health
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To: Healthcare Stakeholders

INVITATION TO COMMENT ON THE SCOPE STATEMENT FOR THE REVIEW OF THE METHODOLOGY FOR INTERNATIONAL BENCHMARKING (IBM) OF PRICES OF MEDICINES AND SCHEDULED SUBSTANCES IN SOUTH AFRICA, 2010

The Medicine Pricing Committee established in terms of Section 22G of the Medicines and Related Substances Act of 1965, has commenced the review of the Methodology for the International Benchmarking published in 2010.

1. As South Africa (SA) moves towards Universal Health Coverage (UHC), affordability and accessibility of health interventions remains a primary concern.
2. The SA government has incorporated international benchmarking (IBM) in the country's medicine pricing policy as a mechanism to ensure fair prices. However, the IBM methodology has not been fully implemented since its publication in 2010.
3. Continuous evaluation and updating of medicine pricing policies, including IBM methodologies, are essential to ensure their effectiveness and relevance in addressing society's evolving needs.
4. The review of the methodology for IBM of medicine prices involves several crucial components that need to be addressed.
5. Firstly, it requires a clearly defined methodology and criteria for selecting comparator countries or regions and determining the comparative pricing benchmarks.
6. Secondly, the review necessitates the establishment of a transparent and evidence-based process for data collection, analysis, and decision-making.
7. Furthermore, stakeholder engagement is vital to ensure that the benchmarking process aligns with the needs and priorities of various stakeholders.

8. This includes active involvement from pharmaceutical companies, logistics service providers, healthcare providers, payers, patient advocacy groups, and other relevant parties. Their input and feedback are crucial for developing a benchmarking process that accurately represents the diverse interests and concerns within the healthcare and pharmaceutical industries.
9. Relevant stakeholders should prepare and submit proposals addressing each technical issue for the revision of the IBM methodology. These proposals should follow the numbering system and topics in the chronological order presented in the Scope Statement
10. The consolidation of these submissions and comments will be incorporated into a Stakeholder Consultation Document. A revised Scope Statement, identifying methods agreed upon as out-of-scope, will be published as the final Scope Statement on the website of the National Department of Health.
11. The Director-General will present a summary of the consultation feedback and proposals for further improvements to the IBM methodology for consideration and endorsement by the Pricing Committee.
12. The management of a public consultation process for the proposed Revision of the IBM methodology will be published in the Government Gazette and will again invite comments.
13. The accepted consultation feedback will be incorporated into the draft revised IBM methodology.

DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 23/09/2024

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2030 NDP

SCOPE: FRAMEWORK FOR THE INTERNATIONAL BENCHMARK METHODOLOGY OF MEDICINES AND RELATED SUBSTANCES IN TERMS OF THE TRANSPARENT MEDICINE PRICING REGULATIONS

2024 PRICING COMMITTEE |
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ACRONYMS

BEE	Black Economic Empowerment
DG	Director General
GMP	Good Manufacturing Practices
HTA	Health Technology Assessment
IBM	International Benchmarking
IPR	Intellectual Property Rights
MoH	Minister of Health
NDoH	National Department of Health
OECD	Organization for Economic Cooperation and Development
PC	Pricing Committee
PIC	Pharmaceutical Inspection Co-operation Scheme
SA	South Africa/n
SEP	Single Exit Price
WHO	World Health Organisation
UHC	Universal Health Coverage

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1. Introduction

As South Africa (SA) moves towards Universal Health Coverage (UHC), affordability and accessibility of health interventions are top concerns. The country is working to ensure its citizens have fair access to essential medicines at reasonable prices. recognising the link between medicine pricing, healthcare spending, and patient outcomes, the SA government has included international benchmarking (IBM) in the country's medicine policy as one of the mechanisms to ensure fair prices. However, the IBM methodology has never been fully implemented.

Continuous evaluation and updating of medicine pricing policies, including IBM methodologies, are essential to ensure they remain effective and relevant in meeting society's evolving needs.

In its commitment to being a responsive policy development entity, the Pricing Committee (PC) is undertaking a comprehensive review of the methodology for IBM of medicine prices. This endeavor necessitates active participation from stakeholders, including healthcare providers, pharmaceutical companies, payers, patient advocacy groups, and the public. Diverse perspectives and robust discussions are invaluable in shaping the future of our medicine pricing policy.

The review of the methodology for IBM of medicine prices involves several crucial components that need to be addressed. Firstly, it requires a clearly defined methodology and criteria for selecting comparator countries or regions and determining the pricing criteria. This selection process is essential for ensuring that the benchmarking accurately reflects the international landscape of medicine prices and further benefits the South African health context.

Secondly, the review necessitates the establishment of a transparent and evidence-based process for data collection, analysis, and decision-making. This includes outlining the specific sources of data, the methodologies for data analysis, and the criteria for decision-making based on the findings.

