	0.007 (0.006)
	Total	365	− 210.52 (− 0.64)	167.28 (0.54)	− 43.24 (− 0.10)	0.182 (0.068)

Note: *- Value in parenthesis present outcome in number of insurance claims per package per month.

Table 2. Impact of price revision on utilization of insurance claims across overall*, public and private sector in Punjab state.

Package category (Cost price differential)	Significantly under-priced (< 50%)			Moderately under-priced (50-75%)			Appropriately priced (75-110%)			Overpriced (>110%)			All categories		
Sector	Overall *	Public	Private	Overall*	Public	Private	Overall*	Public	Private	Overall*	Public	Private	Overall *	Public	Private
Sample size	316	314	260	159	155	139	99	89	93	39	33	38	613	591	530
Pre slope*	−177.35	−197.48	−202.51	−49.30	−56.54	−7.34	−77.34	−57.15	−20.65	40.24	−7.04	45.92	−276.69	−316.38	−489.72
	(−0.55)	(−0.58)	(0.23)	(−0.27)	(−0.27)	(−0.01)	(−0.79)	(−0.54)	(−1.44)	(0.91)	(−0.34)	(1.08)	(−0.36)	(−0.57)	(0.12)
Change in slope*	559.80	182.30	449.40	116.43	48.23	74.45	68.12	39.76	27.72	15.33	3.46	10.99	774.78	281.71	655.74
	(1.84)	(0.60)	(1.41)	(0.76)	(0.24)	(0.55)	(0.68)	(0.38)	(0.69)	(0.39)	(0.15)	(0.34)	(1.22)	(0.50)	(0.88)
Post slope*	382.45	−15.18	246.89	67.13	−8.31	67.11	−9.22	−17.39	7.07	55.57	−3.58	56.91	498.09	−34.67	174.02
	(1.29)	(0.02)	(1.64)	(0.49)	(−0.03)	(0.54)	(−0.11)	(−0.16)	(−0.75)	(1.30)	(−0.19)	(1.42)	(0.86)	(−0.07)	(1.00)
p-value*	0.019	0.080	0.008	0.019	0.009	0.118	0.111	0.007	0.408	0.264	<0.0001	0.471	0.002	0.036	0.013
	(0.001)	(0.066)	(0.012)	(0.017)	(0.039)	(0.106)	(0.117)	(0.002)	(0.126)	(0.373)	(0.006)	(0.407)	(0.009)	(0.039)	(0.026)

*- Overall represents public and private sector analysis, Value in parenthesis present outcome in number of insurance claims per package per month.

P9

Pharmaceutical care in Austria: A survey on services provided by community pharmacies

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Background: Community pharmacies provide patients with access to safe and effective medicines. Given their essential role in patients' pathway to accessing and taking medicines, pharmaceutical policymaking may consider measures to realise the potential of community pharmacies for optimising the use of medicines. Internationally, the role of community pharmacies has evolved beyond dispensing, counselling, and producing medicines, moving towards the provision of pharmaceutical care (i.e. improving patient outcomes through medicines optimisation). There has been no systematic analysis of the range of services provided by community pharmacies in Austria.

Objectives: This study aimed to survey the range of community pharmacy services provided in Austria and to understand the role of community pharmacies in the Austrian health system.

Methodology: A two-stage, representative survey of services provided in community pharmacies in Austria was conducted. First, pharmacists in 25 participating community pharmacies tracked their activities for one week. Second, an online survey among pharmacists working in community pharmacies across Austria was conducted to obtain nationally representative data on the frequency of different services provided and the time taken to provide these services. The design of the survey was informed by a literature review of services provided by community pharmacies in other countries.

Region covered: WHO EURO region: Austria (national level)

Time period: 2023

Results: 1,218 of 6,298 community pharmacists responded to the survey (response rate: 19.3%). Survey participants were nationally representative in terms of pharmacy location and size. Services provided by community pharmacists in Austria tend to be focused on core pharmacy services (dispensing, counselling, compounding, quality control), which accounted for 81.0% of the time spent by participating pharmacists on all documented services. The remaining 19.0% of the time was spent on non-medicines related

services, including testing, referring patients to other health care providers, and health promotion. Core pharmacy services are provided by the vast majority of community pharmacists, including dispensing of medicines and advising on taking them (99.7% of participants) as well as compounding (90.1%). Health tests were conducted by 77.1% and Covid-19 tests by 67.2% (although testing on other infectious disease were conducted by only 6.9%). Some of the services provided varied by pharmacy location.

Conclusions and lessons learned: This study provides empirical evidence on current services provided by community pharmacies in Austria. While there is an international trend towards increased provision of services beyond core medicines-related activities, this survey suggests a more traditional approach in current pharmacy service provision in Austria. The range of services provided in Austria reflects the legal framework, which defines the role that community pharmacy can take in the health system. Changes to the legal framework in Austria introduced in 2024 allow for an expanded role with additional competencies for medicines optimisation and testing. The effects of these reforms on patient and health system outcomes should be evaluated.

Keywords: community pharmacy, pharmaceutical care, survey, pharmacy service

Funding source: Austrian Chamber of Pharmacists

P10

Financing and Payment Systems for Haemophilia Treatment in Europe: A Case study of Valoctocogene Roxaparvovec (Roctavian®) and Etranacogene Dezaparvovec (Hemgenix®)

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Background: In the last decade, Europe has experienced an increase in approved gene therapies, particularly in the treatment of rare diseases, posing financial challenges for healthcare systems due to their high prices. This research paper examines the funding and payment schemes for the two newly approved gene therapies for haemophilia (Valoctocogene roxaparvovec - Roctavian®, Etranacogene dezaparvovec - Hemgenix®) in European

countries. Unlike other disease areas where gene therapy is often the sole treatment option, haemophilia has an effective but very expensive alternative treatment, making it well-suited for a case study on gene therapies.

Objectives: The research question is to investigate the funding and payment schemes being utilized in European countries to address uncertainties and financial risks with respect to the implementation of the gene therapies Valoctocogene roxaparvovec (Roctavian®) and Etranacogene dezaparvovec (Hemgenix®). Drawing from these insights, the study aims to develop a generalized framework for funding and payment schemes in the area of gene therapies that ensures successful and timely patient access to such drugs without imposing excessive financial burden on healthcare systems.

Methodology: A case study will be conducted, specifically examining the funding and payment schemes for the two gene therapies. Data will be collected from public sources, including Health Technology Assessment (HTA) institutions in various European countries. Additionally, it is intended to approach pricing and reimbursement institutions through the Pharmaceutical Pricing and Reimbursement Information (PPRI) network to request information.

Region covered**:** The study focuses on various European countries, gathering country-specific information to enable comparative analysis for researchers and decision makers in the field.

Time period: The study will cover the period from the approval of the gene therapies Valoctocogene roxaparvovec (Roctavian®) and Etranacogene dezaparvovec (Hemgenix®) by the European Medicines Agency in August 2022 and April 2023, respectively, and will extend until the end of 2024.

Results: The study is expected to provide insights into the funding and payment schemes utilized for the implementation of gene therapies for haemophilia in Europe and how they address the uncertainties and financial challenges involved with this novel class of drugs. Additionally, the paper seeks to develop a generalized framework for successful and timely patient access to such drugs without imposing excessive financial burden on healthcare systems.

Conclusions and lessons learned: The study will draw conclusions on the effectiveness of the funding and payment schemes for gene therapies in Europe and provide lessons learned for future implementation of similar treatments.

Keywords: Gene therapy, haemophilia, funding, payment schemes, healthcare systems

Funding source: none

P11

Approaching two decades of information sharing between competent authorities: Experience from the Pharmaceutical Pricing and Reimbursement Information (PPRI) network

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Background: Two decades ago, policy-makers expressed a call for sharing information about policy implementation and experience across countries. In response, the Pharmaceutical Pricing and Reimbursement Information (PPRI) network of competent authorities was established in 2005.
Objectives: To take stock of the activities of the PPRI network.
Methodology: A narrative review based on an analysis of PPRI documents and expert knowledge of PPRI network members

Regions covered: The PPRI network comprises around 90 institutions (competent authorities for pricing and/or reimbursement) from 50 countries (all 27 EU Member States, Albania, Armenia, Australia, Brazil, Canada, Egypt, Iceland, Israel, Kazakhstan, Kyrgyzstan, Kosovo, North Macedonia, Moldova, Norway, Saudi Arabia, Serbia, Singapore, South Africa, South Korea, Switzerland, Türkiye, United Kingdom and Ukraine) and European and international organisations (European Commission, OECD, WHO).

Time period: 2005–2024
Results: Since its launch in 2005, the PPRI network has expanded from 31 countries, mainly European Union member states, to 50 countries in the WHO European Region and globally. Information-sharing about policy implementation takes place through different channels: One to two PPRI network meetings (usually face-to-face) are held each year, supplemented by webinars on topics of interest (e.g., biosimilar policies, Alzheimer's medicines). Additionally, PPRI network members have been launching ad-hoc queries to inquire about policy details in the other countries (more than 650 queries in total). In addition to sharing of policy experience among the peers in the PPRI network, evidence generated in the PPRI network which is of interest to the public is disseminated on the publicly accessible website (ppri.goeg.at), through public events (PPRI Conferences) and

publications. The latter include country reports of pharmaceutical pricing and reimbursement systems (PPRI Pharma Profiles and Briefs), cross-country comparisons of policies (PPRI Reports) and methodological guidance documents (e.g., reporting templates, indicators and glossaries). While focusing on pharmaceutical pricing and reimbursement, PPRI also addresses further topics such as medicine shortages, COVID-vaccinations in community pharmacies. In 2017, a sub-group on pricing and reimbursement of medical devices was established.

Conclusions and lessons learned: Given current and future challenges in the pharmaceutical systems, the informal exchange within the PPRI network based on trust will continue to play an important role. The growth in terms of countries and topics in PPRI during its almost 20 years of existence confirms the need for this model of collaboration. Similar concepts of connecting competent authorities, information sharing and mutual learning could be implemented in other parts of the world, building on the lessons of PPRI.

Keywords: networking, policies, information sharing, cross-country learning
Funding source: The PPRI Secretariat is funded by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection.

P12

Improving timely and affordable access to PD-(L)1-inhibitors - experiences from Norway

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Background: Over the past years, immune checkpoint inhibitors have played an important role in improving health outcomes in cancer treatment (Lawlor et al., 2021). At the same time, there are challenges with these new high-cost innovative medicines with multiple indications (OECD, 2020): Firstly, the number of health technology assessments (HTAs) and its administrative burden is significant for HTA agencies, payers, and decision makers as well as for pharmaceutical companies. Secondly, the potential budget impact of reimbursement is high. Consequently, Norway has introduced a new reimbursement scheme to improve affordable and timely patient access.

Objectives: To shorten time to reimbursement and reduce the use of HTA resources without compromising the affordability for a therapy area where multiple HTAs have already been performed.

Methodology: Policy evaluation in the Norwegian hospital sector

Region covered: Norway - national level

Time period: The time frame for the scheme is 4 years from December 2023.

Results: A new imbursement scheme for PD-(L)1 inhibitors has been introduced to diminish the administrative burden of assessment and achieve a significantly faster access to new therapies for patients. PD-(L)1 inhibitors enrolled in the scheme avoid the ordinary HTA process, given that the cost of the treatment is below a predetermined level. Thus, medicines can be introduced and included in the hospital formulary shortly after the time for marketing authorization (MA). Key features of the reimbursement scheme:

• Includes PD-(L)1 inhibitors used in monotherapy or in combination with biosimilars or generic drugs or inexpensive chemotherapy. • A price ceiling is set by Decision Forum (payer entity) calculated as the annual drug cost per patient (excluding administration costs). The price level is confidential and is communicated to each company separately. • Enrolment in the scheme is optional. • The reimbursement price serves as a future maximum price level which applies to all indications for the drug in question.

Drug companies that opt out of the scheme still need to apply for HTA. Once included in the hospital formulary, the drug may be subject to disease-specific tenders. As of February 2024 (2 months after introduction) two drug companies have opted into the scheme, and more are expected to enter soon.

Conclusions and lessons learned: The scheme could apply to approximately 30 existing and new indications during the next two years. Time from MA to reimbursement is expected to be shortened significantly from 180-360 days to approx. two months per indication and will impact patients' access to PD-(L)1-inhibtors, physicians' treatment alternatives and the predictability on time to reimbursement for drug companies.

Keywords: access, affordability, procurement, reimbursement, policy implementation

Funding source: Direzione Generale Cura della Persona Salute e Welfare, Servizio Assistenza Territoriale, Area Farmaco e Dispositivi Medici, Regione Emilia Romagna, Bologna, Italy.

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P13

Bridging perspectives: identification of best practices for public and patient involvement in pharmaceutical pricing and reimbursement policies – a comprehensive study

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Background: This study endeavors to bridge the gap between policy making and public and patient perspectives in pharmaceutical policy, specifically focusing on pharmaceutical pricing and reimbursement.
Objectives: The research aims to uncover and analyze best practices for effective public and patient involvement in shaping pharmaceutical policies.
Methodology: The research employs a dual-method approach, integrating a desk review and insightful interviews. The desk review delves into scientific literature, policy documents, and case studies, providing a comprehensive overview of public and patient engagement in pricing and reimbursement, and procurement of pharmaceutical products in the current landscape of the 5 WHO regions. Qualitative interviews will be conducted with decision-makers, policy makers, and representatives from patient organizations to capture diverse viewpoints and experiences. Desk Review: The desk review sheds light on different public and patient engagement approaches in pricing and reimbursement of pharmaceuticals, and their impacts on stakeholders. It scrutinizes existing frameworks, regulatory mechanisms, and case studies, discerning the strengths and weaknesses of current models to identify best cases. The best practice cases make the foundation for identifying further gaps and opportunities in public and patient involvement in pharmaceutical policy decisions. Interviews: Based on results from the desk review, 24 semi-structured interviews are conducted with key decision-makers, including government officials, regulatory authorities, and industry

representatives in a selected group of countries where best practices have been identified. Additionally, patient organisation representatives actively advocating for patient rights and access to affordable medications are interviewed. The collected qualitative data provides nuanced insights into the challenges faced and the strategies employed by decision-makers and patient advocates. Directed content analysis will be applied.

