Workshop for micro, small and medium-sized enterprises (SMEs)

"*Focus on Scientific and Regulatory Advice*"

FRANCE

Afssaps support to innovative structures

26 May 2011

EMA-SME Office

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Agence française de sécurité sanitaire des produits de santé

Agenda

- 1) Incentives in place
- 2) Some figures and statistics

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Agence française de sécurité sanitaire des produits de santé

1) Afssaps “innovation” policy

Implemented in November 2008

- After 2 years of discussion with internal and external stakeholders in order to establish purposes, limits and procedures.

Scope

- **Innovative healthcare products**
  - Without a clear definition, it’s an open discussion, but we have some key principles
    - New active substance and / or for new development for unmet medical needs
    - Biological products
      - ex : Advance Therapy Medicinal Product
    - Areas where there is no established scientific, legal and regulatory experience / Guidelines
    - New technology
    - Potential clinical impact…
- **Not only medicinal product, also medical device (MD, AIMD, IVD-MD), “combined” products, borderline products…**

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1) Afssaps innovation policy

Aim

- Not to promote innovation, as this is not in Afssaps mission,

But, in the scope of Afssaps public mission, the wish to help development of new healthcare products by taking into account

  - the current knowledge of a given condition,
  - targeted patient population,
  - existing treatment modalities
  - specificities of the product being developed.
  - regulatory requirements and existing guidelines

- In order to
  - anticipate evaluation difficulties due to the innovation
  - avoid inappropriate development
  - avoid regulatory issues
  - identify new product / technology which needs regulatory modifications
  - accelerate access to patients (CT-ATU-AMM…) due to the quality of the evaluation realized by the applicant.
- With always in mind :
  - Patients' security
  - Patients' needs

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1) Afssaps innovation policy

Before 2008

Only “scientific advice” (since 1993)
Powerful tool, but

- only identified by “pharmaceutical groups”, few SME or academic structures asked for it
  - Afssaps = Police ?
  - No clear contact point ?
  - No communication
- usually, only one meeting due to amount of request received
- limited to scientific aspects, no regulatory question
- not always adapted to early stage of development
- not always adapted to academic, SME
- only for medicinal products

Now

Based on

- the qualification of the product (medicine, MD, ?),
- the “regulatory knowledge” of the applicant
- the status of development
- the type of questions

Various tools in place

- Innovation meeting
- Scientific advice
- CTA pre-submission
- Follow-up meeting

With one-stop « shop »

