IPRP
International Pharmaceutical Regulators Programme

Mandate Document

Cell Therapy Working Group (CTWG)

Version 1.0

endorsed by the MC on 9 June 2015

Document History

Version number	Action	Date of endorsement
v1.0	First version of the Mandate document (dated 18 Nov 2014) presented to the MC for endorsement at the meeting in Fukuoda, Japan in June, 2015.	**9 June 2015**

1. General Considerations

1.1. Statement of the Perceived Problem

Harmonized approaches for evaluating the safety and efficacy of cell therapy products in an environment where regulations vary in specific regions is essential to enhance the global availability of safe and effective CT products has been lacking.

1.2. Expected Benefits

The CTWG provides an international networking forum to discuss emerging scientific developments and concerns for the regulation of cell therapy products. This open forum allows for the less experienced regulators to learn from the more experienced regulators and supports the efforts of APEC, PAHO and ICH.

1.3. Background to the proposal

As an emerging product category, cell and tissue-based therapies became a topic for the Regulators Forum in 2011. At the onset, the group established a set of operating principles utilizing a stepwise approach to identify topics for regulatory convergence. The approach included (1) surveys to identify topics of interest; (2) scoping exercises to determine the regulatory landscape for specific topics (3) Identification of topic leads and co-leads; (4) developing the scope of the topic; (5) collection of information on the topic; (6) drafting of a communication of results.

In 2013, the Regulators Forum Cell Therapy Group was formalized under the International Pharmaceutical Regulators Forum (IPRF). Since then the CTWG has held in-person meetings in Auckland, New Zealand to work on a project on the degree of regulatory oversight for specific categories of cell therapy products. The meeting report on this project can be found at http://www.iprp.global/working-group/cell-therapy. The CTWG also held an in-person meeting in London, UK to review the draft Reflection Paper on the nature and duration of follow-up for patients receiving cell therapy products. The final draft will be presented to the IPRI Management Committee at their November, 2018 meeting.

Effective November, 2017, the IPRF and International Generic Drug Regulators Programme (IGDRP) were consolidated into the International Pharmaceutical Regulators Programme (IPRP). The group is currently known as the IPRP Cell Therapy Working Group.

2. Scope

- The products to be discussed in this group include cell therapy products without gene modifications, tissue-engineered products, and xenotransplantation products.
- Non-proprietary information regarding regulatory experiences with CT products including focused topic discussions to enable sharing of views and regulatory best practices among international regulators.
- Topics that with adequate rationalization are potentially suitable for regulatory convergence or harmonisation

3. OBJECTIVES AND KEY DELIVERABLES

The primary goals of the Working Group are information sharing and regulatory convergence.

3.1. Objectives

- Objective 1: Maintain knowledge of regulatory activities in participating regions

  At each meeting or teleconference, a roll call of regulatory updates to include new regulations, new guidance or guidelines, and recently approved products takes place. An annual compilation of updates will be prepared to keep participants up-to-date on current activities for each region.

- Objective 2: Identify Topics for regulatory convergence or harmonization

  Identify possible topics for harmonization or regulatory convergence by conducting scoping exercises to identify commonalities and differences in regulatory approaches.

- Objective 3: Collaborations and information sharing with other international and regional bodies

  Explore information-sharing processes with other international (ICH) and regional bodies (APEC, PANDRA, etc.) and to collaborate in terms of training of international regulators

3.2. Key deliverables

- Deliverable 1: Post results of projects on IPRP website

  Provide meeting summaries and results of specific projects to the MC for posting on the IPRP website.
- Deliverable 2: Draft Reflection Papers

  Reflection Papers will be drafted on topics for regulatory convergence or to communicate to stakeholders the current state of regulation for gene therapy products.
- Deliverable 3: White Papers and Journal Articles

  The CTWG will publish articles in trade journals and peer-reviewed journals as appropriate topics are developed

4. COMPOSITION

The CTWG is comprised of international regulatory authorities and persons representing harmonization initiatives (APEC, WHO, and PAHO), who are interested in the convergence of regulatory approaches for cell therapy products.

5. SPECIFIC ORGANISATION

5.1. Designation of a Chair Supporteur

The Chair Supporteur will provide secretariat support services, including setting up teleconferences, writing agendas and reports. The CTWG will discuss the rotation of this responsibility annually.

5.2. Organisation of meetings

Teleconferences will be held quarterly depending on the availability of participants. Face to face meetings will be held on an ad hoc basis. Chairs and co-chairs of meetings will rotate per a schedule agreed upon by CTWG participants.

5.3. Contact with stakeholders

Contact with stakeholders includes participation in society meetings, publications in peer-reviewed journals., and publications on the IPRP website.