



The EMEA Innovation Task Force



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Stimulation of innovation



- One of the goals of the long-term strategy of the Agency is to foster research and innovation uptake in the development of pharmaceuticals
- EMEA priority set out in the EMEA Road Map and Work Program
- The Agency provides sponsors with assistance & guidance through different procedures and initiatives, in particular:
 - Scientific Advice
 - SME office and
 - **Innovation Task Force (ITF)**



EMEA Innovation Task Force (ITF)



Human Medicines - Medicines and Emerging Science - Innovation Task Force - Microsoft Internet Explorer

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Innovation Task Force

The Innovation Task Force (ITF) is a multidisciplinary group that includes scientific, regulatory and legal competences, set up to ensure EMEA-wide coordination in the areas of interest and to provide a forum for early dialogue with applicants ([click here for ITF mandate](#)).

The ITF, within eight weeks of receipt of a request from an applicant, arranges free-of-charge briefing meetings to facilitate the informal exchange of information and the provision of guidance early in the development process. Where appropriate, this is done in liaison with EMEA scientific committees, working parties and expert groups, and takes into account ongoing international activities.

Briefing meetings are also meant to complement and reinforce existing formal regulatory procedures (e.g. designation of orphan medicinal products, CHMP scientific advice etc).

The ITF – in liaison with the CHMP and, where appropriate, the European Commission – provides regulatory advice on whether new medicinal products for emerging therapies and borderline products are eligible for EMEA procedures. This advice is provided free of charge within 60 days of receipt of a valid request from an applicant.

The scope of the briefing meetings covers regulatory, scientific and other issues arising from the development of new therapies and technologies and borderline products. The applicant's information is kept confidential. EU scientific experts may participate as appropriate.

Briefing meetings may also be the first step for regulatory advice concerning those medicinal products for which confirmation is needed, with regard to their status and the applicability of pharmaceutical legal provisions.

To request a briefing meeting, please complete the request form below and return it to:
ITFsecretariat@emea.europa.eu

Contact Point

For general queries on matters covered by this page please send an e-mail to:
ITFsecretariat@emea.europa.eu

All other queries should be sent to: info@emea.europa.eu

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ITF objectives

Established in 2001 to improve early contacts with Sponsors (EU “soft” landing zone) to:

- Identify and monitor progress of emerging science with potential regulatory implications
- Provide sponsors (Academia, SMEs, Industry) with a platform for early, informal scientific discussion
- Guide through the tools available at the EMEA to meet the needs of sponsors





Products within the scope of ITF activities

- **Emerging therapies**

- gene therapy products, cell therapy and engineered tissues, new targeted therapies, nanomedicines, novel routes of administration and delivery systems

- **Emerging technologies**

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

- **Borderline therapeutics**

- combination of pharmaceuticals and devices, medicinal products borderline to nutrition supplements



for which there is no established EMA scientific, legal and regulatory experience

ITF composition

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- A vertical blue bar with five yellow stars, positioned to the left of the list.
- Multidisciplinary EMEA group from scientific, regulatory and legal sectors
 - ITF members are organised in specialised groups as follows:
 - Cell therapy products
 - Gene therapy products
 - Nanomedicines
 - Genomics
 - Borderline combination products

ITF Tasks



Main tasks:

- Briefing meetings with sponsors
- Regulatory advice on the eligibility of innovative and borderline products to EMEA procedures (“classification”)



To fulfil its tasks the ITF consults:

- EMEA scientific committees (e.g. CHMP, COMP)
- Working Parties (e.g. Cell Products WP, Gene therapy WP, Biologics WP)
- or individual EU experts





Briefing Meetings with sponsors

- Early informal dialogue to encourage exchange of scientific and regulatory information during the development process
- Provide early guidance on the the different EMEA services (e.g. Orphan Designation, SME incentives, Scientific Advice), pharmaceutical legislation and requirements

To request a meeting, sponsors need to:

- contact ITF secretariat (ITFsecretariat@emea.europa.eu),
- fill in a request form and a briefing document

Details on the process are publicly available on ITF website

(<http://www.emea.europa.eu/htms/human/mes/itf.htm>)



Regulatory Advice (Classification) procedure

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- Innovative products often span regulatory boundaries
 - The applicable Regulatory Framework is not always easy to define (medicines, combination products, advanced therapies)
 - However it needs to be clarified early in the development since **there are different regulatory requirements for the development of e.g. a medicinal product compared to a medical device**
 - Early dialogue with the Regulatory Authorities is needed
 - EMA is not a classification body, but can express an opinion on whether the product in question fulfils the criteria of the medicinal products' Regulation

