IFPMA statement

Delivered at the 21st WHO Expert Committee on the Selection and Use of Essential Medicines

By Brendan Shaw, IFPMA Assistant Director General

Geneva, 27 March 2017/ Thank you for the opportunity to make this statement today on behalf of the research-based pharmaceutical companies and associations across the globe. It seems appropriate that today, forty years after the creation of the World Health Organization's essential medicines list (EML) and in the midst of the Sustainable Development Goals agenda, we reflect on the progress that has been made and share concerns about the barriers that still prevent essential medicines from reaching patients.

We believe that the WHO Model List of Essential Medicines should continue to be used for the purpose it was created for; namely, as a guide for countries and procurement agencies in making their own decisions about the medicines in their own formularies.

The research-based pharmaceutical industry is proud of having played a key role in the development of the more than 400 medicines currently on the EML. Yet, despite the fact that more than 90% of the medicines currently in the list are now generic, or arrangements have been made by the research-based pharmaceutical industry to advance availability, many people still do not have access to these medicines. This is due to barriers such as weak, insufficient or poorly funded health system infrastructure, insufficient healthcare funding, supply chain inefficiencies, a lack of frontline health workers, a lack of specialized capabilities in certain diseases areas, and the pervasive presence of counterfeit and substandard medicines that undermine public health generally[1].

Listing medicines on the WHO Model List can be an important step to prioritizing access to quality medicines. Intellectual property protection and a predictable and supportive policy environment are important elements to encourage the development of essential new medicines, but so too is effective stewardship of these medicines.

We are a solution partner to healthcare systems and patients. Over the past decade, the research-based pharmaceutical industry has initiated and supported over 300 partnerships[2], working with governments, civil society, and healthcare workers to address barriers to access to medicines, improve capabilities, and increase R&D for neglected diseases. Taking these efforts one step further, this year we launched Access Accelerated[3], an industry-led collaboration of 23 pharmaceutical companies committed to working together with a range of partners to improve access to care of chronic conditions (NCDs) in low- and lower-middle income countries. This initiative will be supported by a robust evaluation framework to demonstrate progress and learn best practices.

---

[1] Lancet Commission on essential medicines for universal health coverage, 7 November 2016, http://dx.doi.org/10.1016/S0140-6736(16)31599-9 accessed 21/3/2017; Mattke, S. et al. 2011. Improving Access to Medicines for Non-Communicable Diseases in the Developing World, RAND Health, http://www.rand.org/content/dam/rand/pubs/occasional_papers/2011/RAND_OP349.pdf (accessed 3/5/2016).

[2] http://partnerships.ifpma.org/pages/

[3] http://www.ifpma.org/partners-2/access-accelerated-a-global-initiative-to-address-rise-of-ncds/

International Federation of Pharmaceutical Manufacturers & Associations
Ch. des Mines 9
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org

IFPMA statement

In relation to EML applications to be assessed this week, we kindly ask the WHO Expert Committee to take into consideration the following elements that will help countries to provide their citizens with the best, most appropriate, care:

1. Some national regulatory agencies (NRAs) are still in the process of adapting their regulatory frameworks to support biotherapeutic medicinal products. As a result, there are some countries where non-comparable biotherapeutic products have been licensed under regulatory pathways that are not appropriate for these medicines. As these products are included in the Model List, we would like to encourage the WHO Secretariat and the Expert Committee to reinforce to Member States the scientific principles behind robust regulatory approval for the protection and safety of their patients. The IFPMA has flagged these issues in its recent letter to the WHO on this topic.

2. The inclusion of newer, innovative medicines on the WHO Model List or national essential medicines lists does not guarantee that these treatments will be readily available to a community or that patients will benefit of expected outcomes. For example, as a Quintiles IMS Institute report[4] on essential medicines released last year shows, oncology care requires a complex degree of management to match the complexity of the disease. This includes having facilities for managing imaging tests and tissue biopsies in the initial diagnosis, cold storage facilities, well-equipped laboratories and trained specialists. The report suggests that oncology is one of the disease areas where emerging countries do not currently have sufficient health infrastructure to ensure the effective use of essential medicines. However, there are examples of impactful cancer treatment initiatives in emerging countries that have overcome significant health infrastructure challenges through close coordination and collaboration of multiple stakeholders, including the pharmaceutical industry.

3. Countries should assess their ability to provide treatments before including medicines on their national essential medicine lists. Public and private funders of health care systems have a crucial responsibility to ensure that infrastructure and funding, including public reimbursement, are in place to safeguard effective patient access to these essential medicines. This can and should be done in genuine partnership with the pharmaceutical industry.

4. We would like to reiterate our concerns about patient safety regarding the use of medicines for unapproved indications on economic grounds. While acknowledging the exceptional need to invoke off-label use of medicines in certain circumstances, we strongly support a careful and consistent approach for their inclusion within the WHO Model List. To this end, we consider that such recommendations should remain exceptional and be strictly limited to specific cases where urgent unmet medical needs exist and no other licensed therapies are available.

5. We would also like to caution about the transferability of cost-effectiveness analysis. Analysis of cost-effectiveness for the WHO EML may not be relevant to many country-specific EMLs as it would not be reflective of the realities of the country's healthcare system, requirements or costs. Most of the cost-effectiveness information for WHO assessments is derived from studies conducted in developed countries and may not be

[4] Quintiles IMS Institute, 2016, Ensuring Essential Medicines Satisfy Priority Healthcare Needs of Populations, November, http://www.ifpma.org/wp-content/uploads/2016/11/2016-QuintilesIMS.pdf (accessed 21/3/2017).

International Federation of Pharmaceutical Manufacturers & Associations
Ch. des Mines 9
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org

applicable to low and middle income countries since the interpretation of cost-effectiveness would depend on country-specific factors such as health system costs, resources, treatment alternatives, and disease prevalence.

6. Access to antibiotics is a complex issue where challenges vary depending on geographic regions, healthcare settings and the type of infections. Nowadays approximately 95% of the volume of antibiotics is generic, yet we know that there are still more deaths resulting from lack of access to antibiotics than from drug-resistant infections. Efficient public health policies and healthcare infrastructures are critical to ensure that patients have access to the right treatment at the right moment. For example, strong health system infrastructure is critical to ensure access to intravenous antibiotics that are commonly used to treat serious infections. Overuse and misuse of antibiotics exists worldwide. We commend WHO's efforts to put in place a more systematic and robust approach towards stewardship. Improving the appropriate use of antibiotics is a complex process and should not be limited to simply restricting access. We would like to caution the use of a global approach on stewardship and access; we recommend a case-by-case approach taking into account local antibiotic resistance patterns and tailored towards national health system capabilities. As described in the Davos Declaration and Industry Roadmap for Progress on AMR[5], the pharmaceutical industry is committed to supporting national efforts around antimicrobial stewardship and enhancing global access to novel antibiotics while limiting inappropriate use.

In conclusion, the addition of new, innovative medicines on an international or national essential medicines list does not guarantee that this treatment will be readily available to a community.

In keeping with the spirit of the Sustainable Development Agenda's call for a "revitalized global partnership", a holistic, multi-stakeholder approach to addressing all these challenges is essential.

As an industry that actively contributes to improving global health, we are ready to play our part.

Thank you.

About IFPMA:
IFPMA represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

For further information, please contact:

Sadia Kaenzig | Communications Manager | s.kaenzig@ifpma.org | +41795134442

[5] http://www.ifpma.org/partners-2/declaration-by-the-pharmaceutical-biotechnology-and-diagnostics-industries-on-combating-antimicrobial-resistance-amr/