Forum Discussion Paper

Pricing approaches sensitive to health systems’ ability to pay and the need for accelerating towards Health Sustainable Development Goal

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Contents

BACKGROUND: FACILITATING UNIVERSAL HEALTH COVERAGE THROUGH AFFORDABLE PRICING OF MEDICINES AND HEALTH PRODUCTS .......................................................................................................................... 3

About this discussion paper ................................................................................................................................................................................. 3

TOPIC I: CROSS-BORDER COLLABORATIVE INITIATIVES TO BRING ABOUT MORE AFFORDABLE PRICING OF VACCINES AND MEDICINES .................................................................................................................. 4

Country pharmaceutical pricing policies .................................................................................................................................................. 4
Conceptualizing and assessing affordability ........................................................................................................................................ 5
Current international initiatives to facilitate affordable pricing and access ......................................................................................... 5
Achievements and limitations of international pricing initiatives ..................................................................................................... 6
Key problems to solve .............................................................................................................................................................................. 9
Some questions for discussion during the Forum ............................................................................................................................................... 10

TOPIC II: PRICE AND VALUE OF HEALTH PRODUCTS IN PUBLIC HEALTH CONTEXT .......................................................................................................................... 11

Could pricing informed by value assessment facilitate better access? ................................................................................................. 15
Some questions for discussion during the Forum ............................................................................................................................................... 18

TOPIC III: REGULATING EXCESSIVE PRICING AND RETURNS ALONG THE SUPPLY AND DISTRIBUTION CHAIN .................................................................................................................. 19

Conceptualization of excessive and unfair pricing .......................................................................................................................... 19
Assessing excessive and unfair prices and its challenges ..................................................................................................................... 21
Should government intervene on excessive and unfair pricing? ............................................................................................................... 22
Country regulatory measures for managing excessive pricing ............................................................................................................... 23

Opinions of the working group on additional options to manage affordable pricing to mitigate excessive and unfair pricing .................................................................................................................. 24
Some questions for discussion during the Forum ............................................................................................................................................... 25

REFERENCES ............................................................................................................................................................................................................. 26
Background: Facilitating universal health coverage through affordable pricing of medicines and health products

Ensuring affordable access for all people in need of health products has been a long-standing challenge for global public health, especially for people living in lower income countries. In recent years, high prices of medicines have also come to the attention of world’s wealthiest countries, as these prices contribute further to patient access challenges and threaten the financial sustainability of their health systems. This signifies that *unaffordable pharmaceutical pricing is now a global problem.*

The COVID-19 pandemic starkly unveiled various deficiencies of the health systems, including problems pertaining to the pricing and affordability of vaccines and medicines. Importantly, the public health emergency has reminded the world that these issues are not simply a technical problem about resource allocation, nor is it merely a question of financing; affordable access to health products is a matter of fairness, human rights, and indeed, life and death. The problem of access to pharmaceutical products is a multifaceted issue, which includes unaffordable and unsustainable pricing. The problem now truly warrants global community’s collective wisdom, commitment and action, so that coherent and enduring approaches can be found, that would facilitate affordable and fair access to health products to achieve health for all.

*About this discussion paper*

This discussion paper presents an overview of three pricing approaches that might facilitate affordable access to medicines for achieving universal health coverage. This draft is informed by the discussions from one of the two working groups set up in preparation for the Fair Pricing Forum 2021*. Three broad topics were discussed:

1. Cross-border collaborative initiatives to bring about more affordable pricing of medicines;
2. price and value of health products in the context of public health; and
3. regulating excessive pricing and returns along the supply and distribution chain.

In considering these topics, the working group considered health systems’ ability to pay and the ultimate goal of achieving universal coverage in line with Sustainable Development Goals Target 3.8† and Target 3.8‡. Several principles were repeatedly emphasized during the working group deliberations, including being evidence-informed, transparent, solution driven, operationally sound,

*The second working group seeks to understand the alignment of incentives and different models for incentivizing health innovation
† “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”
‡ “Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all”
and focusing on public health needs. In particular, consideration for the need to achieve price and pricing transparency has been a recurring theme across all the topics discussed. The working group also referred frequently to World Health Assembly resolution WHA72(8) Improving the transparency of markets for medicines, vaccines, and other health products, including transparency of price and funding across the value chain§.

Across all topics, some fundamental questions at the core of the problems were raised. For example, how to assess affordability and excessive pricing; whether fair pricing could be achieved without transparency of price and costs from the supply side; whether fair pricing could mean that in the spirit of solidarity, higher income countries should pay higher prices than lower income countries; and whether States should play a greater and collective role in ensuring fairness in the pricing of and access to vaccines and medicines.

Several limitations should be noted from the outset. This paper, in its brevity, only intends to describe the main issues for discussion. Any proposed approaches presented are only preliminary drafts intended for stimulating discussions during the Fair Pricing Forum 2021. The purpose is to advance the discourse and identify potential solutions and further areas of work. The contents are non-comprehensive work-in-progress. All views in this paper reflect a snapshot of the discussions that took place in the Working Group. These views do not necessarily represent the World Health Organization’s position or policy.

**Topic I: Cross-border collaborative initiatives to bring about more affordable pricing of vaccines and medicines**

**Country pharmaceutical pricing policies**

Sound policies on the pricing of pharmaceutical products at the country level, in conjunction with other broader system-strengthening policies across sectors (e.g. health, science, technology, law, trade, industry, and so on), could put health systems in good stead for improving access to affordable pharmaceutical products while ensuring continuity of supply.

Over the years, many governments globally have implemented a range of regulatory and non-regulatory measures that have direct or indirect impacts on the prices of medicines. These include, but not limited to, policy measures to promote greater competition (e.g. trade, intellectual property, local production), pricing based on an assessment of the medicines’ comparative ‘value’, costs, prices in other countries or products with similar therapeutic effects, tendering and negotiation.

In 2020, WHO published *Guideline on Country Pharmaceutical Pricing Policies* (1). This guideline has been revised to reflect the years of country experiences and the existing evidence on pricing policies. It contains recommendations for ten pricing policies commonly considered in countries to manage medicine prices, as well as pragmatic considerations for what is required to implement these policies according to the objectives and context of individual health systems.

§ For example, discussions relating to price transparency across the value chain: “Seeking to progressively enhance the publicly available information on inputs across the value chain of health products, the public reporting of the relevant patents and their status, and the availability of information on the patents landscape covering a particular health product as well as its marketing approval status” and transparency of public sector contribution to R&D: “Noting the importance of both public- and private-sector funding for research and development of health products, and seeking to improve the transparency of such funding across the value chain”.

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Note: The text above is a continuation of the document, focusing on the forum discussion topic and the implications of pricing policies for public health. The discussion highlights the importance of transparency in pricing and its role in enhancing access to affordable medicines. The text also refers to a guideline published by WHO, which provides recommendations for countries on how to manage medicine prices efficiently while ensuring continuity of supply.
The Guideline provides strong recommendations on promoting the use of quality-assured generic and biosimilar medicines. It recommends countries enable early market entry of generic and biosimilar medicines through legislative and administrative measures; use multiple pricing policies to achieve low prices for generic and biosimilar medicines that are informed by the cost of production; and implement, and enforce as appropriate, a suite of policies to maximise the uptake of generic and biosimilar medicines (1).