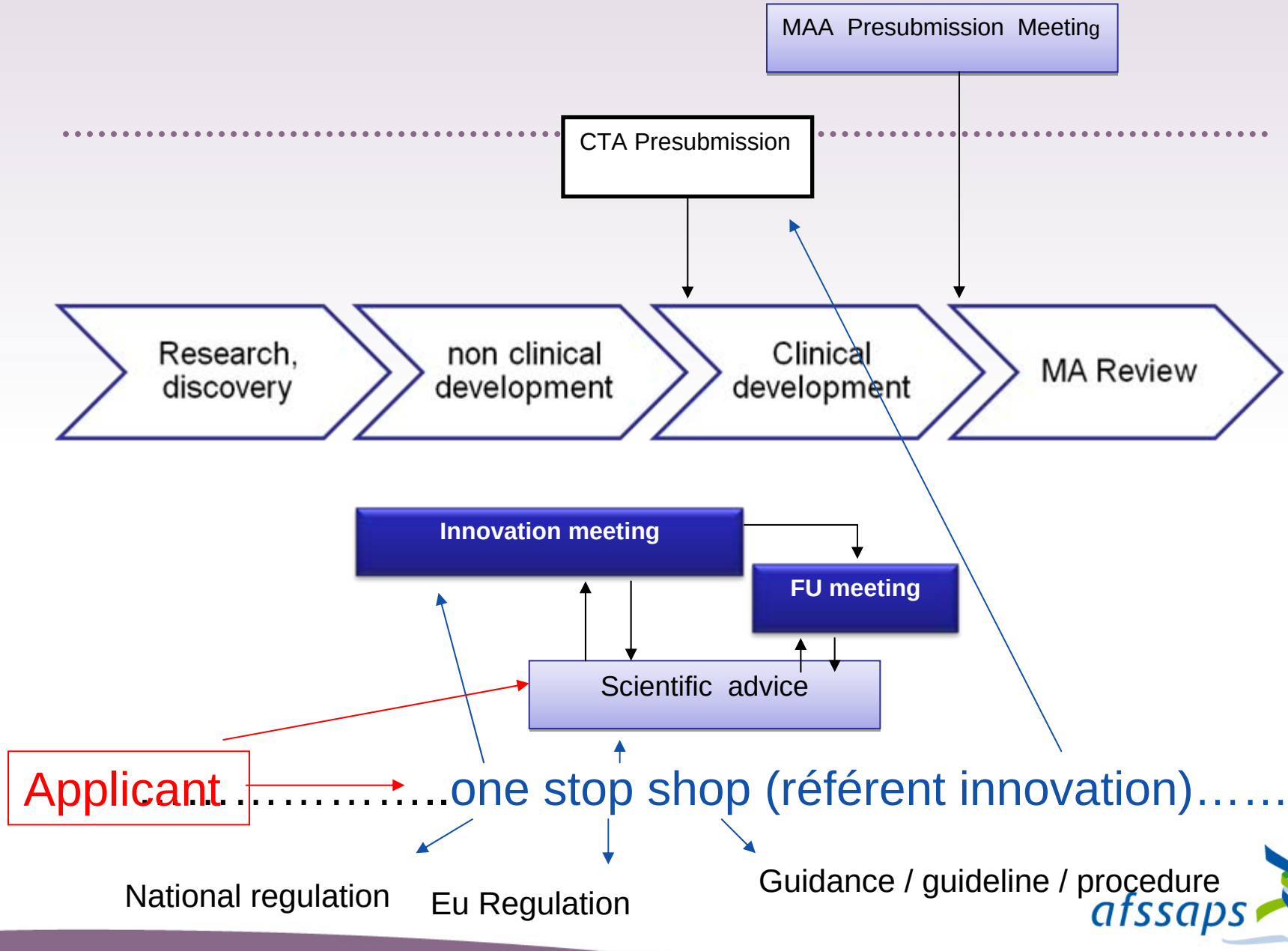
With a pro-active communication (Web site, News, Bulletins, symposium) **on**

- New guidelines
- Regulatory changes
- Aid in place (call for projects etc)
- Workshops for SME /Academics…

1) Afssaps innovation policy

"One stop shop" :

- « le référent innovation »
  - A single interface for all innovative structures
    - Advise on regulatory, administrative and procedural issues
    - Facilitate communication
    - Based on demand and If necessary, find / organize the best type of meeting with the applicant (innovation meeting)
    - Organize workshops/training sessions


MAA Presubmission Meeting
CTA Presubmission
Research, discovery
non clinical development
Clinical development
MA Review
Innovation meeting
FU meeting
Scientific advice
Applicant
one stop shop (référent innovation)
National regulation
Eu Regulation
Guidance / guideline / procedure

1) Afssaps innovation policy

« Innovation meeting »
For MD, IVD-MD, Medicines, borderline products…
Involve Afssaps transversal network (medicine, medical device, legal, clinical trails, quality, inspection…), but may involve external expertise if needed

Early informal dialogue with Applicants => **ANTICIPATE**

- Regulatory advice on classification
- Regulatory assistance
- Regulatory strategy
- Advice on quality, non-clinical evaluation
- Prepare for future formal steps : scientific advice, CTA pre-submission, FU meeting etc

- Procedure in place with a request form
- http://www.afssaps.fr/Activites/Accompagnement-de-l-innovation/Afssaps-et-innovation/(offset)/0

Key contact : Stéphane PALIES

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1) Afssaps innovation policy

Scientific Advice
Only for medicine.
⇒SECURE DEVELOPMENT,
⇒ Scientific advices are organized in order to provide responses to specific questions such as:

- Clinical development (e.g. endpoints, trial duration, …)
- Quality aspects (e.g. viral safety, specific tests to be performed during the development of biotechnological product)
- Non clinical

The questions asked by a Company should be as clear as possible and Company's position justified.
A national scientific advice may be useful in identifying the most important points to discuss at the EMEA if an EMEA advice is planned by a company
The advice will not be given:
If a company has already obtained the EMEA advice
When rapporteur and co-rapporteur for MA request have already been designated by the CHMP
http://www.afssaps.fr/Activites/Avis-scientifique-de-medicaments/Avis-scientifique-de-medicament/(offset)/0
Key contact : Caroline AURICHE

1) Afssaps innovation policy

• Always free of charge,
• You are free to use or not for the tools; the Afssaps is free to accept or to refuse a request

• Always face to face meetings,
• External expertise is always involved for scientific advice meetings and may or may not be required in the case of innovative meetings

• The delay will depend on the availability of experts; in most cases, meetings are organized within 2 months after the receipt of the request
• Minutes are prepared by the applicants, and reviewed by Afssaps

• FU meetings are proposed only for the most complex products or the most promising ones or for products with potential new risks (nano…), and applicants are usually informed of that possibility at the end of the meeting.