Time period: September 2023-June 2024

Results: Preliminary findings: Key themes of desk reviews emerge, including the importance of transparent communication, health literacy, deficient legal and societal structures, early and continuous engagement, and establishing collaborative platforms for informed decision-making.

Conclusions and lessons learned: This study synthesizes desk review findings and interviews insights to present a comprehensive overview of best practices for enhancing public and patient involvement in pharmaceutical pricing and reimbursement policies. It provides a roadmap for policy makers and stakeholders to develop more inclusive and effective pharmaceutical policies.

Keywords: public and patient involvement, pharmaceutical pricing and reimbursement, best practices, global perspective

Funding source: N/A

P14

Benchmarking U.S. Medicare Drug Price Negotiation Against European Nations' HTA and Drug Price Negotiations

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Background: The Inflation Reduction Act (2022) (IRA) directs the Center for Medicare and Medicaid Services (CMS) to negotiate Medicare drug prices starting mid-way through the patent duration using a regulated process. CMS employs new methods that take into account American market prices and manufacturer cost data.

Objectives: To: (1) identify key elements of regulations and negotiation options for CMS and manufacturers; and (2) compare Medicare negotiation against European practices.

Methodology: Review of legislation and regulations, analysis of negotiation theory and literature, interviews, legal and policy analysis.

Regions covered: AMR, EURO U.S., France, Germany, United Kingdom
Time period: 8/1/2022–2/31/2024

Results: CMS must employ a consistent methodology and follow regulations to negotiate the maximum fair price (MFP). CMS proposes an MFP by reference to the Medicare price of a comparable drug (or if none exists, the price paid by other federal government purchasers), and adjusts for six factors bearing on fairness and on manufacturer market and cost data. The manufacturer makes a counteroffer, justified by the same factors and data. The final MFP must provide at least a specified discount (which increases with the duration since FDA marketing authorization) from the average private sector price. If CMS and the manufacturer don't agree by the deadline, then CMS sets the MFP and there is no appeal. The manufacturer must accept the MFP or terminate sale of all its drugs to Medicare and Medicaid. If CMS and the manufacturer cannot agree on principles of fairness, each will consider their best alternative to a negotiated agreement; leverage will drive the concession made. Negotiations are confidential unless the manufacturer discloses information. In confidential discussions CMS and manufacturer might consider other matters of interest to reach an agreement (Rodwin & Lantos, 2024). Unlike in France, Germany or the U.K. (Rodwin, 2021), for Medicare there is no independent HTA, or analysis of cost effectiveness, or QALYs, or required reference to prices in other nations, see Figure 1 (Rodwin, 2022). The study also reviews other differences between Medicare and EU pricing policies.

Conclusions and lessons learned: The IRA establishes a negotiation paradigm that sets parameters for Medicare drug prices and ensures discounts from current Medicare and average private market prices. It does not control initial Medicare or private sector prices, so manufacturers might set these higher in the future. It employs a structured negotiation process that includes comparative effectiveness pricing used in many European nations without reference to European prices.

Keywords: comparative-effectiveness, HTA, negotiation
Funding source: Suffolk University

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Health Technology Assessment Caps New Drug Reimbursement

France (1993), U.K. (1999), Germany (2011) introduce health technology assessments to determine the value of new drugs and to cap reimbursement.

***External Reference Pricing* (A European Price Index)**

France (1999), Germany (2011) develop a price index and cap reimbursement (only for new drugs that are superior to existing products) to amounts paid by other European nations.

Reference Group Pricing for Comparable Drugs

Germany (1989), France (2003) group together comparable drugs which receive the same maximum reimbursement. U.K. cost-effectiveness appraisals (1999) produce similar result.

Maximum Reimbursement Not Adjusted for Inflation

France (1993), U.K. (1999), Germany (2011) do not adjust reimbursement caps for inflation.

Volume Discounts

France (1993), Germany (2007), U.K. (2017) decrease price as the volume purchased increases.

Procurement through Public Tenders

U.K., France, Germany procure drugs through public tenders when comparable products exist and pay less than maximum allowed reimbursement.

Global Pharmaceutical Spending Budgets

France (1999), U.K. (2014) introduce global budgets. If total spending exceeds the budget, manufacturers pay clawbacks to help recoup overspending.

Figure 1. Pharmaceutical price and cost control strategies in France, Germany & the United Kingdom and year of adoption.

P15

Is it economically efficient for Europe, to manufacture its own generic medicines, rather than importing from low manufacturing cost countries?

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Background: EU countries spend > € 70 Billion / year on generic medicines. If EU cost of production is relatively higher than lower cost countries (e.g. India), savings can be generated by increasing imports from these low cost options.

Objectives: European national healthcare expenses are growing at higher rate than GDP growths. In 2021, EU spent € 1179 billion or 8.1% of GDP

on healthcare. This is the second largest item of general government expenditure. One option in reducing healthcare costs is procurement of generic medicines at lower prices. However, relatively high cost of manufacturing within EU, result in shortages if procurement prices go below the EU27 production costs. Supporting continued local production, defies the objective of reducing costs. The ongoing doctorate research aims to find the equilibrium that addresses economic efficiency of make versus import choices.

Methodology: 1. Investigate Revealed Comparative Advantage in international trade of EU 27 in generics, for the top 10 EU countries (totalling 91% of exports in these trade categories) and India for year 2022, in categories HTC 3003 & 3004, using ITC Trade data for both Import and Export, and adjusting for GDP/capita using the formula of 'A New Class of Revealed Comparative Advantage Indexes' (Buitrago & Stellian, 2022):

$$[(RCA[X]-1)/(RCA[X]+1)-(RCA[M]-1)/(RCA[M]+1)]*2^{(1-y[i]/y*)}$$

where, RCA [X] = RCA of Exports; RCA [M] = RCA of Imports; y* = the mean value of GDP per capita for the countries of the data set; y[i] =the GDP per capita of country i,

2. Create Model to analyse manufacturing costs, import entry costs, profit margins and resulting prices and simulate different prices along with supply concentration to derive prices that are workable for suppliers, buyers and avoid shortages (due to suppliers dropping out as a result of non-viable prices) while meeting objective of containing costs for the healthcare system.

Region covered: The academic work is on EU27 and India. It involves research at International, National and Company level.

Time period: 2018 onwards. The academic work is still ongoing. The data for the Covid 19 years is being scrutinized for atypical behaviour.

Results: Below are the RCA results:

Belgium	Denmark	France	Germany	Ireland	Italy	Netherlands	Slovenia	Spain	Sweden	India
0.09	0.38	0.39	0.35	0.22	0.32	0.06	0.16	0.00	0.43	2.30

The formula adjusted for trade (that is, not just calculating for exports) and GDP per capita, demonstrates in the above result that India that has a lower GDP/capita than the other countries in the data set, shows higher RCA. That is, India with lower resources has higher comparative advantage. The absence of comparative advantage of EU27, restricts their exports to within the trade block and Switzerland.

Conclusions and lessons learned: The research done till now reveals that the EU27 countries do not have comparative advantage in international trade of generic medicines. Almost all of their exports are only within the trade block and with Switzerland. One of the reasons EU27 is not able to compete internationally could be their higher cost of manufacturing. Possible protection

provided by regulatory requirements, enables high priced sales within the block. This goes contrary to the objective of reducing healthcare costs.

Keywords: healthcare costs, generics, RCA, make or import
Funding source: none

Reference

Danna-Buitrago, J. P., & Stellian, R. (2022). A New Class of Revealed Comparative Advantage Indexes. *Open Econ Rev*, 33, 477–503. https://doi.org/10.1007/s11079-021-09636-4

P16

Prices and affordability of essential medicines in regions affected by conflict: the case of hypertension, diabetes, and epilepsy essential medicines in Northern Syria

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Background: Armed conflicts affect the functioning of health systems, including the performance of pharmaceutical systems and access to essential medicines. In Syria, the pharmaceutical system has deteriorated since the conflict's start in 2011, leading to systematic shortages of essential medicines. Prices increased by up to 50%, forcing many families to choose between securing food or medicines. The conflict turned manageable chronic diseases into life-threatening conditions. However, as often in conflict areas, accurate data on medicines' prices and affordability are scarce.

Objectives: We are conducting a study on the prices and affordability of essential medicines for hypertension, diabetes and epilepsy in Northern Syria, in order to illustrate the impact of the conflict on access to essential medicines.

Methodology: This is an explanatory mixed-methods study. First, we conducted semi-structured interviews, to capture the needs, perceptions and experiences of patients, pharmacists, representatives of NGOs and other stakeholders involved in health care and regulation. Interviews were conducted remotely, with purposefully-selected, consenting participants, in Arabic. They were recorded, transcribed, and translated into English. Following the thematic content analysis approach, data are coded and categorized and themes identified. Second, we will use the

WHO/Health Action International (HAI) methodology for measuring prices and affordability of essential medicines, adapting it to the constraints of the conflict-context. Prices will be expressed as median price ratios, and affordability will be estimated using the daily wage of the lowest-paid unskilled government worker and by determining the number of days' wages required to purchase the course of treatment. As we focus on NCD medicines, we will consider that if the total cost of a one-month treatment is lower than the minimum daily wage standard, the medicine is affordable, and vice versa.

Region covered: Northern Syria

Time period: March 2023–April 2024

Results: Preliminary results: For the qualitative component, we conducted, transcribed and translated 35 interviews. Thematic analysis is ongoing. For the quantitative component, data collection will start in early February. Five pharmacies and one primary care center have already informally agreed to participate, out of a planned sample size of 25 pharmacies and primary care centers.

Conclusions and lessons learned: The preliminary results of both components will be available in early April 2024, and they will be presented and discussed. We will also present and discuss the methodological adaptations required by this specific settings, and the experience of remotely engaging with representatives of the local community.

Keywords: conflict, access to medicines, non-communicable diseases, price, affordability

Funding source: King Baudouin Foundation (Fund Maurange)

POSTER PRESENTATIONS STRAND 2
P17

Twelve years of European cancer drug approval – a systematic investigation of the 'magnitude of clinical benefit'

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Background: In the context of a growing cancer burden due to higher life expectancy, as well as rising cancer drug expenditures for individual therapies and for the quantity of all therapies, it is ever more important to provide funders with objective information for their decisions. To maintain universal

health coverage, stakeholders and policymakers have to thoroughly decide on which medical interventions should be reimbursed.

Objectives: Thus, we aimed to identify the clinical benefit of cancer drugs and their authorised indication extensions at the time of European Medicines Agency (EMA) approval between 2009 and 2020 via two versions of the Magnitude of Clinical Benefit Scale (MCBS) developed by the European Society for Medical Oncology (ESMO). Scores resulting from the assessment with the original ESMO-MCBS were contrasted with a locally adapted version of the ESMO-MCBS utilised by the Austrian Institute for Health Technology Assessment (AIHTA). In addition, we compared two authorisation timeframes (2009–2014 versus 2015–2020) to investigate potential changes in ESMO-MCBS scores (original and adapted) over time.

Methodology: Originator solid cancer drugs and indication extensions that were approved between 1 January 2009 and 31 October 2020 by the EMA were included in our analyses. To evaluate the clinical benefit of these cancer indications, the original ESMO-MCBS (v 1.1) and a locally adapted ESMO-MCBS version were applied to the study sample.

Results: A total of 144 cancer indications intended as curative ($n = 9$) or non-curative ($n = 135$) treatment options were eligible for an ESMO-MCBS assessment. Solely a minority of the assessed cancer indications met the meaningful clinical benefit (MCB) criteria independent of the applied version of the scale and treatment intention (original: $n = 48/144$, 33.3% versus adapted: $n = 27/144$, 18.8%). Comparing the two EMA approval timeframes, a growing number of approved cancer indications could be observed: 2009–2014: $n =$ 9/year versus 2015–2020: $n = 14$/year. In addition, almost no difference in the proportion of cancer indications that have met the MCB criteria was detectable when comparing the predefined authorisation timeframes (MCB increase original: +4.1% and adapted: +3.9%) (Grössmann, Wolf, Rothschedl, & Wild, 2021).

Conclusions and lessons learned: Applying both versions of the ESMO-MCBS can help to identify potentially beneficial cancer indications, but also those with rather uncertain or low clinical benefit and thus, support the fair allocation of limited health care resources.

Keywords: -

Funding source: none

Reference

Grössmann, N., Wolf, S., Rothschedl, E., & Wild, C. (2021). 12-years of European cancer drug approval – a systematic investigation of the "magnitude of clinical benefit". *ESMO Open*. https://doi.org/10.1016/j.esmoop.2021.100166

P18

Needs Examination, Evaluation and Dissemination (NEED): A needs assessment framework and evidence database to support needs-driven innovation and policy in healthcare

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Background: Healthcare innovation and policy is currently predominantly supply-driven, leading to lack of innovation in financially less attractive health areas, inefficient use of public healthcare resources and unmet patient and societal needs (abbreviated here as UN). Scientific evidence on health-related UN is required to support the move towards more needs-driven healthcare policy and innovation.
Objectives: The NEED (Needs Examination, Evaluation, Dissemination) initiative aims at developing a common framework for identifying and assessing UN that can be used at European level, including explicit UN criteria and standardized procedures for collecting high-quality scientific evidence on UN. The ultimate aim is to establish a public UN evidence database to support different types of decision makers.
Methodology: To develop the UN assessment framework, two systematic literature reviews were conducted to identify potential patient, respectively societal, needs criteria. Draft versions of the framework were discussed with Belgian and international experts and stakeholders between April and November 2023. For each criterion, measurable indicators and data sources -quantitative and qualitative- were defined, or guidance on evidence generation was developed. A proof-of-concept was performed in Crohn's disease and Malignant Melanoma. A common methodology was used, including literature review, secondary data analysis, online patient surveys and semi-structured patient interviews. Survey results were analyzed using descriptive statistics, interview transcripts were analyzed using a thematic analysis.

Possible uses of the NEED database were discussed with (inter)national panels of experts, stakeholders and decision-makers.
Results: The NEED framework addresses patient, societal, and future needs across health, healthcare, and social domains. Patient-level needs encompass 5 criteria in the health domain, 4 in the healthcare domain and 4 in the social domain. Societal needs encompass 4 health-needs criteria, 2 healthcare-

needs criteria and 2 social needs criteria. Future needs criteria (2) are future burden of disease and economic burden. Equity is included as transversal dimension, requiring disaggregation of UN data by population sub-groups.

