EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The Innovation Task Force (ITF)

EMA/SMEs Workshop 2011

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WHY we have the ITF?
Innovation: a moving target!

Set up in 2001

- to provide an informal "soft landing zone" to initiate and facilitate dialogue with applicants developing innovative methods and medicines
- to ensure Agency-wide coordination in innovative areas of interest to support the scientific committees
- to promote knowledge sharing and preparedness
- to complement and prepare for formal procedures
- to contribute to and catalyze dialogue with stakeholders on innovation

Who is the ITF?

A multidisciplinary group with "flexible design"

- **ITF secretariat (operational and scientific coordination)**
- **ITF core members and specialised EMA staff (competences and consistency)**
- **Experts from the EMA network (scientific expertise)**

Who is the ITF?
Secretariat and core members

Current areas of activities

- Biomarkers (special focus on genomics) and personalised medicine
- ATMPs and regenerative medicine
- Borderline and combined products
- Nanotechnology applications
- Emerging therapies and technologies (including synthetic biology)

ITF briefing meetings: definition

Free-of-charge informal meetings to open the dialogue on regulatory, technical and scientific issues.

Scope:

> Innovative therapies, methods and technologies, borderline and combined products

Objectives:

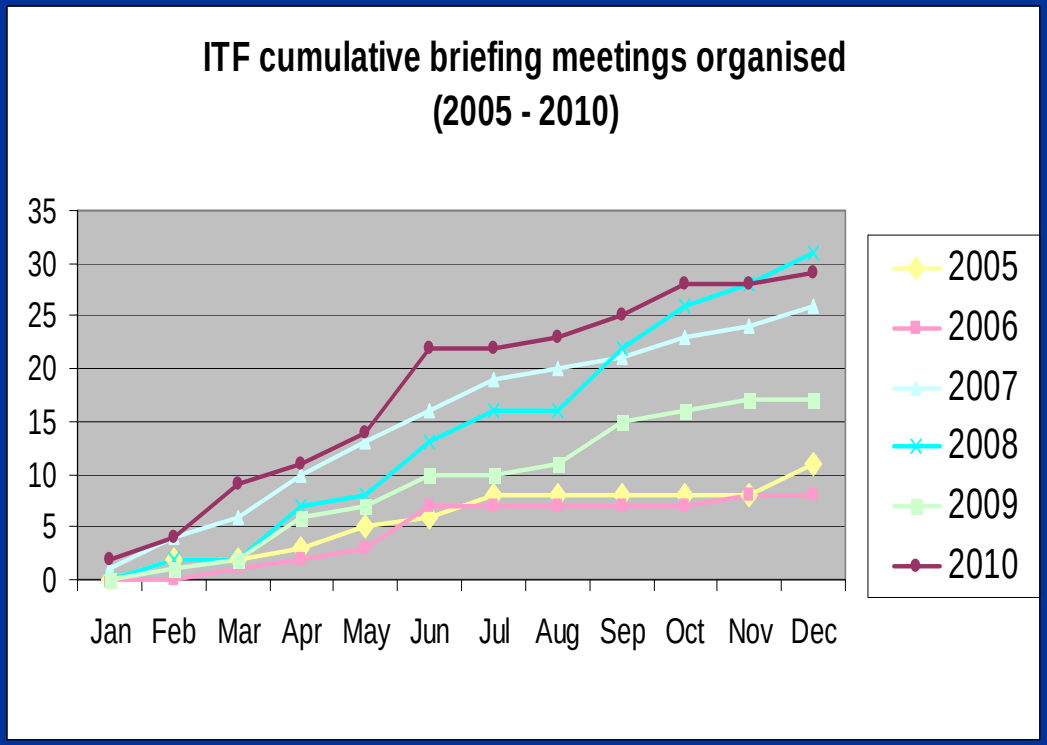
> Contribute to preparedness of both EMA and Applicants

