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MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

6 October 2009

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Secretary: J. Luttrell

Mr Tas Luttrell
Principal Research Officer, Trade Sub-Committee
Joint Standing Committee on Foreign Affairs,
Defence and Trade
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear Mr Luttrell,

Re: Questions on Notice

Thank you for the opportunity to appear before the Joint Standing Committee on Foreign Affairs, Defence and Trade on 11 September 2009.

I agreed to provide more information on patent term restoration and I took the following questions on notice:

(i) What is the legal basis for rejecting the proposal to amend the *Patents Act 1990* to allow manufacture of generic pharmaceuticals for export during the period of patent term restoration?
(ii) Do members of Medicines Australia manufacture or market generic medicines?
(iii) Are innovator pharmaceutical companies involved in facilitating access to affordable medicines in developing countries?

Patent Term Restoration

In 1999 the Australian Government granted pharmaceutical companies the right to seek "patent term restoration" – that is, the right to apply for up to five years of extension of patent term, in order to achieve an effective patent life of up to 15 years from the date of first entry of their products on the Australian Register of Therapeutic Goods.

The reasons for granting this right are stated in the second reading of the *Intellectual Property Laws Amendment Bill 1997*. These are:

- to compensate pharmaceutical patent holders for delays in obtaining regulatory approval for new products;
- to provide incentives for pharmaceutical companies to continue to invest in R&D in Australia;
- to provide an effective patent life more in line with that available to inventions in other fields of technology; and
- to create a patent regime for pharmaceuticals which is in line with Australia's competitors.

Advanced economies around the world provide extended patent terms for

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pharmaceuticals. In addition to Australia, these include Japan[1], South Korea, Israel, the United States[2] and most of the member states of the European Union[3]. Although there are no internationally agreed standards for patent term restoration, the provisions in those countries that provide for it contain many common features, for example:

- extension is not automatic; the patent holder must make a specific application;
- the length of the extension granted depends on the length of time between the date of filing of the patent application and the date of marketing approval;
- a maximum extension of five years is provided; and
- the rights of the patent owner in respect of the patent maybe limited during the extended term compared with the rights available during the original term **but** only insofar as the limitation apply to seeking regulatory approval of generic copies of patented molecules or seeking exemption for research or "experimental use".

(i) What is the legal basis for rejecting the proposal to amend the *Patents Act 1990* to allow manufacture of generic pharmaceuticals for export during the period of patent term restoration?

If implemented, Medicines Australia believes that the proposed amendment would have:

- contravened Article 28 of the WTO TRIPS[4] (reflected in section 13 of the *Patents Act 1990*) which gives patent holders the exclusive right to make, use and offer for sale (including for export or import) any product related to the patented invention for the term of the patent;

- contravened Article 33 of the WTO TRIPS (reflected in section 67 of the *Patents Act 1990*) which requires WTO members to grant patent holders at least 20 years of [effective] patent protection, (noting that establishing the safety and efficacy of new medicines can take between half to two-third of the standard 20-year patent term); and

- contravened Article 17.9.8(b) of the AUS-FTA[5], which reinforces the concept of patent term restoration and expressly refers to an adjustment of patent term, while making no suggestion that the rights conferred during

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[1] An extension of the patent term by up to 5 years may be granted for pharmaceutical patents but only if regulatory delays exceed 2 years. The maximum patent term cannot exceed 15 years.

[2] An extension of term of up to 5 years may be granted as a result of delays in first marketing of a product due to regulatory review after the patent has been issued. The maximum patent term cannot exceed 14 years, excluding other technical incentives such as a 6 month patent term extension for conducting paediatric trials.

[3] An extension of the patent term is obtained by seeking a supplementary protection certificate (SPC). The SPC takes effect for a maximum of 5 years after the expiry of the original patent term, extending the exclusivity for particular medicinal products to a maximum of 15 years.

[4] The complete text of the World Trade Organisation's Trade Related Aspects of Intellectual Property Rights (WTO TRIPS) [Agreement] is available at: http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs.

[5] The complete text of the Free Trade Agreement between the United States of America and Australia is available at: http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/index.html. Article 17.9.8(b) of the Agreement states that: "With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process".

the adjusted patent term should be less than the full patent rights as defined in TRIPS.

On 22 July 2009, Senator the Hon Kim Carr, Minister for Innovation, Industry, Science and Research advised Medicines Australia that the Government had determined that the proposals to amend the *Patents Act 1990* would not proceed.

The Government's final decision confirmed Medicines Australia's positions.

Commenting on why the Government decided to reject the proposal to amend the *Patents Act*, Minister Carr said, "[the] proposed changes had ramifications for the nation's economy, as well as the system of IP protection and our international trade obligations".[6] For further information, please contact the Minister's Office.

(ii) Do members of Medicines Australia manufacture or market generic medicines?

Yes.

Once a medicine is out of patent, the innovator biopharmaceutical company will continue to market the medicine in Australia.

In addition, there is diversification occurring in the industry whereby companies are expanding into the generic market beyond the ongoing supply of their out of patent innovator medicines. Several innovator biopharmaceutical companies, including some whose local subsidiaries are members of Medicines Australia, also manufacture and/or market generic medicines, either in their own company's name or through separately established subsidiaries.

Sandoz (a subsidiary of Novartis Pharmaceuticals), Winthrop (a subsidiary of sanofi-aventis) and Ranbaxy (a subsidiary of Daiichi Sankyo) are well-known generic pharmaceutical companies that are subsidiaries of innovator biopharmaceutical companies. In addition, innovator companies Pfizer, GlaxoSmithKline, Abbott Laboratories and Merck & Co, among others, have substantial and growing investments in the manufacture and marketing of generic medicines.

(iii) Are innovator biopharmaceutical companies involved in facilitating access to affordable medicines in developing countries?

Yes.[7]

For over fifty years, the innovator pharmaceuticals industry has been one of the most important partners in addressing global health needs. There are numerous examples of companies collaborating with governments and non-

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[6] Quoted in *Herald Sun* (29 July 2009), Olga Galacho "Spike Drug Deal Bitter Pill for Exports", Melbourne, retrieved 1 October 2009.

[7] The International Federation of Pharmaceutical Manufacturers and Associations publishes an annual report of industry-led global health partnerships. In 2008, over fifty companies were involved in donating medicines and health services worth more than $4 billion.

governmental organisations to bring affordable essential medicines to developing countries.

For example, in June 2009, sanofi-aventis donated 100 million doses of vaccines to the World Health Organisation to combat H1N1 (or swine flu).

In some cases, product donations by pharmaceutical companies have been the only means of protecting vast populations from deadly diseases. Merck & Co.'s Mectizan® Donation Program is one of the leading examples of industry philanthropy making a profound difference in the lives of millions of people around the world, especially in Africa, who suffer from Onchocerciasis (also known as River Blindness).

Thank you again for the opportunity to contribute to this inquiry. Medicines Australia looks forward to ongoing dialogue with Government on all aspects of industry and innovation policy in Australia.

If you have questions about views expressed in this letter, or if you would like further information, please do not hesitate to contact me at: deborah.monk@medicinesaustralia.com.au or at **02 6122 8500**.

Yours sincerely,

Deborah Monk
Director, Innovation and Industry Policy