Furthermore, stakeholder engagement is vital to ensure that the benchmarking process aligns with the needs and priorities of various stakeholders. This includes active involvement from pharmaceutical companies, logistics service providers, healthcare providers, payers, patient

advocacy groups, and other relevant parties. Their input and feedback are crucial for developing a benchmarking process that accurately represents the diverse interests and concerns within the healthcare and pharmaceutical industries.

Lastly, the PC, as custodians of the IBM should clarify the exact output and outcome intended for introducing this policy. Further, the committee must ensure that the policy is carefully planned and carried out, and regularly checked and revised according to changing conditions and dynamics (WHO, 2020).

1.1 Legislative Framework

Section 22G of the Medicines and Related Substances Act 101 of 1965, as amended (Medicines Act), is crucial in regulating medicine pricing in South Africa. This section gives the Minister of Health the authority to establish a PC responsible for setting the single exit price (SEP) of medicines, in line with specified provisions, including conformity with international benchmarks.

Regulation 5(2)(e) of the medicines pricing regulations specifies that the Minister, upon recommendation of the PC, must determine and publish in the Gazette a methodology for conforming with international benchmarks. This methodology considers various factors, including prices at which medicines or scheduled substances are sold in other countries where pricing is regulated and published.

Key points highlighted in this regulation are:

The Minister, in consultation with the PC, is responsible for establishing a methodology for conforming with international benchmarks. This methodology serves as a framework for assessing and aligning medicine prices with those observed in other jurisdictions.

Also, methodology must take into account not only the prices of medicines in other countries, but also the factors that influence pricing. This ensures a comprehensive approach that considers various market dynamics, regulatory environments, and other relevant factors.

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Once the methodology is determined, it must be published in the Gazette, ensuring transparency and accessibility to relevant stakeholders, including pharmaceutical companies, payers, healthcare providers, and the public.

Within three months of publication of the methodology in the Gazette, the SEP of each medicine or scheduled substance must conform with international benchmarks as per the established methodology. This timeframe underscores the urgency and importance of aligning medicine prices with global standards.

Overall, this provision sets up a strong framework for regulating medicine pricing in South Africa. It emphasizes the importance of international benchmarks in determining the SEP of medicines. It reflects the government's commitment to promoting transparency, fairness, and affordability in the pharmaceutical sector for the benefit of all citizens.

2. Rationale for International Benchmarking

The rationale for IBM in medicine pricing policy is supported by the World Health Organization (WHO) International Guidelines, which emphasise the crucial role of access to medicines in improving patient health outcomes and reducing mortality (WHO, 2020). Medicine pricing is a key factor in ensuring access to medicines in local and international markets.

In low and middle-income countries, medicine expenditure can make up a significant portion of healthcare spending. The WHO states that medicines can account for 20 to 60% of healthcare spending in these countries, compared to 18% in the Organization for Economic Co-operation and Development (OECD) countries (WHO, 2020). Additionally, up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, which often constitutes the largest family expenditure after food.

Research has indicated that affordability is improved in countries where medicine prices are regulated (Mensa Sorato *et al,* 2020). International market trends have led to the adoption of various pricing intervention options to ensure fair and reasonable medicine prices, promoting equitable patient access to medicines. These interventions include Health Technology Assessment (HTA) and International Benchmarking (IBM). The combination of various

interventions has been suggested as the optimal approach. Twenty-four out of twenty-eight OECD countries use an IBM approach, establishing it as a global precedent for medicine pricing policy.

To this end, the PC, and the National Department of Health (NDoH) consider introducing IBM as one of the policy interventions to evaluate fair and reasonable medicine pricing for the benefit of all South Africans. These interventions can assist in final price assessments and recommendations. Stakeholders' initial engagement is invited via comments on the IBM scope document.

The proposed (IBM) initiative in South Africa aims to ensure that all South Africans have access to quality medicines at comparable prices in other countries worldwide. Under the IBM framework proposed in terms of the Medicine Pricing Regulation, it is essential to consider whether it will be applied to all medicines (originators, and generics/biosimilars); retrospectively (medicines already in the market) or prospectively (future new entrants); and whether it includes medicines available through Section 21 medicines as per act 101 of 1965. This involves examining the potential impact of using the framework to both existing drugs and future developments and considering how it will affect both the originators and generic manufacturers. It also requires evaluating the implications for licensing, pricing, and patient access to these medicines.

2.1 Retrospective or Prospective International Benchmarking

Retrospective IBM of medicine prices in South Africa involves comparing the prices of medicines that are already on the market with those in other countries whereas prospective IBM of medicine prices involves assessing the prices of medicines before they enter the market in South Africa. Both retrospective and prospective IBM approaches offer valuable insights into medicine pricing dynamics. While retrospective analysis provides a historical perspective and ease of implementation, prospective methods offer predictive insights and the ability to influence current pricing decisions. Policymakers may benefit from using a combination of both approaches to gain a comprehensive understanding of medicine pricing trends and inform evidence-based policy decisions.