• Procedures in place and available on our website for all the tools,

1) Afssaps innovation policy

CTA pre-submission
For MD / Medicines
Before FIM or First CT in France

⇒ **Give time for evaluation / discussion**

This procedure allows the sponsor to ask Afssaps to carry out a preliminary assessment before the official request,

“Real” evaluation

http://www.afssaps.fr/Activites/Medicaments-et-produits-biologiques/Pre-soumission/(offset)/8

If multinational CTs => The Clinical Trials Facilitation Group (CTFG)

- The CTFG offers to clinical trials sponsors a coordinated and simultaneous assessment of multinational clinical trials applications by the national competent authorities concerned, on a voluntary basis : the Voluntary Harmonisation Procedure (VHP) http://www.hma.eu/uploads/media/VHP_version_2_March_2010.pdf

1) Afssaps innovation policy

In conclusion :

• No specific financial provisions for SMEs applicable to human healthcare products.

• However, various procedures are in place in order to help development of innovative heathcare products.

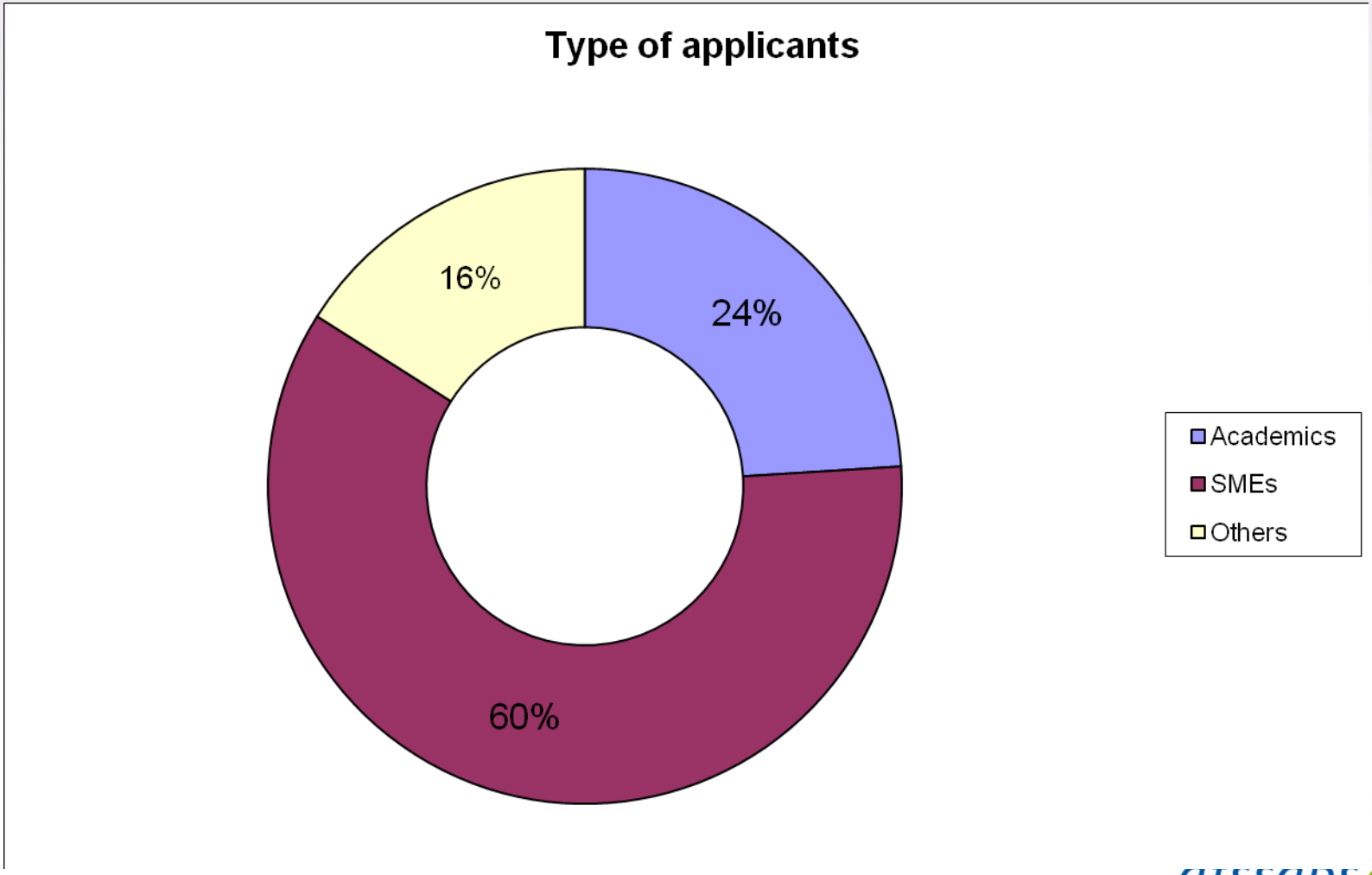
- Early meeting with Afssaps => innovation meeting
- Scientific Advice during medicinal product development or before submission of marketing authorization
- Pre-submission procedure for clinical trials

