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EDITORIAL

Can we achieve affordable cancer medicine prices? Developing a pathway for change

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Cancer patients face high financial burden in many low- and middle-income countries but also in high-income countries such as the US [1]. Large price variations have been identified between countries, even of similar income [2–4]. Globally, cancer medicines are largely unaffordable, also and in particular if they have to be paid by the patients: For instance, a course of standard treatment for early-stage HER2 positive breast cancer would cost about ten years of average annual wages in India and South Africa and 1.7 years in the US [5].

Such 'financial toxicity' [6] has been observed against the backdrop of limited (therapeutic) value in terms of clinical parameters and patient-reported outcomes. Several studies explored the relationship between prices of cancer medicines and their therapeutic benefits, based on the value frameworks of the American Society of Clinical Oncology and the European Society for Medical Oncology, for instance, and could not identify any significant association for several cancer medicines [7–12].

The World Health Organization (WHO) classified several cancer medicines as 'essential medicines' [13], i.e. those that satisfy the priority health-care needs of the population. As such, they should be made available at a price the individual and the community can afford [14].

To implement the 2030 Sustainable Development Goals (SDG) agenda, governments have committed to 'achieve universal health coverage, including financial risk protection [...] and access to safe, quality and affordable essential medicines and vaccines for all' (SDG target 3.8) [15]. Progress toward universal health coverage by introducing social health insurance, expanding the scope of safe and cost-effective medicines in the benefits package scheme, and reducing co-payments would help ease the financial burden for patients.

Even in high-income countries with solidarity-based health systems (i.e. those with a large share of public funding, based on a national health service or social health insurance), there is lack in access to cancer medication since public payers cannot afford the high prices. Bent Høie, Minister of Health and Care Services of Norway, one of the richest countries of the world, reported that in 2019 Norway 'had to reject 22% of new medicines and treatments due to very high prices. This means we were not able to offer these medicines to patients who need them' [16].

1. Using or overhauling the current policy toolbox?

Cancer medicine prices are often determined by the interplay of external price referencing (EPR) and managed-entry agreements (MEA). EPR is applied in numerous countries globally, including all current 27 European Union Member States except Sweden; the Balkans such as Albania, Macedonia and Serbia; Canada; Latin American countries (e.g. Brazil, Colombia, Ecuador, Mexico); Asian countries (e.g. South Korea, Vietnam) and countries in the Middle East (e.g. Jordan, Kuwait, Qatar, Saudi Arabia) [17–26]. In EPR-based decisions, prices of the same medicine in other countries are considered. As a major limitation, EPR incentivizes marketing authorization holders to launch their products first in countries of higher price levels, with the aim not to reduce the benchmark price. This has major implications for patient access: Countries of lower income are offered the medicines months and years later (availability issue), and by referencing to the official list prices of first launch countries, they relate to high prices which are frequently not the real prices paid since the latter have been negotiated in confidential deals [27–30]. The determined EPR-based benchmark price of several cancer medicines is unaffordable to many (publicly funded) health systems, or – if affordable in the short term – it may challenge financial sustainability. In response, public payers negotiate pricing arrangements, which are commonly known as MEA [31]. MEA can take different designs such as financially based MEA (e.g. discounts, caps, price-volume agreements) and performance-based MEA, which link payments to clinical outcomes (e.g. risk sharing, pay-for-performance). A commonality of most MEA is their confidential character, though its scope varies: Some countries do not disclose which medicines are subject to a MEA whereas others do but they do not publish the type of discount [26,32–34]. However, the details of the discount are kept confidential in de facto all countries. Until 2017, Norway had transparent net prices [34]. To the author's knowledge, Switzerland is the only (European) country today that

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still publishes the net prices of medicines in some cases, but a legal change is currently under discussion [35].

It is a vicious circle [31]. Public authorities and payers reported they feel pressurized into accepting conditions and prices they consider unfavorable [36]. There is no way to assess the correctness of the promise of a supplier that the purchaser is offered the 'best deal' through confidential discounts. The secrecy is also attributable to a dearth of studies which examine net prices [37]. One of the very few studies pointed to a situation in which Italy and Spain – countries with large markets – were granted considerably higher discounts for some cancer medicines compared to Central and Eastern European countries. The latter paid the full list price of several studied medicines or did not have any access at all [4].

