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Human Medicines Research and Development Support Division

Mandate of the EMA Innovation Task Force (ITF)

Background

The EMA and the Committee for Human Medicinal Products (CHMP) have put in place measures[1] to ensure that the medicines evaluation system is solid enough to stand the challenges of new therapeutics. Scientific, technical and legal issues associated with their development are carefully monitored in EU.

In order to provide support to medicines innovation in EU, the EMA established an internal EMA horizontal cross-sectorial group, the EMA Task Force on Innovation (ITF), to focus in particular on *Emerging Therapies and Technologies*.

The ITF brings together competences from the areas of Quality, Safety, Efficacy, Pharmacovigilance, Scientific Advice, Orphan Drugs and good practices compliance[2], as well as legal and regulatory affairs.

Objectives of ITF

- Establish a discussion platform for early dialogue with Applicants in particular SMEs to proactively identify scientific, legal and regulatory issues of emerging therapies and technologies.
- Address with relevant EMA Committees and their Working Parties impact of emerging therapies and technologies on current scientific, legal and regulatory requirements.
- Identify early the need for specialised expertise.
- Provide in conjunction with the CXMP (Committees for Medicinal Products, human and veterinary) and the European Commission – as appropriate – regulatory advice to applicants on the eligibility to EMA procedures as a Medicinal Product e.g.
    - where there are uncertainties on whether the concerned therapeutic product(s) would contain a medicinal substance
    - for borderline products,

[1] Initiatives include fact-finding workshops, issuance of reflection papers, multidisciplinary guidelines, eligibility procedure, and reinforcement of scientific advice

[2] GMP, GLP, GCP etc.

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- for (medicinal) substances incorporated in medical devices for which the medicinal and ancillary functions are borderline.

o Review of the regulatory and scientific implications of emerging therapies and technologies, in conjunction with the EMA Committees, their Working Parties and NCAs (National Competent Authorities)

o Increase EMA awareness and learning in emerging therapies and technologies

Scope and task of ITF

The scope of the ITF activities encompasses emerging therapies and technologies and borderline therapeutics for human and veterinary health for which there is no established EMA scientific, legal and regulatory experience.

Emerging therapies include:

- gene therapy products, cell therapy and engineered tissues, new targeted therapies, nano-medicines, novel routes of administration and delivery systems – e.g. ex vivo, by surgical implant.

Emerging technologies include:

- new development strategies (e.g. use of genomics or proteomics surrogates), new definitions of target populations in therapeutic fields (e.g. pharmacogenomics), new manufacturing approaches (e.g. use of transgenic plants and animals).

Borderline therapeutics include:

- combination of pharmaceuticals and devices3, medicinal products borderline.

The main tasks of the ITF are to:

1. Provide, in addition to existing EMA formal pre-submission meetings, a multidisciplinary platform for early informal dialogue (briefing meetings) with Applicants[4] of emerging therapies and technologies, especially SMEs, in order to:

o Share information with the Applicant on any identified legal, regulatory or scientific issues for selected product(s) in their pipeline. Some topics may need to be formally addressed at a later stage within the existing procedures (e.g. Scientific Advice or Orphan Medicinal Product designation)

o Discuss, where applicable, issues relating to the eligibility to EMA procedures

o Provide information on EMA structure, role and responsibilities, and on all available EMA procedures and their benefits

o Increase awareness of the European Pharmaceutical Legislation and requirements

[3] Such as combinations of devices with either NCEs or blood and plasma derivatives

[4] The is early dialogue recommended on these areas to all sponsors and especially to SMEs in view of the complex implications that might be identified for the types of products herein considered.

- Identify early the need for specialised expertise in these new fields.

2. Provide EMA scientific opinion to Applicants on the eligibility for access to EMA procedures where applicable, before access to EMA procedures e.g. scientific advice, orphan medicinal product designation and marketing authorisation procedures. The ITF will involve as appropriate EMA staff, CXMP Working Parties, European Commission and NCAs.

3. Exchange information and establish networks both internally, with EMA scientific committees and Working Parties, and externally with EU networks and specialists[5] to develop and maintain overall network expertise in these new fields.

4. To identify areas for legal, regulatory and technical guidance preparation and proposals for consideration by the EMA Committees and Working Parties and to contribute to relevant EC initiatives and legislation.

The Deliverables are as follows:

Product specific

- Summary report of the briefing meetings with Applicants
- EMA scientific opinion on eligibility to EMA procedures (e.g. Scientific advice, Orphan drug designation, consultations on ancillary medicinal substances and blood and plasma derivatives in devices).

General

The ITF will provide:

- Contribute to EMA environmental assessment with the experience in emerging therapies, technologies and borderline products (in parallel with the EMA reporting cycle)
- Reflection papers upon request.

Composition of the ITF

ITF members are scientific and legal administrators appointed from all areas of the Agency.

Core members are appointed on the basis of competence, areas of interest and commitment. Network experts participate in meetings as needed for discussions relating to their specialised area.

Working methods

The members will contribute to the work program to be executed in the plenary sessions of the ITF.

For the organisation and conduct of briefing meetings and for the scientific opinions on eligibility relevant SOPs apply.

To fulfil its tasks the ITF may consult, as appropriate EMA scientific Committees and Working Parties or individual experts.

[5] EMA Policy on the Handling of Conflicts of Interests for EMA Scientific Committees Members and Experts (EMA/H/31653/03/Final) will apply.