The pilot studies showed it is feasible to identify important UN, but challenges remain, such as generalizability across regions and patient representativeness. For some criteria, e.g. environmental impact of current treatment, data are not (yet) available.

Conclusions and lessons learned: The NEED assessment framework can lay the foundations for a shift towards more needs-driven healthcare policy and innovation. The NEED evidence database will collect evidence on UN, given current standard of care, independent of specific new products or services. It can be used by research funders, (drug) developers, regulators, HTA agencies, etc. for prioritizing areas for research or assessing the extent to which proposed 'solutions' meet the most pressing UN. Important challenges remain on different aspects of evidence collection, but through additional case studies, UN research will improve over time.

Keywords: unmet need, need assessment, health-related need, societal need, patient need

Funding source: This study was funded by the Belgian Health Care Knowledge Centre and Belspo, the Belgian Science Policy Office

P19

How to price advanced therapies? Mixed approach for valuing a new CAR-T Cell for Multiple Myeloma in Brazil

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Background: Multiple Myeloma (MM) is a challenging hematological malignancy, primarily treated with autologous stem cell transplantation (ASCT). However, relapse or refractoriness is inevitable, necessitating alternative treatments such as systemic chemotherapy with bortezomib and a 2nd

ASCT. Ciltacabtagene autoleucel, a novel therapy, has been presented as an alternative to a second ASCT.

Objectives: We have used two approaches for valuing ciltacabtagene autoleucel in the context of Brazilian health services (SUS): the Efficiency Frontier (EF) and the Pharmaceutical Innovativeness Index (PII).

Methodology: The PII is an HTA-based framework proposed as a tool to inform decision-making processes involving value-based pricing, reimbursement, and R&D investment. PII encompasses two clinical and two methodological domains, which are summed to compose the PII score (range from 0.0 to 1.0). The EF analysis suggests a maximum justified cost, providing a framework for pricing decisions. We conducted a comparative analysis using data from CARTITUDE-1 clinical trial and a Brazilian real-world cohort of MM patients who performed a 2nd ASCT in SUS.

Results: Ciltacabtagene autoleucel received the same ratings as the 2nd HPSCT in all PII domains. Both technologies showed important Therapeutic Need, and Added Therapeutic Value was moderate for both, with a 10% to 15% increase in overall survival. Studies were deemed to have inadequate study design. For Methodological Quality, evidence was assessed with a low risk of bias. The PII score was 0.705 for both technologies. PII results suggest ciltacabtagene autoleucel market value be equivalent to a 2nd ASCT (BRL193,114; i.e. USD39,654), as they share the same innovativeness. In the analysis of cost-effectiveness, ciltacabtagene autoleucel demonstrated a 7.27% increase in Area Under the Curve for overall survival over 48 months. The incremental cost was USD11,133 per month of survival. Over a 10-year horizon, the estimated cost for ciltacabtagene autoleucel was significantly higher than that for the 2nd ASCT. Using the EF approach, the cost of ciltacabtagene autoleucel should not exceed USD46,864.

Conclusions and lessons learned: Ciltacabtagene autoleucel demonstrates the same score of innovativeness than a 2nd ASCT and a significant antitumor activity in relapsed/refractory MM, with a survival advantage. In addition, the two approaches suggested similar prices for ciltacabtagene autoleucel. However, its international price is estimated at around USD456,000, approximately 10 times more than suggested by our analyses. The PII and the EF are tools adaptable to reduce analysis subjectivity and aid decision-making, including value-based pricing. This study highlights the importance of balancing innovation with comparative clinical effectiveness in price of medicines decision-making.

Keywords: pharmaceutical innovation, therapeutic value, innovativeness, assessment of health technologies.

Funding source: This project is the result of a partnership between the Department of Management and Incorporation of Health Technologies of the Secretariat of Science, Technology, Innovation, and Health Complex of the Ministry of Health (DGITS/SECTICS/MS) and UFMG.

P20

Prescrire's list of 'Drugs to avoid' 2023: a descriptive analysis on expenditure and consumption in Italy during 2022

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Background: Each year Prescrire, an independent French drug bulletin, releases a list of 'drugs to avoid', marketed in either France or the European Union between 2010 and 2022, that should not be used in clinical practice because they are considered to be more harmful than beneficial for patients (La Revue Prescrire, 2023). The aim is to improve the prescribing appropriateness of medicines and to evaluate their impact on national pharmaceutical policies and regulations (Mintzes & Vitry, 2021).
Objectives: This study aims to evaluate the number of drugs to avoid marketed in Italy and to review consumption and expenditure of those commercialized during 2022.
Methodology: Drugs to avoid listed by Prescrire in April 2023 were categorized by WHO Anatomical Therapeutic Chemical code. For each drug generic name, formulation, dosage, and regulatory status in Italy (defined as non-approved, approved but non-reimbursed, reimbursed, and reimbursed but non-commercialized in May 2023) was recorded. For all drugs reimbursed, national data on consumption, as Defined Daily Dose (DDD) per 1000 inhabitants per day and expenditure in 2022 were calculated by using the following national pharmaceutical databases: (i) OsMed flow for medicines dispensed by community pharmacies; (ii) Drug Traceability flow for medicines purchased by public healthcare facilities.

Region covered: EURO (Italy). The study is carried out at national level.

Time period: 2022

Results: In all, 56 (48.7%) of 115 drugs to avoid were marketed in Italy in 2022, the remaining 59 were excluded because not approved (20), not reimbursed (36), not commercialized (three). The 56 drugs belonging to 11 therapeutic categories were responsible for an overall expenditure of 1,150.93 million euros (4.9% of the national pharmaceutical expenditure) corresponding to a total consumption of 86.2 DDD/1000 inhabitants per day (6.9% of the consumption of all reimbursed drugs) for the year 2022. High levels of

consumption and expenditure were observed for only 15 drugs (out of 56 reimbursed) and olmesartan alone or in combination with hydrochlorothiazide or amlodipine was found as the most consumed drug on the list.
Conclusions and lessons learned: Few studies examining marketing status of Prescrire 'drugs to avoid' were available, and none in Italy. Our study showed that half of drugs to avoid were commercially available in Italy, but few were widely prescribed, resulting in a limited impact on national pharmaceutical expenditure and consumption. Prescrire's assessments could provide a reliable external benchmark to assess the national pharmaceutical policies.
Keywords: drugs to avoid, consumption, expenditure, reimbursement, national formulary, evidence-based medicine
Funding source: Italian Medicines Agency (AIFA)

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P21

Using the efficiency frontier analysis to guide pricing decision-making for an advanced therapy

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Background: Multiple Myeloma (MM) is a challenging hematological malignancy, primarily treated with autologous stem cell transplantation (ASCT). However, relapse or refractoriness is inevitable, necessitating alternative treatments.
Objectives: This study evaluates ciltacabtagene autoleucel, a novel therapy, against a second ASCT, using an efficiency frontier approach to assess its therapeutic value and cost-effectiveness. Employing efficiency frontier

analysis, it compares the novel therapy with second autologous stem cell transplantation.

Methodology: We conducted a comparative analysis using data from CARTITUDE-1 clinical trials and Brazilian Health Services (SUS) data of MM patients treated under SUS. We estimated survival curves and Area Under the Curve (AUC) for both interventions over 48 months and projected the curves for a 10-year horizon using parametric distributions. Cost-effectiveness was assessed by calculating the incremental cost per month of survival. Efficiency frontier methodology was employed to determine a proportional price for ciltacabtagene autoleucel, based on the cost and median survival benefits compared to the second ASCT.

Results: Ciltacabtagene autoleucel demonstrated a 7.27% increase in Area Under the Curve (AUC) for overall survival over 48 months compared to the second ASCT. The incremental cost was BRL54,219.15 (USD11,133.30) per month of survival. Over a 10-year horizon, the estimated cost for ciltacabtagene autoleucel was significantly higher than that for the second ASCT. Using the efficiency frontier approach, the cost of ciltacabtagene autoleucel should not exceed BRL228,226.42 (USD46,863.74), considering its survival benefit and cost of production.

Conclusions and lessons learned: Ciltacabtagene autoleucel demonstrates significant anti-tumor activity in relapsed/refractory MM, with a notable survival advantage. Efficiency frontier analysis suggests a maximum justified cost, providing a framework for pricing decisions. This study highlights the importance of balancing innovation with cost-effectiveness in healthcare decision-making.

Keywords: Multiple Myeloma, Ciltacabtagene Autoleucel, Efficiency Frontier, Cost-Effectiveness

Funding source: This project is the result of a partnership between the Department of Management and Incorporation of Health Technologies of the Secretariat of Science, Technology, Innovation, and Health Complex of the Ministry of Health (DGITS/SECTICS/MS) and UFMG.

P22

Role of Health Technology Assessment in Pricing of Anti-Cancer Drugs in India

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Background: In developing nations, access to anti-cancer treatments is frequently determined by financial constraints. While newer anti-cancer drugs promise improved health outcomes, they often come with higher costs. Efficiency in a health system is gauged by its ability to maximize health gains from available resources. This necessitates assessing whether the added cost of new treatments justifies the additional health benefits. Health technology assessment (HTA) aids in making informed decisions by evaluating the relative costs and benefits of available interventions.

Objectives: Our study aimed to assess the cost-effectiveness of 16 anti-cancer drugs selected for price regulation by India's National Pharmaceutical Pricing Authority (NPPA). The objective was to inform the design of health benefit packages by incorporating cost-effective medications and determining the price point at which a drug becomes cost-effective in the Indian context.

Methodology: Using mathematical modelling, we estimated lifetime costs and consequences, measured in quality-adjusted life-years (QALYs) and life-years, for cancer patients. Separate models were developed for each drug, delineating health states of progression-free survival (PFS), progressive disease (PD), and death. Effectiveness parameters were based on Indian data, including PFS and overall survival (OS) for treatment arms. Survival curves were derived from literature and digitized, with the best-fitting distribution selected based on statistical criteria, visual inspection, and clinical plausibility. Monthly transition probabilities were estimated, and societal costs of drug regimens were considered, including direct non-medical expenditures. Data on these costs and health-related quality of life were sourced from a nationally representative Cancer Database on Costs and Quality of Life (CaDCQoL) study. Incremental cost-effectiveness ratios were compared against the cost-effectiveness threshold equivalent to India's annual per capita gross domestic product (GDP). Price threshold analysis was conducted to identify the cost-effective price for each drug.

Region covered: The study covers SEARO and was carried out at national level in India.

Time period: Date Begun- 1st June 2020. Date ended- 31st May 2022.

Results: Among the drugs analyzed, only two were deemed cost-effective within the current pricing structure. Substantial price reductions ranging from 35% to 90% were necessary to make the remaining drugs cost-effective. The specific outcomes for each drug, along with the required price adjustments, are summarized in Table 1.

Conclusions and lessons learned: These economic evaluations provide evidence-based pricing for cost-effective anti-cancer drugs, which could be achieved through regulatory measures or bulk purchasing. Public procurement agencies can use this evidence for negotiating prices effectively. HTA holds promise in enhancing the efficiency, affordability, and equity of oncology services. However, challenges persist due to India's fragmented health financing system, necessitating alignment between national insurance schemes and HTA evidence. Legislative support for HTA could play a crucial role in achieving universal coverage and an efficient health system for Indian patients.

Keywords: economic evaluation, oncology, cost effectiveness, drug pricing, India

Funding source: Department of Health Research, Ministry of Health and Family Welfare, Government of India

Table 1. Summary of cost-effectiveness analyses conducted as a part of study.

Type of cancer	Drugs /Regimen	Incremental cost per QALY gained	Whether cost-effective or not?	Value-based price
Metastatic Renal Cell Carcinoma	Sunitinib	₹143,269	Cost-effective	-
Chronic Myeloid Leukemia	Dasatinib	₹ 237,583	Not cost-effective	21 % in the reimbursement rate (₹ 5,500 to ₹ 4,345)
Metastatic Breast cancer Scenario I: Payer's perspective Scenario II: Societal perspective (using market prices)	Fulvestrant	Scenario I: ₹ 660,797 Scenario II: ₹ 963,208	Not cost-effective	Scenario I: 72 % reduction in the reimbursement rate (₹ 12,000 to ₹ 3,360) Scenario II: 78% reduction in market price (₹ 12,000 to ₹ 2,640)
Cervical cancer	Bevacizumab plus chemotherapy	₹ 25,75,624	Not cost-effective	-
Gliobastoma Multiforme	Temozolamide plus radiation therapy	₹212,354	Not cost-effective	90 % in the market price (₹ 12,000 to ₹ 3,360)
Breast cancer adjuvant chemotherapy	Trastuzumab along with ₹ 178,877	Not cost-effective	35% reduction	

(*Continued*)

Table 1. Continued.

Type of cancer	Drugs /Regimen	Incremental cost per QALY gained	Whether cost-effective or not?	Value-based price
at 1 year/9 months/6 weeks			in market prices (₹ 16,998 to 11,049)	
Chronic Lymphocytic Leukemia	1st Line Bendamustine and 2nd line Ibrutinib	₹ 3,45,689	Not cost-effective	80% for Ibrutinib
Chronic Lymphocytic Leukemia	Single Line Bendamustine/ Ibrutinib	₹ 1,66,126 (for BR) and ₹ 4,94,340 (for IBR)	Not cost-effective	90% for Ibutinib
Metastatic breast cancer	Zoledronic acid 4 mg (4 weekly)	Ranging between ₹ 69,444 and ₹ 75, 578 (according to molecular subtype of MBC)	Cost-effective	-
Metastatic breast cancer	Denosumab 120 mg (12 weekly)	Ranging between ₹ 29,859,330 and ₹ 53,625,910 (according to molecular subtype of MBC)	Not cost-effective	-
Multiple myeloma (Newly diagnosed transplant-eligible- Stage 1, 2 and 3)	Bortezomib, Lenalidomide and Dexamethasone (VRd) alone versus Bortezomib, Thalidomide and Dexamethasone (VTd) alone	₹ 2,20,093	Not cost-effective	50% reduction in the market price, i.e., from ₹ 17,800 to ₹ 8,900 for VRd, ₹ 7200 to ₹ 3600 for pomalidomide plus dexamethasone, ₹4800 to ₹ 2400 for lenalidomide and societal cost of transplant from ₹3,53,027 to ₹1,76,513
	VTd alone versus Bortezomib, Cyclophosphamide and Dexamethasone (VCd)	₹ 4,19,920	Not cost-effective	
	VRd followed by Autologous stem cell transplantation (AHSCT) versusVRd alone	₹ 3,14,530	Not cost-effective	
	VTd followed by Autologous stem cell	Extendedly dominated	Not cost-effective	

(*Continued*)

Table 1. Continued.

