The EMEA Innovation Task Force

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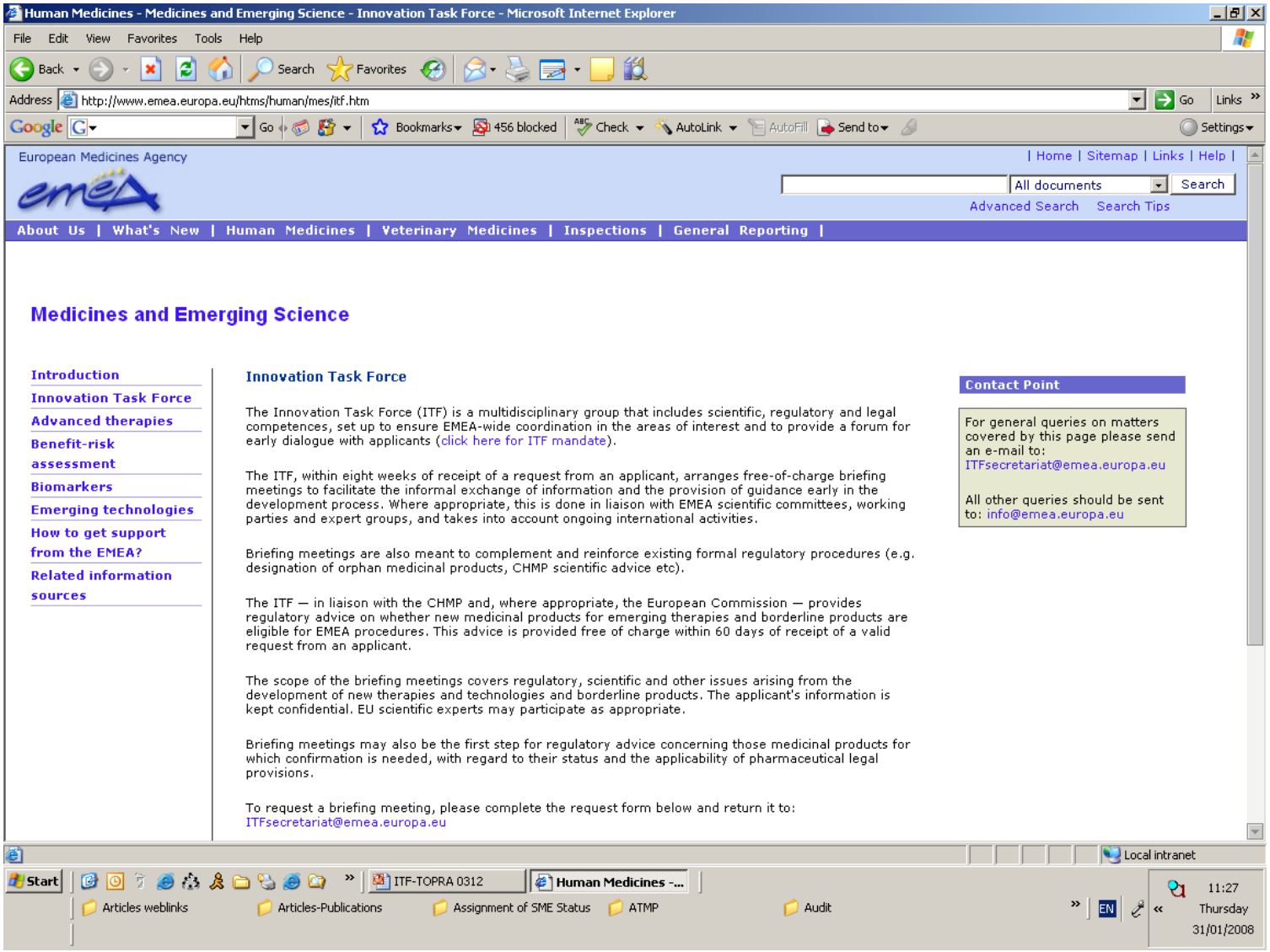
Stimulation of innovation