MEA may contribute to earlier access [38], and they allow access to high-priced (cancer) medicines that would not be affordable otherwise [32]. However, theory and empirical evidence showed that MEA have led to higher list prices [34]. Over the years, frustration has replaced optimism that authorities and payers had had about this policy in the beginning. There are major concerns on transparency issues, the high administrative burden, and continuing lack of evidence that had not been generated as intended through the performance-based MEA [39].

Data is key to inform pricing and reimbursement decisions, and thus health technology assessment (HTA) is a valuable supportive instrument. Even if a cost-effective cancer medicine might still be unaffordable for public payers [40] (who eventually may see no alternative but negotiate an MEA), knowledge on the – in some cases missing – (added) therapeutic benefit of a medicine strengthens the bargaining power of payers [7,8].

Fragmentation in the health system, with hospitals individually purchasing, is a barrier to affordability. It offers industry the possibility to price-discriminate and will likely lead to higher prices for individual 'small' purchasers compared to pooled procurements at regional or central levels [41]. Similarly, pumping money in the system through dedicated budgets for cancer and other groups of medicines without any assessment of their cost-effectiveness may be beneficial for patients, but produces 'budget silos' [42] disconnected to the health system. Before its reform in 2016, the Cancer Drug Fund in England offered public funding for cancer medicines that were not cost-effective [43,44] and provided an incentive for industry to charge higher prices [45].

An analysis of the current toolbox would be incomplete without mentioning biosimilar medicines. They have a potential to bring down prices and thus improved affordability of cancer medicines [46,47]. While acknowledging the higher complexity in handling biosimilar medicines compared to generics, policy-makers can still draw from the lessons learned from the implementation of demand-side measures on generics (i.e. actions targeting physicians, pharmacists and patients, e.g. INN prescribing or substitution at pharmacy level). One key component is to build trust of patients and health professionals in biosimilar medicines.

Despite the limitations of some of these policies, there is no need to overhaul existing pricing and reimbursement policies. But they can and should be improved based on evidence base, transparency, collaboration and solidarity. Application of these principles allows incremental progress of current policies and, more importantly, realizing of a vision for the future that brings governments and society closer to affordable prices. Moving forward this way, however, requires strong political will of decision-makers and the willingness of pharmaceutical industry to accept a 'new business model'.

2. Major principles of the roadmap for change

Ensuring generation and appropriate consideration of robust evidence requires investments, including capacity-building, to strengthen technical expertise and, moreover, commitment of policy-makers. Based on the argument that assessments are not possible and/or too resource-intensive for some medicines (e.g. orphan medicines), defined groups of medicines have been exempt from HTA in some countries, or real-world data were not collected during performance-based MEA. If policy-makers intend to grant privileges to cancer medicines (e.g. allow higher prices or fund them despite comparably low therapeutic value), they can do so otherwise, e.g. by derogatory procedures and changes in methodologies, such as applying modified value assessment frameworks that are more specific to the challenges of cancer medicines. Refraining from data collection is a lost opportunity.

Linked to evidence is transparency. While the discussion has focused on transparency of 'net prices' (discounted prices) and on research and development costs, data knowledge is a major prerequisite for informed pricing and reimbursement decisions, and it improves the bargaining power of authorities. However, needed data are frequently missing, not only in lower-resourced countries. For instance, in Austria, a high-income country and among the first launch countries for cancer medicines, no aggregate data on volumes and spending of cancer medicines in the hospital sector are available. The resolution 'Improving the transparency of markets for medicines, vaccines, and other health products' of the World Health Assembly in 2019 (WHA 72.8) called on the WHO and its Member States to improve transparency in net prices and R&D costs and also in further pieces of information such as volume data, revenues, marketing costs, incentives, patent expiry, and marketing authorization status [48]. The WHA resolution and other initiatives to improve transparency, including price transparency (cf. Table 1), suggest a strong will of some governments for change.

Recent years have seen a rise in cross-border collaborations led by governments, such as the Beneluxa Initiative, Fair and Affordable Pricing (FAAP) and the Valletta Declaration in Europe, to name a few. These initiatives aim to collaborate in horizon scanning (i.e. systematic identification of medicines in the pipeline), HTA, joint price negotiations or procurement. Despite their novelty and challenges due to different organizational and funding systems and legal barriers, some cross-country collaborations can already present examples of success [60]. In addition to cross-border collaboration in technical areas, collaborative approaches of policy-makers are required for implementing visionary political changes since a single

Table 1. Initiatives to promote price transparency.