Type of cancer	Drugs /Regimen	Incremental cost per QALY gained	Whether cost-effective or not?	Value-based price
	transplantation versus VCd followed by Autologous stem cell transplantation			

P23

Market entry agreements for innovative pharmaceuticals subject to indication broadening: a case study for pembrolizumab in the Netherlands.

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Background: Managed entry agreements (MEAs) and especially financial based agreements are commonly used in European countries for innovative cancer pharmaceuticals. These agreements facilitate access to innovative treatments while mitigating financial risks for payers (Godman et al., 2021).
Objectives: This study focuses on the confidential price agreement made by the Dutch government for the reimbursement of pembrolizumab, the implications of broadening indications on cost-effectiveness, and the viability or desirability of said agreement.
Methodology: We selected five indications where pembrolizumab was deemed effective and developed portioned survival models for each indication. Survival and progression-free survival data from the published trials were utilized to recreate individual patient data and were extrapolated –using parametric models– to a time horizon of 30 years. Inputs for both quality of life and costs were derived from available literature and were indexed if needed.

Region covered: The MEA in this case study is from the Netherlands. However, the results might also be relevant for other EU member states

that engage in financial based agreement for pembrolizumab or other cancer medicines subject to indication broadening.

Time period: Reimbursement started in 2017 for the Netherlands. New indications were included till 2022.

Results: The incremental cost-effectiveness ratios (ICERs) ranged between €35,313 and €322, 349 per quality-adjusted life-year (QALY) depending on the indication. Only one indication fell under the €80,000 (or €100,000) cost-effectiveness threshold. When applying the average reported discount on intramural pharmaceuticals in the Netherlands, ICERs ranged between €20,881 and €252,934 per QALY gained, and the €80,000 (or €100,000) threshold was met in three indications out of five.

Conclusions and lessons learned: Our results show that pembrolizumab could be cost-effective in some indications, depending on the confidential price agreement established. However, the possibility of reimbursing not cost-effective care when the price is anchored in one indication remains possible. Indication-based pricing (IBP) could help align value and price for innovative pharmaceuticals that are subject to indication broadening.

Keywords: managed entry agreements, value based pricing, cost-effectiveness, pricing, pharmaceutical pricing, Pembrolizumab

Funding source: No funding was received for this study.

Reference

Godman, B., Hill, A., Simoens, S., Selke, G., Selke Krulichová, I., Zampirolli Dias, C., et al. (2021). Potential approaches for the pricing of cancer medicines across Europe to enhance the sustainability of healthcare systems and the implications. *Expert Review of Pharmacoeconomics & Outcomes Research*, *21*(4), 527–540.

Table 1. Deterministic ICERs.

Trial and indication	Type utility	ICER	incremental costs	incremental Qalys
keynote-006 melanoma	TTD	€154,025	€237,402	1.54
keynote-006 melanoma	HS	€176,709	€237,402	1.34
keynote-010 advanced NSCLC	TTD	€173,449	€159,218	0.92
keynote-010 advanced NSCLC	HS	€196,758	€159,218	0.81
keynote-024 NSCLC	TTD	€35,313	€83,907	2.38
keynote-024 NSCLC	HS	€45,576	€83,907	1.84
keynote-048 R/M HNSCC	HS	€126,330	€84,977	0.67
keynote-426 advanced RCC	TTD	€322,349	€223,766	0.69
keynote-426 advanced RCC	HS	€312,793	€223,766	0.72

Non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), renal-cell carcinoma (RCC), recurrent or metastatic (R/M), time-to-death (TTD), health state (HS).

Table 2. ICERs across studied indications with a 33.6% price reduction of pembrolizumab price.

Trial and indication	Type utility	ICER	incremental costs	incremental Qalys
keynote-006 melanoma	TTD	€50,747	€78,218	1.54
keynote-006 melanoma	HS	€58,221	€78,218	1.34
keynote-010 advanced NSCLC	TTD	€112,323	€103,108	0.92
keynote-010 advanced NSCLC	HS	€127,418	€103,108	0.81
keynote-024 NSCLC	TTD	€20,881	€49,615	2.38
keynote-024 NSCLC	HS	€26,949	€49,615	1.84
keynote-048 R/M HNSCC	HS	€75,468	€50,764	0.67
keynote-426 advanced RCC	TTD	€260,662	€160,539	0.69
keynote-426 advanced RCC	HS	€252,934	€160,539	0.72

Non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), renal-cell carcinoma (RCC), recurrent or metastatic (R/M), time-to-death (TTD), health state (HS).

P24

A new methodological framework for valuing Health Technologies Innovation: The Pharmaceutical Innovativeness Index (PII)

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Background: The pricing of any pharmaceutical product should be based on its value, with value understood as its therapeutic benefits in consideration of social health needs. Health Technology Assessment (HTA) is crucial for informing decision-making on pricing, reimbursement, investment, also providing a means to determine the quality and value of pharmaceutical innovations. However, defining innovation or assessing the value of pharmaceutical products can be challenging.

Objectives: Existing published methodologies aim to evaluate the value of innovation (i.e., innovativeness) but often display a high degree of subjectivity and lack transparency regarding the criteria used. Interpreting innovativeness as the added therapeutic value, accounting for the preferences and needs of society, this study introduces a transparent framework, complete with clearly defined criteria and a script, to determine innovativeness. This tool can serve as a foundation for Value-Based Pricing (VPB) strategies.

Methodology: The study was developed by adapting two HTA-based methods identified in the literature through a comprehensive search. The instruments were applied to oncology drugs approved by the FDA between 2011 and 2021 by a group of researchers who, after each round of evaluation, discussed and aligned parameters, criteria, and domains in consensus meetings. For domains identified as relevant, objective criteria were established for classification into levels, and each level received a grade according to its relevance.
Results: The Pharmaceutical Innovativeness Index (PII) was proposed, along with an evaluation framework, domains, criteria, and an algorithm. The evaluation should begin by defining the clinical indication, outcomes of interest, identification of therapeutic alternatives, perspective, and data sources for analysis. Four domains were considered: (1) Therapeutic Need, evaluates the existence and benefits of alternatives; (2) Added Therapeutic Value, assesses the incremental clinical benefit compared to alternatives; (3) Study Design; and (4) Methodological Quality. The criteria for the drug to be categorized at each level can be adapted according to the clinical indication and predefined outcomes. Domain weights were assigned by the researchers considering the social perspective and further validated in a focus group with clinicians.
Conclusions and lessons learned: The PII framework considers clinical and social value weighted by the methodological limitation of available evidence to determine the value of innovation of pharmaceutical products. It stands out as a transparent, adaptable, and reproducible tool, aiming to reduce the subjectivity of analyses and has the potential to inform decision-making processes involving VBP, reimbursement, pharmaceutical market investors, researchers, physicians, governments, and R&D investment.
Keywords: pharmaceutical innovation, therapeutic value, innovativeness, assessment of health technologies
Funding source: This study was supported by the Department of Management and Incorporation of Health Technologies of the Secretariat of Science, Technology, Innovation, and Health Complex of the Ministry of Health (DGITS/SECTICS/MS) and funded through doctoral scholarship from the Minas Gerais State Research Support Foundation (FAPEMIG).

P25

Review of definition of the high-cost medicines for pharmaceutical spending management in South Korea

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Background: Recently, expensive drugs such as Zolgensma® and Kymriah® have been listed and health insurance expenditure has increased due to policies to strengthen patient accessibility. It therefore became necessary to manage reimbursement for expensive drugs. As a starting point for this, it has become important to define high-cost medicines, select target drugs and manage them according to their clinical and financial characteristics, utilizing policies such as performance-based managed entry agreements (MEA). There is no clear definition of high-cost drugs in Korea.
Objectives: To operationally define high-cost drugs in Korea.
Methodology: An operational definition of high-cost drugs was created through review of domestic and international regulations, literature review, claim data analysis, expert consultation, and focus group interviews (FGI) and in-depth interviews (IDI) (34 people). We reviewed the definition of high-cost medicines by the WHO, UK, Canada, Australia, Taiwan and pre-existing definition in regulations and research papers. We also analyzed the Korean National claims data (number of products, patients and amount) according to the standards of definition of high-cost medicines such as 1,000 South Korean won (KRW), 3,000 KRW, 5,000 KRW, 10,000 KRW and 30,000 KRW. Through FGI and IDI, we gathered the various stakeholders' opinions about the definition of high-cost medicines. Considering all factors, we finally made the definition of high-cost medicines in Korea.
Results: There is no consistent definition of high-cost drugs in other countries, but recent definitions of high-cost medicines stated that the annual treatment cost per person was 100,000 dollar and more (Canadian PMBRB, Taejin Lee et al. 2022 and others). Claims data analysis showed an annual medication cost of 100 million KRW or more per person accounted for the top 1.2% of drugs (39 ingredients, 41 items, approximately 400 billion KRW). Through monitoring, FGI, and IDI stakeholder opinion collection, 11 out of 34 people responded that 100 million KRW was appropriate.

Conclusions and lessons learned: In Korea, high-cost drugs are defined as those costing more than 100 million KRW based on the annual treatment cost per person. High-cost medicines will be managed through a new high-cost medicines policy utilizing performance-based MEA from 2024.
Keywords: -
Funding source: no financial support

P26

Real world data based pricing policy for ATMP in France

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Background: Advanced therapy medicinal products (ATMP), especially gene therapies, represents a growing challenge for the payers. These products claiming long lasting effects after their administration often provide limited clinical data to demonstrate it. Moreover, the claimed prices for ATMP have skyrocketed over the years. The current pricing system makes it difficult to take long-term uncertainty into account, leading de facto to a 'pay to see' policy threatening the sustainability of the healthcare system.
Objectives: The French government is implementing a reform of the pricing policy applied to ATMP (Article 54 of the social security financing law (SSFL) for 2023) aiming at moving towards a 'see to pay' approach, while limiting the impact of ATMP on healthcare establishments (HE) cash flow.
Methodology: This is a description of a policy under implementation.
Region covered: This measure will be applied nationally in France.
Results: Article 54 of SSFL 2023 introduces the setting of an 'innovative therapy lump sum' corresponding to the maximum amount that can be invoiced when the treatment is administered, and the establishment of complementary payments as part of a mandatory performance-based pricing agreement negotiated with the economic committee (EC). At the treatment administration, the HE will make an initial payment (1) to the laboratory corresponding to the threshold set by the ministers. This payment will be reimbursed by the national health fund (NHF) (2). Then, if needed, the laboratory will have to organise and finance (partially or fully) the collection of data measuring the effectiveness of the treatment in real life for each patient (3). The amounts paid by the NHF (4) will be determined on the basis of clinical results, in accordance with the agreement drawn up

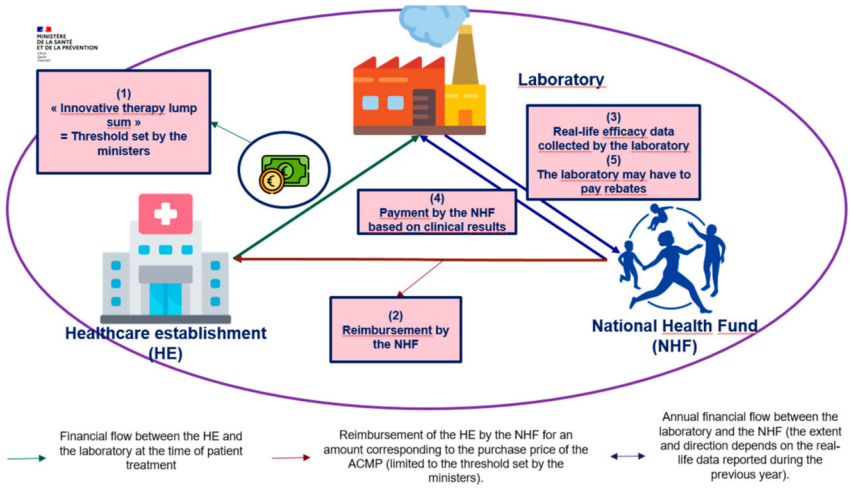

Figure 1. Money and data exchanges.

between the laboratory and the EC. This follow-up can last up to several years. In the event of partial or total failure of the treatment, the NHF's payments to the laboratory for the treatment of this patient may be reduced or interrupted, or lead to a call for rebates (5) (Figure 1). The implementing regulations are in the process of being published.

Conclusions and lessons learned: This measure represents an innovative approach to managing long-term clinical uncertainty and pricing innovative treatments such as gene therapies, thereby improving access for French patients while ensuring the sustainability of the healthcare system.

Keywords: ATMP, performance-based pricing, RWE

Funding source: Direction de la Sécurité Sociale

P27

Establishing National hospital Costing Systems: Learnings from the Indian Experience

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Background: Launched in 2018, PM-JAY is India's largest health assurance scheme, but accurate cost estimates are hindered by limited data patient-level information, affecting pricing decisions (Singh et al., 2022). Similar challenges exist in low- and middle-income settings due to data limitations and digitization gaps.

Objectives: A cost-surveillance pilot was initiated that gathered patient characteristics and resource data to determine price weights for varying disease severities. A qualitative evaluation was undertaken to outline challenges and implementation recommendations for India and other LMICs.

Methodology: We conducted in-depth interviews for a qualitative study involving empanelled providers, National Health Authority (NHA), and State Health Authority (SHA) representatives. Seven facilities were selected from each state based on ownership, bed capacity, pilot enrolment status, and NABH accreditation. Both participating and non-participating hospitals were included. We also interviewed three NHA representatives and five SHA officials from the sampled states. All participants gave informed consent for publication.