- 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)



http://www.emea.europa.eu/htms/human/mes/itf.htm

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 EMEA scientific, legal and regulatory experience

ITF composition

- 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)

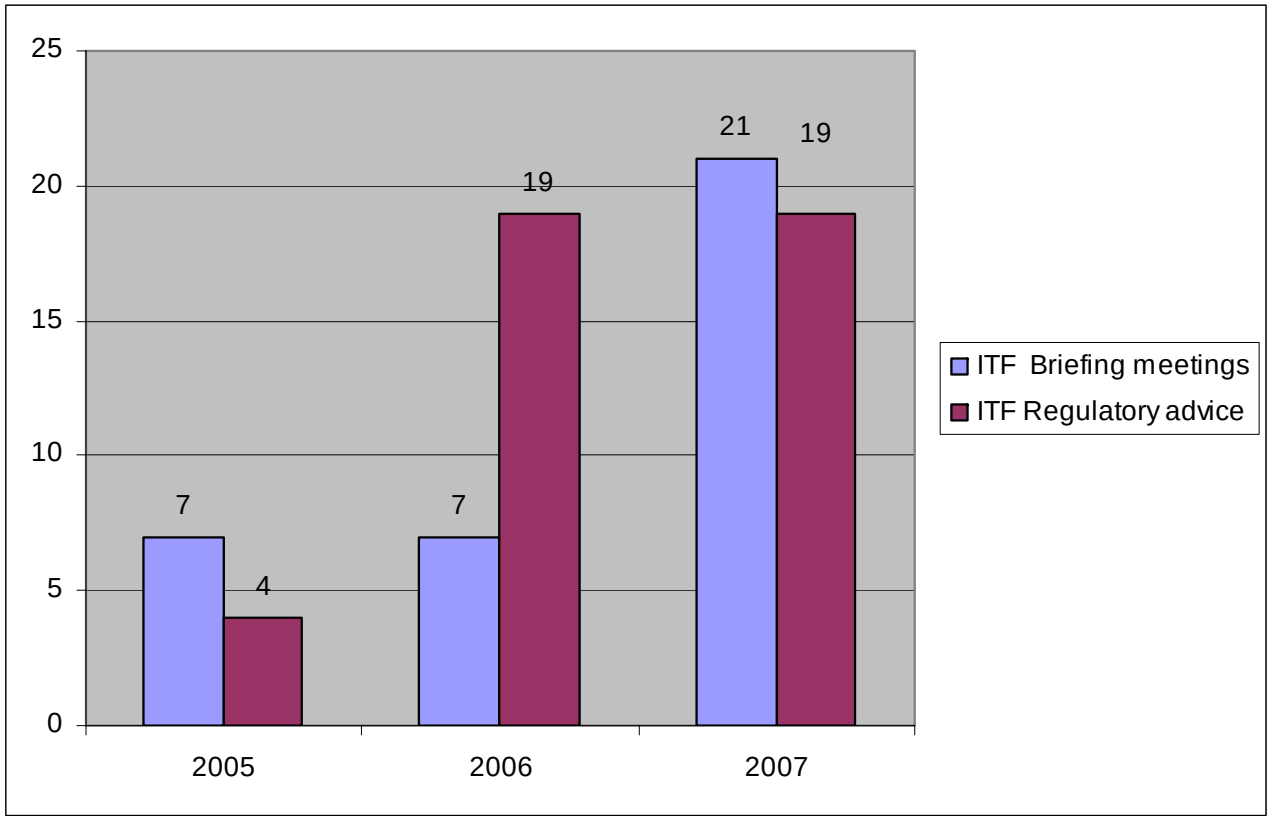
Regulatory Advice (Classification) procedure

- 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
- EMEA 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/htms/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

- ✓ 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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