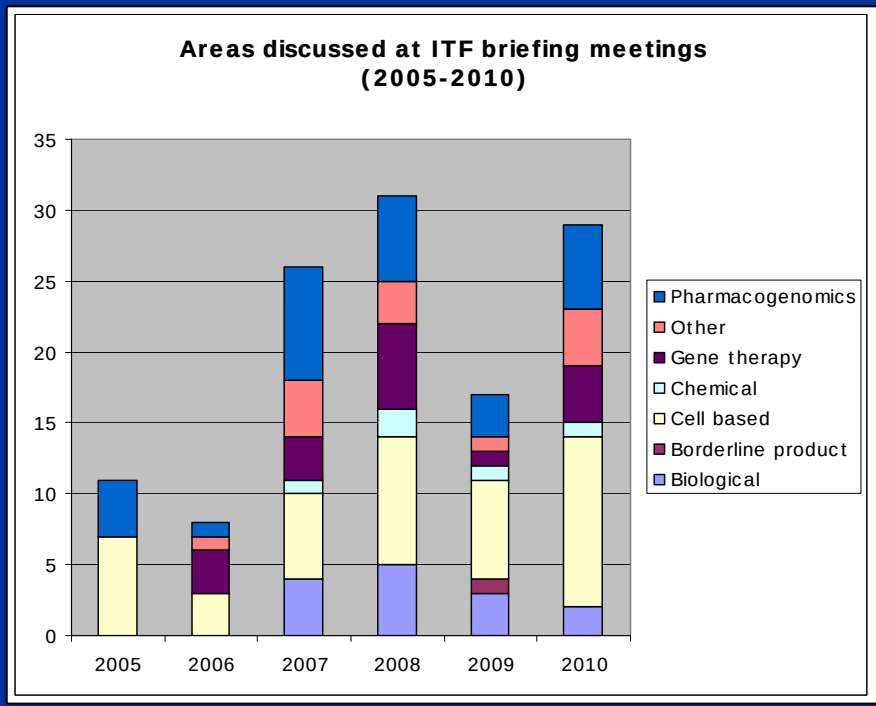
> Complement and reinforce existing formal regulatory procedures

The briefing meetings "profile"

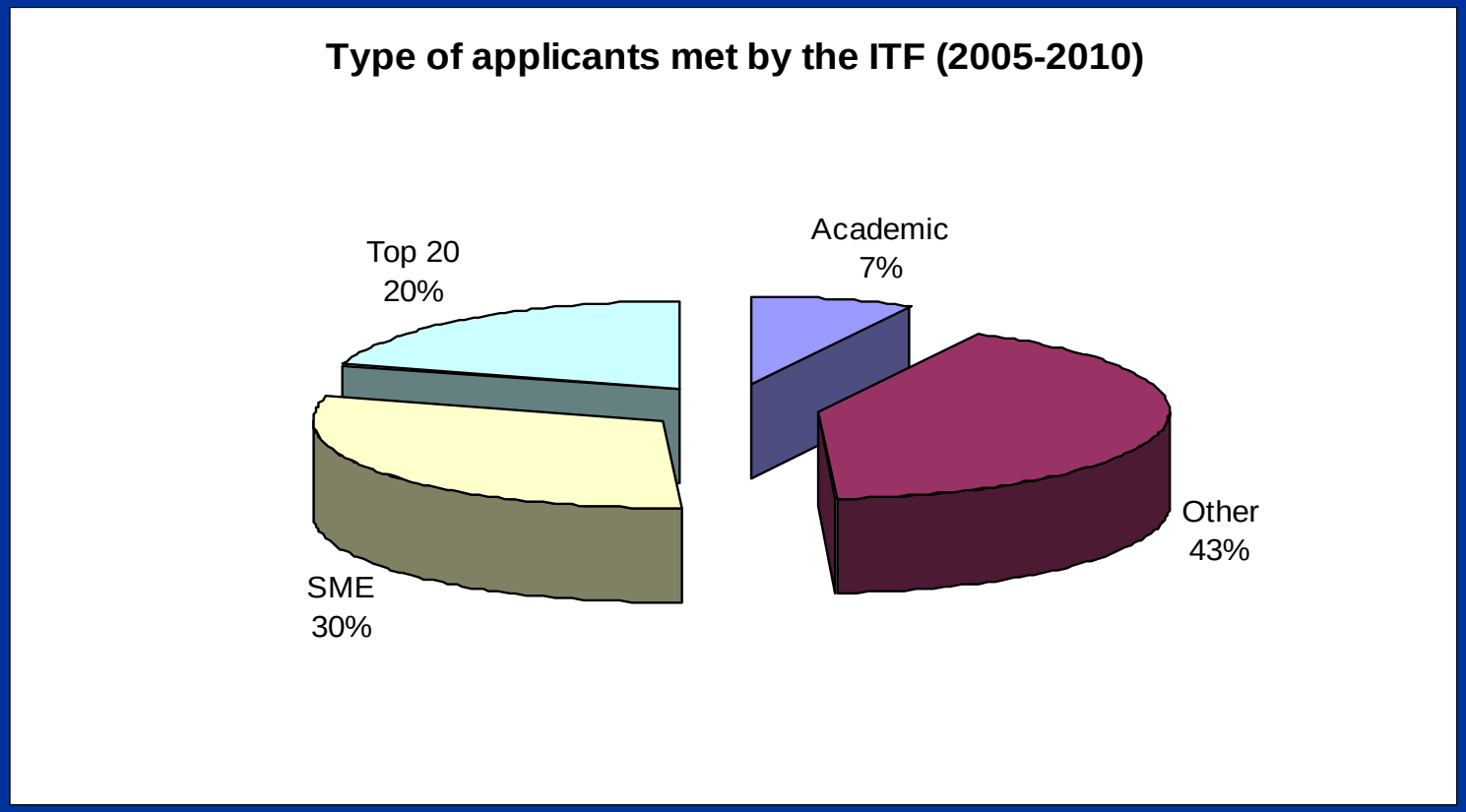
- Profile of the product / technology (sponsor's scientists)
- Development strategy / program: quality, safety, efficacy, manufacturing, RMP (as applicable at the time of the meeting) (sponsor's scientists)
- Key scientific or regulatory areas (all)
- Guidance towards relevant related guidelines, services (e.g. SMEs office) or scientific procedures (e.g. Scientific Advice, OMP designation) in line with the presented strategy of the company (all)
- Identified areas for further reflection and on the regulatory opportunities discussed (all)