Region covered: The study evaluated the PM-JAY cost-surveillance pilot in India (WHO Southeast Asia region). It was conducted in five states (Haryana, Kerala, Chhattisgarh, Maharashtra, and Kerala), encompassing 61 PM-JAY empanelled hospitals. We sampled Haryana, Chhattisgarh, and Kerala based on the pilot's initiation date and geographical location.

Time period: The NHA initiated the cost-surveillance pilot in October 2022. Qualitative interviews were conducted across three states from January to February 2023, followed by verbatim transcript development, coding, and thematic analysis over the next two months.

Results: Our study found significant challenges in reporting cost data at the hospital level. Firstly, existing hospital staff lacked sufficient capacity to provide complete and high-quality data due to basic non-medical qualifications, limited training, and frequent turnover (Figure 1). Secondly, the process was resource and time-intensive, straining constrained capacity. Thirdly, there were operational issues with the TMS, including concerns about speed, user-friendliness, and frequent page expirations, particularly in small to medium-sized providers. Finally, existing patient records did not reliably capture information on consumables used and prices of certain inputs.

Conclusions and lessons learned: Generating accurate cost information for price-setting is complex and resource-intensive, but essential for evidence-informed health policy decisions and promoting efficient service delivery. The ongoing cost surveillance pilot for PM-JAY marks progress towards robust and evidence-based price-setting processes. To ensure sustainability, capacity-building at all healthcare levels is crucial for accurate data capture.

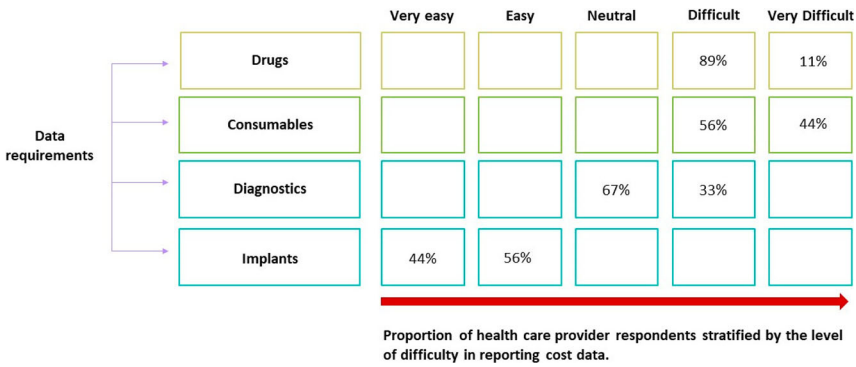

Figure 1. Difficulty in reporting healthcare cost data to the transaction management system.

Integration into existing digital infrastructure is necessary to prevent additional burdens on healthcare providers and ensure data quality. India's journey and strategies offer valuable lessons for other lower- and middle-income countries striving for Universal Health Coverage.

Keywords: Ayushman Bharat, publicly finances health insurance, provider-payment reforms, price setting, digital health

Funding source: Bill & Melinda Gates Foundation

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POSTER PRESENTATIONS STRAND 3
P28

Increasing prices to ensure availability of medicines? Financial incentives implemented as shortage mitigation policy in PPRI member countries

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Background: There have been indications that financial incentives, in particular higher prices for generic medicines, have increasingly been granted by authorities to mitigate medicine shortages.
Objectives: To survey the implementation of financial incentives as a policy measure to reduce or avoid medicine shortages in Europe and globally.
Methodology: A 2023 survey was conducted with public authorities that are members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. The methodology was based on a previous survey on this topic conducted in 2020 (Vogler & Fischer, 2020), however extended by questions on financial incentives.

Regions covered: Globally, with a focus on the WHO European Region: Information is available from 34 WHO European Region countries (thereof 24 European Union Member States) and four further countries (Australia, Brazil, Canada, Saudi Arabia).

Time period: Information was collected on policy measures taken in the period from 2020 to 2023. 2023 data relate to Q4/2023 for 27 countries and to Q2/2023 for 11 countries.
Results: 18 of the 38 countries of the study reported to have granted incentives related to prices or reimbursement, usually targeting generic medicines with comparatively low prices. The majority of the countries assessed on a case-by-case basis requests of pharmaceutical companies for higher prices; additionally, some countries systematically introduced increases of prices (or reimbursement amounts) for defined medicines, and/or passed legislation for doing so. Common ways of implementation were price increases for medicines priced below a defined limit (e.g., Australia and Portugal), increases of the reimbursement amounts (e.g., Netherlands), compensation of supply chain actors for increased costs (e.g., Germany, Norway) and exemptions for defined medicines from standard pricing and reimbursement policies (e.g., Brazil, Germany, Greece). Reimbursement procedures were eased, e.g., to facilitate patient access to magistral preparations produced in a community pharmacy (Austria, Switzerland), and co-payment rules were relaxed to reduce price competition (Germany). A move to prioritisation of security of supply over price was observed in tenders (e.g., Germany). Most financial incentives were introduced in late 2022 or in 2023.
Conclusions and lessons learned: The study showed that several countries added financial incentives, mainly targeted at the pharmaceutical industry, to the toolbox of policy options for mitigating medicine shortages. Implementation was done through different approaches, but price increases tend to dominate. No indication was found for systematically linking financial incentives to obligations from suppliers (e.g., securing availability). While an impact assessment of the incentives was beyond the scope of this study and it may be too early, governments are urged to ensure evaluation of the policies.
Keywords: drug shortage, price increase, incentive

Funding source: The financial support of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection to the PPRI Secretariat for the management of the PPRI network is gratefully acknowledged.

Reference

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P29

Using futures methods to think through financing for medicines R&D and issues of access

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Background: Financing plays a key role in determining the medicines that will be available in the future and whether they will be accessible. However, the financial ecosystem for medicines R&D is complex -- Public, private and third sectors all play a role, each with their own motivations, interests and ways of working. A wide variety of inter-connected factors influence the financial system, including public policy, global events, and developments in health systems and financial markets (Parkinson, Romanelli, Phillips, Alom, & Marjanovic, 2021).
Objectives: We conducted a study for the Dutch Ministry of Health, Welfare and Sports to provide an evidence base to inform dialogue around the financial ecosystem for medicines R&D. As part of this study, we conducted a futures exercise to gather evidence about potential future developments in the financial ecosystem for medicines R&D. The objective of this exercise was to bring key stakeholders from across sectors together to consider the challenges, risks and opportunities that may arise in the future, and what should be done today to be more prepared.
Methodology: The futures exercise consisted of developing future scenarios describing how the financial ecosystem for medicines R&D may develop over the next ten years using a structured approach. Three future scenarios were then presented and discussed by 15 participants in a two-hour workshop.
Results: This exercise highlighted several areas where the financial ecosystem for medicines R&D may be made more prepared for future challenges, risks

and opportunities. Potential actions to improve the sustainability of the financial ecosystem for medicines R&D include: Investment in basic science and research infrastructure to promote a steady supply of scientific and technological advances; Clearly signalling demand and willingness to pay for innovations in key areas that align with societal needs; Building capacity to absorb innovation in healthcare systems; Improving how data and digital technologies are used in medicines R&D; and Considering different payment models (e.g. value-based pricing and subscription models) and push and pull incentives to help balance the need to reward investors for taking risks with the need to ensure access to innovations (Kalindjian et al., 2022).

Conclusions and lessons learned: This futures exercise revealed the importance of taking a joined-up approach to research, industrial and healthcare policy. More generally, it demonstrated the utility of futures methodologies in thinking through policy options in contexts of uncertainty and complexity.

Keywords: futures methodologies, future scenarios, medicines R&D, financing

Funding source: Dutch Ministry of Health, Welfare and Sports

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P30

Break on through (to the other side). A case study on increasing access to affordable CAR-T therapy through an academic hospital's alternative innovation model

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Background: High costs and limited availability of advanced therapy medicinal products (ATMPs) such as Chimeric Antigen Receptor T-Cell (CAR-T) therapies have raised concerns about the sustainability of health systems and equitable access to these technologies, despite their transformative potential for patients. These concerns highlight the need for alternative innovation models and policies that can offer greater affordability and accessibility to these cutting-edge technologies.
Objectives: We explore the potential of academic development of CAR-T therapies in Europe as alternative innovation models, by studying the regulatory, economic, political and social factors that shaped the development of ARI-0001 (Varnimcabtagene autoleucel) by Hospital Clínic Barcelona (HCB). This is the first CAR-T therapy developed in Europe, currently priced two-thirds lower than comparable therapies from the pharmaceutical industry.
Methodology: We applied thematic analysis (framework method) to 22 semi-structured interviews with HCB staff, representatives of regional and national health departments, regulatory agencies, academics, and civil society and patient groups. The conceptual framework draws from the application of complex adaptive systems to the pharmaceutical research and development (R&D) system. The framework used categorized the resources used (e.g., funding, knowledge, manufacturing capacity, relationships with actors) and practices implemented (e.g., knowledge management, access practices) by HCB.

Region covered: EURO region (Spain), global scope.

Time period: From the start of ARI's development (2010s), to the present.
Results: HCB's alternative innovation model draws from two different logics, each one with its strengths and weaknesses. As part of the healthcare system, societal norms shaped access and affordable pricing of ARI-0001, but also posed organizational challenges to operate as a drug developer. As an academic institution, HCB followed academic norms in sharing knowledge and technology openly with peers, However, they struggled to access academic funding to cover the late-stage clinical trials and EMA's regulatory costs. Lastly, HCB leveraged its in-house regulatory expertise, collaborated with different actors, and used the hospital exemption clause to break on through some of the challenges of entering the 'industrial logic'.
Conclusions and lessons learned: As policymakers consider how to amend the EU's pharmaceutical legislation during 2024, our findings underscore the potential of the hospital exemption to facilitate the academic development of affordable ATMPs. By enhancing regulatory and financial support to academic hospitals, strengthening coordination across the value-chain (from developers to regulatory and purchasing agencies), and conditioning public support on affordability and access, Europe and other countries adopting

similar rules can consolidate this alternative innovation model to balance innovation with accessibility and affordability in a cutting-edge technological area.

Keywords: access to medicines, alternative innovation models, pharmaceutical policy, pharmaceutical innovation, advanced therapy medicinal products

Funding source: Swiss National Science Foundation PRIMA Grant (179842)

P31

Defining fair prices for new health technologies

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Background: Rising list prices for new health technologies and concerns about their budget impact on publicly financed health system raise the question of what a fair price for new medicines and medical devices should be. Patients, payers, manufacturers, researchers, and other stakeholders have different understandings of fair pricing for health technologies. It is unclear what aspects these stakeholders emphasise when defining fair prices.

Objectives: The objective of this study was to review existing definitions of fair prices for new, potentially innovative, health technologies and to understand which elements make up these definitions.

Methodology: We reviewed existing definitions of fair prices for medicines and medical devices published from 2014 to 2023 to identify common themes. Using pre-specified inclusion and exclusion criteria, we identified existing definitions through database searches in MEDLINE via PubMed and Google Scholar, through websites of organisations and associations working in the field of pricing and reimbursement of pharmaceuticals and medical devices, and through expert consultation (research partners and advisory board members of the EU-funded ASCERTAIN project representing various stakeholder groups).

Time period: Documents published from 2014 to 2023 were included.

Results: We reviewed 1,206 unique records and included 37 definitions of fair pricing for new health technologies. None of the definitions focused on medical devices. Four core themes for fair pricing were commonly included

in existing definitions. Affordability of medicines and financial sustainability for health systems and patients was mentioned in 59% of definitions. The costs of bringing a medicine to the market, including research and development, production and other costs, was mentioned in 57%, but not in any of the three definitions from industry authors. 65% mentioned the value of new health technologies, covering different aspects, including (additional) therapeutic value, reflections of societal preferences and, in economic terms, welfare. 62% mentioned profits for companies to reward innovation, incentivise future innovation, and ensure supply of medicines in the long term. None of the included definitions considered environmental sustainability.

Conclusions and lessons learned: Existing definitions of fair prices for medicines clustered around four core themes: costs of developing and manufacturing them, affordability for health systems and patients, value to patients and / or society, and profits for companies. Even though there was overlap with respect to these general themes across definitions, a joint understanding of fair pricing for new health technologies has not been established. More work is also needed to define fair pricing for medical devices. Existing definitions may need to be expanded to address changing societal priorities, including the environmental impact of health technologies.

Keywords: Fair pricing, pharmaceuticals, value-based pricing, cost-based pricing

Funding source: Funded by the European Union. Views and opinions expressed are however those of the authors only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them. Grant 101094938.

P32

The financial impact of novel therapeutic entities in Italy

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Background: Pharmaceutical spending is increasing, especially in the hospital setting due to higher costs of new medicines, technological advancement as well as longer life expectancy. The introduction of new drugs has been considered as one of the major drivers for the pharmaceutical spending

increase. Nevertheless, studying spending trends for new drugs and estimating their impact on the national budget is considered challenging because of difficulties with retrieving data. To our knowledge, there is a paucity of studies assessing the key drivers of pharmaceutical spending and, specifically, the impact of novel therapies in the European jurisdictions and in particular in Italy. Several studies were conducted in the USA and Canada.

Objectives: The aim of this paper was to analyse the financial impact of the new therapeutic entities (NTEs) on public pharmaceutical expenditure from 2014 to 2022 in Italy. Moreover, the sales and mean cost NTEs since the first market entry were also estimated.

Methodology: NTEs marketed in Italy, having at least one package sold, were identified in the period 2014–2022. Medicines with multiple manufacturers (more than one firm) and those with expired patent were excluded. The first date of generic entry in the transparency list database was considered as a proxy of its patent expiry. Moreover, medicines with authorization time longer than 15 years were excluded. In order to evaluate the sales and mean cost per defined daily dose (DDD) trend since first marketing, only medicines with first commercialization in 2014 were considered; they were identified among those with no packs sold in 2013.

Region covered: EURO Region: Italy. The study was conducted at national level. Time period: 2014–2022

Results: The NTEs spending, going from 5.1 billion euro in 2014 to 8.5 billion euro in 2022, has steadily grown in the 2014–2022 period, with an increase of 65% (compound annual growth rate (CAGR) of 5.7%), compared to a 26% public health facilities growth in the same period (CAGR of 3%). The incidence of the expenditure of NTEs on the total NHS expenditure recorded in each year from 2014 to 2022 has increased over the years, going from a share of 25.3% in 2014 to 34.3% in 2022. An important growth was recorded in the share of orphan drugs on the NTEs spending and for medicines belonging to ATC L. It was observed that in the third year of marketing, sales were doubled compared to that of the first year and the cost per DDD was descending.