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2.2 Originator, Biosimilar, Generic medicine prices

Various factors and considerations influence the decision to include only originator, biologics or generic medicine prices in IBM. For the purposes of the IBM methodology biosimilars will be considered as generics.

Benchmarking only original medicines allows the Director-General (DG) to assess the pricing of innovative medicines, which drive healthcare advancements and may represent a significant portion of pharmaceutical spending. Original medicines are often subject to patent protection, making them more standardised and easier to compare across countries. By focusing on original medicines, policymakers can tailor pricing policies to support innovation. These medicines typically enter the market at higher prices, reflecting the costs of research, development, and regulatory approval. Benchmarking these prices provides insights into global market dynamics and pricing strategies.

Nonetheless, excluding generic medicines from benchmarking may overlook opportunities for cost savings and affordability, particularly in countries where generic competition is strong. Furthermore, benchmarking only originator medicines may provide an incomplete picture of overall medicine pricing dynamics, as generics/biosimilars often dominate the market and represent a significant share of pharmaceutical spending.

Including originator and generic medicines in benchmarking provides a more comprehensive analysis of medicine pricing dynamics, capturing the full spectrum of available therapies. Benchmarking generic medicine prices allows for assessing the affordability and accessibility of all medicines, particularly in low- and middle-income countries where generic medicines play a critical role in healthcare delivery. Comparing originator and generic medicine prices incentivises price competition among pharmaceutical manufacturers, leading to potential cost savings for healthcare systems and patients. Benchmarking originator and generic medicines reflects the diverse range of products available in the market and the different pricing strategies that pharmaceutical companies employ.

The complexity of IBM can be that:

- Generic medicines may vary in formulation, dosage forms, and therapeutic equivalence, making direct comparisons more challenging than originator medicines.

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- Generic medicines may be subject to different regulatory requirements and approval processes across countries, complicating benchmarking efforts.
- Collecting reliable pricing data for generic medicines, particularly in countries with fragmented healthcare systems or limited regulatory oversight, may pose challenges for benchmarking analysis.

The decision to include only originator medicines or both originator and generic medicines in international benchmarking should be based on the analysis's specific objectives, the country's healthcare context, and the availability of reliable pricing data. In many cases, a balanced approach that considers both types of medicines may provide the most comprehensive insights into medicine pricing dynamics and inform evidence-based policy decisions.

The pricing of generic medications in countries can vary significantly due to differences in healthcare systems, regulatory frameworks, market dynamics, level of competition and pricing policies. However, there are some standard practices and trends observed in the pricing of generic medicines across many countries.

Many countries use reference pricing systems for generic medicines. In this system, the price of a generic medicine is compared to that of a reference product, which is often the corresponding originator brand or the lowest-priced generic in the market. The price of the generic is then set at a percentage of the reference price.

Several countries regulate the prices of generic medicines through government-imposed price controls or regulations. These measures may include price ceilings, price freezes, or mandatory price reductions over time to ensure affordability and cost containment.

The current pricing regulations make provision for the regulator to request information on the cost of manufacturing or the cost of sales to evaluate the fairness of medicine prices. The regulations for generic medicines, which aim to promote cost-effectiveness in healthcare delivery, incentivise the use of lower-cost generic alternatives, which can achieve significant cost savings while maintaining the quality and accessibility of healthcare services.

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2.3 Application of the benchmark pricing to Single Exit Price

The intention of the scoping document is to initiate a transparent engagement by all stakeholders on the merits of IBM, to improve South Africans' access to affordable medicines. It will also serve as a prerequisite for the granting of an SEP to a medicine, prior to its introduction to the South African market. Medicine conformity with IBM will be a criterion for the medicine been granted annual SEP increases. These interventions can assist in final Single Exit Price assessments and recommendations.

The granting of new medicine entrants' SEP will be dependent on compliance with new IBM criteria. South African medicines will undergo a country cross price reference of its SEP, to a basket of countries utilising a predetermined IBM methodology. This process will be implemented post the IBM gazette publication. The scope document, requests, stakeholder evidence-based comments on the future IBM process.