Name	Initiator/Participants	Timing	Aim/Description	Ref.
Fair Pricing Initiative	Initiated by WHO Addressing all MS and the private sector Informal Advisory Board and technical working groups	Started in 2016, ongoing	To launch a dialogue with relevant stakeholders (MS, private sector such as pharmaceutical industry and the civil society) to discuss options for a fair pricing system for medicines Done through a series of Fair Pricing Forums (Amsterdam – 2017, Johannesburg – 2019), evidence produced by the members of the Informal Advisory Board Endorsed by the WHA 72.8 resolution	[49–54]
Oslo Medicines Initiative	Initiated by the Norwegian government and WHO Regional Office for Europe Addressing MS and the private sector in the WHO European Region	Started in 2020, ongoing	To create a neutral platform on which the public and private sectors can come together to outline a joint vision for equitable and sustainable access to effective, innovative and affordable medicines Activities include virtual consultations with MS and non-state actors, webinars and technical sessions, discussion based on commissioned background papers, outline of the new vision Follow-up action on the WHA 72.8 resolution	[55]
European Fair Pricing Network (EFPN)	Collaboration of cancer research institutes in more than ten European countries, coordinated by the Netherlands Cancer Institute[1]	Official launch in 2020, ongoing	To achieve fair prices for cancer medicines and, more broadly, work toward a pharmaceutical market which produces accessible and truly innovative medicines for patients Activities include research and advocacy	[56]
'Clearing house' mechanism	Agreement between the 'reform partners' (i.e. federal state, provinces, social health insurance) in Austria	Plan: 2019, currently on hold	Plan to establish a 'clearing house' mechanism to exchange in an anonymous manner information of net prices and volumes of selected medicines Plan included an information exchange between public purchasers (social insurance, hospital owners) in Austria in a first implementation phase and an extension at the European level at the later stage. The project is currently on hold (no information exchange yet done)	[57]
Euripid price database	Initiated and led by the Hungarian social health insurance, with more than 26 European countries participating, financially supported by the European Commission	Originally started in 2009, ongoing	Online database of official list prices of publicly reimbursed, mainly outpatient medicines Data providers and eligible users are competent authorities for pricing. Consideration of possible inclusion of 'net prices' (request of the European Parliament in 2015)	[58,59]

MS = Member State(s), Ref. = references, WHA = World Health Assembly, WHO = World Health Organization, [1] While the EFPN seeks collaboration of the governments, it is – in contrast to the other initiatives – not a government-led collaboration.

country will not take the decision to step away from confidential deals, for instance.

As cross-border collaborations currently mainly exist for countries of similar income, economic development and size (as this facilitates cooperation), solidarity across regions is additionally needed to overcome large variations in access to cancer medicines globally.

3. Expert Commentary

It is the responsibility of governments to bring this change forward. In terms of solidarity, policy-makers of high-income countries and of large economies, whose voices are heard more easily, could take the lead. While the governments must be in the 'driving seat,' pharmaceutical industry also has an important role since the private sector can engage in reform projects or oppose them. Several pharmaceutical companies will perceive governments' approaches for ensuring affordable (cancer) medicine prices as a threat. However, it is unlikely that in the long run the current 'business model' will survive, and companies that are among the first ready for change might even be financially rewarded. In addition, further stakeholders such as the civil society and health-care providers as well as other public bodies than payers and pricing authorities (e.g. regulatory agencies) are essential players whose cooperation should be sought to move forward. Eventually, as the political will of governments is a decisive factor for change, it considerably depends on the commitment of policy-makers on how many years it will take for the implementation of the new business model. In the meantime, for the sake of cancer patients, even minor and incremental policy improvements should be implemented. They include flagging MEA in price databases (without disclosing confidential content), capacity-building activities on HTA and data generation as well as the performance of more joint health technology assessments, price negotiations, and procurements. By endorsing the principles of evidence generation, transparency, collaboration and solidarity, these measures pave the way for a more substantial reform. Achieving affordable cancer medicine prices globally is a long-term vision but there is no alternative but to continue progressing.

Declaration of interest

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes

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