• Not limited to drugs development, but also to MD / IVD-MD

• These procedures are free of charge for all structures, SME or not.

For more information see:
http://www.afssaps.fr/Activites/Accompagnement-de-l-innovation/Afssaps-et-innovation/(offset)/0

2) Some figures and statistics



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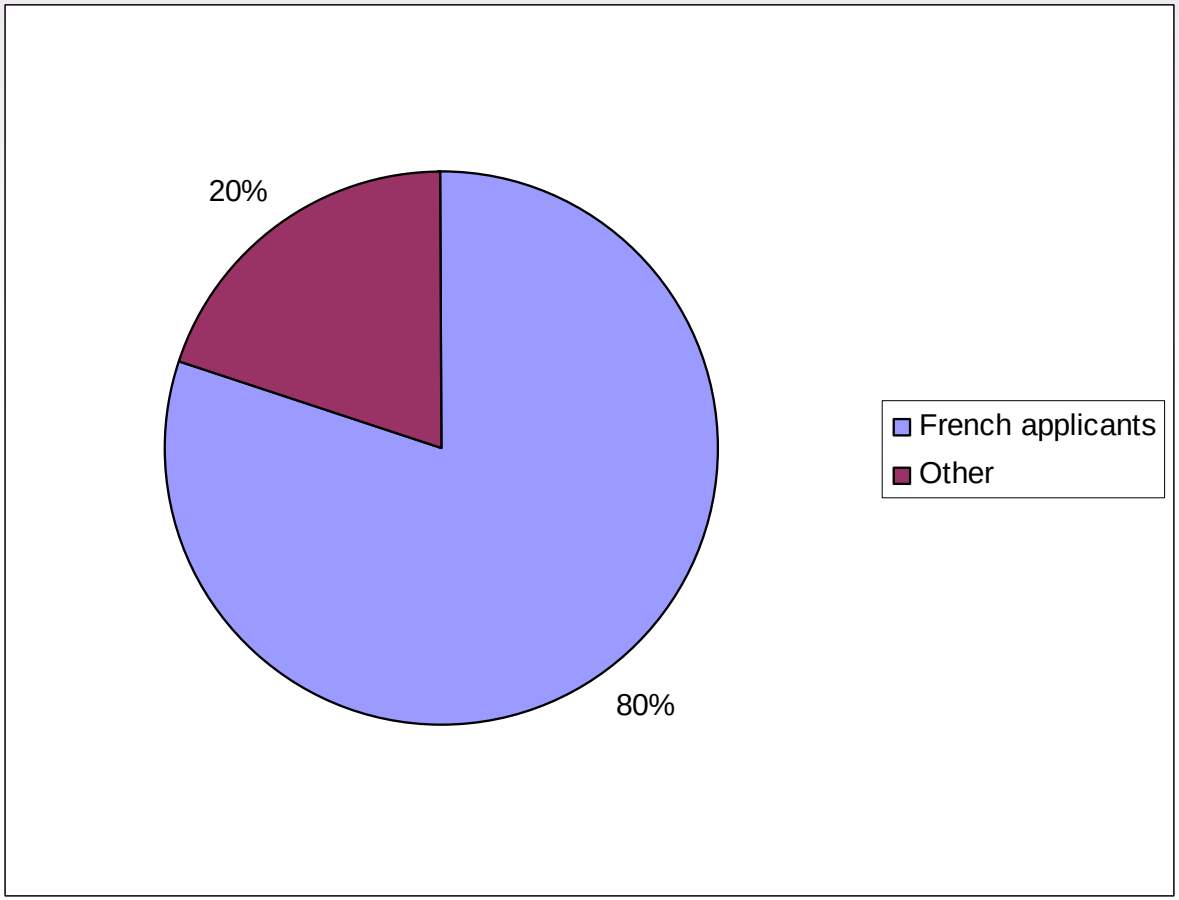

