IPRP
International Pharmaceutical Regulators Programme

Mandate Document

Nanomedicines Working Group

Version 1.1

endorsed by the MC on 20 November 2019

Document History

Version number	Action	Date of endorsement
v1.1	Revision of the Mandate document based on the updated template presented to the MC for endorsement at the meeting in Singapore in November 2019.	**November 2019**
v1.0	First version of the Mandate document (November 2018) presented to the MC for endorsement at the meeting in Charlotte, NC, USA (November 2018).	**November 2018**

1. General Considerations

1.1. Statement of the Perceived Problem

Nanomedicines are a rapidly emerging and evolving drug product category with the potential to provide earlier disease detection, improve the precision of diagnosis and improve patient outcomes while potentially reducing adverse reactions and health care costs. This working group uniquely functions to disseminate knowledge in this field between international regulatory agencies thereby improving the community's understanding and capability to effectively regulate these products.

1.2. Expected Benefits

The work of this group will ultimately improve the regulation of nanomedicines and nano-enabled medical products providing more rapid access to high quality, effective medicines.

1.3. Background to the proposal

The International Regulators Working Group on Nanotechnology was established in summer of 2009 to discuss nanotechnology related issues relevant to regulated products that may contain nanoscale materials. The U.S. Food and Drug Administration (FDA) hosted the first meeting. Discussions focused on key issues such as the definition of nanotechnology, standards, biocompatibility, risk/safety assessments, and labeling.

The EMA hosted the first International workshop on Nanomedicines in 2009 and chaired since then biannual webinars / teleconferences with the International Working Group on Nanomedicines under confidentiality agreements.

As an emerging product category, nanotechnology-based therapies became a topic for the Regulators Forum in 2014. EMA updated the MC about the already existing International Working Group on Nanomedicines and asked whether IPRF could provide an overall "home" for the topic. It was proposed to have an inclusive Nanomedicines WG within IPRF for the exchange of non-confidential information. The proposal was supported by HC, Japan, ASEAN, Swissmedic, FDA and ANVISA, among others.

Agreement was reached to establish a Nano WG under IPRF to share non-confidential information. EMA agreed to collect comments for a draft mandate and work plan for the new WG.

2. Scope

- Products to be discussed by this group include nanomedicines / nanomaterial in drug products and borderline and combination products, nano-enable emerging technologies and follow-on nanomedicines.
- Methodologies used during the development and evaluation of such products shall be considered as well.

3. Objectives

- Non-confidential information sharing, regulatory harmonization or convergence focused on nanomedicines / nanomaterial in drug products, borderline and combination products and follow-on nanomedicines.

- Discussion and information sharing on novel or emerging nano-enabled technologies
- Regulatory cooperation, including work-sharing, in specific areas of nanomedicines / nanomaterial in drug products with other related international bodies.
- Collaboration of training organization between international regulators.
- Promotion of potential consensus finding on standards.

4. COMPOSITION

Rotating co-chair position (staggered 1 year terms)

Current co-chairs:

Michael Johnston, Health Canada, Canada

Chris Schyvens, Therapeutic Goods Administration, Australia

Regulatory members/scientific experts (39 total individual members)

- Argentina - Administración Nacional de Medicamentos, Alimentos y Tecnología
- Australia - Therapeutic Goods Administration
- Brazil - Agência Nacional de Vigilância Sanitária
- Canada – Health Canada
- Europe - European Commission & European Medicines Agency
- Japan - Ministry of Health, Labour and Welfare & Pharmaceuticals and Medical Devices Agency
- Mexico - Comisión Federal para la Protección contra Riesgos Sanitarios
- Republic of Korea - Ministry of Food and Drug Safety
- Singapore – Health Sciences Authority
- Switzerland - Swissmedic
- Taiwan - Taiwan Food and Drug Administration
- United Kingdom - Medicines and Healthcare products Regulatory Agency
- United States - Food and Drug Administration
- Netherlands - Netherlands National Institute for Public Health and the Environment
- Frederick National Laboratory for Cancer Research

5. SPECIFIC ORGANISATION

5.1. Designation of a Chair Supporteur

5.2. Organisation of meetings

2-3 teleconferences per year

1 annual face-to-face meeting coinciding with an international nanomedicine conference

5.3. Contact with stakeholders

Contact with stakeholders usually occurs through sessions at an international conference