ITF briefing meetings: figures

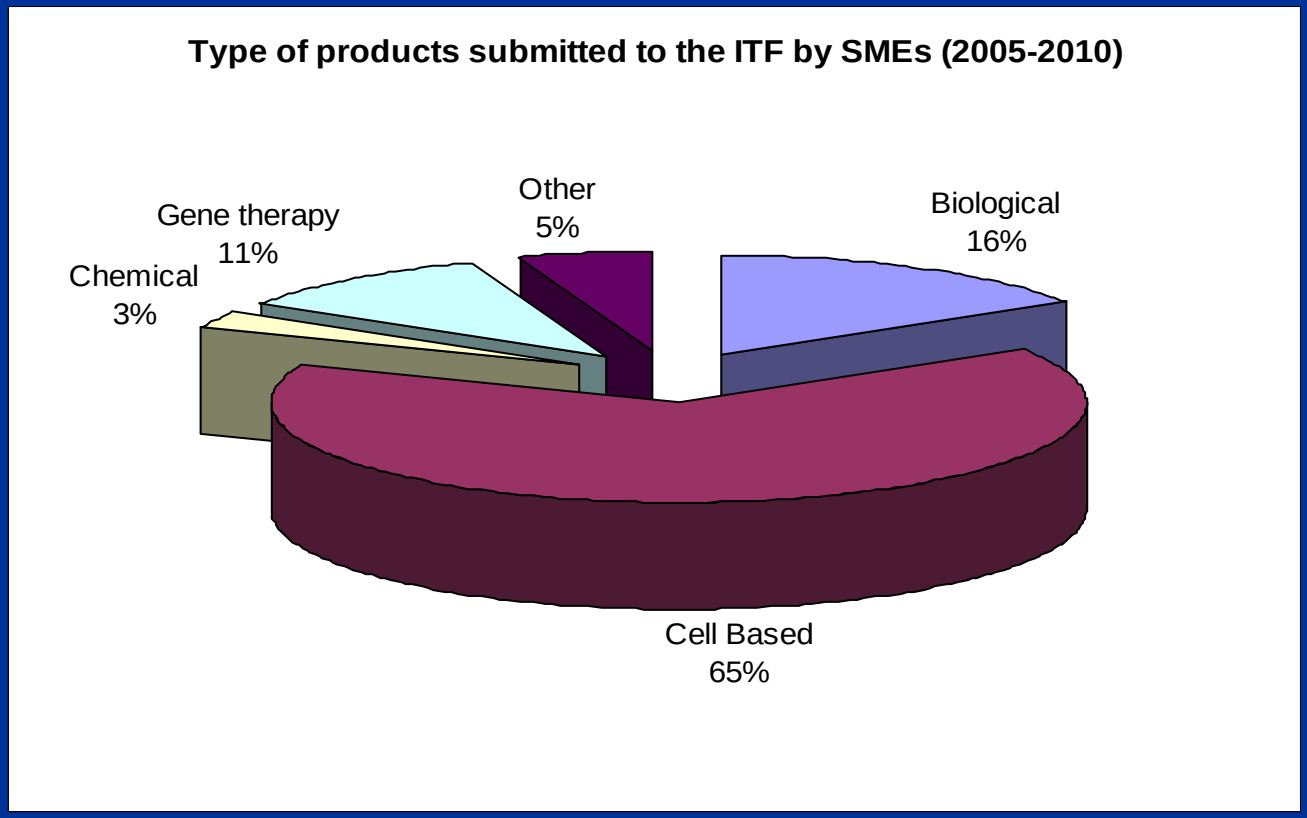