Conclusions and lessons learned: The NTEs represented a critical share of the public pharmaceutical spending in Italy and their financial impact has been growing over time. This implies the need to develop appropriate methods for spending projections in order to adequately allocate resources and to apply appropriate policies for the pricing of these drugs.

Keywords: new drugs, pharmaceutical spending

Funding source: none

P33

Made in Europe - assessing the feasibility of reshoring active pharmaceutical ingredient (API) production to Europe

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Background: Some active pharmaceutical ingredients (APIs) are mainly produced in Asian countries where manufacturing costs are lower compared to European countries. To reduce the dependency on Asia for certain APIs and potentially prevent future medicine shortages, the relocation of API production to Europe (reshoring) has recently been discussed.
Objectives: To explore key enablers and barriers that impact reshoring of API production to Europe and to identify prerequisites for successful reshoring processes.
Methodology: A review was conducted, identifying peer-reviewed publications as well as grey literature. As the results of the literature review were inconclusive, focus group interviews with national stakeholders, representing policy-makers, the pharmaceutical industry and research from three countries (Austria, France and Spain) were conducted to gain insights into stakeholder perspectives. These countries were selected based on their size and experiences in reshoring initiatives. The results of the three focus group interviews held between October and November 2023 were examined applying a qualitative content analysis.

Region covered: Global, with specific focus on Austria, France, and Spain.

Time period: The review included literature published between 2010 and 2023. The focus group interviews were conducted in Q4/2023.
Results: A list of critical APIs for reshoring activities, European coordination of reshoring and encouraging local production in form of financial incentives were identified as key enablers regarding reshoring. The cost of API production in Europe was considered as a main barrier. Further perceived obstacles included different legal frameworks and practices in public procurement of medicines (price as main or exclusive award criterion, single-winner bids). Fostering innovative technologies for manufacturing, the willingness of stakeholders to invest

in reshoring and improved cooperation, particularly between industry and policymakers, were mentioned as prerequisites for reshoring during the interviews. Interviewees indicated coordinated stockpiles and the diversification of API suppliers as alternative solutions to medicine shortages.

Conclusions and lessons learned: While stakeholders in France and Spain perceived reshoring API production to Europe as a realistic and highly promising approach, Austrian stakeholders expressed doubts whether it would be feasible. In any case, strengthening of (existing) local production of APIs was considered high priority in all countries. As a first step to support reshoring, stakeholders felt that it would be important to incentivize and encourage local production by changing current pharmaceutical pricing and procurement practices. Moreover, a European framework and stronger cooperation between industry and policymakers were mentioned as important prerequisites to coordinate API production in Europe.

Keywords: reshoring, local production, API production

Funding source: The study was partially funded by the European Parliament.

P34

Exploring the Environmental, Social, and Governance (ESG) Performance in the Pharmaceutical Sector and its Impact on R&D

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Background: The healthcare sector significantly contributes to greenhouse gas (GHG) emissions, responsible for 4.4% of global emissions and accounting for 12% and 27% of the global healthcare carbon footprint in the EU and US, respectively. This sector is a major concern under the United Nations' 2030 agenda and the European Green Deal, as it contributes to environmental degradation.

Objectives: This study aims to present a descriptive analysis of panel data on the ESG performance trends of the pharmaceutical and healthcare sector in Europe and the US. The study also seeks to develop a theoretical framework to analyze the impact of ESG performance on research and development (R&D) investment.

Methodology: This study presents a descriptive analysis of ESG performance and employs ordinary least square (OLS) and generalized method of moments (GMM) regression models to provide empirical evidence on the

relationship between ESG performance and R&D investment using a panel data sample of European and US healthcare firms from 2016 to 2022 using Refinitve database.

Region covered: EU27, UK, and Switzerland. Northern and Latin America.

Time period: 2016–2022

Results: We posit a positive and significant association between ESG performance and R&D investment based on a holistic perspective of stakeholder, resource-based and agency theories. Moreover, we reveal that the social aspect of ESG in the healthcare sector across Europe, Northern, and Latin America outweighs the environmental and governance aspects. Despite the adverse impact of the healthcare sector on (GHG) emissions, our analysis further shows that the environmental pillar of ESG carries the lowest weighting. The higher social and governance pillar scores indicate that the healthcare sector positively impacts product access and affordability, product quality and safety, human capital development, diversity, and inclusion. Our analysis shows that pharmaceutical firms have the lowest ESG scores compared to other healthcare industries, such as life sciences tools and services and healthcare equipment and supplies. However, healthcare technology firms tend to score lower on all ESG factors due to their growth stage and lack of direct control over factors affecting their ESG rating.

Conclusions and lessons learned: This study has important implications for practitioners and policy makers considering the role of ESG performance in R&D investment. Specifically, our analysis reveals that healthcare firms prioritize the social aspect of ESG to manage relationships with all stakeholders despite their negative impact on environmental sustainability. At present, healthcare firms seem to struggle with managing the full range of ESG issues that may impact them.

Keywords: ESG performance, R&D investment, pharmaceuticals, Europe, US.

Funding source: This project has received funding from the European Union's horizon Europe research and innovation programme under grant agreement number 101095593.

P35

From Concept to Action: The Development of a Horizon Scanning System at the Directorate for Pharmaceutical Affairs in Malta

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Background: Prior to the implementation of the DPA-HSS, DPA lacked horizon scanning capabilities for medicines. This deficiency resulted in lack of forsesight for pipeline medicines, hindering effective assessment and planning in pricing and reimbursement.
Objectives: The DPA Horizon Scanning System (DPA-HSS) project aimed to establish a HSS to provide insights on pipeline medicines, allowing decision-makers to maximize budgetary decisions and strategic policymaking (Vogler, 2022). This poster describes the setup and functioning of the DPA-HSS.
Methodology: DPA developed Malta's first HSS for medicines in 2020 (Directorate for Pharmaceutical Affairs, 2021). After policy research examining international HSSs and other data sources, followed by a piloting period, an SOP including an application form was developed. The DPA-HSS is request-based, activated when stakeholders request information on a medicine, class, or disease. Requests are prioritized according to urgency. Information is gathered from free public sources (HSSs, databases, grey literature, and data from manufacturers). For each request, a HS report including core information and additional information is requested, is prepared. HS reports and statistics are maintained in an internal database.
Results: The DPA-HSS has seen a year-on-year increase in use since launch, with 11 requests processed in 2020, 15 in 2021, 15 in 2022 and 21 in 2023. The prevalent disease areas were malignancy (53.7%), skin (18.5%), musculoskeletal (18.5%) and nervous system diseases (9.3%) (Figure 1). The DPA-HSS is also used to produce annual pipeline biosimilar reports. Use of the DPA-HSS has so far been limited to pharmaceuticals.
Conclusions and lessons learned: Despite limited resources, the DPA-HSS is proving valuable as a policy tool for DPA by providing early information on pipeline medicines. It improved strategic decision-making in medicines access and aided health technology assessors in the HTA review process. Inclusion of medical devices, direct liaison with manufacturers for pipeline information, and the use of HS information in price negotiations are being explored. Limitations include limited access to data from free public sources.
Keywords: Horizon, scanning, pipeline, emerging, medicines

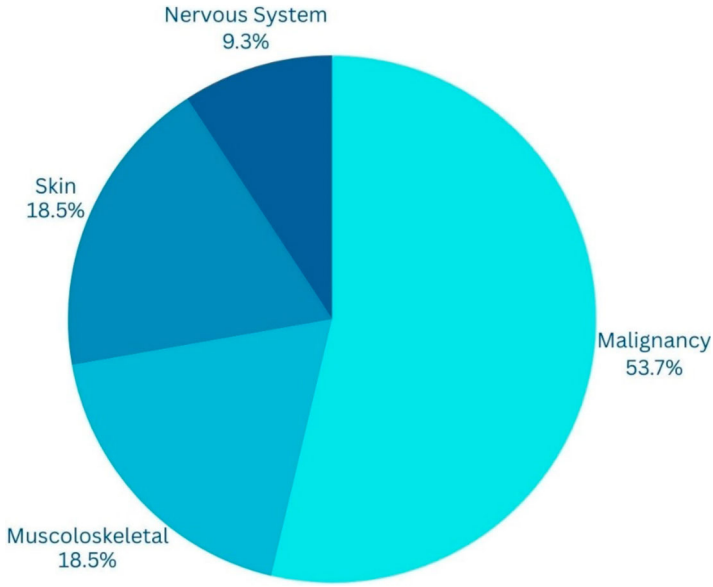

Figure 1. Most common disease areas for HS requests.

Funding source: Directorate for Pharmaceutical Affairs

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P36

Evaluation of National Formulary Policy Implementation in Primary Health Care: Lesson Learned from Indonesia

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Background: Essential medicines were a priority to fulfil the needs of the population. The Indonesian government has implemented the national formulary policy to improve public access and ensure the quality of medicines. There has been no evaluation of this policy at the primary healthcare level during the universal health coverage program implementation in Indonesia since 2004.

Objectives: To evaluate the implementation of national formulary policy in primary health care facilities from Indonesia.

Methodology: A mixed-method research design with an embedded approach was used in this study. Quantitative data was taken from the medicine utilization report and request sheets for the June-December 2022 period. Data was taken from the district health office. Conformity to the national formulary in primary healthcare was defined as percentage of the number of medicines that comply with the national formulary divided by the number of medicines available in primary care. Qualitative data used was an online questionnaire form filled by the pharmacy staff in primary health care facilities. The questionnaire used was sourced from the Indonesian Minister of Health regulations No. 54/2018 about the Preparation and Implementation of The National Formulary in the National Health Insurance program. This study covers five provinces in Indonesia, namely Bali, Daerah Istimewa Yogyakarta, Jambi, East Java, and South Sulawesi.

Region covered: The region covered was the World Health Organization South-East Asia (WHO SEARO) and the country was Indonesia. The study was carried out at the national level with five provinces participating.

Time period: This research was done from January until October 2023.

Results: Quantitative data was obtained from 68 of 87 (78.2%) district health offices from five provinces. Qualitative data was obtained from 674 respondents. Conformity to Indonesian Essential Medicine List was 93.23% while conformity to the national formulary in primary healthcare was 87.25%. Non-formulary medicines were vaccines, vitamins, and therapies for COVID-19. There are also several cough and cold medicines that do not comply with the national formulary. Challenges to the implementation of the national formulary were knowledge of the prescriber about the national formulary medicines list, knowledge of the patients about national formulary policy, geographical factor, and referral back program implementation.

Conclusions and lessons learned: Medicines utilization in primary healthcare was in congruence with the Indonesian Minister of Health regulation because the conformity to the national formulary is more than 80%. Several challenges need to be addressed for the national formulary policy implementation in primary care in Indonesia.

Keywords: universal health coverage, national formulary, primary health care, policy implementation, policy evaluation.

Funding source: This study was funded by WHO Indonesia.

P37

Restoration of Medical Devices in France as a new measure for a sustainable healthcare and a circular economy

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Background: The healthcare sector in France is responsible for 8.2% of greenhouse gas emissions. In 2020, the government developed its 4th National Health and Environment Plan aiming to reduce the healthcare ecological footprint, for instance by limiting healthcare product waste. The French social security financing law (SSFL) for 2020 (1) supports this commitment by introducing the restoration of several Medical Devices (MD) allowing their use by another patient as well as another reimbursement by the French health insurance.
Objectives: To introduce the restoration of MD to good working order and its economic, environmental, and societal benefits in France.
Methodology: The Ministry of Health has implemented the use of restoration of MD to good working order since the SSFL for 2020, modifying the French social security code and French public health code. Additional official texts will list all the necessary conditions.

Region covered: Study is located in France.

Time period: From 2020 until now

Results: Restoration of MD to good working order consists in allowing the reuse of a MD by another user after the original owner and assuring that all maintenance and servicing operations are carried out on that device without altering its performance and safety. It is only possible for certain MD listed by the Ministry of Health. Centers or professionals that will carry out this restoration must be certified attesting their conformity with the requirements defined by a French standard (AFNOR) in order to guarantee the quality and safety of restored MD. The decree also allows the reimbursement of certain restored MD by the health insurance. A MD specific-flat fee set by the French Healthcare Products Pricing Committee will finance the restoration. In order to ensure the traceability of these reimbursed restored MD, they must be identified in an information system called the Registration of the Official Circulation of MD (ECO-DM). Wheelchairs are the first MD concerned by the restoration to good working order. Annual savings of €10 million for the French health insurance could be expected as well as an estimated reduction of 3.15 × 106 kg eCO2.

Conclusions and lessons learned: Restoration of MD to good working order will demonstrate long term advantages in ecological footprint, patient access, sustainability and efficiency of health insurance costs. Following this modification, new green measures have been introduced in 2023 such as financial penalties for MD generating supplementary medical waste and introduction of single-use MD reprocessing.

Keywords: restoration of medical device, safety, quality, circular economy, sustainable healthcare

Funding source: Ministry of Health

P38

Strengthening primary health care through a stronger emphasis on patient and community centered medicines and pharmaceutical services

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Background: Equitable access to safe, effective, quality-assured, and affordable essential medicines and vaccines for all has been defined as one of the UN Sustainable Development Goals. Since the Declaration of Alma Ata, the understanding about medicines and vaccines within PHC-oriented health systems has expanded, with medicines/vaccines not simply being regarded as commodities or infrastructure but being seen and accepted as community-centred pharmaceutical care offering futureproofing services.

Objectives: To describe and suggest innovative PHC-oriented policies to improve access to medicines and pharmaceutical services

Methodology: The research is based on a pragmatic scoping review (performed in Q1/2023) of published peer-reviewed and grey literature on access and affordability to medicines in PHC-oriented systems. Results from literature were firstly categorized into challenges of access to medicines and pharmaceutical services using the Levesque et al. (2013)'s adapted framework of access dimensions, including affordability, availability, acceptability, appropriateness and approachability (awareness). Secondly,

innovative PHC-oriented policy solutions were collected and then described per access dimension including practical examples from different countries around the world. Finally, four best practice country examples were identified to describe in more detail different PHC-oriented policy solutions.

