Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA)

SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

I, Othmar Engelhardt

Organisation/Company:

Country:

Declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

1.1 Employment

No interest declared

1.2 Consultancy

No interest declared

1.3 Strategic advisory role

No interest declared

1.4 Financial interests

No interest declared

1.5 Principal investigator

No interest declared

1.6 Investigator

No interest declared

1.7 Grant / Funding to organisation /institution

Name of pharmaceutical company	Subject Matter
IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)	Generation of influenza high_growth reas

1.8 Close family member interest

No interest declared

1.9 Repurposing of a medicinal product

No interest declared

1.10 Any other interests or facts

I am employed at the Medicines and Healthcare products Regulatory Agency. The Medicines and Healthcare products Regulatory Agency is an Agency of the UK Government's Department of Health. As the UK Agency responsible for the regulation of medicines and medical devices, including in vitro diagnostic medical devices (IVDs), it is important that the Medicines and Healthcare Products Regulatory Agency avoids Conflicts of Interest in the delivery of its activities, including those of its centres. To this end, the Agency adheres to a Conflicts of Interest Policy which is published on the Agency's web_site (provided on request) One activity that the MHRA fulfils in order to perform an important public health role is the standardisation and control of biologicals used in medicine. This work is performed at the Agency's South Mimms Site, which has previously operated under the name The National Institute for Biological Standards and Control NIBSC. The Institute's strategy includes the following objectives: • to anticipate emerging quality and safety issues associated with existing and future biological medicines; • to facilitate the development of novel biological medicines. Both of these strategic objectives require active engagement with commercial organisations. In addition, MHRA interacts with industry to ensure that its inventions are developed to a stage where they can have a tangible public health benefit. In some instances, it is appropriate for MHRA to charge commercial and other organisations for its products and services, in line with guidance issued from HM Treasury ('Fees & Charges Guide' and 'Selling into Wider Markets'). MHRA endeavours to make the same products and services equally available to commercial organisations, without prejudice. For example, MHRA: • provides reference and other biological materials on a charged basis to commercial and other organisations on a charged basis (recipients number approximately 5,000 organisations worldwide) • carries out Official Control Authority Batch Release testing of biological materials on a charged basis • provides testing of biological materials on a charged basis where such data either will not be included in a European regulatory submission, or is not decision_critical • carries out research that is for the general benefit of public health, and does not favour any one biological medicine manufacturer. • provides advice to organisations in line with the MHRA's internal policy. In accordance with the Agency's Conflicts of Interest Policy, all work performed with third parties by the MHRA is assessed for potential conflicts of interest. Any proposed work that falls outside those activities listed above is reviewed at a high level for the potential for a conflict of interest, the public health imperative to carry out the work, and possible mitigations that could be put in place. Where a decision is made to proceed, this is managed using a transparent, auditable framework, and is declared where appropriate to expert groups/committees. This approach ensures that the Agency retains independence and does not impede its research programme or otherwise reduce the Agency's ability to deliver its core mission and responsibilities.

1.11 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

No interest declared

2.7 Grant / Funding to organisation /institution

Name of pharmaceutical company	Subject Matter
IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)	Generation of influenza high_growth reas

2.8 Close family member interest

No interest declared

2.9 Any other interests or facts

No interest declared

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality as long as the information or document has not been made public/is not in the public domain.
- Not to disclose (or authorise any other person to disclose) in any way to any third party [1] any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.
- When expressing views to indicate clearly that the views are my own if acting in my own capacity or those of the EMA, Management Board, Committee, Working Party, Expert Group or other group if acting on behalf of that group.
- Not to disclose any commercially confidential information.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate and complete to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

1. Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

Full Name:	Othmar Engelhardt
Date:	2023-03-22

For definitions of activities etc, refer to the policy on handling of competing interests.