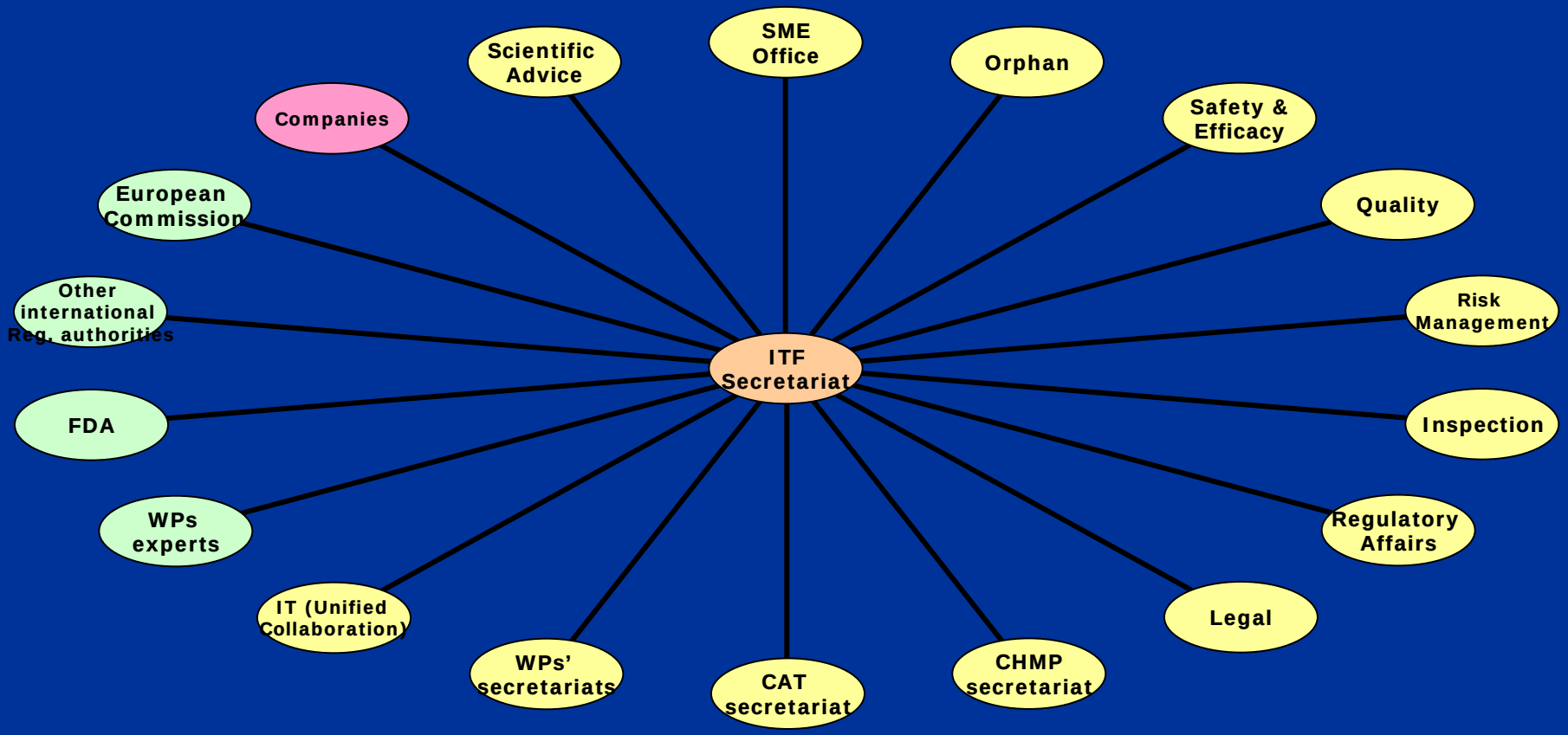
Types of applicants to ITF briefing meetings



