International Federation of Pharmaceutical Manufacturers & Associations

IFPMA

IFPMA Considerations on the Policy Analysis of Access and Inclusion of PD-1 / PD-L1 Immune Checkpoint Inhibitors on the EML

17TH APRIL 2025, GENEVA - The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) recognizes the WHO Essential Medicines List (EML) as an important instrument in global health, guiding countries in addressing priority healthcare needs. In the context of the 25th Expert Committee on Selection and Use of Essential Medicines, IFPMA would like to offer some considerations regarding the policy analysis of access and inclusion of PD-1/PD-L1 immune checkpoint inhibitors for multiple cancers in the WHO EML. Delivering comprehensive cancer care requires a strong health infrastructure, with specialized health, pathologists, and sophisticated side-effect management in order for specialized medicines to be administered properly and safely to patients. Listing these medicines on the EML without first addressing the minimal health system requirements and necessary investments will not improve patient access or appropriate use.

We are particularly concerned with considerations made in the aforementioned report, including policy recommendations on areas such as licensing, technology transfer, procurement and pricing. The issues discussed in the document engage in complex commercial policy areas, involving legal, economic, logistical, and trade considerations. This could stretch the WHO Expert Committee beyond its core expertise and may inadvertently impact the clarity and robustness of the guidance provided to Member States. Maintaining the EML's focus on scientific and public health criteria relevant to its mandate ensures that it remains a trusted and effective tool for its member states and other relevant stakeholders.

The report on financial implications of PD-1/PD-L1 immune checkpoint inhibitor delves into areas that require careful consideration:

1. **Intellectual Property Protections:** A robust intellectual property framework is a key enabler for innovation that improves patients' lives. Measuring the benefits of pharmaceutical innovation and the value it brings to a country's health system is within the competency of national HTA bodies. A generalized cost-effectiveness assessment will have limited value in informing decision-making and EML recommendations. Therapeutic progress is often achieved through multiple waves of innovation. Medical devices, medicines and vaccines undergo permanent improvements: adding serotypes in new vaccines, changing of characteristics of the product (changing storage or transportation conditions like cold chain), improving adherence to therapy through 1-pill combinations in HIV. These improvements do not hinder the development of biosimilars nor any other types of competition. However, improvements like developing a subcutaneous indication for a drug involve a multifaceted process, including

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formulation, drug delivery device design, clinical trials, and regulatory approval, all while considering factors like absorption rate, patient convenience, and safety. Intellectual property in this case protects the improvements such as the delivery or the devices but not the molecules, which patents may expire.

2. **Compulsory Licensing**: Compulsory licensing is misleadingly presented in the report as a straightforward and efficient means to enhance access to medicines, without fully addressing the complexity of its legal, economic, and logistical factors. This oversimplification creates a false sense of ease in its implementation, overlooking the substantial challenges related to its application, such as the need for robust legal frameworks, potential impacts on innovation and voluntary licensing, and the coordination required across multiple stakeholders to ensure sustainable access to medicines. Furthermore, implementing compulsory licensing demands substantial resources from all parties involved and often entails a lengthy and uncertain process, with no guarantee of achieving the desired outcomes in terms of accessibility or affordability for patients. Its broad application can inadvertently affect the delicate balance between encouraging pharmaceutical innovation and ensuring patient access. Other strategies exist that can enable access without undermining innovation. IFPMA member companies actively engage in voluntary licensing agreements and other collaborative arrangements to facilitate access on mutually agreed terms, including in resource-limited settings where solutions tailored to local healthcare systems needs are designed. These initiatives are often planned even before product launch, reflecting our industry's proactive approach to ensuring that life-saving treatments reach those in need wherever they are.

3. **Pooled Procurement Mechanisms:** While pooled procurement is presented as an expedient solution and mechanism that can enhance purchasing power and reduce costs, the report fails to adequately emphasize and substantially address the needed requirements that this mechanism demands, such as robust governance structures and a clear understanding of market dynamics to prevent potential drawbacks, such as reduced supplier diversity and increased risk of supply disruptions. Moreover, sustainable funding from contributing countries and stakeholders is another crucial pre-condition that must be addressed to ensure the long-term viability of such mechanisms, along with products that might be eligible. A more comprehensive exploration of these factors would provide a clearer and realistic picture of the challenges involved and strengthen the overall argument for pooled procurement. Good tendering practices should be followed (e.g. EU Procurement Directive) which applies the MEAT (Most Economically Advantageous Tender) criteria, other factors than just price such as supply, quality etc.

Discussions around these areas would be more appropriately addressed within specialized forums equipped to navigate the intricacies of the innovation ecosystem, international law & trade agreements and health systems strengthening strategies more broadly. IFPMA is actively engaging in such fora and will continue to do so to ensure global health issues are comprehensively addressed.

The inclusion of innovative medicines on the EML is vital for meeting the evolving standards of care, addressing patient needs and tackling global health challenges. For this reason, it is important that the EML fulfils its mandate by recommending medicines that have proven their clinical benefit and are

deemed essential for addressing the priority health needs of populations. By safeguarding innovation, we can ensure that new, life-saving treatments adapted to patient needs are developed and made accessible, ultimately enriching the EML and benefiting global health.

In addition, it will be important that the EML Expert Committee also considers the feasibility, i.e. health system requirements, to ensure patient access to the medicines proposed. The WHO EML's integrity and focus are paramount in ensuring it continues to serve as a reliable guide for member states and relevant stakeholders. By concentrating on its core competencies and collaborating with relevant entities on complex policy issues, the WHO can effectively contribute to improving global health outcomes. Engaging in policy areas that intersect international trade laws, national sovereignty, and economic policies require specialized expertise and are best conducted in appropriate international forums where all stakeholders can contribute meaningfully. Simultaneously, fostering an environment that incentivizes R&D and actively engaging in access initiatives will ensure that innovative medicines continue to enrich the EML, ultimately benefiting patients worldwide.

About IFPMA

IFPMA represents the innovative pharmaceutical industry at the international level, engaging in official relations with the United Nations and multilateral organizations. Our vision is to ensure that scientific progress translates into the next generation of medicines and vaccines that deliver a healthier future for people everywhere. To achieve this, we act as a trusted partner, bringing our members' expertise to champion pharmaceutical innovation, drive policy that supports the research, development, and delivery of health technologies, and create sustainable solutions that advance global health.

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