European Medicines Agency
Directorate

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Dr Rohan Hammett
National Manager
Therapeutic Goods Administration

Dear Dr Hammett

The Therapeutic Goods Administration (TGA) of the Australian Government Department of Heath and Ageing on the one side, and the European Medicines Agency (EMEA) on the other side (the Participants) have identified a need to increase their technical and scientific co-operation through enhancing the exchange of information between the Participants.

As the regulatory authorities with responsibility for ensuring the quality, safety and efficacy of therapeutic goods/ medicinal products in their respective jurisdictions, the Participants have a history of co-operation and a high regard for each other's regulatory practices and systems.

The success of existing regulatory co-operative measures on harmonisation of technical requirements and on a common format for the submission of certain regulatory information to the respective medicines regulatory authorities has led to the desire from both sides to increase the range of information that can be shared in the interest of enhanced regulatory co-operation. This will build on the successful agreement between the TGA and the European Community on mutual recognition in relation to conformity assessment, certificates and markings.

In this context, the Participants see value in establishing an arrangement to enhance the exchange of regulatory information, including through early discussion and sharing of position papers concerning the development of draft guidance documents as well as information related to authorisation, pharmacovigilance and inspections of therapeutic products/medicinal products for human use, authorised or under review both in Australia and in the European Union.

Future collaboration between the Participants may also include activities such as the exchange of personnel, work sharing initiatives and the collaborative planning of joint workshops, conferences, seminars or meetings.

The EMEA is therefore pleased to co-operate with the TGA to facilitate the sharing of information related to establishing the safety, quality and efficacy of:

- 'medicinal products' as defined in Directive 2003/94/EC and for the purposes of this exchange, meaning those subject to evaluation or authorised under the centralised procedure in the European Union (EU), as well as medicinal products authorised at

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national level by the EU Member States that are subject to official European Community arbitration and referrals.

- ‘therapeutic goods’ approved or under evaluation in Australia, and for the purposes of this exchange, meaning ‘therapeutic goods’ as defined by the *Australian Therapeutic Goods Act 1989*, as amended from time to time.

In the context of this arrangement, therapeutic goods include prescription medicines, over-the-counter medicines, complementary medicines (including herbal medicines), biologicals and active pharmaceutical ingredients.

The type of information that may be shared includes, but is not limited to:

- guidance documents, policies, procedure and other technical documents for which the Participants have responsibility, including draft and final documents;
- post marketing pharmacovigilance data, particularly those of an urgent nature as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments;
- information contained in applications for scientific advice, orphan medicines designation, medicines authorisation or post-authorisation activities of significant public health interest and complementary medicine listings;
- information relating to any cases, or possible cases, of counterfeit therapeutic goods/ medicinal products;
- risk management plans;
- information relating to administrative arrangements including fees and charges; and
- information technology systems supporting regulatory processes.

As this type of information may include that which is not public, both sides agree, the extent permitted by their respective laws, to keep the information exchanged confidential. At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA.

The Participants reserve the right to limit the scope of the above information that may be released should its dissemination or exchange undermine any government policy, specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interest of the European Union or Australia, or the protection of the Participants’ interests in the confidentiality of their proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

Participants note that it is an essential element of this arrangement that confidential information emanating from the other participants will be treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from the EMEA, the TGA shall consult with the EMEA. Likewise, on each occasion there is a request for disclosure of non-public information from the TGA, the EMEA shall consult with the EMEA. Any exchange of confidential information may be undertaken under more binding arrangements.

TGA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the EMEA, and will

protect such information as information not to be disclosed. The TGA understands that the EMEA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. For the purpose of this arrangement, sharing of information between the TGA and its experts shall not be deemed as public disclosure. The TGA affirms that they have the authority to protect non-public information, including confidential commercial information, provided to their experts by the EMEA, and that TGA's experts can be prevented from unauthorised use and release of such information to any other party.

Similarly, the EMEA affirms that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the TGA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The EMEA understand that the TGA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. For the purpose of this arrangement, sharing of information between the EMEA and its experts shall not be deemed as public disclosure. The EMEA affirms that they have the authority to protect non-public information, including confidential commercial information, provided to their experts by the TGA, and that EMEA's experts can be prevented from unauthorised use and release of such information to any other party.

The arrangement is not intended to create obligations under international or other law, nor is it intended to diminish or otherwise affect the authority of the Participants in carrying out their technical and scientific responsibilities. All activities under the arrangement will be subject to relevant laws in each jurisdiction and the availability of appropriate resources in each agency.

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under the arrangement.

The arrangement can be varied via an exchange of letters and may be terminated on thirty days written notice by one Participant to the other. However the termination of this cooperative arrangement will not affect any commitments or undertakings given under or as a consequence of this arrangement in respect of any exchange of information or action taken during the period before the termination takes effect.

The arrangement will not modify existing co-operative activities, nor will it preclude the Participants from entering into separate arrangements for specific activities that could be handled more efficiently by special arrangements.

We look forward to implementing this arrangement, which embodies understandings of the parties, that allows for the sharing of non-public information, and to continuing cooperative activities to further enhance the relationship between the EMEA and the Therapeutic Goods Administration.

Yours sincerely,

Thomas Lönngren
Executive Director
European Medicines Agency