Informal Advisory Group on the Availability and Affordability of Cancer Medicines

Report of the meeting 4 – 6 April 2018

Geneva, Switzerland

World Health Organization

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Contents

Acronyms and abbreviations

EML	Essential Medicines List
EMP	Essential Medicines and Health Products (WHO Department)
ERP	External reference pricing
HAI	Health Action International
HTA	Health technology assessment
IAU	Innovation, Access and Use (WHO Unit)
MND	Management of Noncommunicable Diseases (WHO Unit)
NVI	Noncommunicable Diseases, Disability, Violence and Injury Prevention (WHO Department)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization

Executive summary

At the Seventieth World Health Assembly in 2017, World Health Organization (WHO) Member States adopted resolution WHA70.12, Cancer prevention and control in the context of an integrated approach, and WHO was requested to prepare a technical report on pricing approaches for cancer medicines for presentation to the Executive Board. An informal advisory group meeting was convened by WHO in April 2018 to obtain relevant input from experts nominated by all WHO Regional Offices. The consultation aimed to provide expert advice on the scope of the report, on the benefits and consequences of various pricing approaches for cancer medicines and on options for improving the availability and affordability of cancer medicines.

The advisory group agreed that the resolution is meaningful for countries across income levels, although specific issues faced will differ. It acknowledged that although the remit of the technical report is an analysis of pricing of cancer medicines, there is a need to set oncology spending in a broader context of cancer diagnosis and treatment. It is also clear that pricing strategies for cancer medicines need not necessarily differ from pricing of other medicines, although calls for access have led many countries to pilot cancer-specific pricing policies.

Experts discussed policy and economic objectives related to pricing of cancer medicines, as well as price regulation and procurement policies across countries. It was agreed that different health systems and production capacities of countries must be considered in developing the technical report. Key issues raised also concerned countries' pricing policies, including the need to develop and enforce policies for equitable access, sustainable supply and procurement.

Options were proposed for national and regional levels to strengthen pricing approaches and policies, and for building the capacity to implement actions across the pharmaceutical value chain.

Suggestions for improving the availability and affordability of cancer medicines include:

- Strengthening pricing policies at the national and regional levels
    - Improving the consistency of policies across health and other sectors;
    - Designing of differential pricing sensitive to health systems' ability to pay;
    - Enhancing system ability to review and adjust prices, and divest if required;
    - Creating competition among substitutable cancer medicines, with respect to price, quality and supply.
- Improving the efficiency of expenditure on cancer medicines
    - Prioritizing the selection of medicines with high(er) clinical value with reference to existing guidance and country context;
    - Considering the costs of the model of care as part of the pricing approach;
    - Considering managed entry agreements for expenditure control in specific cases such as medicines with anticipated high expenditure and uncertain longer-term clinical benefits;
    - Avoiding the use or establishment of funds earmarked for the provision of cancer medicines, unless such funds are essential for access to medicines with proven clinical and economic value;
    - Implementing pre-authorization as a measure to ensure appropriate use.

- Improving the transparency of pricing approaches and prices of cancer medicines
    - Disclosing the net transaction prices of cancer medicines to relevant stakeholders;
    - Disclosing and controlling prices along the supply chain;
    - Reporting the costs of research, development and production, including any public sources of funding;
    - Communicating pricing and reimbursement decisions to the public when appropriate, to foster a common understanding and promote accountability.
- Promoting cross-sector and cross-border collaboration for information sharing, regulation, and procurement
    - Sharing information on medicine prices and technical assessments;
    - Harmonizing regulatory requirements for biosimilar medicines to ensure safety and quality , and to promote competition;
    - Streamlining cross-border regulatory requirements and supply management of medicines in shortage;
    - Pooling sub-national, national and regional resources for joint negotiation and procurement;
    - Applying TRIPS flexibilities for patented medicines where appropriate.
- Managing factors that would influence demand for medicines
    - Removing financial / non-financial incentives for prescribing cancer medicines of limited clinical value;
    - Restricting promotional activities of cancer medicines to clinicians and the public;
    - Correcting any misperception of inferior quality of generic or biosimilar medicines;
    - Implementing regulatory measures upon identification of substandard and falsified medicines.
- Realignment of incentives for research and development
    - Incentivizing research for cancers that affect smaller populations;
    - Focusing on health service research to improve system efficiencies, rational use of medicines and packages of care.

The feasibility of these preliminary recommendations is under assessment, and an updated set of options to enhance the affordability and accessibility of cancer medicines will be included in the technical report to the Executive Board at its 144th session.

Milestones for developing the technical report

- Experts to provide ongoing additional data and information to support technical analyses and case studies.
- Member State and stakeholder discussions to be held on the technical report in the third quarter of 2018.
- Technical report to be submitted to the Executive Board by October 2018 for discussion in January 2019.

I. Background and objectives of the consultation

At the Seventieth World Health Assembly in 2017, Member States adopted resolution WHA70.12, Cancer prevention and control in the context of an integrated approach. As part of this resolution, the Director-General was requested "to prepare a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on availability and affordability of medicines for the prevention and treatment of cancer, including any evidence of the benefits or unintended negative consequences, as well as incentives for investment in research and development on cancer and innovation of these measures, as well as the relationship between inputs throughout the value chain and price setting, financing gaps for research and development on cancer, and options that might enhance the affordability and accessibility of these medicines".