The Guideline also suggests that countries improve the transparency of pricing and prices through (1) sharing the net transaction prices of pharmaceutical products to relevant stakeholders, within and external to the country; (2) disclosing prices along the supply and distribution chain; (3) reporting publicly research and development (R&D) contributions from all sources; and (4) communicating pricing and reimbursement decisions to the public. In addition, WHO suggests that countries improve the transparency of pricing and prices through clear description of pricing approaches and their technical requirements (1). Based on the set of recommendations in this guideline, WHO will continue to work with countries in coming years to develop sound pharmaceutical pricing policies, with a view to bring about affordable access at the country level.

**Conceptualizing and assessing affordability**

The extent to which country pharmaceutical pricing policies reduce price, improve affordability and patient access to pharmaceutical products is dependent on a range of market and policy factors. It is also important to recognize that country pharmaceutical pricing policies may also have other policy objectives, such as improving equity, good governance, promote efficiency, incentivize enterprise and efficiency.

While it is simpler (not simple) to assess the level of price reduction following pricing policies, it is difficult to find an objective benchmark to indicate affordability, in part, because of the subjective nature of affordability threshold. Nonetheless, different approaches have been proposed to assess the affordability of health products, including assessing price or cost against macro-level benchmarks such as gross national income per capita, share of the existing expenditure, population level incomes (e.g. poverty line), and average cost of living; and micro-level indicators such as individual incomes (e.g. salary and wages net of spending on basic necessities) and out-of-pocket expenditure. There are also methods using composite measures of macro- and micro-level indicators (e.g. (2)).

Affordability of a medicine may also be conceived using the “health opportunity cost” approach (3). In this approach, from a public health perspective, a medicine could be considered as affordable if the health benefits it offers exceed the health benefits that could have been delivered if the additional resources required to fund this medicine were instead made available to the health care system for funding other existing technologies. This approach would utilise a range of within-country and cross-country data to inform the assessment of pricing and affordability (3).

Notwithstanding the technical challenges and the different approaches in ascertaining affordability, it is important to be reminded that the debate on affordability of pharmaceutical pricing is often triggered by prices that are far in excess of the ability of health systems or patients in many countries to pay.

**Current international initiatives to facilitate affordable pricing and access**

At the international level, various institutions have also implemented programs to broaden access to health products needed for addressing important public health problems. These include health products for managing HIV, malaria, HPV, tuberculosis, and hepatitis C.
Notable examples include global initiatives such as UNICEF’s procurement and supply of vaccines funded by Gavi, the Vaccine Alliance (Gavi); Stop TB Partnership’s Global Drug Facility; and Medicines Patent Pool funded mainly by Unitaid.

There are also regional initiatives, such as the PAHO “Revolving Fund for Vaccine Procurement” (PAHO Revolving Fund) and “Regional Revolving Fund for Strategic Public Health Supplies” (PAHO Strategic Fund), sometimes in conjunction with joint negotiation among members of the South American trade bloc (MERCOSUR); Pharmaceutical Procurement Services of the Organization of Eastern Caribbean States; pooled procurement services for member states of the Southern African Development Community; and joint reimbursement and pricing negotiations through the Beneluxa Initiative and the Valletta Declaration Group. Nordic countries have also established and performed joint procurement for several pharmaceuticals in the last three years, with the establishment and methodology facilitated through the Nordic Pharmaceutical Forum. There are also other cross-border initiatives, such as in trade, intellectual property management and local production, to achieve affordable prices for medicines.

These initiatives aim to generate more affordable prices through joint negotiation, pooled procurement, and encouraging greater competition. For example, the Global Drug Facility had negotiated a single global access price for bedaquiline for 132 countries at USD340 for a bottle of 188 tablets (4), which corresponds to about 6-month supply per patient. The Medicines Patent Pool reached a pricing agreement with Roche, broadening access to valganciclovir for 138 countries at USD202 (‘ex-work’) for a pack of 60 tablets (5), which corresponds to about 1-month supply per patient. Countries participating in the PAHO Revolving Fund could also benefit from the lower single prices negotiated based on pooled demand across the participating countries.

Other initiatives have negotiated multi-tier pricing arrangement, with eligibility defined according to criteria such as the World Bank’s country classification by income level. For example, UNICEF has negotiated the following 2-tier pricing arrangements for the HPV tetravalent vaccine (6):

(i) **Tier 1**: USD4.50 for countries eligible for GAVI funding i.e. countries with average Gross National Income (GNI) per capita ≤ USD1,630 over the past three years;
(ii) **Tier 2**: USD14.30-USD26.75 for middle income countries procuring through UNICEF.

Another example is promoting greater competition through licensing agreements negotiated by the Medicines Patent Pool. The negotiated Terms allow voluntary licensing agreements that facilitate authorized generic manufacturers to distribute low-cost generic products. Most recently, in response to the COVID-19 pandemic, an initiative known as the COVID-19 Vaccine Global Access (COVAX) Facility was jointly established by the Coalition for Epidemic Preparedness Innovations, Gavi, and WHO, with a view to providing at-risk populations in participating countries with access to at least 2 billion doses of COVID-19 vaccines. While final prices of vaccines through the COVAX facility are not reported, tiered pricing approach may have been conceived, at least at the discussion stage, as a way to account for varying ability to pay among participating countries.

**Achievements and limitations of international pricing initiatives**

The international initiatives mentioned above have greatly improved the affordability of medicines and vaccines for the countries within the program scope. The outcomes reflect the collective strength of joint efforts from all stakeholders in improving accessibility in lower income countries. For example, the procurement volume through the PAHO Strategic Fund in 2020 was 81% higher than 2018. From 2016 to 2020, the program delivered 68.3 million medicines and public health supplies, benefiting an estimated 7.5 million people in member countries (7). The Medicines Patent Pool reported having facilitated the distribution of generic products through its licensing arrangements in 141 countries, providing treatments to more than 31.4 million patient-years from January 2012 to December 2019 (8).
Despite the undoubtedly significant achievements of these programs, especially given the tremendous challenging environments in which these programs operate in (e.g. differences in health systems, available resources for program managements), pricing arrangements as applied in these programs may have not been able to universally broaden access to medicines and vaccines. In addition to broader health system challenges, one notable limitation in some of the mechanisms often noted by stakeholders is the frequent omission of middle-income countries and the large low-income population in these countries. In part, it is due to the use of country’s GNI per capita as the proxy for eligibility for participating in some of these pricing arrangements. GNI per capita is known as not being a robust predictor of the varying health outcomes in different countries (9). It also does not reflect inequalities in income distribution (10) and health needs, making it a poor proxy for affordability and supporting access. The metric becomes even less sensitive to capturing varying health needs and affordability when eligibility to access the negotiated prices is based on the broad four-tier country classification by the World Bank, which is intended for operationalizing its lending policy (10).

The limitations of the World Bank’s classification of countries by income group when used for operationalizing pricing and access arrangements for health products are demonstrated below. First, the categories are not sensitive to the different health needs. Using burden of disease as measured by disability adjusted life years as a proxy, the categories encompass a broad range of disease burdens, both in number and rate (Fig. 1). The differences would be even more visible at the level of individual diseases.