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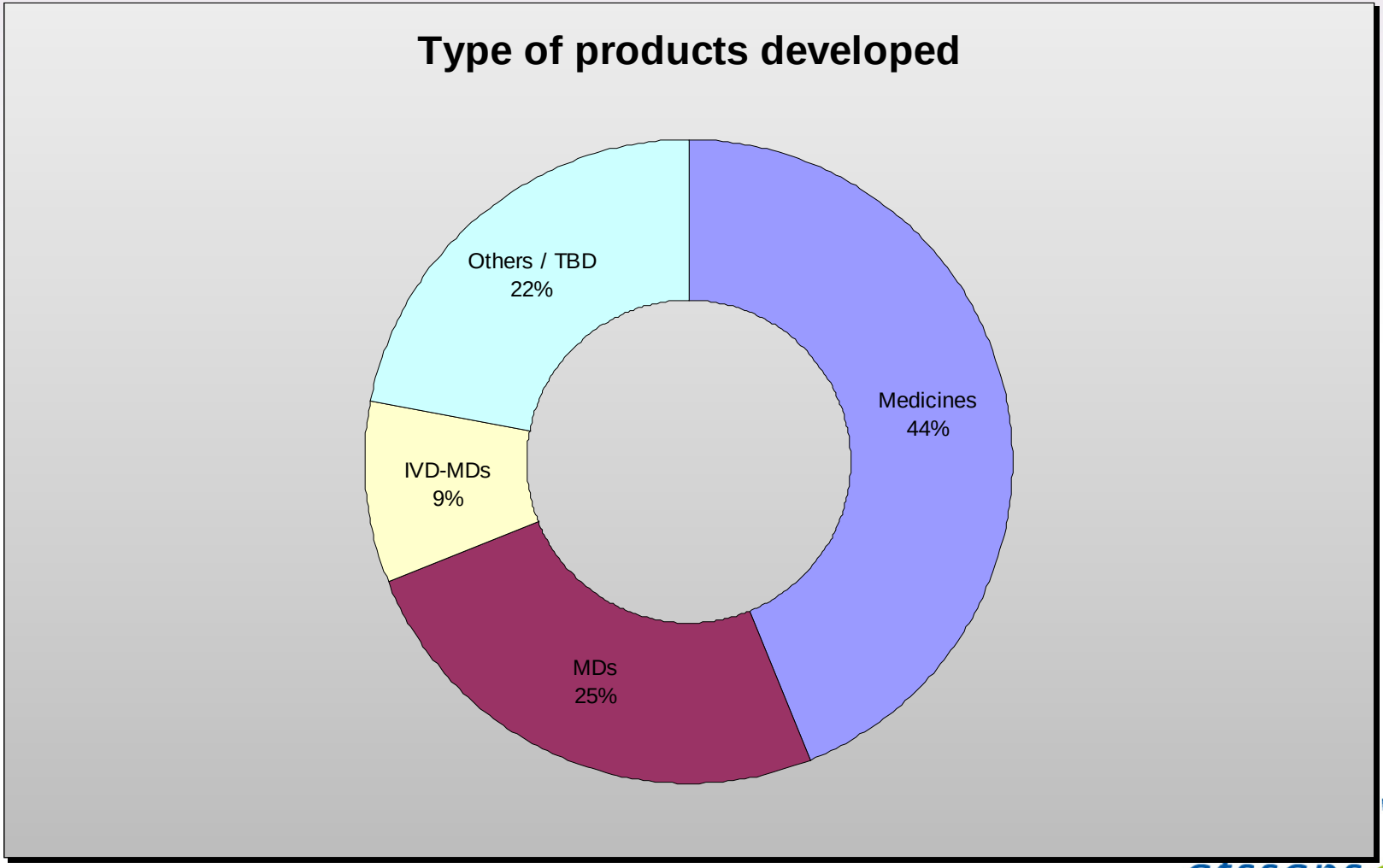