Region covered: The research represents global findings with four case study examples from Brazil, Thailand, England and India.

Time period: 2023

Results: Ensuring public coverage of essential medicines for PHC is key to protect individuals and households from financial hardship and guaranteeing access to needed medicines. Demand-side measures such as generic substitution and prescribing by international non-proprietary name are additional key steps to promote affordability and appropriate use. Patient involvement in prioritizing medicines and empowering communities to enhance medication management is a necessary but often neglected core element of a PHC-oriented health system. Policy interventions which help improve medicine literacy can foster trust in generics, biosimilars and vaccines, and this is a prerequisite for their adequate use. Bringing medicines closer to patients and collaboration between health professionals and across sectors supports the concept of PHC for medicines and pharmaceutical services. Finally, multi-sectorial collaboration such as health and educational sector are needed but underutilized.

Conclusions and lessons learned: A PHC-oriented system requires a shift from viewing medicines as commodities and supply-side focused policies towards demand side-oriented policies with emphasis on multi-sectoral collaboration and community engagement to build trust. The pathways to progress towards effective PHC should be accompanied by monitoring and evaluation. The findings from this review on different access dimensions of medicines and pharmaceutical services illustrate that without appropriate evaluation it is not possible to know whether the policies and programs achieve their desired objectives and how to mitigate unintended consequences. Evaluation strategies should be built in the PHC implementation from the very beginning, including the development of key indicators and data required to measure them.

Keywords: primary health care, affordability, availability, acceptability, appropriateness, pharmaceutical services

Funding source: World Health Organization / European Observatory on Health Systems and Policies

Reference

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P39

Pharmaceutical pricing system in Saudi Arabia

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Background: In 2020, the World Health Organization (WHO) published the WHO Guideline on Country Pharmaceutical Pricing Policies (GCPPP) (Wolrd Health Organziation, 2020) which recommended 10 policies to be utilized by decision-makers in setting pharmaceutical pricing guidelines for their respective countries.

Objectives: It is not clear if the Saudi healthcare system has adopted policies in the WHO GCPPP when pricing or reimbursing pharmaceutical products. The study aims to describe the Saudi Pharmaceutical Pricing System (SPS) based on the revised pharmaceutical pricing rules published by the SFDA and assess the utilization of different pricing policies according to GCPPP. It will also recommend key policies to be integrated into SPS. The findings of the study would help in closing the literature gap on the current landscape of the pricing system and help researchers, policymakers, pharmaceutical industry, and interested individuals to understand pharmaceutical pricing processes in Saudi Arabia.

Methodology: This is a descriptive study to illustrate the current concepts applied to pricing of pharmaceuticals in Saudi Arabia. The study examined the presence of GCPPP within SPS under the respective jurisdiction of each governmental authorities. A database search was conducted on available policies, guidelines, and official documents regarding pharmaceutical pricing within Saudi Arabia. The study looked into published literature, Arabic or English, on the Saudi healthcare system between February and May 2022.

Region covered: Saudi Arabia

Time period: 2/2022 till 5/2022

Results: Of the 10 policies in GCPPP, 4 are fully practiced in SPS (Figure 1). An accumulated 82% of GCPPP presence in SPS was calculated. Based on the reviews conducted on SPS and GCPPP, there were a set of recommendations to be considered for the SPS such as: establishing a countries selection process for the utilization in the ERP, developing an affordability monitor system, inclusion of budget impact and affordability analyses, publishing pharmaceuticals' assessments reports, developing a value definition applicable across the healthcare system, create remuneration or mark-up regulations that incentivize supply of specific pharmaceuticals or for specific

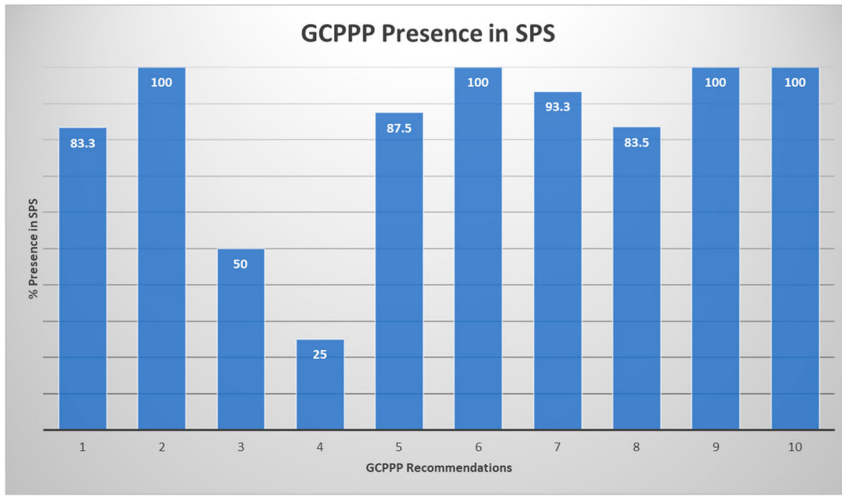

Figure 1. GCPPP presence in SPS.

Table 1. Description of articles in the Saudi PPR and its related policy in the GCPPP.

Article No.	Article Description in the Saudi PPR	Related Policy No. in GCPPP
1	Defining terms and meanings mentioned in the Saudi PRR to provide clear understanding of the guidelines	5
2	Listing of information taking into consideration when pricing pharmaceutical products	5
3	Explaining the different mechanisms of pricing innovative and biological pharmaceutical products giving the information in article 2	1, 2, 3, 5, 6, 9
4 5	Describing the reduction to innovative pharmaceuticals upon the introduction of identical generic and the mechanism for pricing these generics	2, 5, 7
6 7	Describing the reduction to biological pharmaceuticals upon the introduction of identical biosimilars and the mechanism for pricing these biosimilars	2, 5, 7
8	Explaining the mechanisms utilized to price combined pharmaceutical products	2, 5
9	Limiting the discount applicable to pharmaceuticals when repriced to 30% of its previous price	5
10	Allowing the pricing committee to revise pharmaceutical's price after two years of first registration if they are expensive and/or have uncertainties surrounding their health outcomes	3, 5, 6
11	Allowing the pricing committee to revise pharmaceutical's price during registration if the pharmaceutical is within therapeutic group price revision, the pharmaceutical's price decreased in home country or marketed countries, or the pharma company requested a price revision for its pharmaceutical	1, 2, 5, 6
12	Explaining the mechanisms of pharmaceuticals' repricing when re-registration is due (usually every 5 years) and the consequences for the price-linked products of the repriced pharmaceutical	2, 5, 7
13 14 15	Referring to the situations requiring price revision or fixation during marketing or manufacturing transfer for established and emerging pharma companies	5, 6
16 17	Describing the mechanisms for pricing pharmaceuticals with different pack-sizes, dosage forms, or medical indications than that of the registered pharmaceutical	2, 3, 5

(*Continued*)

Table 1. Continued.

Article No.	Article Description in the Saudi PPR	Related Policy No. in GCPPP
18	Stating that an addition of 2% for insurance and fright is given for a pharmaceutical if priced from the home country or manufacturing price in marketed countries	1, 5, 9
19	Allowing the pricing committee to provide an additional 20% for a pharmaceutical that establish added value to the registered alternative therapies	2, 3, 5
20 21	Explaining how the handling process will be for innovative / biological pharmaceuticals when they are applying for registration after their withdrawal from the market or the registration of an identical generic / biosimilar pharmaceutical	5, 7
22	Stating that a pharmaceuticals will not be discounted twice within a period of two years from its last price reduction	5
23	Stating that the price set by the committees is considered as a celling price, and pharma companies has the right to sell the pharmaceutical product at a lower price if needed	3, 5, 6, 8
24	The committee reserve the right to exclude any pharmaceutical from this guideline if there is any possible consequence that affects the availability of pharmaceuticals in Saudi Arabia	5, 6
25	The pharma company has the right to appeal any price decisions made for its pharmaceutical products within 60 days of the committee decision	5, 6
26	The pharma company has the right to apply for the price before registration service after providing the required documents, and the price would be valid for 9 months if the pharmaceutical product is registered within that period	5, 6

populations, publish prices and methods for setting up mark-ups along the supply chain, set a regular review of mark-up regulations that analyze the pharmaceutical market to protect from out-of-pocket expenditures, develop incentives for dispensers that encourage utilization of low-priced generics and biosimilars, and publish policies and procedures for financing healthcare in Saudi Arabia including pharmaceuticals pooled procurement (Tables 1-2).

Conclusions and lessons learned: SPS is practicing most of the policies included in the GCPPP with a huge emphasis on process transparency. In future studies, we recommend exploring each policy in the GCPPP independently to assess the utilization in practice.

Keywords: Saudi Arabia, pharmaceutical pricing system, pharmaceutical pricing rules, WHO Guideline on Country Pharmaceutical Pricing Policies

Funding source: none

Reference

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Table 2. Linking policies in the GCPPP with SPS.

Policy No.	Policy Description in GCPPP	Presence in SPS
1. ERP	A. WHO suggests the use of ERP under the following conditions: I. EPR is used in conjunction with other policies (especially price negotiation) II. There are resources to implement ERP III. Reference countries are selected based on explicitly stated factors IV. The prices obtained from verified sources V. Reference prices have accounted for taxes, discounts, and rebates if any VI. Mechanisms for setting the prices follow a consistent and clear process	Partially present (83%), as the policy (1.A) is found in the Saudi PPR (articles 3, 11, and 18) with resources available at the SFDA, except for (1.A.III) where there is no published selection factors for reference countries
	B. WHO suggests that countries undertake regular price revisions at pre-specified frequency when using external reference pricing	Fully present (100%), as the policy (1.B) is found in the Saudi PPR (articles 3, 11, and 18)
	C. WHO suggests that countries monitor the impacts of implementing external reference pricing on price, affordability, and access to pharmaceuticals	Partially present (67%), as the policy (1.C) is found in Saudi PPR (articles 3, 11, and 18) and availability of pharmaceuticals is tracked and monitored by the SFDA while access is handled by the MOH. But pharmaceuticals' affordability are not monitored by the authorities after pricing
2. IRP	A. WHO suggests the use of IRP for generic and biosimilar pharmaceuticals according to the principles of generic / biosimilar linkage pricing, under the following conditions: I. IRP is used in conjunction with policies to promote the use of quality assured generic and biosimilar pharmaceuticals. II. The prices obtained are from authenticated sources III. Consistent and clear criteria for generic / biosimilar pharmaceuticals pricing are explicitly evaluated and stated based on an established methodology.	Fully present (100%), as the policy (2.A) is found in the Saudi PPR (articles 3 to 8, 11, 12, 16, 17, and 19)

(*Continued*)

Table 2. Continued.

Policy No.	Policy Description in GCPPP	Presence in SPS
	B. WHO suggests the use of IRP for pharmaceuticals according to the principles of therapeutic reference pricing, under the following conditions: I. IRP is used in conjunction with other pricing policies II. The prices obtained are from authenticated sources III. Consistent and clear criteria, including therapeutic or dose equivalence, are explicitly evaluated and stated based on an established methodology.	Fully present (100%), as the policy (2.B) is found in the Saudi PPR (articles 3 to 8, 11, 12, 16, 17, and 19)
3. VBP	A. WHO suggests the use of VBP for pharmaceuticals to support price setting, and reimbursement decision-making where appropriate, under the following conditions: I. VBP is utilized in conjunction with other pricing policies, such as price negotiation, IRP, ERP, and policies to promote the use of quality-assured generic and biosimilar pharmaceuticals II. There are resources to implement VBP III. VBP utilizing HTA must include an analysis on budget impact and affordability from the perspective of the payer and the patient IV. There should be a well-established governance for VBP using HTA to ensure processes are clear, and assessment reports and decisions are disseminated publicly V. Methods and perspective for defining value are clear VI. Decisions and evidence should be periodically reviewed and re-evaluated	Partially present (50%), as the policy (3.A) is found in Saudi PPR (articles 3, 10, 16, 17, 19, and 23) with resources available at the SFDA, except for (3.A.III-V) where there are no specific definitions, guidelines, structure, or published reports for this policy
4. Mark-Up Regulation	A. WHO suggests the use of mark-up regulation across the supply and distribution chain for pharmaceuticals under the following conditions: I. Mark-ups should be utilized in combination with other pricing policies II. Mark-up structure should be regressive, where the rate decreases as the price increases rather than a fixed percentage mark-up for all pharmaceuticals	Fully present (100%), as the policy (4.A) is found in the law of pharmaceutical and herbal establishments and preparations (2020)

	B. WHO suggests that countries consider using remuneration and mark-up regulation as incentives for supplying specific pharmaceuticals or to protect access to pharmaceuticals for specific patients (e.g. generic and biosimilar pharmaceuticals, low volume pharmaceuticals, pharmaceuticals for vulnerable patients, populations living in isolated areas)	Not present (0%), as the policy (4.B) is not found in law of pharmaceutical and herbal establishments and preparations or Saudi PPR
	C. WHO suggests that countries ensure transparency of prices and methods when setting up mark-ups along the supply and distribution chain, including disclosure of any rebates and discounts	Not present (0%), as the policy (4.C) is not applied in Saudi where the SFDA do not publish prices across the supply chain
	D. WHO suggests regular review of mark-up regulation to protect patients from out-of-pocket expenditures	Not present (0%), as the policy (4.D) is not changed in the law of pharmaceutical and herbal establishments and preparations in the last 50 years
5. Price Transparency	A. WHO suggests that countries improve the transparency of pricing and prices through the following mechanisms: I. Sharing of pharmaceutical prices with relevant stakeholders II. Disclosing prices along the supply chain III. Reporting R&D contributions publicly from all sources IV. Sharing pricing decisions to the public	Partially present (75%), as the policy (5.A) is practiced by the SFDA and PPED, except for (5.A.II) where there are no published prices across the supply chain
	B. WHO suggests that countries improve the transparency of pricing and prices through clear description of pricing approaches and their technical requirements	Fully present (100%), as the policy (5.B) is found in the Saudi PPR (all articles) and SFDA's Drug Master File (DMF) Guidance for Submission
6. Tendering and Negotiation	A. WHO suggests that countries use tendering for pharmaceutical products under the following conditions: I. Considering other criteria alongside price level such as product quality, availability, supply security and reliability, and charges along the supply chain II. Tendering should be used in combination with other policies to improve affordability and availability	Fully present (100%), as the policy (6.A) is the sole purpose of NUPCO where it's usually following the registration process at the SFDA to ensure there are harmonization between the two entities and their processes

(*Continued*)

Table 2. Continued.