**Fig. 1: Disability adjusted life years expressed in (a) total number and (b) rate, by WB country income group**

![Diagram showing disability adjusted life years](image)

Source: Institute for Health Metrics and Evaluation (11)

The World Bank’s categories are also not sensitive to the distribution of individual incomes across and within countries. As demonstrated through data showing the estimated proportions of population falling below poverty line ‘thresholds’, Fig. 2 shows the broad income inequalities among upper-middle-income countries (UMIC) as classified by GNI per capita thresholds. As illustrated in one of the dotted yellow lines, population incomes in some UMICs closely resemble those of lower income countries.
In the absence of financial support, an additional one-third of global population would be forced below the international poverty line of US$1.90 if they need a medicine costing US$110 per month, or US$1,320 per year, for a newly diagnosed health condition (not shown in Fig. 2). Indeed, weighted average of current health expenditure per capita suggests that health systems in low- and middle-income countries may not, on average, provide sufficient funding for offering such treatment (Fig. 3). With many new medicines now with an annual price tag in the tens of thousands, any pricing arrangements aiming to address the issue of affordable access ought to take the vast income disparities and varying health system financial capacities into consideration.

Single negotiated global and regional prices represent the lowest possible prices from the joint negotiation. While aiming to be the collective welfare-maximising price, and generally conferring some pricing advantage for all participating countries, single price achieved through joint negotiation may not differentiate varying ability to pay and health needs in individual participating countries. As such, when applying single global prices, an important question is how to reconcile the notion of fairness in situations where low-income countries are paying the same price as high-income countries. A single price might also favour countries with relatively higher ability to pay and lower disease.
burden, potentially leaving some countries behind and widen the health gaps among countries. Indeed, in WHA Resolution 72.8, Member States also acknowledges the “importance of differential pricing” (14)**. Furthermore, arguably, such situation would be considered as incompatible with existing price differentiation approach applied within countries, where elderly’s health expenses are commonly subsidized more than wage-earning adults. For multi-tier pricing or royalty arrangement, the extent to which the final effective prices are evidence-informed by health needs or affordability is unknown.

In contrast, beyond the scope of cross-border initiatives, individual countries would not be able to leverage the collective bargaining power to achieve lower and more affordable prices, particularly for newly launched medicines. Lower income countries often face higher prices for these medicines than those in higher income countries because of their relatively limited negotiation capacities and market sizes. Furthermore, lower income countries often rely on list prices of medicines in high income countries to ‘benchmark’ their prices (e.g. through external reference pricing). These list prices had confidential rebates and discounts, making them unreliable benchmarks.

**Key problems to solve**

In summary, how could existing cross-border pricing arrangements be further optimized to facilitate affordable and fair access to health products universally, given the observations below?

- **Global problem requires global country collaboration**: Unaffordability of medicines and vaccines is now a problem affecting countries of all income levels, but there is no global framework to facilitate country collaboration and governance to address this problem collectively, especially for medicines and health products important for addressing public health needs. Countries, particularly those with smaller markets and less resources to facilitate robust policy, may find themselves as price-takers as the industry sets prices as high as the individual markets could bear and according to commercial goals. Meanwhile, any global country collaboration would also need to incorporate country-specific considerations relating to individual health system ability to pay and characteristics (including institutional and legal frameworks).

- **People are being left behind**: While impactful, existing cross-border initiatives, including but not limited to pricing arrangements, have not adequately covered lower income countries. This is particularly so for middle-income countries, where there is a large number of low-income people without adequate financial protection from the states. Prices of medicines and vaccines achieved in existing mechanisms may be higher than countries could afford. The existence of intellectual property rights and their effects on price in these countries further limit the effectiveness of cross-border pricing arrangements.

- **Pricing may not be informed by evidence on health needs, affordability and other factors considered important by stakeholders**: World Bank classification with four country income tiers bears weak relationship, if any, to health needs and affordability, but it is widely used in existing pricing initiates. There is also a lack of transparency on costs and pricing. Pricing not fully informed by evidence can have negative impacts on the financial strength and sustainability of the health systems.

- **Non-transparent process and outcomes**: Pricing of pharmaceutical products and related contractual arrangements remain largely non-transparent, causing difficulties in formulating adequate policy responses to facilitate affordability and universal access. Good governance also demands transparency for pricing policies and contractual arrangements, especially when the public expects full accountability for public spending.

**“Seeking to enhance the publicly available information on the prices applied in different sectors, in different countries and the access to and use of this information, while recognizing different national and regional legal frameworks and contexts and acknowledging the importance of differential pricing”**
Some questions for discussion during the Forum

Below lists some preliminary set of questions to be debated at the Fair Pricing Forum.

1. How can cross-border collaborative initiatives be further enhanced to bring about more affordable pricing of vaccines and medicines?

2. In what ways could countries and other stakeholders play in facilitating and supporting collaborative initiatives?
Topic II: Price and value of health products in public health context

Value-based pricing is an approach that aims to set prices for pharmaceutical products based on the measured and quantified “value” or worth that patients and health systems attribute to pharmaceutical products (1). In recent years, there have been increasing use of value assessment through Health Technology Assessment (HTA) in countries to inform the pricing of pharmaceutical products. If done robustly, the systematic approach of HTA could guide more informed decision making by answering the following important questions:

- What are the additional health benefits and additional costs of a new medicine (or other health product) to the health system?
- If additional resources are required to fund the new medicine, what are the health effects of other medicines or health interventions the health system could choose to do, or other health systems would be likely to do, if the additional resources to fund the new medicine were made available for these other uses?
- If funding the new medicine would displace the funding for existing interventions, what are the health effects of those interventions we will need to give up, or others are likely to give up?

Furthermore, some proponents of value-based pricing have promoted pricing approach away from the traditional cost-based approach, arguing that prices should reflect the worth of the medicines to the health systems, patients and broader society, rather than the costs of production (11). By rewarding the innovator through higher or lower prices reflecting the relative worth of the innovation, they claim that over time, such approach would encourage innovators to focus on attributes that society and governments value most. To them, value-based pricing could prevent pricing irregularities, such as when medicine prices bear little relationship to their relative clinical benefits or harms.

In contrast, with prices being far above the costs of production (15,16), some commentators have presented cost-plus pricing as a preferred way to facilitate broad access to pharmaceutical products. Cost-plus pricing has been characterized as the “antithesis of value-based pricing”, which is “inherently fair and nondiscriminatory to customers” and “easier to communicate or to justify” (17).

In addition, the shortcomings of value-based pricing have been widely documented. These include not having a consensus on the technical approaches for assessing value, incomplete evidence at the time of price setting, assessing the value by comparing to inefficient practices, and having different perceptions of value by different stakeholders (e.g. patients and policy makers) (18). There are also concerns about the lack of consideration for affordability in value-based pricing because value assessment often focuses on cost-effectiveness analysis, and does not capture the full consequences of budgetary impacts. When not done robustly, value-based pricing may lead to the paradox of a medicine being “cost-effective but unaffordable” (19,20). The tension between value and price (and affordability by extension) has raised various opinions on how affordability should be considered (21–23). There are also differences in the value of medicines as perceived by individual patients compared to decision makers. In any case, a widely accepted view is that “there is little value in new drugs that patients cannot afford—and there is no value in drugs that do not exist” (24). There is also relatively little value if the price set for a medicine far exceeds the benefits it would confer.