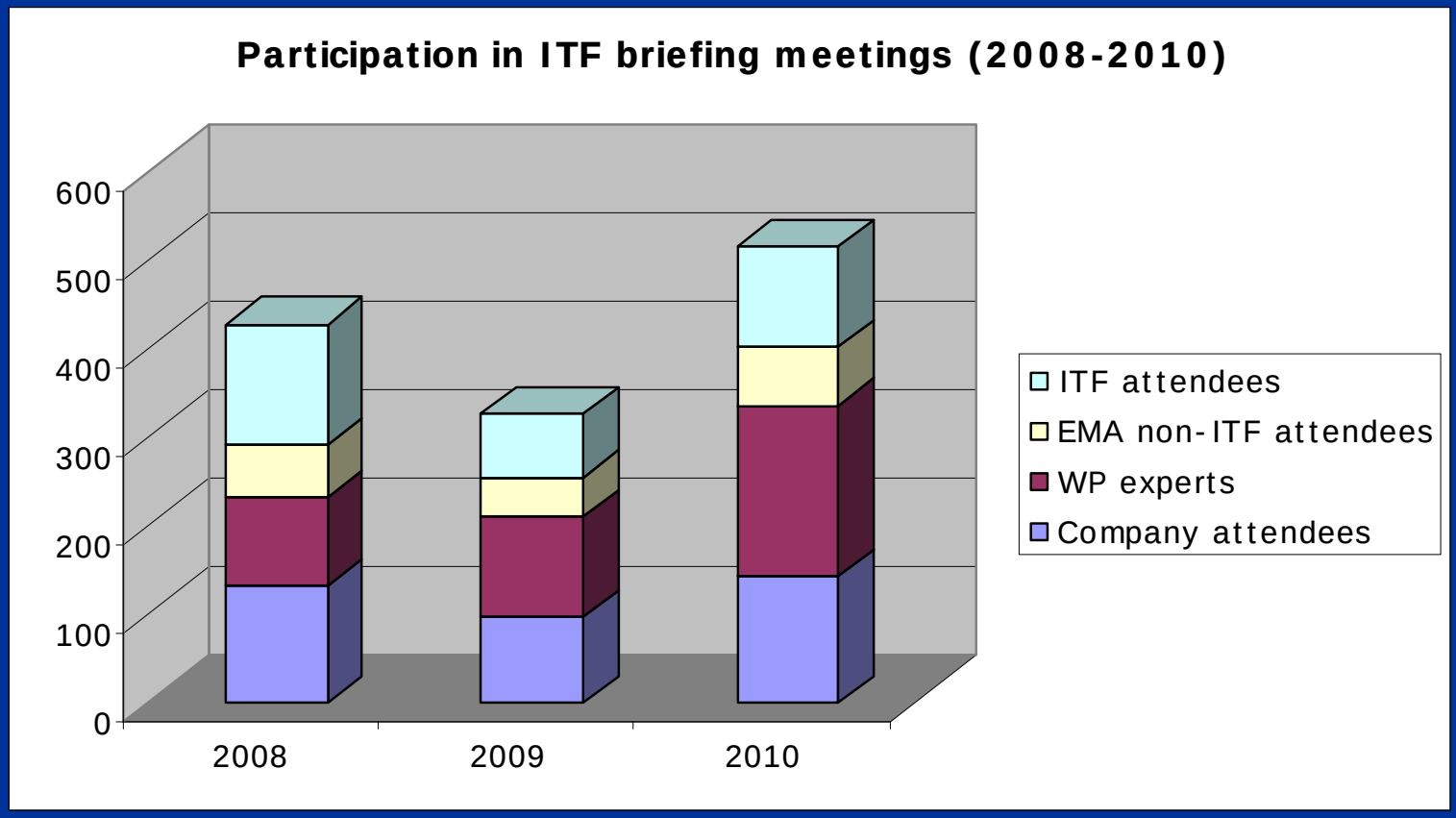
Briefing meeting with SMEs



The ITF coordination "Wheel"



