Dear Mr Harris,

We appreciate the opportunity to provide comments on this Panel's Draft Report.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents national pharmaceutical associations and research-based pharmaceutical companies from across the globe. Based in Geneva, IFPMA has official relations with the United Nations and the World Trade Organization, and contributes industry expertise to help the global health community find sustainable solutions that improve global health.

Many of the Draft Report's findings and recommendations would have serious and adverse international implications for the innovative pharmaceutical industry and therefore it is crucial to bring these key concerns to your attention. These comments do not cover all the issues raised by the Draft Report and primarily seeks to complement the detailed comments submitted by Medicines Australia with an international dimension.

Long-Term View of the National Interest

There are increasingly clear trends of global convergence in the pharmaceutical sector. Pharmaceutical research and development (R&D) is being increasingly conducted in an international collaborative environment, in which Australia is solidly inserted. Even when developed by a single company, a pharmaceutical product is, almost always, the result of research efforts of various scientific teams from different parts of the globe. In fact, many clinical trials are conceived, already at its drafting stage, with a global population in view. Medical benefits of innovative medicines are enjoyed by patients in every country, and not only by those where the originator's company is headquartered. In other words, pharmaceutical products are developed globally, for a global market, saving and improving lives of patients across many borders. It is in the national interest of both small and large economies to support a global environment conducive to pharmaceutical innovation.

1 For an overview of the different trends and challenges facing modern biopharmaceutical industry, please see IFPMA. The New Frontiers of Biopharmaceutical Innovation (2012). Available at http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf
In this manner, it does not make much sense to discuss a country's national interest in isolation of the broad international context in which it is inserted. Australia is part of a group of countries that have traditionally defended and promoted a sound international IP system, and we disagree with the Report's finding that, in doing so, it has failed to take into account Australia's national interests. Australian patients greatly benefit from the medical advancements of the global pharmaceutical research and it is in their direct interest that the government should adopt policies to support a vibrant pharmaceutical industry. Australia plays an important example-setting role in many multilateral fora and we see little merit in the argument that because Australia is a small market, some proposed changes would have little implication to the global Industry.

**Patent Term Extension and Subsidies**

The role of governments and the private sector in fostering medical research are complementary, yet distinct. A pharmaceutical company has to constantly assess the feasibility of its different research and development projects taking into account a wide range of scientific and economic considerations. This is fundamental for research to be conducted in an efficient and cost-effective way, and require a dynamic decision-making process that takes into account the full lifecycle of pharmaceutical R&D. Governments do not normally have the necessary know-how and decision-making structure to allocate pharmaceutical R&D in the most cost-effective way. A direct subsidy, as proposed in the report, would likely cause suboptimal allocation of taxpayer's resources.

The pharmaceutical industry heavily relies on sound intellectual property systems. A patent term extension scheme is an integral part of the incentives needed to foster pharmaceutical research. It is not meant as a tool to allow governments to shape R&D activities. Its policy objectives are to compensate pharmaceutical innovators for any delays during the regulatory review process that governments require to assess the quality, safety and efficacy of the medicines, delays that prevent the adequate enjoyment of the market exclusivity period awarded in a patent, and that are specific to the pharmaceutical industry.

Patent term extensions are specific to a given product in a given market. The Australian patent term extension was designed to compensate innovators for the long delays for medicines registration in Australia. There is no sense to link it to patent expiration in other countries, as doing so could unjustly deprive a given product of its rightful protection for reasons foreign to the Australian system.

Subsidies make good government policy in areas where there is not enough commercial incentive to justify the risk and investment needed for pharmaceutical research. This is the case in many of the so-called “neglected diseases” and in some areas of antibiotic research. However, this should not come at the expense of jeopardizing the incentives for companies to invest in the many areas where there is no market failure.

---

2 In 2012, IFPMA member companies were involved in 132 R&D projects. Of those 112 are product development partnerships (PDPs) involving a member companies, the remaining 20 (15%) projects are company-only undertakings. The number of medicine and vaccine R&D projects has increased by over 40%, from 93 in 2011 to 132 in 2012.