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11 However, recouping the costs of R&D have also frequently been used to justify the high prices of pharmaceutical products.
11 Setting prices by considering the manufacturing costs, costs of R&D, costs associated with regulatory processes and compliance, overheads and other operational expenses, and a profit to determine a price.
55 Cost-plus pricing may also result in unaffordable prices if the costs and profit margins are high.
Operationally, value assessment through HTA is resource-intensive and is not yet feasible for many countries that have neither the technical skills nor the administrative capacities for using value-based pricing in a reliable way. These countries also have limited access to market intelligence to inform the process or decision-making based on value assessment. Even in well-resourced countries, the considerable time taken to perform HTA and the disagreements on value assessment have sometimes created controversies. For all these reasons, critics have been less enthusiastic about the usefulness of value-based pricing in the context of global public health. To them, value assessments through HTA could be used to inform price negotiation rather than to ascertain the price point. At worst, they fear that value-based pricing could be misused to superficially justify high prices.

Notwithstanding the challenges, given the global trend in using value assessment through HTA to inform pricing, it is important to discuss whether pricing based on value assessment could be one of the right tools among a suite of policy instruments to bring about more affordable access to medicines and health products, particularly in lower income countries, in line with broad public health objectives.

What is the observed relationship between value and medicine prices?

Current evidence suggests that prices do not seem commensurate with the clinical benefits of certain medicines. Examples are numerous among cancer medicines, where the costs are often in the tens of thousands per patient while the size of health benefits do not seem to be comparatively large from a clinical point of view (e.g. aflibercept (25), abiraterone (26)).

Given the challenges in ascertaining ‘value’, few studies have systematically evaluated the relationship between value and drug prices. One such example is a recent regression study that examined the relationship between the costs (based on list prices) and the clinical benefits of new cancer medicines in Australia, France, the UK, and the US (27). This study found that at a societal level, “costs for new cancer medicines are high and, at best, only weakly associated with drug clinical benefits” (27). The study also observed significant variations in the relationship across the four countries. This perhaps reflects the differences in the ways different dimensions of ‘value’ (Fig. 4, p.13) could be conceived, quantified or incorporated into pricing and funding decision in different health system contexts and for different medicines.

Ascertaining and connecting value to price become even more challenging when consideration for social values is warranted. For example, society generally holds a perceived duty and proclivity for helping individuals in greater need, including people who are nearing the end of life or people with severe conditions with little alternatives. In this case, the challenges of balancing the needs of all individual patients against the collective interests of the whole community is particularly difficult, especially when there are divergent views on the value of therapies between patients, payers and policy makers (28). Funding medicines for rare diseases and costs of the providing the treatment are often in the hundreds of thousands of dollars, while the longer-term clinical effects of the medicines might be uncertain or modest. The methodological and process challenges of measuring and translating value to price have also been noted (29,30). The dilemma of funding the treatment becomes much more pronounced when the clinical benefits are shown to be clinically important. To illustrate, the quoted price of nusinersen for the treatment spinal muscular atrophy (SMA) has been as high as US$125,000 per injection, making the total treatment cost (except other medical expenses) at US$750,000 in the first
year and US$375,000 every year thereafter***. The main clinical trial shows that 51% of babies receiving nusinersen showed progress in developing head control, rolling, sitting, crawling, standing and walking after one year of treatment, while similar progress was not observed in any of the babies who received placebo (31). Another treatment for SMA - onasemnogene abeparvovec – has a quoted price of US$2.1 million per single treatment course. With an average health expenditure of less than US$5,000 per person even in most high-income countries (Fig. 3), the affordability of these treatments to the health system and individual patients has generated much controversy.

Fig. 4: Dimensions that may be considered for determining the value of medicines

<table>
<thead>
<tr>
<th>Needs for the proposed medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of condition</td>
</tr>
<tr>
<td>Availability of treatment alternatives</td>
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**Clinical evidence**

- Comparative health outcomes (benefits / harms, quality of life)
- Level of confidence in the level of evidence

**Economic impacts**

- Comparative cost-effectiveness
- Health and non-health related e.g. productivity gains

**Financial impacts**

- To patients & families (protection against financial catastrophe)
- To insurance scheme and healthcare system
- To non-health sectors (e.g. social welfare)

**Access**

- Equitable access
- Ability to target towards patients most likely to benefit

**Public health consideration**

- Burden of disease
- Public health interests (e.g. communicability, drug resistance)

**Research and development**

- Innovativeness
- Potential positive scientific externalities for local industry
development or future knowledge generation

**“Hope” and public expectation**

- Patients’ willingness to take risks and pay more for medicines with a small probability of producing positive health outcomes
- “Real option value” – if a health technology can extend life because this opens up possibilities for individuals to benefit from future advances in medicine

Source: WHO (18) based on various sources

The relationship between value and price may also evolve over time. When new medicines present evidence with uncertain benefits or harms at the time of decision-making, or when the expenditure is expected to be high or uncertain, some healthcare payers have entered an arrangement known as “managed entry agreement” (MEA) with the medicine suppliers. Under this arrangement, the payers would specify conditions relating to performance (e.g. clinical efficacy and effectiveness, cost and cost-effectiveness) on which the medicine must achieved when used in the real world clinical context (i.e. post market), or set a financial limit on the budget. Because the medicine effective price is subject to future assessment of the performance or financial impact, the relationship between value and price may change. In practice, commentators have noted that MEAs are an onerous tool because of their administrative and technical burden in collecting evidence and information, as well as enforcing agreement terms (32–36). For example, clinicians may not have the time, resources and financial incentives to collect evidence relating to the benefits of a medicine under performance-based MEAs. This often leads to data that poorly addresses the uncertainties they intend to mitigate, and has created many questions about managing the value-price relationship.

*** Some countries, such as Argentina and Brazil, were able to negotiate a substantially lower price based on a combination of policy strategies. In Argentina, the secretary of commerce set a price of US $27,000 per dose. See: https://www.boletinoficial.gob.ar/detalleAviso/primera/231517/20200701
Indeed, providing funding to medicines with prices that are disproportional to their value, at least when clinical benefits are uncertain, could have large impacts on resource use. A well-documented example is a program called the “Cancer Drugs Fund” in the UK. The program was initiated in 2010, with the policy intent of providing patients in England faster access to cancer medicines that were (1) available on the market but not yet appraised by The National Institute for Health and Care Excellence (NICE); (2) not recommended by NICE on the basis of cost-effectiveness after appraisal; and (3) used outside of marketing authorizations (i.e. so-called off-label use). Various evaluations of the program later found that the program incurred £968 million in expenditure between 2010 and 2015; overspent the allocated budget for 2014–2015 by 48%; failed to deliver “meaningful value to patients and society”; and did not make access to new cost-effective cancer medicines faster (37–39).

In many ways, the debate on the relationship between value, price, cost in health care is not new. Many of the points raised in the current debate mirror those raised in past policy debates, including that triggered by the “Child B case” in the UK decades ago (40). However, the difference is that finding a balanced policy solution to address the issues on value and price will become more acutely needed because of greater differentiation of disease and treatments, as well as an increasing number of high-cost products and the demand for them.

In summary, when using value assessment to inform pricing, it is important to have a clear understanding of which attributes of ‘value’ in addition to health benefits (e.g. equity, budgetary constraints and public expectation) are important (i.e. which attributes) and what the relative importance of these attributes are within the decision context (i.e. how to weigh different attributes). It is also important to understand what relative trade-offs should be made among these different attributes.