An informal advisory group was appointed based on the Terms of Reference previously developed and approved by the Assistant Director General of Medicines, Vaccines and Pharmaceuticals. To ensure the representation of Member States of various income levels and contexts, nominations for experts with experience in cancer care and/or cancer medicines research and development, pricing or supply chain were solicited from all WHO regions. The final composition of the group respected gender balance, regional representation, diversity of technical competence and expertise.

The group met from 4 to 6 April 2018 to provide expert advice on:

- the scope of the report, analytical feasibility and case studies;
- the benefits and consequences of various pricing approaches for cancer medicines;
- options for improving availability and affordability of cancer medicines.

A separate group, the Cancer Medicines Working Group (CMWG) met 22-23 March 2018 to review selected cancer medicines for the Essential Medicines List (EML). The aim of that meeting was to establish clear principles that can guide the selection of optimal medicines to be considered for EML inclusion and review the available tools and thresholds for clinical and public health relevance of a medicine. The CMWG was established at the recommendation of the 2017 meeting of the WHO Expert Committee on Selection and Use of Essential Medicines, where the potential to identify thresholds of benefits for cancer medicines was discussed. A summary of that meeting is published as a companion to this report.

II. Outcomes of discussions on interpreting the resolution and defining the scope of the technical report

- **The resolution is relevant to all countries.** It was agreed that the resolution is relevant for countries across all income levels, although specific issues faced will differ. Health care expenditure on cancer medicines can be significant. Countries with a high proportion of out-of-pocket expenditure experience high rates of financial catastrophe and resulting poverty. Existing reimbursement schemes are often insufficient to minimize financial harm. Priorities must be set to ensure that public expenditure on cancer treatment is equitable and efficient.

- **The technical report needs to be positioned in a context broader than medicines.** The experts acknowledged that the remit of the technical report to the Executive Board is an analysis of pricing of medicines. However, oncology spending needs to be described in a broader context that includes diagnosis, surgery, radiotherapy, palliative care, and other interventions in addition to pharmacological treatment. While this may go beyond the scope of the informal consultation and technical report, experts requested that the report refer to the broader context and related WHO initiatives.

- **Quality of medicines is vital but beyond the scope of the technical report**. Experts expressed a fundamental concern on ensuring the quality of medicines. Nonetheless it was agreed the report should focus on pricing approaches for quality medicines. Any potential impact on the quality of medicines resulting from pricing should be raised.

- **Infrastructure, guidance and a competent workforce are essential.** Pricing policies must be considered in the context of adequate selection principles and affordable diagnostic approaches, along with a workforce that is competent to detect and manage cancer.

- **Approaches to pricing cancer medicines may differ from those for other medicines**. It was agreed that, in principle, cancer medicine pricing should not differ from pricing medicines for other diseases. On the other hand many countries have piloted pricing policies unique to cancer medicines. It would be useful for the technical report to examine whether such approaches have been successful or could appropriately serve as an indication for pricing of other medicines. Experts strongly advised that the principle of affordability should be held central.

- **The technical report must be relevant to policy makers, and feasible to implement.** The report should aim to help countries in the short term in addition to identifying longer-term strategies. It should address elements of access that include receiving the medicines at the right time and in the right doses.

III. Outcome of discussions on pricing approaches and potential impact

- Policy and economic objectives: Key policy issues identified during the consultation include cost containment, incentives for innovation, promotion of local production and the use of generics or biosimilars. Economic objectives cover sustainability of the pharmaceutical industry, encouraging competition, patent systems and competition law. More attention is needed to demand side policies in addition to value chain policies.

- Off-label prescribing: Because of its unique emotional power and calls for access, cancer care prompts political will to permit more off-label prescribing than many other specialties. However, in principle there are no differences in policy objectives for cancer medicines and medicines in general.

- Price regulation and procurement: A discussion of a variety of price regulation and procurement policies across countries led to agreement that the technical report must consider different health systems and production capacities of countries. Some countries may not provide strategic procurement resources to undertake good procurement practices. Health systems should enhance the ability to review and adjust prices, and divestment if required, based on routine monitoring as well as on evaluation of evidence on utilization, clinical value, prices, quality and supply.

- Pricing policies in countries: Countries are urged to create and enforce policies for equitable access, sustainable supply and procurement. It is difficult to establish how industry sets prices, since there are variable markets and information asymmetry. The price setting for patented products is different from generic products. Some prices of patented medicines are confidential and therefore non-transparent, though there is some indication that policymakers are becoming increasingly aware of the impact and consequences of policies that rely on external reference pricing (ERP, see below).

- Controlling costs: Launch prices can be high, although mechanisms such as health technology assessment (HTA), ERP, and additional negotiation may result in substantial discounts. The experts recommended that the report should discuss the role of negotiation in obtaining affordable prices for cancer medicines and describe the relative success across countries. Proactive engagement by governments in determining initial pricing for a product and improving negotiation skills could be initial steps in controlling spending. There is a lack of knowledge