3 See, for instance, IFPMA GPF Highlights: How to Combat Antimicrobial resistance http://www.ifpma.org/fileadmin/content/Innovation/Anti-Microbial%20Resistance/IFPMA_Forum_Highlights_AMR_7_April_2011.pdf
Manufacture-for-Export and Stockpiles

We note with serious concern the Report’s recommendations that Australia should seek to amend IP rules to allow manufacturing for export and stockpiling of patented medicines. Exclusivity to make, use, and offer for sale are integral parts of a patentee’s reward for publically disclosing its invention. In doing so, Australia would openly contravene Australia’s international obligation under the WTO Trade Related Aspects of IP Rights (TRIPS) Agreement and set a negative precedent for the multilateral IP system that would likely go beyond the pharmaceutical sector.

Generic companies are free to negotiate with the relevant rights holder a licensing agreement, a common practice in the pharmaceutical sector. The holder of the patent will examine the specifics of the case and, if the parties can agree, will license out the product through a voluntary license. One of the main advantages of this approach is that it often includes transfer of the know-how needed to ensure high-quality medicines are produced efficiently.

It is also relevant to point out that the WTO has adopted a system to implement paragraph 6 of 2001 “Doha Declaration on TRIPS and Public Health” to address concerns that countries “with insufficient or no manufacturing capacities in the pharmaceutical sector” would not be able to procure generic versions of medicines patented in third countries. This system addressed the concerns by facilitating exceptions to TRIPS under agreed, specific circumstances, and is supported by the research-based pharmaceutical industry. As stated by the WTO General Council’s Chairperson’s statement, "Members recognize that the system (...) should be used in good faith to protect public health and, (...) not be an instrument to pursue industrial or commercial policy objectives.” By pursuing an export policy with explicit commercial goals, as currently proposed by the Report, Australia would seriously undermine the delicate compromise reached at the Doha declaration, to which it has subscribed. A more constructive approach would be to recommend that the Australia Government finishes the legislative process necessary to correctly implement the “paragraph 6” system.

Incremental Innovation

The Draft Report seems to show an unfortunate bias against incremental innovation, failing to appropriately highlight its benefits. Incremental innovation increases treatment options available to healthcare providers and adapts medicines to patients’ needs. This process is marked by expanding the number of medicines within a therapeutic class, increasing the number of available dosing options, discovering new physiological interactions, and improving other properties of existing medicines. Such innovations often require as much research and development (R&D) and clinical trial investments as first-in-class medicines.

1 In particular, articles 28 and 33. See also Canada – Patent Protection of Pharmaceutical Products, WT/DS114 (2000).
2 Available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm
4 Saporito B, (1 April 2013) The Conspiracy to End Cancer – One Small Victory at a Time. TIME p 20-27
5 Concrete examples of the benefits of incremental innovation can be found at the IFPMA Publication Incremental Innovation: Adapting to Patient Needs (2013). Available at http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf

| International Federation of Pharmaceutical Manufacturers & Associations | Fédération Internationale de l’Industrie du Médicament | Federación Internacional de la Industria del Medicamento | Ch. Louis-Dunant 15 P.O. Box 195 1211 Geneva 20 | Tel: +41 22 338 32 00 Fax: +41 22 338 32 99 | Switzerland | www.ifpma.org |
Medicines are constantly improved. As more information becomes available about disease and patient behavior, this can be used to modify products to ensure that the specific needs of patients are met even more effectively. Such information becomes available early during clinical trials through patient and physician input and continues after a product is approved as part of “post-marketing surveillance” programs. Based on this information, researchers can explore how to meet patients’ needs by investigating new ways to interact with an underlying physiological pathway, reformulating an existing medicine, or proving the efficacy of known medicines for a new indication.

Inventors have every right to seek patent rights for improved medicines. Such patents only cover the specific improvements and cannot affect the exclusivity rights to the original medicine. Likewise, the exclusivity period of a first-in-class medicine cannot be extended through such patents. Once that exclusivity period expires, generic manufacturers will be free to market copies of the innovator’s medicine.

Conclusion

Implementation of the Draft Report’s recommendations would seriously damage Australia’s international reputation and place the country in direct contravention to many international obligations to which it has subscribed. It would certainly create a disincentive for companies to invest and speedily introduce new medicines in Australia.

We would like to thank you for the opportunity to provide comments to this Draft Report and reiterate that IFPMA, Medicines Australia and our members companies remain at your disposal for a constructive dialogue on how to improve Australia’s IP system.

Yours sincerely,

Eduardo Pisani
Director-General