31 January 2012

The Hon Kevin Rudd MP
Minister for Foreign Affairs
Parliament House
CANBERRA ACT 2600

RE: Patent Disclosure Requirements under discussion with the World Intellectual Property Organisation's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

Dear Minister

On behalf of Medicines Australia and AusBiotech, we would like to provide our comments regarding the upcoming twentieth session of the World Intellectual Property Organisation's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which will discuss the issue of access to genetic resources and the role of the patent system in achieving the objectives of the Convention on Biological Diversity (CBD). We wrote to you on a similar subject on 30 September 2010.

Medicines Australia and AusBiotech greatly appreciate the position that the Australian Government has taken to date in these international negotiations, specifically in opposition to the inclusion of new disclosure requirements within the patent system. We ask that Australian Government negotiators maintain their vocal support of this position which ensures the preservation of the current balance of rights and obligations that exist within the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and related international agreements.

Our comments in this letter are guided by the principle that we wish to see a regime which effectively promotes access and benefit sharing on a mutually agreed terms. In order to do this, any new regime must maintain incentives to generate the benefits that are to be shared. So the new regime must enable both provider countries and those who access genetic resources to have confidence that genetic resources will be accessed and used in accordance with local laws and agreed terms and must not undermine the incentives for research and development (including intellectual property) which generate the benefits. Equally, the new regime should not delay the journey to market of innovative products that will generate benefits to be shared by the society as a whole.

WIPO IGC

In its upcoming session, the IGC will further discuss the proposals concerning patent related disclosure requirements which, as you know, entail stating the country of origin and/or the source of the genetic resource on patent applications. The stated objective of such requirements remains unclear as some proponents believe they will prevent acts of "bio-piracy", while others believe they will prevent erroneously granting of patents and/or ensure "benefit-sharing" as defined by the CBD. Medicines Australia and AusBiotech believe that it is crucial that there is a clear consensus on the objectives to be achieved before adopting any new legal approach.

Our industries are firm supporters of the CBD objectives, which include the fair and equitable sharing of benefits arising from the use of genetic resources. However, we have serious concerns that the above proposals will significantly undermine innovation related to genetic resources, including, for example, natural product research and development, whilst not addressing the aforementioned objectives.

The aim of the patent system is to incentivise innovation, but inserting such requirements into the patent system would create significant levels of legal uncertainty that will serve only to deter R&D. This is particularly true if competitors use these provisions to invalidate patents. R&D related to genetic resources is notoriously difficult and any extra risk would be clearly detrimental. This must be avoided, given that the products developed bring evident societal benefits.

If a patent were to be held invalid due to disclosure requirements, both the patent owner and the holder of the genetic resources would likely suffer significant financial loss, thereby limiting any resulting benefits.

Medicines Australia and AusBiotech believe that the most effective way of preventing acts of "bio-piracy" and ensuring benefit sharing, is through access and benefit-sharing agreements. These agreements between the transferor and the transferee of a genetic resource are based on mutually agreed terms, which may include terms related to intellectual property, where both parties have a clear understanding of rights and responsibilities. This facilitates the control of genetic resources leaving their country of origin.

It is important to reassess these discussions in the light of recently agreed Nagoya Protocol on Access and Benefit Sharing under the CBD. Full consideration should be given to exploring and developing a system capable of ensuring the needed monitoring and transparency concerning the transfer and use of genetic resources in order to achieve a fair and mutually-agreed sharing of the benefits in accordance with the CBD. A single checkpoint entity, such as the competent national authority for access and benefit-sharing described in the Nagoya Protocol, would fulfil the required functions and would be relevant to the utilisation of genetic resources or the collection of information **at any stage** of research, development, pre-commercialisation or commercialisation. Such an implementation would not only address concerns over "bio-piracy", but would avoid the legal uncertainty and erosion of innovation incentives implicit in the proposal patent disclosure requirements.

In conclusion, Medicines Australia and AusBiotech greatly appreciate the Australian Government's continued collaboration and consultation on this important topic. We look forward to working with the Government and other stakeholders to help provide practical solutions and an on-the-ground industry perspective on these issues.

Yours sincerely

Dr Brendan Shaw
Chief Executive
Medicines Australia
Level 1, 16 Napier Close
DEAKIN ACT 2600
Ph: 02 6122 8500

Dr Anna Lavelle
Chief Executive Officer
AusBiotech Ltd.
Level 1, 322 Glenferrie Road
MALVERN VIC 3144
Ph: 03 9828 1400

cc. Hon Craig Emerson MP, Minister for Trade
Hon Justine Elliot MP, Parliamentary Secretary for Trade
Hon Greg Combet AM MP, Minister for Industry & Innovation
Ms Ruth Adler, Assistant Secretary, Department of Foreign Affairs & Trade
Ms Tiffany MacDonald, Department of Foreign Affairs and Trade