Policy No.	Policy Description in GCPPP	Presence in SPS
	B. WHO suggests utilizing price negotiation to complement tendering as well as other policies	Fully present (100%), as the policy (6.B) is practiced by both the SFDA in price setting (in PPR articles 3, 10, 11, 13 to 15, and 23 to 26) and by NUPCO in the tendering process
7. Promoting the Use of Generic and Biosimilar	A. WHO recommends the early market entry of generic and biosimilar pharmaceuticals through legislative directives, with a view to encourage early submission of regulatory applications allowing for prompt and effective review of these pharmaceuticals	Fully present (100%), as the policy (7.A) is practiced by the SFDA and the Guidance for Priority Review of Product Registration to fasten the entry of the first and second generic or biosimilar
	B. WHO recommends that countries use multiple pricing policies to achieve low prices for generic and biosimilar pharmaceuticals that are informed by the cost of production to lower patient co-payments. These pricing policies may include: IRP, mark-up regulation, direct price controls, tendering, promoting price transparency	Fully present (100%), as the policy (7.B) is found in the law of pharmaceutical and herbal establishments and preparations and the Saudi PPR (articles 4 to 7, 12, 20, and 21) and practiced by the SFDA
	C. WHO recommends that countries should implement and mandate a set of policies including: I. Legislation to allow generic and biosimilar pharmaceuticals substitution by dispensers, where applicable II. Legislative structure and incentives for prescribers to prescribe by International Non-proprietary Name (INN) III. Appropriate financial or non-financial incentives for dispensers, including dispensing fees that encourage utilization of low-price generic and biosimilar pharmaceuticals IV. Regressive mark-up structure where lower rates of mark-ups are applied for higher-priced pharmaceuticals V. Education programmes for consumers and professionals regarding the quality, safety, efficacy and price of generic and biosimilar pharmaceuticals	Partially present (80%), as the policy (7.C) is found in the law of pharmaceutical and herbal establishments and preparations and practiced by the SFDA, MOH (2017), and SHC, except for (7.C.III) where there are no incentives indicated for dispensers in any legislative document
8. Pooled Procurement	A. WHO suggests the use of pooled procurement of pharmaceuticals under the following conditions:	Partially present (67%), as the policy (8.A) is practiced by NUPCO, except for (8.A.III) where there are no clear information on the financing or budget allocation for pharmaceuticals' procurement

	I. Pooled procurement should be utilized in combination with other pricing policies, such as tendering and negotiation. II. Procurement processes are transparent and accompanied with high standard of governance III. Financing for pooled procurement must be sustainable and predictable with dedicated resources to stabilize initial regional pooled procurement efforts	
	B. WHO suggests considering initiation of pooled procurement of pharmaceuticals under the following conditions: I. Pooled procurement is initiated with a clear awareness of the price and non-price benefits to be achieved (e.g. quality, availability, administrative efficiencies, bargaining power, improved capacity to forecast, collective technical expertise) II. Pooled procurement is initiated with a clear interpretation of the regulatory policies, quality assurance, patent laws, and financing processes in participating jurisdictions	Fully present (100%), as the policy (8.B) is practiced by NUPCO with coordination with different governmental entities such as SFDA (to ensure comply with article 8 in the PPR) and MOH to be aware of related policies and directives
9. Cost-Plus Pricing	A. WHO suggests against utilizing cost-plus pricing as a primary policy for setting the price of pharmaceuticals, given the current lack of transparency or an agreed framework among stakeholders regarding the inputs for price determination using this policy	Fully present (100%), as the policy (9.A) is found in the Saudi PPR (articles 3 and 18) to be utilized in conjunction with other policies and not considered as a stand-alone pricing policy
10. Tax Exemptions	A. WHO suggests that countries consider exempting essential pharmaceuticals and active pharmaceutical ingredients from taxation	Fully present (100%), as the policy (10.A) is practiced by the Zakat, Tax and Customs Authority in Saudi, where there are no taxes on pharmaceuticals (ZATCA, 2020)
	B. WHO suggests that countries consider any tax reductions or exemptions, with measures to ensure that the policy results in lower prices of pharmaceuticals to patients and consumers	Fully present (100%), as the policy (10.B) is practiced by the Zakat, Tax and Customs Authority in Saudi, where there are no taxes on pharmaceuticals (ZATCA, 2020)

P40

Strategic Framework for Effective Price Control in the Indian Medical Device Market: A Methodological Approach

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Background: The Indian government actively regulates medical device pricing through two strategies: fixed ceiling prices via formula-based calculations and restrictions to curb excessive hikes. Addressing COVID-19 challenges, the National Pharmaceutical Pricing Authority (NPPA), India in July 2021 aimed to enhance affordability by regulating pulse oximeters, Blood pressure monitors, nebulizers, thermometers, and glucometers, capping their trade margins. Only few devices like intrauterine devices, condoms, coronary stents, drug-eluting stents, and orthopedic implants are currently price-controlled in India using the Trade Margin Rationalization (TMR) (National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Government of India, n.d).

Objectives: Despite these efforts, there is no uniform national policy for medical device price control. To foster industry growth, encourage innovation, and improve product accessibility and affordability, the NPPA should implement a streamlined regulatory framework for comprehensive medical device price control. The objective of this paper is to formulate a comprehensive framework for the price regulation of medical devices in India, emphasizing the delicate balance required between ensuring accessibility and affordability of essential medical devices, while concurrently fostering innovation and market competition.

Methodology: The methodology employed involved a focused literature review of diverse policies pertaining to price regulation, complemented by consultations with key stakeholders including policymakers and researchers. This paper presents an innovative pricing framework for medical devices, synthesized from comprehensive analysis of available data and resources (Table 1).

Results: The suggested framework (Figure 1) categorizes medical devices into scheduled and non-scheduled devices similar to drugs, with the latter subject to price monitoring. Within the scheduled category, devices are further classified into Homogenous and Non-Homogenous. For Homogenous devices with minimal variation in design and function, a Ceiling Price determined by the median of market prices is recommended. On the other hand, non-homogenous

devices, characterized by significant variations, are subcategorized based on their health and non-health benefits. For devices offering health benefits, a risk-based classification (Class A, B, C, D) using the Central Drugs Standard Control Organization (CDSCO) criteria is proposed. Moderate and high-risk devices (Class C and D) would be subject to value-based pricing employing Health Technology Assessment Informed Ceiling Prices. Class A and B devices, along with devices offering non-health benefits, would follow a Differential TMR approach. This approach considers two criteria for differentiation: a regressive approach based on the original price, prioritizing high costs with less markup, and a second criterion based on inclusion in the Pradhan Mantri Jan Arogya Yojana package, warranting a reduced markup.

Conclusions and lessons learned: In addition to implementing the framework, it is proposed to systematically monitor and assess the execution and effects of various proposed strategies on the pricing, accessibility, and affordability of devices.

Keywords: price control, value based pricing, trade Margin Rationalization, Medical Devices, Price Regulation

Funding source: none

Reference

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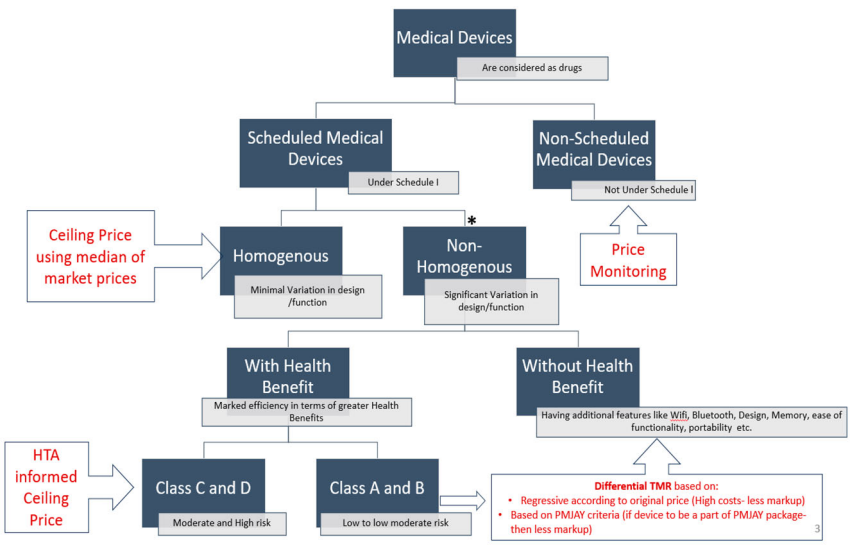

**If there is variant of medical device/product by company that has additional feature that offer significant health benefit or non-health benefit, it should be given different price.*

Figure 1. Proposed framework for price control strategies for medical devices in India.

Table 1. Intent and rationale for recommending the different approaches for price control strategies in India and mapping of the requirements for application of the framework, existing resources, and potential stakeholders.

Approaches recommended	Intent for recommending	Rationale for recommending	Requirements	Current status of resources/ capacity and stakeholders
Price Monitoring for Non-Scheduled Medical Devices	Balance strict price control policies with market dynamics; allow non-scheduled devices to compete freely, but with controlled price increments.	Recognizing potential negative implications of rigid price controls, this approach encourages free market competition for non-scheduled devices. The controlled price monitoring ensures reasonable increases, maintaining a balance between affordability and market dynamics.	Information on Market Prices of all Medical devices	This has been done for drugs, similar can be replicated for Medical Devices National Pharmaceutical Pricing Authority (NPPA)
			Classification of Medical Devices into Scheduled and Non-Scheduled Medical Devices	Can be replicated as done for the drugs – NPPA
Trade Margin Rationalization (TMR) for Class A and B devices offering significant health benefits and devices offering non-health benefits	Utilize the TMR approach, previously employed by NPPA for drugs and some medical devices.	Recognizing the applicability of TMR, this approach ensures a fair pricing structure. Acknowledging the diversity in medical devices, two potential mark-up methods are suggested, as a single fixed mark-up would not be appropriate.	Differentiation of Scheduled Medical devices into Homogenous and Non-Homogeneous, and their benefits in terms of health benefits and non-health benefits	This needs to be done with clear defining Criteria, and then companies may be asked to justify their product in one of the Category- NPPA, or an independent technical committee
			Risk based classification of Medical Devices (Class A, B, C, D)	Already Existing- Central Drugs Standard Control Organisation (CDSCO)
Ceiling Price using median of market prices for Homogenous Scheduled Medical Devices	Enhance affordability of essential medical devices and implement price controls, mirroring the model for scheduled drugs.	By adopting the median instead of the mean of market prices, the approach addresses skewed price data. This ensures a more robust measure and aligns with successful practices from the pharmaceutical sector.		

Health Technology Assessment (HTA) informed Ceiling Prices for devices offering significant health benefits and falling into risk Category C and D	To promote innovations and implement value- based pricing, focusing initially on Class C and D categories.	This approach introduces a novel mechanism for price setting in India. By limiting it to riskier categories with significant health benefits, it balances the need for affordability with fostering innovation.	Conduct of Health Technology Assessment to Inform Ceiling prices	Can be out-sourced to Department of Health Research (DHR), as they have capacity to conduct such exercises- Health Technology Assessment in India (HTAIn), DHR

P41

A concept for multi-winner tenders for medicinal products with balancing between efficient prices, long-term competition and sustainability of supply

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Background: Achieving price efficiency via tenders, the sustainability of competition, and the prevention of shortages are hot topics in the debates about shaping the pharmaceutical markets. Single-winner tenders receive growing criticism for concentrating on achieving low prices at the expense of the long-term maintenance of a competitive pharmaceutical industry, the security of continuous supply, and disregarding the therapeutic needs of patient populations with specific conditions (Németh et al., 2023).
Objectives: The study aimed to draft a concept to assist the design of multi-winner tenders for medicinal products with a focus on supply and sales guarantees, price efficiency, and equity in access. The concept shall be generally applicable to all kinds of medicinal products including generics, biosimilars, and on-patent products in the out- and in-patient sector.
Methodology: Five general principles of multi-winner tenders for medicinal products are selected by the authors based on the relevant literature and a number of delimitations are made in order to get rid of factors that prevent clairvoyance amid the various pricing and reimbursement systems. The steps to plan and implement a multi-winner tendering procedure are drafted on the basis of the defined principles.

Region covered: not applicable (the concept can be implemented in all regions at the national, provincial/regional or local level)

Time period: not applicable
Results: The tender should consist of planning, bidding, preparation, sales, and evaluation phases. Pharmaceutical companies shall make bids with price and quantity pairs, which shall be ranked by prices and potentially take into account other factors. The contractor shall predefine market shares to the various places of the ranking. A double ceiling shall be

applicable for the sales of the winners: their sales must not exceed their quantity offer and the predefined market share applicable to their place in the ranking.

Conclusions and lessons learned: Multi-winner tenders can contribute to the long-term competitiveness of the pharmaceutical markets and as a consequence can contribute to the maintenance of price efficiency. Additionally, they may mitigate the risk of shortages and can better meet the therapeutic needs of patient populations with special conditions. The concept addresses the challenges of introducing sales and supply guarantees and suggests measures to further decrease the risk of shortages. The concept's delimitations allow its general applicability within settings but would require careful planning in the adaptation to the local conditions and specificities of the tender market. The concept focuses on price as a selection criterion; however, it allows the inclusion of additional criteria for the winners. Transparency and clear communication during the whole period of the tendering are essential. Corrective measures shall be set up for the case of non-compliant behaviour, which shall be further elaborated and adapted to concrete tenders.

Keywords: multi-winner tender, price efficiency, shortage prevention, supply guarantee, sales guarantee

Funding source: National Research, Development and Innovation Office in Hungary & Ministry of Human Capacities of Hungary

Reference

Németh, G., Mágó, M. L., Kaló, Z., Lám, J., Balogh, T., & Brodszky, V. (2023). A concept for multi-winner tenders for medicinal products with balancing between efficient prices, long-term competition and sustainability of supply. *Frontiers of Medicine*, *10*, 1282698. doi: 10.3389/fmed.2023.1282698