Who creates the value, who should pay for the value created, and in what form?

Another way of conceiving ‘value’ is to understand how value of pharmaceutical products is created along the ‘value chain’, in what form should that value be rewarded, and with what relationship should value be connected to the costs of research and development (R&D) and production.

Fig. 5 shows a simplified representation of the pharmaceutical value chain from R&D to the use of the products when the value is realized. Each step along this value chain typically involves multiple contributors, from governments, researchers to clinicians. Each step might also include a range of financial and non-financial rewards, including direct financial payments, and indirectly through tax credits and infrastructure supports. Further to the challenges in measuring value, having multiple contributors makes it difficult to accurately attribute the value created to individual sector of contributor and align the rewards accordingly, including through pricing.

Fig. 5: Pharmaceutical value chain

In the context of pharmaceutical pricing, there have been much discussion on the various contributions along the pharmaceutical value chain from the public and non-profit-making sectors, and by extension tax-payers and philanthropists. These include, but not limited to, direct grants towards the discovery and R&D of pharmaceutical products. Given public sector’s role in value creation and sharing the risks of R&D, they questioned whether the tax-payers should reclaim at least
some of the value created, and accordingly receive compensation for public sector investment through fair pricing (41–43). To address this question, the importance of improving the transparency of both public- and private-sector funding across the value chain has been highlighted, including World Health Assembly resolution WHA72(8) Improving the transparency of markets for medicines, vaccines, and other health products (14).

Another point in support of aligning pricing with value is the argument that such pricing would incentivize R&D towards finding future innovations that society and governments value most, that is, to create future value through current pricing approach (related to the concept of dynamic efficiency in economic lexicon). If so, what is the relationship between value-based pricing and future innovations? Could high, and potentially excessive, prices in one therapeutic area lead to duplication and inefficiencies, and crowd-out R&D in other areas of public health importance that have become relatively less commercially ‘attractive’? Could value-based pricing be more effective in incentivizing innovation than granting time-bound market exclusivity for health innovation? To what extent should R&D be incentivized through pricing rather than other incentive devices? This is an area of topics discussed by the second preparatory working group of the Fair Pricing Forum 2021.

Could pricing informed by value assessment facilitate better access?

By assessing the benefits additional (net) costs, pricing informed by transparent assessment of evidence on ‘value’ through HTA, if conducted robustly, could improve efficiency and facilitate affordable access. If affordability is conceptualized based on health opportunity costs, a medicine could be considered as affordable if the health benefits it offers exceed the health benefits that could have been delivered if the additional resources required to fund this medicine were instead made available to the health care system for funding other existing technologies. Research suggests that using this transparent and evidence-based assessment, it is possible to determine the maximum amount individual health care systems can afford to pay for the health benefits of new technologies in the respective health care systems. Using HPV vaccines as an example, research suggests that the maximum prices may be lower than previous defaults; this lower prices would facilitate affordable access more broadly (44). However, like all methodology, if assessment of evidence on ‘value’ through HTA is conducted poorly (e.g. fail to consistently assess all consequences), there would be a risk of reducing health and non-health benefits, while increasing prices and worsening the problem of unaffordability.

To advance the discussion on value and price of pharmaceutical products, the working group has identified the following policy priorities which broadly relates to four overlapping areas:

- **Understanding impacts** of pricing based on value assessments, including the relationship between value assessments and affordability and accessibility, as well as the value-based pricing and R&D, if any.
- **Methodology** for conceptualizing and assessing the meanings of value to different stakeholders for the purpose of pricing; and for establishing a common understanding of the applicability of pricing approach informed by value assessment in different health care contexts; and for understanding how value assessments can be expanded to capture factors important for decision making, such as cost and price transparency, health opportunity costs, and budget impact analysis, equity, among others;
- **Country experiences** in using value assessment to inform pricing, including the benefits, drawbacks and challenges; and understand the conditions for which value assessment could be used to expand affordable access, including transparency of price and costs (e.g. costs of services); WHO may facilitate ‘verification’ of prices from pharmaceutical companies to promote transparency and reliability of price information, as well as ensuring prices have a sound evidence base;
- **Building country capacity** by understanding how to strengthen the roles of government authorities (and payers) in performing health technology assessment (HTA) more effectively to inform pricing, including for low- and middle-income countries, as well as other high-income countries without a mature system for performing HTA.

The working group has also discussed some topic areas that could be explored further.

⚠️ **Developing a HTA information exchange platform to enhance countries and stakeholders understanding of price and value**

HTA has increasingly been used in evaluation, pricing and reimbursement of health products and services to inform Government’s decision making about what and how to allocate resources. Despite the broad purposes of HTA††, many HTAs on pharmaceutical products have a particular focus on cost effectiveness analyses, and report findings on (incremental) effectiveness, costs and cost-effectiveness ratios without other dimensions of decision making (e.g. budgetary impacts). The technical complexity of these analyses, including different scope of value consideration, also creates difficulties for readers to fully understand the applicability of the findings to specific decision contexts. Currently, there are databases developed to facilitate exchange of information (e.g. PAHO and RedETSA’s BRISA, EUnetHTA’s EVIDENT database, EUnetHTA’s Planned and Ongoing Projects (POP) database; INAHTA’s database, Tufts’s CEA Registry). Some of these databases provide open access (e.g. BRISA, INAHTA), while others are limited to members, or may be restricted by a fee. The scope of reporting may be non-standardized or limited in number.

**Suggestion:** An information exchange platform could be developed to freely share information sourced from a small set of HTA authorities. To facilitate comparability, the information platform would specify standardized reporting data fields, including:

- Summary of the context of use: population, intervention, comparator and outcome measures;
- Summary of health needs, including epidemiological profile;
- Summary of clinical evidence on efficacy and safety;
- Summary of comparative health economic evidence, including approaches for translating and extrapolating the evidence, modelling approach, price and costs of associated services, estimated total health benefits, estimated ICER;
- Summary of budgetary impacts, including projection of uptake and transition from existing interventions; and
- Summary of decision and underlying considerations, including value considerations, ethical, legal, social, equity, organizational aspects and special access arrangements (e.g. managed entry agreements).

The information platform may initially focus on new medicines considered for listing on the WHO Model Lists of Essential Medicines. It would include decisions both for and against the medicines.

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†† HTA may be applied to support decision-makers in numerous instances, among which: (i) implementing broad public health programmes; (ii) priority setting in health care; (iii) including a new medicine into a reimbursement scheme; (iv) identifying health interventions that produce the greatest health gain and offer value for money; (v) setting prices for medicines and other technologies based on their cost–effectiveness; (vi) formulating clinical guidelines; (vii) advising on the organizational systems within which health care is provided; (viii) supporting decisions on diagnostics and medical equipment; (ix) improving resource allocation and distribution particularly for high-cost technologies; (x) helping managers of hospital health-care networks and other health-care organizations; (xi) making decisions regarding technology acquisition or adoption; and (xii) informing clinicians, providers, and patients about the proper use of health-care interventions for particular health problems.(75)(75)
Potential benefits: The platform would be beneficial for knowledge transfer through standardization of information and may minimize language barriers if information is presented in a common language. By presenting information with a consolidated view of the basis of recommendations in different jurisdictions, it may facilitate country’s appraisals of evidence and decisions in a more structured way and without duplicating efforts (e.g. therapeutic equivalent doses of medicines considered therapeutic equivalent). It may also enable comparative research with regard to pricing and funding decisions, including considering how “value” was conceived and considered by different authorities. Finally, it would improve transparency and process efficiency, especially if the database are connecting with other initiatives such as price databases and “regulatory reliance” (45).