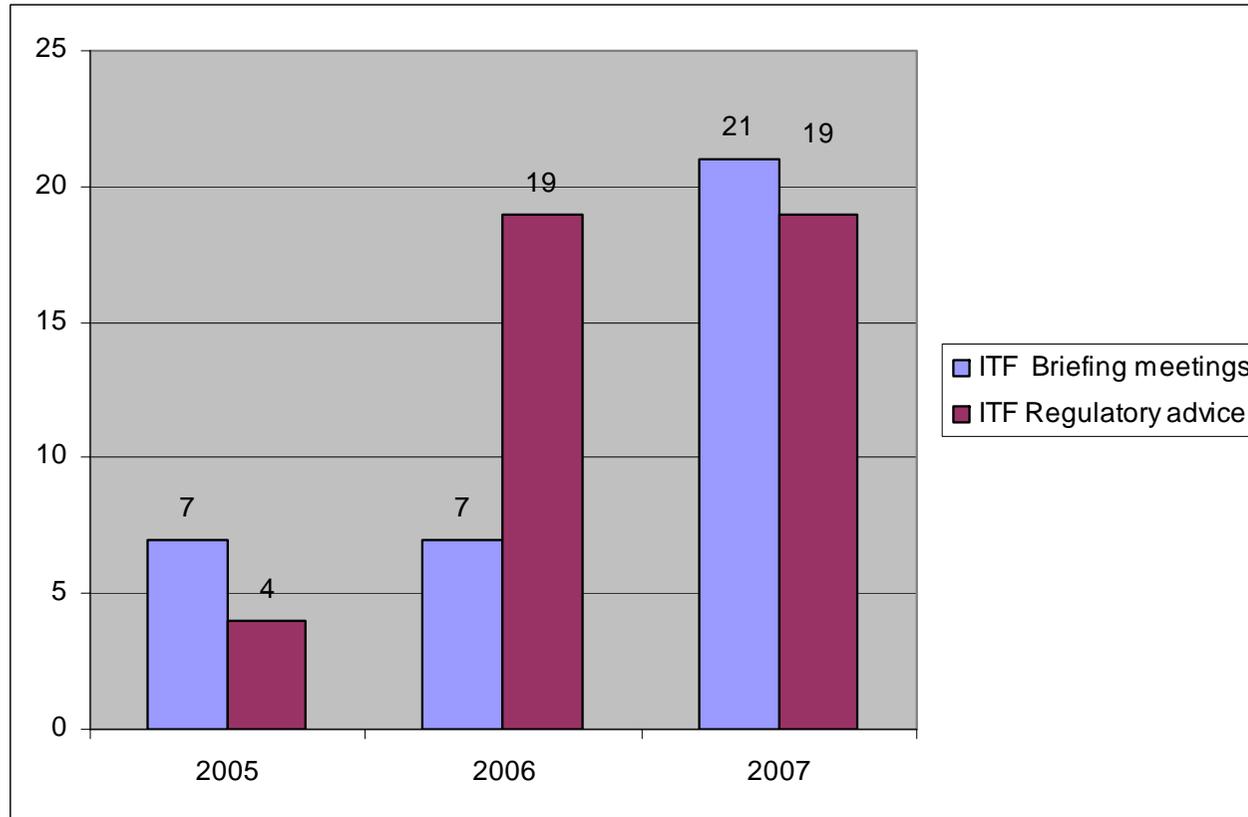


Regulatory Advice (Classification) procedure

- Provided free of charge within 60 days of receipt of a valid request from an applicant.
- Advice prepared by ITF with CHMP/EC involvement, when there is not regulatory precedence
- Details on the process are publicly available on the ITF website

<http://www.emea.europa.eu/htmls/human/mes/itf.htm>





An increasing number of cell-based products, gene therapy and pharmacogenomics-based products have requested EMEA support in recent years

- L-Antineoplastic and immunomodulating agents (42%)
- A-Alimentary tract and metabolism (16%)
- C-Cardiovascular system (12%)

Conclusions

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- A vertical blue bar on the left side of the slide, containing five yellow stars arranged vertically, serving as a decorative element for the list of conclusions.
- ✓ EMEA is publicly engaging in support of innovative products
 - ✓ The ITF model of informal dialogue with sponsors from early stages in the development has been proven to be effective in:
 - Providing sponsors with a better insight on potential regulatory implications when developing their products
 - Allowing regulators increase their understanding on emerging science.
 - ✓ Early dialogue with the Regulatory Authorities should increase possibilities for marketing authorisation of novel ideas
 - ✓ **Opportunities for dialogue in the run-up to implementation of advanced therapies regulation**



Thank you!

Aknowledgements

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