The DG and Minister of Health (MOH) have the right to request pharmaceutical companies to justify the pricing of medicines already in the market. This is a crucial part of the medicine price policy framework. By reserving the right to ask for justification for medicine prices that may not align with international benchmarks, the DG and MOH can ensure that pharmaceutical companies comply with pricing regulations and guidelines set by the government. This helps to maintain fairness, transparency, and accountability in the pharmaceutical market. This provision will enable the government to address any differences between current medicine prices and international benchmarks, thus promoting alignment with global pricing standards. It also identifies and corrects instances where medicine prices may be unreasonable. Through ad hoc retrospective reviews of medicine prices, the DG and MOH can demonstrate their commitment to protecting the interests of South African citizens, ensuring that medicine prices remain affordable and accessible to all segments of society, especially those with limited financial means. The requirement for pharmaceutical companies to justify their pricing decisions fosters greater transparency and accountability in the pharmaceutical industry. It encourages companies to provide clear and evidence-based justifications for their pricing strategies, thereby promoting stakeholder trust and confidence.

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This provision is essential for maintaining a fair and competitive pharmaceutical market in South Africa. It ensures that medicine prices are in line with international benchmarks and accessible to all citizens. The provision demonstrates the government's commitment to promoting transparency, accountability, and affordability in the healthcare sector.

3. Selection of International Benchmark Reference Countries

Establishing criteria and indicators for selecting international benchmark reference countries is crucial for ensuring a comprehensive and effective benchmarking process.

3.1 Proposed Criteria for Selecting Benchmark Countries:

(a) Select countries with healthcare systems that share similarities with South Africa regarding organisation, financing, and delivery of healthcare services.

(b) Countries with robust regulatory frameworks for pharmaceuticals including pricing regulations, reimbursement policies, and market access requirements, should be included in the basket.

(c) Harmonizing pharmaceutical inspection standards among benchmark countries ensures consistent quality assurance and regulatory compliance, supporting confidence in imported medicines. Pharmaceutical Inspection Co – Operation (PIC) aligned countries can be favorable in aligning quality standards of Good Manufacturing Practices (GMP) between countries.

(d) Countries with economic profiles comparable to South Africa's, including GDP per capita, healthcare expenditure per capita, and inflation rates are appropriate for proposed benchmark countries.

(e) Countries with pricing policies that align with South Africa's objectives for affordability, accessibility, and healthcare quality. For example, countries that employ reference pricing systems, price controls, and mechanisms for promoting generic competition.

(f) Countries with transparent and reliable data on medicine prices, including publicly accessible databases, regulatory publications, and market research reports. Comprehensive pricing data facilitates accurate benchmarking analysis.

(g) Consider countries with favourable health outcomes and indicators indicating effective healthcare delivery and access to essential medicines. This ensures that benchmarking countries prioritise patient health outcomes and access to medicines.

(h) Countries from different regions should be selected to capture diverse market dynamics and pricing variations. This includes both developed and developing countries to provide a comprehensive global perspective.

(i) Prioritise countries where relevant stakeholders accept and endorse international benchmarking practices, including government agencies, pharmaceutical industry associations, and healthcare providers.

(j) Larger pharmaceutical markets or those with similar population sizes to South Africa may provide more relevant comparisons due to economies of scale and market dynamics.

(k) Consideration of healthcare system Organisation, such as public vs. private provision, insurance coverage, and reimbursement mechanisms, ensures alignment with South Africa's healthcare landscape

(l) Assess countries with transparent and accessible pricing data, including publicly available databases, regulatory publications, and market research reports, to facilitate accurate benchmarking analysis

4. Requirements for inputs to the scope

Project Scope Description: Identify and rationalise both an IBM country basket and price methodology to be utilised, comments on various country basket options. Agreed pricing exchange methodology across currencies. Other than price there may be other factors that need to be considered in the IBM process.

Project Exclusions/Exemptions: Give input and rationale on any potential exemptions.

Project Constraints: Comment on how we can overcome the challenge of achieving true country net prices. We need to evaluate true transactional prices, in our comparator countries versus the South African SEP.

Project Assumptions: The result of IBM will be that South Africans will not be at risk of paying higher prices of medicines versus an agreed basket of countries. The process will trigger the granting of a new medicine SEP, if the medicine meets the IBM published criteria. All stakeholder's inputs will be considered.

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5. Conclusion

The PC will consider the final scope consultation document when reviewing international benchmarking methodologies. All relevant stakeholders must provide detailed, evidence-based responses or submissions regarding the proposed methodology and matters raised in this scope document.

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6. References

i. Mensa Sorato, M., Davari, M., Abdollahi Asl, A., Soleymani, F., & Kebriaeezadeh, A. (2020). Why healthcare market needs government intervention to improve access to essential medicines and healthcare efficiency: a scoping review from pharmaceutical price regulation perspective. *Journal of Pharmaceutical Health Services Research*, *11*(4), 321-333. Available from: https://academic.oup.com/jphsr/article/11/4/321/6133274

ii. WHO (2020). WHO guideline on country pharmaceutical pricing policies. Available from: https://iris.who.int/bitstream/handle/10665/335692/9789240011878-eng.pdf