9 December 2011
EMA/CAT/CPWP/669140/2011
CAT Cell-based products temporary working party

Work plan for the Cell-based products working party 2012

Chairperson:

Paula Salmikangas (Chair)

Egbert Flory (Vice-chair)

Status

December 2011 - adopted

1. Meetings scheduled for 2012

- 23 – 24 February 2012
- 3 - 4 May 2012 (virtual meeting)
- 25 – 26 October 2012 (to be confirmed)

Pending the workload, separate drafting group meetings may be organised by teleconference.

2. Guidance documents

Guideline on the risk-based approach according to annex I, part IV of directive 2001/83/EC applied to advanced therapy medicinal products

Action: Public consultation and revision of draft guideline jointly with GTWP.

Comments: The Guideline on cell-based medicinal products (EMEA/CHMP/410869/2006) as well as revision to Annex I, Part IV of Dir 2001/83/EC, as amended, introduce a risk based approach for the development of advanced therapy medicinal products (cell-based products and gene products). This will provide further guidance on how to perform and present this risk analysis for initial marketing authorisation application. This guideline will complement the EMA Guideline on Post-authorisation follow-up of safety and efficacy, and risk management of Advanced Therapy Medicinal Products (EMEA/14995/2008).

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Involved WPs BWP, SWP, PhV WP

Reflection paper on clinical aspects specific to tissue engineered products

Action: Draft reflection paper to be released for public consultation, revised and finalised.

Comments: The guidance includes recommendation for tissue engineered product-specific clinical endpoint, surgical trials and structural endpoints.

Involved WPs SWP, EWP Therapeutic groups

Reflection paper on comparability of cell-based medicinal products

Action: Draft reflection paper to be developed.

Comments: The reflection paper is intended to cover comparability issues during development, Pre-authorisation and Post-authorisation phase (i.e. variations).

Involved WPs BWP, BMWP

Concept paper/Reflection paper on investigational cell-based medicinal products

Action: Consideration on the need to develop guidance for cell-based investigational medicinal products.

Comments: To address the specific quality and non-clinical issues in relation to various stages of clinical development with a special emphasis on first-in-man studies.

Multidisciplinary guidance in collaboration with SWP, BWP and the Clinical Trial Facilitation Group.

The initial reflection on the need for guidance should consider available guidance on the subject (ICH, CHMP guidelines) and propose content, scope and benefit of the proposed guidance.

Flowchart of existing guidelines for cell-based medicinal products

Action: To develop a flow chart of existing guidelines for cell-based medicinal products and to develop a user-friendly way of navigating EMA/ATMP guidelines.

Comments: With reference to CAT focus group on 'navigating EMA/ATMP guidelines for cell therapies'.

3. Awareness on scientific issues

Preparation of scientific reports on matters of public interest and emerging issues pertaining to cell-based therapy. In particular, the working party intends to address the following scientific topics:

- collaboration with CAT/BWP/EDQM concerning standardisation of raw materials for production of cell-based medicinal products.

- collect information on hot topics in the cell-based area (e.g. mesenchymal stem cells and tumourigenicity, immunotherapeutic products).

Information on regulators views on scientific issues specific to cell-based therapy (via commentary, or participation to/preparation of workshop / expert panel, regulators training subject to outcome publication, etc).

4. Other activities and activities at the request of CAT

4.1 Contribution to scientific advice, marketing authorisation evaluation, post-authorisation procedure evaluation, classification, certification, paediatric investigation plan evaluation and orphan designation on general and product specific matters related to cell-based products;

4.2 Contribution to guidance documents of other EMA Committees and Working Parties/Groups where cell-specific expertise is required (e.g. indication specific guidelines);

4.3 Contribution to briefing meetings related to cell therapies with external parties (pharmaceutical companies, academia, public/private partnership or patients' associations) through the participation of experts in close collaboration with the Innovation Task Force;

4.4 Liaison with interested parties (e.g. learned societies, trade organisations, industry, academia, patient's organisations) in close collaboration with the CAT. (See VI. Rules of procedure);

4.5 International cooperation on cell-based products related matters;

4.6 Contribute to training for quality, preclinical and clinical assessment of cell-based products, as agreed or requested by the CAT and contribution to and organisation of external workshops and trainings related to cell-based products, where requested.

4.7 Constitute a rapid-acting crisis group to take on board specific issues related to cell-based products with the objective of exchanging information on a European level and to co-ordinate responses to the public in a timely manner, where requested;

4.8 Any other task delegated by the CAT for example liaison with the EC, other committees and working parties on matters relevant to cell-based therapy.