Potential drawbacks: In setting up the platform, it should be mindful of potential misuse of information where information might be directly transplanted from one country to another without considering the specific decision-making context (i.e. “copying and pasting”). Developing and maintaining such data platform would also require significant resources, especially for maintaining the quality of information. One way to mitigate this is to invite contributors from competent authorities or in collaboration with academic institutions so as to distribute the workload and resource requirements.

Expanding value consideration to include health opportunity costs, budget impacts, equity impacts and other factors

Value assessments and pricing should account for health opportunity costs. This is so that the decision to provide funding for an intervention would not result in health losses (i.e. benefits forgone) that are higher than the additional health benefits the intervention would confer. In other words, it is important to assess not only the budget impacts of an intervention, but also the opportunity costs of budget impacts.

First, budget impact assessment is an important part of HTA when being used to inform pricing and reimbursement decision, as recommended by WHO and other HTA networks (INAHTA, HTAI and ISPOR). However, budget impact analyses have not always been conducted (46), or have poor methodological quality when conducted (46,47). This means that decisions are not fully informed about potential budget implications over time. For example, one review found that “BIAs, [Budget Impact Analyses] funded by pharmaceutical companies appear to be tailored to show short-term savings induced by new, highly priced products” (47). Furthermore, there are instances where HTA finds an intervention “cost effective but not affordable” (e.g. funding of direct acting antiviral for HCV), indicating that the value assessment has not fully captured the opportunity costs of funding decisions (20).

Pricing policies solely based on ‘value’ often dissociates prices from factors many stakeholders consider as important. These factors include equity impacts, cost of productions, and financial and non-financial contributions by the public sector towards the research and development. For example, equity has been an important and explicit public health goal, and has been is a key component in countries’ decision-making process. However, consideration on equity impacts has frequently been ignored in value assessment, and has not been formally incorporated in HTA111 (48). This means that while the impacts on clinical health outcomes are better understood, much less is known about the impacts on health inequality when making funding decision for a new health product. Some suggested methods to assess equity impacts include disaggregating the total health effects by social groups (49), or applying equity weights to group of people with higher health needs (e.g. Australian indigenous population) (50).

111 “There are (a) failure of HTA methodologists to develop - and hence practitioners to use - tools for the consideration of equity in economic appraisals of health care technologies; (b) a similar and reinforcing failure to devise and implement processes of decision making that would facilitate the incorporation of equity in HTA” (47)
It is also important to recognize that when access is not universal, for example due to unaffordable prices, new medicines and health technologies could aggravate inequity. On the global scale and within countries, many medicines and health technologies considered standard care in higher income countries or for higher-income population remain out of reach of many people in lower income countries, thereby worsening health disparities. For these reasons, it is important to consider value and pricing in the global context, including other national and international policies, with a view to making sure that affordable access to health technologies of established safety and efficacy is expanded at a rate that would minimize health inequity.

**Some questions for discussion during the Forum**

1. Has the policy trend towards pricing based on value assessment contributed to unaffordable prices that are far above the cost of production?
2. Is pricing based on value assessment one of the right tools among a suite of policy instruments to meet public health objectives? Have value assessments brought about more affordable access to medicines and health products, particularly in lower income countries?
3. Has value-based pricing incentivized research and development in practice?
4. In what way could value assessment through health technology assessment contribute to affordable pricing of medicines?
5. How could these factors many stakeholders consider as important (e.g. equity impacts, cost of productions) be better incorporated in value assessment?
6. How can affordability and value be incorporated in a transparent way?
Topic III: Regulating excessive pricing and returns along the supply and distribution chain

Excessive pricing is known to cause economic inefficiencies, financial exploitation and psychological distress among people in need, as well as erosion of public trusts. Accordingly, government actions to correct the market from excessive pricing are often justified on economic, moral and political grounds.

In recent years, various country authorities had examined cases of alleged high and unfair prices, with some resulting in penalties and fines. These cases generally involved medicines that had been on the market for decades and no longer under patent protection (e.g. pyrimethamine, phenytin, oxytocin, 5-fluorouracil and so on) but at the time of the allegation, being marketed by dominant companies. The cases occurred in circumstances where there were sudden and significant price increases (c.f. gradual increase over time) accompanied by anticompetitive behaviors by the dominant company (51). There are also ongoing investigations on alleged large-scale anticompetitive practices relating to price fixing and market allocations involving multiple pharmaceutical companies (52).

Competition authorities seem to have been less effective in addressing high prices of on-patent medicines, or gradual increase in prices over time (e.g. insulin products), leading to high prices considered by many stakeholders as excessive and unfair. The reasons are complex, but include the high burden of proof for the authorities to demonstrate an abuse of dominant position by the company, particularly when establishing such proof would not be possible without making the company to disclose proprietary information (e.g. transparency of pricing and costs) to the investigating authorities.

The source or sources of excessive and unfair pricing practices could also emanate from any points along the value chains, including more upstream (e.g. active pharmaceutical ingredients (53)) or downstream during supply and distribution. The latter has indeed become a prominent problem in the current Covid-19 pandemic. This has triggered governments to activate enforcement of anti-price gouging laws or to implement time-limited price regulations (e.g. price caps) on a range of products and services, including protective equipment and facemasks, hand sanitizers, and serological tests for the identification of COVID-19 antibodies (54–57).

This section provides an overview of the how excessive and unfair pricing has been conceptualized and operationalized in policy. It also presents documented challenges in correcting excessive and unfair prices, as well as legal and regulatory options for managing excessive pricing.

Conceptualization of excessive and unfair pricing

The notion of “excessive pricing” has been commonly conceptualized within the framework of competition law, with reference to conventional economic doctrines. For example, within the jurisdiction of the European Union, the Rules on Competition prohibits a company holding market dominance from (58):

- directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- limiting production, markets or technical development to the prejudice of consumers;
- applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; and
- making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.
In other jurisdictions (e.g. Australia, US, Mexico), provisions within consumer laws or anti-price gouging laws aim to protect consumers from excessive pricing or unfair trading provisions (57). Irrespective of the legal systems, the focus of the judiciary in establishing excessive and unfair prices is whether there are underlying structural problems in market competition that need to be addressed.

In the context of public health, prices of pharmaceutical products significantly in excess of the ability of individual patients and health systems to pay will constrain patient access and threaten the financial sustainability of health systems. From this perspective, competition laws may not confer sufficient consumer protection from the impacts of unaffordable prices insofar as there is ‘no problem’ with competition within the interpretation of the laws, because it does not address high prices and their impacts per se (59). This is particularly pertinent for pharmaceutical products where the dominant position is granted by legal patent protection or other forms of intellectual property rights.

