IFPMA

STATEMENT

# IFPMA Statement Delivered at the 24th WHO Expert Committee Meeting on the Selection and Use of Essential Medicines

**24 APRIL 2023, GENEVA** – IFPMA recognizes the importance of the WHO EML in the global health context and is pleased to contribute to the discussion today. The increasing number of products placed on the EML demonstrates the critical role played by the biopharmaceutical industry in creating therapies that are safe, efficacious and essential in reaching the UN Sustainable Development Goals, chief amongst them achieving universal health coverage.

IFPMA represents over 30 leading research-based biopharmaceutical companies and 50 industry national associations from around the world. IFPMA members are dedicated to researching, developing and manufacturing both innovative and established treatments for patients worldwide. We have published 2 statements on our website earlier this month – one on off-label listings and the other on broader comments on the scope of the EML, its utility and updating processes[1], which we summarise as follows:

- **EML's role in achieving better global health outcomes:** The inclusion of innovative medicines on the EML is the first step to enable improved population health but only works if populations have access to those medicines. To maximize access, broader healthcare system investments are needed to support efficient and effective access, delivery and uptake (i.e., devising innovative financing and payment methods, improving health workforce balance and quality, improving service delivery infrastructure and accessibility, etc.). This is especially the case for products on the complementary list that frequently require additional infrastructure and specialized healthcare workers (e.g., cancer, rare diseases). For this reason, having a summary of the minimal infrastructure requirements to implement a new technology would be of great added value. As the EML evolves, it is important to monitor whether the EML is delivering on its objective of improving access to listed medicines. Data on access to EML-listed medicines can help WHO, member states and industry to adopt tailored access strategies, support the strengthening of national healthcare systems to enable increased uptake of listed medicines and assist the EML Committee in making evidence-based decisions with every EML update cycle.
- **Generalized above-country cost-effectiveness assessments in the EML:** As a reference list, the EML should not limit governments, healthcare professionals or patients from adopting other

[1] IFPMA Position Paper, *Key considerations on the scope, utility and processes around updating the WHO Essential Medicines List*, 2023

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treatment options which may not be listed in the EML but are deemed appropriate at a national level. The EML Committee should acknowledge where there are data gaps and be cautious about making recommendations on inconsistent data. A generalized cost-effectiveness assessment that does not take into consideration each country's national context will have limited value in informing decision-making and EML recommendations.

- **Off-label use in the context of the EML:** As comprehensively explained in our submission to the WHO, we would like to express our concern with what we consider to be a misuse of the WHO's Square Box Symbol. While IFPMA supports the revised methodology for a clearer and consistent use of the Square Box Symbol, extra caution is needed when using this tool to list medicines for off label use. In particular, the use of products that have been reviewed and approved by regulatory authorities for a certain indication should be prioritized over the use of off-label products for the same indication. Whilst marketing authorization holders do not recommend off-label use when a regulatory-approved treatment for that same indication exists, if a treatment is listed on the EML for an off-label indication, this caveat should be clearly indicated in the EML to enable countries, patients and healthcare professionals to make an informed decision about their use**.**
- **Industry involvement in the process for developing the EML:** it is important that the processes around the EML are open, inclusive and impartial. Informal advisory groups that establish criteria for EML inclusion (i.e. cancer medicines working group) should include experts with relevant expertise, including from industry, academia and national regulatory agencies who can provide expert advice and knowledge. Many WHO reviews and public comments submitted on time on the applications are still not published on the WHO website which means they are not available to the public and other experts and would be keen to understand when this will happen.

The success of the EML lies in the number of additional patients having access to these essential medicines. IFPMA and its members are committed to work with the WHO, other international agencies, governments and all stakeholders to identify strategies to strengthen health systems and expand universal health coverage that will enable long-term sustainable access to and uptake of essential medicines.

The pharmaceutical industry is today developing a range of new medicines that will benefit the global community now and in the future. It is important that stakeholders work together with the pharmaceutical industry to identify the best ways to ensure sustainable, safe, efficient, and effective patient access to current and future innovation.