ITF briefing meetings: the network

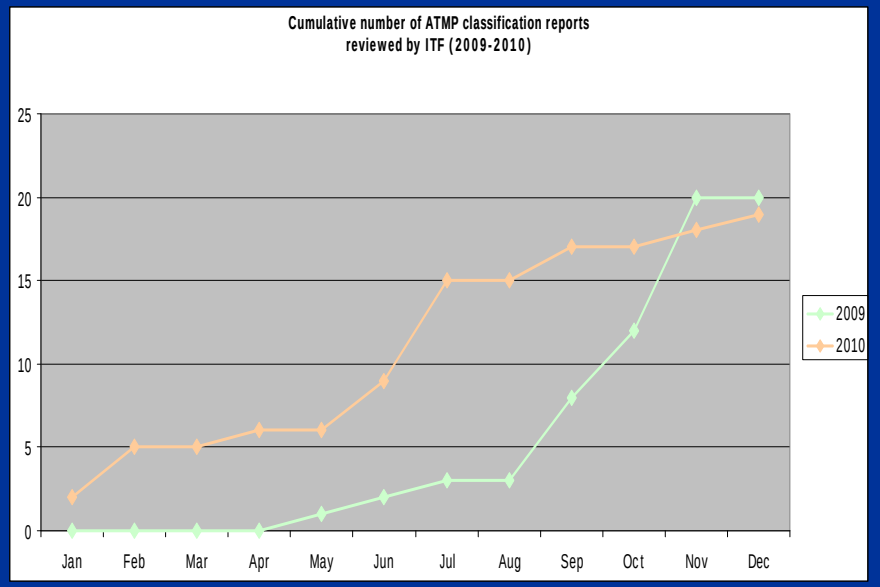


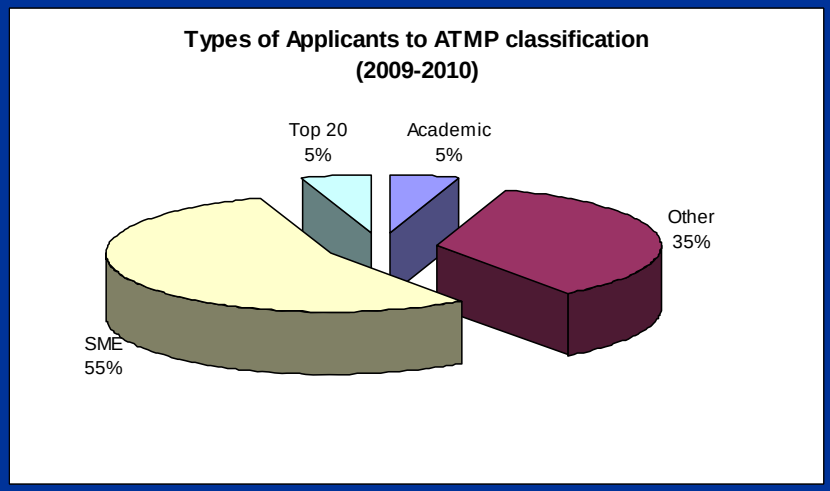
CAT ATMP classification

The **CAT scientific recommendation** on advanced therapy classification is optional … but

Purpose: to determine whether a given product based on genes, cells or tissues meets the scientific criteria which define Advanced Therapy Medicinal Products (ATMPs)

Benefits: special support to ATMPs of SMEs, identify and address early applicable requirements, issues of borderline with other areas. To be done **early** and **before** orphan drug designation, scientific Advice, Paediatric Investigation Plan (PIP), etc.





CHMP Scientific recommendation on eligibility to the Agency's scientific services

The ITF provides, in conjunction with the CHMP and the European Commission, regulatory advice to applicants on the eligibility to EMEA procedures as a Medicinal Product e.g. where there are uncertainties on whether the concerned therapeutic product (s) would qualify as Medicinal product(s).

Regulatory advice frequent areas of uncertainty :

- **Medical Practices (e.g. transplantation)**
- **Medical devices**
- **Food supplements**
- **(Medicinal) substances incorporated in medical devices for which the medicinal and ancillary functions are borderline.**

For further information please contact:

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