Some commentators have considered excessive pricing as solely a competition law concept with legal standards applied to its assessment, and distinction should be made with the concept of affordability. It should however be recognized that the interpretation of ‘excessive price’ solely within the framework of competition and consumer laws may not capture excessiveness and fairness in ways that many stakeholders and the broader communities consider important. These include pricing practices that would bring about equitable access, respect the right to access, and adherence to community ethical standards. After all, the foundation of law ought to be rooted in societal expectations and common values (see e.g. (60)). These societal expectations and common values have been noted formally in numerous sources. For example, the World Health Assembly was “seriously concerned about high prices for some health products, and inequitable access to such products within and among Member States, as well as the financial hardships associated with high prices which impede progress towards achieving universal health coverage” (14). The UN Human Rights Council also emphasized the needs for achieving individual rights to health and State’s obligation for healthcare provision: “According to the UN right-to-health framework, medicines should be economically accessible to all sectors of the population” and that “States have a legal obligation under the right to health to ensure that production of essential medicines by the private sector does not threaten affordability and accessibility of medicines” (61).

Economic research on pricing through the lens of behavioral science suggests that fairness is (or should be) a “constraint on profit seeking” (62), particularly among companies that consider abiding by social norms of fairness is important for retaining their reputation. During the Covid-19 pandemic, there are observations that suggest established sellers are more likely to refrain from engaging in price hikes in response to excess demand for health products than their less-established counterparts (63,64). To what extent these observations had held true, or would hold true, in the pharmaceutical sector beyond the pandemic context is not known. It might also be of interest to understand whether policymakers could use reputation as a policy tool, in line with the theories of behavioral economics, to ‘nudge’ companies to observe fairness in pharmaceutical pricing.

Thomas Aquinas on Just price (based on arguments against usury):

- Not greedy: “avarice is a sin”
- Not under duress: “buyer freely agrees to pay a price provided honest information”
- Align with its intrinsic value: “no man should sell a thing to another man for more than its worth”.

His thesis also recognised that merchants should be paid for their risks in a fair way.

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**FOR FORUM DISCUSSION**

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555 For example, in the context of the United States of America, “the mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free market system” (Jenny 2018 cited in (57))
Assessing excessive and unfair prices and its challenges

In generally, to trigger competition enforcement against exploitative excessive pricing, a thorough economic assessment of the prices and the market circumstances need to be considered in order to establish a finding of excessive and unfair pricing.

To establish excessive pricing, a combination of analytical methods and benchmarks are generally required to determine if the price is either “unfair in itself or when compared to competing products”. These include determining if:

- Price-cost margin is excessive, which involves comparing the price against production costs and intangible good such as Intellectual Property right;
- Price is excessive compared to benchmarks. The benchmarks could be prices charged by the dominant firm in other markets; prices charged by the dominant firm over time; or prices charged by other firms in the same/other markets;
- Profit level is excessive when compared against profit under normal competitive conditions, and profit levels of other companies;
- Price has “no reasonable relation to the economic value of the product supplied” (as defined by the European Court of Justice in the landmark case against the United Brands).

Regarding consideration on the market context, current framework of competition laws in different jurisdictions generally require establishing that the company holds a dominant market position leading to the exploitative pricing practice. It generally requires the following conditions being considered (65):

- whether the company has significant market power close to a monopoly position to dictate the price, causing the market less likely to ‘self-correct’ within a reasonable timeframe (see below);
- whether there are “high and durable barriers” hindering competing companies from entering the market, making market unlikely to self-correct;
- whether judicial intervention may adversely impact research and innovation, potentially causing ‘dynamic inefficiencies’ and costs in the event of enforcement errors;
- Alternative regulatory measures to mitigate the problem must be either “impossible, extremely unlikely, inappropriate or absent”.

In practice, applying these legal tests when assessing excessive and unfair pricing demands a high burden of proof for the authorities. For example, how to quantify and consider economic value is often a point of contention. A common definition of “value” is “maximum amount an individual is willing to pay for a product”, but it has been argued that pricing based on value is inappropriate in competition law as “the observed (and allegedly excessive) price would always be lower than the value ascribed to it by consumers”, and to use such definition would “define the concept of excessive prices under competition law out of existence” (65). This burden of proof may have been established to reflect a position that competition authorities should not intervene in areas where market forces might be corrective, and where other authorities (e.g. health and finance) are considered as having better expertise and positioning to assess price outcomes. The question here is whether such ‘established’ burden of proof is flawed, or does not meet societal expectations and common values, as previously noted.

The complexities of assessing whether a price is excessive and unfair are exemplified in the ongoing legal case since 2015 regarding the alleged excessive and unfair pricing of phenytoin sodium capsules, brought by the United Kingdom Competition and Market Authorities (CMA) against pharmaceutical companies Pfizer and Flynn Pharma (66). In this case, there were opposing legal and economic arguments regarding how to assess whether the price was excessive, including how to consider the economic value, how to evaluate the appropriate benchmarks, and how to consider cost benchmarks.
In 2020, the UK Court of Appeal upheld one of CMA's grounds of objection to an earlier decision from the Competition Appeal Tribunal in 2018, which was in favour of Pfizer and Flynn Pharma. In the judgement, the UK Court of Appeal stated that: “It was quite easy to lose sight of a stark reality, which was that, literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets” (cited in [66,68]). Indeed, in addition to the “stark reality” of the sudden and significant changes in price, assessment on excessive and unfair prices through competition laws may also not fully consider the consequences of alleged excessive and unfair prices on patients and health systems.

Finally, underlying the challenges in assessing excessive and unfair prices is a lack of transparency on prices and costs, both short and long run marginal cost of production, as well as profit margins. There is also a lack of common framework for objective assessment of intangible goods such as an intellectual property right [65].

**Should government intervene on excessive and unfair pricing?**

In view of the ways excessive and unfair pricing is conceived and ‘operationalised’ through competition laws, there remain debates with respect to how best to protect consumers from exploitation and adverse impacts of excessive and unfair pricing. Table 1 presents some of the most common arguments for and against government interventions on excessive prices.

**Table 1: Arguments for and against government interventions on excessive and unfair pricing**

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<th>Against intervention</th>
<th>For Intervention</th>
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<tbody>
<tr>
<td>Monopoly pricing is not illegal because competition law only prohibits abuse of dominant position, not the dominant position itself, especially when the dominant position is acquired by lawful means (e.g. patent or merger).</td>
<td>Primary rationales for competition policy are to limit the potential for exploitative behaviours and to lower prices for the benefits of consumers. Intervention against excessive pricing may be justified in certain circumstances where high prices would not lead to self-correction, at least within a reasonable period (see below). There are also social expectations of fairness not fully captured by competition laws. In some jurisdictions, rights to health and access to medicines are enshrined in laws, which requires government interventions to fulfil its legal obligations.</td>
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In the absence of anticompetitive conducts, excessive pricing is temporary and self-correcting in the absence of interventions, because high prices would attract new market entrants and therefore price competition. | High prices would not lead to self-correction within a reasonable period because of high and non-transitory barriers for potential competition to enter. Patients also have high demand for therapeutic options. Policies to encourage competition might not work because of high barriers for entry due to a lack access to crucial IP and expertise (e.g. access to reference product for developing biosimilars) or barriers to expand (i.e. high switching costs; lack of shopping around by customers; lack of comparable information across suppliers; and asymmetric information between firms and customers). |
### Country regulatory measures for managing excessive pricing

Given the broad scope of competition laws beyond the pharmaceutical sector and current challenges in enforcement, there are views that competition authorities could act as the regulators of last resort when regulators of the pharmaceutical sector do not have sufficient policy measures or powers to address the underlying excessive and unfair pricing practices. To these ends, country pharmaceutical policies for managing and preventing high, excessive or unfair pricing include:

<table>
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<th>Against intervention</th>
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<td>Methodological challenges and high standard of proof making the formulation of appropriate policy intervention challenging. Data unavailable and analysis difficult for ex post analysis, and no clear ex ante benchmarks e.g. what is a competitive price? how could costs be allocated to a specifically over-priced product in a multi-product firm?</td>
<td>Assessment of excessive pricing can be challenging but should not be overstated. Prices often far exceed the costs over prolong period (even following patent expiry and the loss of market exclusivity) and generate supernormal profits for the originator firm, suggesting significant deviations from perfect competition and transfer of consumer welfare to the suppliers. Some price increases were sudden or over time without a clear relationship to the economic value or costs.</td>
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| There are high risks of regulatory failure which might stifle innovation because over-intervention could disincentivize and deter long-term investments, causing dynamic inefficiency. | The perceived impacts on innovation could be overstated. Price is one but many forms of incentives for stimulating innovation. Some economists have also argued that market dominance will hinder future innovations e.g. “monopolist’s incentive to innovate is less than that of a competitive firm, due to the monopolist’s financial interest in the status quo”.

Source: (59,65,69)

For high-cost pharmaceutical products, some governments have implemented demand-side policies that subject patient access having met some pre-specified eligibility criteria based on clinical or economic rationales (e.g. clinical conditions, quotas). While well-structured policy could improve efficiency and promote quality use of medicines, poorly designed measures could unnecessarily limit patient access to essential treatments, to the extent that limited access might cause harms to the patients e.g. (70–72). Furthermore, such measures do not address the underlying issues of high and unaffordable prices that could be excessive and unfair.

Individual countries have also issued a range of specific regulatory measures to address excessive pricing, but the extent of implementations of these measures vary. For example, South Africa’s...
“unreasonably priced medicine” provision in the Medicines and Related Substances Act has never been truly tested in practice. In the European Union, the orphan drug designation stipulates the requirement that “the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development”. However, the orphan status cannot be challenged on the grounds of product profitability if such status was not sought on the basis of the ‘insufficient return on investment’ criterion” (73).

Notwithstanding, there have been recent policies changes to address the issues of excessive pricing. For example, in Canada, the guidelines published by the Patented Medicine Prices Review Board in Canada (PMPRB) in 2020 provides clarifications regarding the power of PMPRB in imposing two main forms of remedy after a hearing on excessive price: “an order may be issued to the patentee that the price be reduced and that measures be taken to offset any excess revenues that may have been earned through sales of the patented medicine at an excessive price” (74). Some legislative and policy responses have also been triggered by the Covid-19 pandemic. In Argentina, the Joint Resolution between the Ministry of Health and the Ministry of Internal Trade established the maximum prices for a set of drugs used for COVID-19 patients treated in intensive care unit (atracurium, pancuronium bromide, fentanyl, midazolam, and propofol), when these products are sold to health organizations of the public, private and social security subsystems. This Resolution also encourages companies along the supply and distribution chain to increase their outputs to the maximum of their capacity and arbitrate the necessary measures to ensure the availability of these medicines throughout the country.

In many lower income countries, there is neither the legislations nor the capacity to enforce competition laws or other regulatory measures to address excessive pricing or implement licensing agreements. In many instances, (list) prices from high-income countries are applied to low- and middle-income countries, which are excessive in these health system contexts especially when rebates for high income countries have not been accounted for. Some countries try to achieve lower prices through pooled procurement.

Finally, in addition to government interventions, it has been noted that civil societies had played and continue to play an important role in challenging excessive pharmaceutical pricing and pushing for government reforms. For example, in South Africa, civil societies have been instrumental in raising the awareness about excessive pricing for medicines and vaccines (e.g. antiretroviral and HPV vaccines). These advocacy efforts had facilitated government’s legislative changes and judicial interventions.

Opinions of the working group on additional options to manage affordable pricing to mitigate excessive and unfair pricing

- For off-patent medicines, pricing authorities should aim for quality at the lowest price globally. Is there a role for managing pricing of off-patent medicines through a cross-border authority rather than leaving it at the national levels? There are some cross-border initiatives to encourage the supply of generic medicines e.g. WHO Prequalification Programme and the African Medicines Regulatory Harmonization initiative. These programs aim to increase access to good quality, safe and effective medicines through harmonized regulations, thereby improving competitions and potentially price. PAHO Revolving and Strategic Funds are regional mechanisms that offer patented and generic medicines through pooled procurement. One suggested idea is to have to facilitate a competitive environment for generic medicines through a centrally managed system that provides price signals through setting or publishing the lowest price benchmarks. These benchmark prices could be used for reference pricing (with some margins).

- Transparency of costs and prices is fundamental for developing sound policies for managing and preventing excessive prices in both the competitive (generic/biosimilar/therapeutically equivalent) and exclusive markets. A lack of transparency makes price negotiation inefficient.
Furthermore, a lack of transparency not only causes high prices for existing medicines, but also has flow-on effects on the prices of future medicines (e.g. generics and new medicines benchmarked against the existing high/excessive prices).

- **Price revisions should be more frequent and systematic, and with enactment of a law to formalize the requirements for price revision where appropriate.** This could mitigate the risk of high and potentially excessive pricing that are evolved over time. In LMIC, price revision is not sufficiently systematic or frequent. This means that high and potentially excessive prices may persist.

- **The variations in the prices of off patent medicines around the world should be better understood.** This could lead to a backstop regulation or support reference pricing for generic medicines.

- **Government should regulate on joint grounds.** Governments should communicate more and facilitate joint efforts to create joint markets to balance the negotiation power with the global industry. This could correct some asymmetries of market and bargaining power, and prevent dominant position that might lead to excessive pricing. For example, countries should be encouraged to share information on prices, product quality, and so on. It was noted that while reference pricing through sharing information is a potential solution, country experience shows that such system may reduce the experience of country pricing authorities in conducting negotiation due to over-reliance on information from other countries. For this reason, reference pricing could be a first step to inform pricing, but such approach must move towards incorporation of robust negotiation to reach a final price.

- **Within country, promoting stronger collaboration between Ministry of Health and other Ministries (e.g. Trade, Finance, payers) to create a holistic approach for addressing excessive pricing is important, in particular for developing countries.** For example, in Argentina, there are joint resolutions between the Ministry of Health and Ministry of Commerce to address excessive pricing. In the case of Nusinersen, the Ministries used an approach similar to a "price comparison" methodology. However, due to a lack of price and cost transparency, there were difficulties in obtaining a realistic comparison against the prices in other countries to support the policy using various approaches (e.g. Price-Cost Margin and Profit comparison). It is important to promote price/cost transparency, as per WHA resolution 72.8.

### Some questions for discussion during the Forum

1. On what grounds and to what extent should governments regulate or not regulate excessive medicine pricing?
2. What should be the focus of government responses to high and unaffordable medicine prices, considered by communities as excessive and unfair?
3. How can market transparency across the value chain be promoted to improve policy responses, with the aim of protecting consumers against excessive and unfair pricing?
4. Has competition law sufficiently protected consumers from the effects of high, excessive or unfair pricing practices?
5. Can governments simply rely on competition to achieve reasonable prices once temporary monopolies expire?
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