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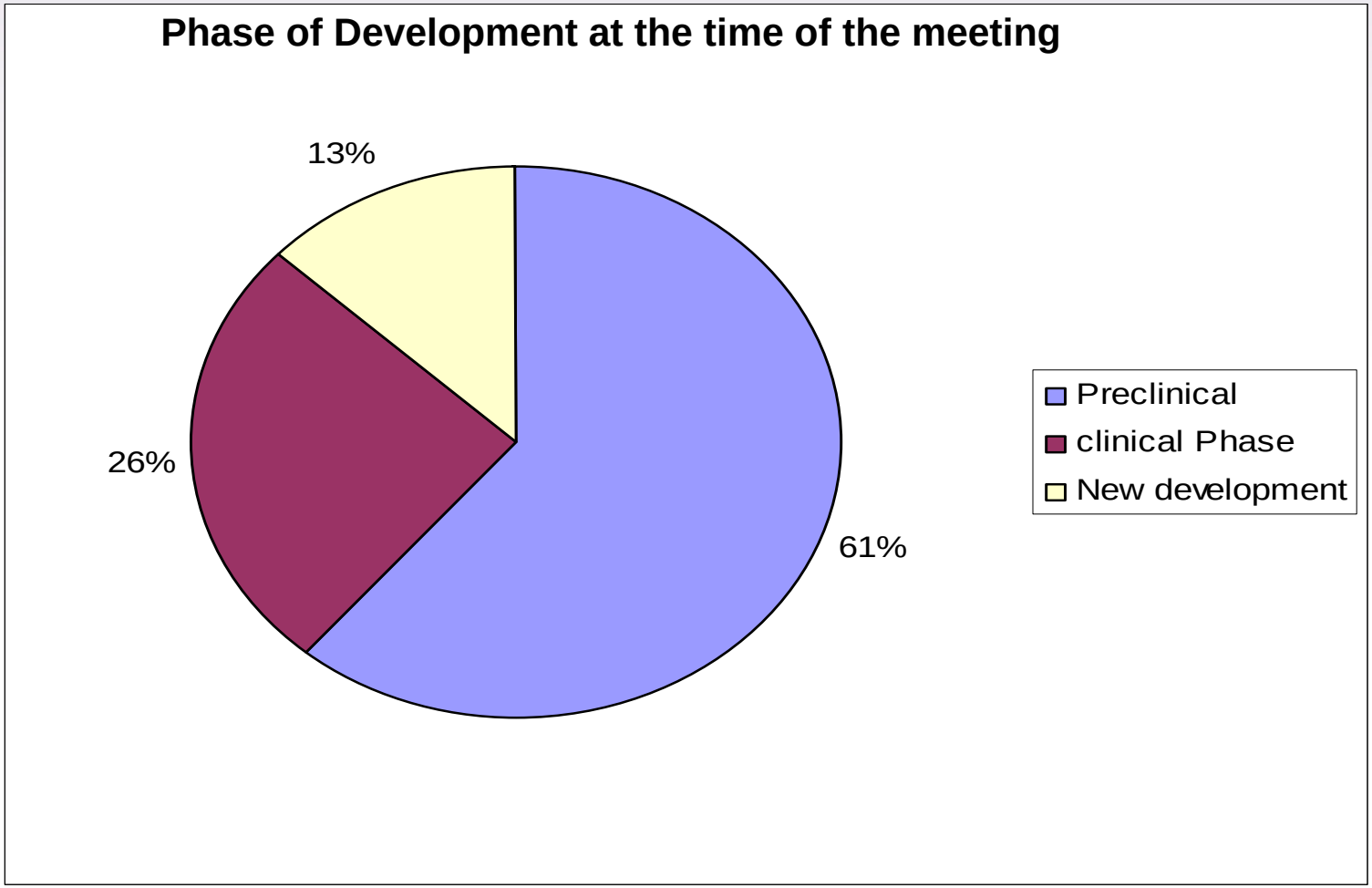

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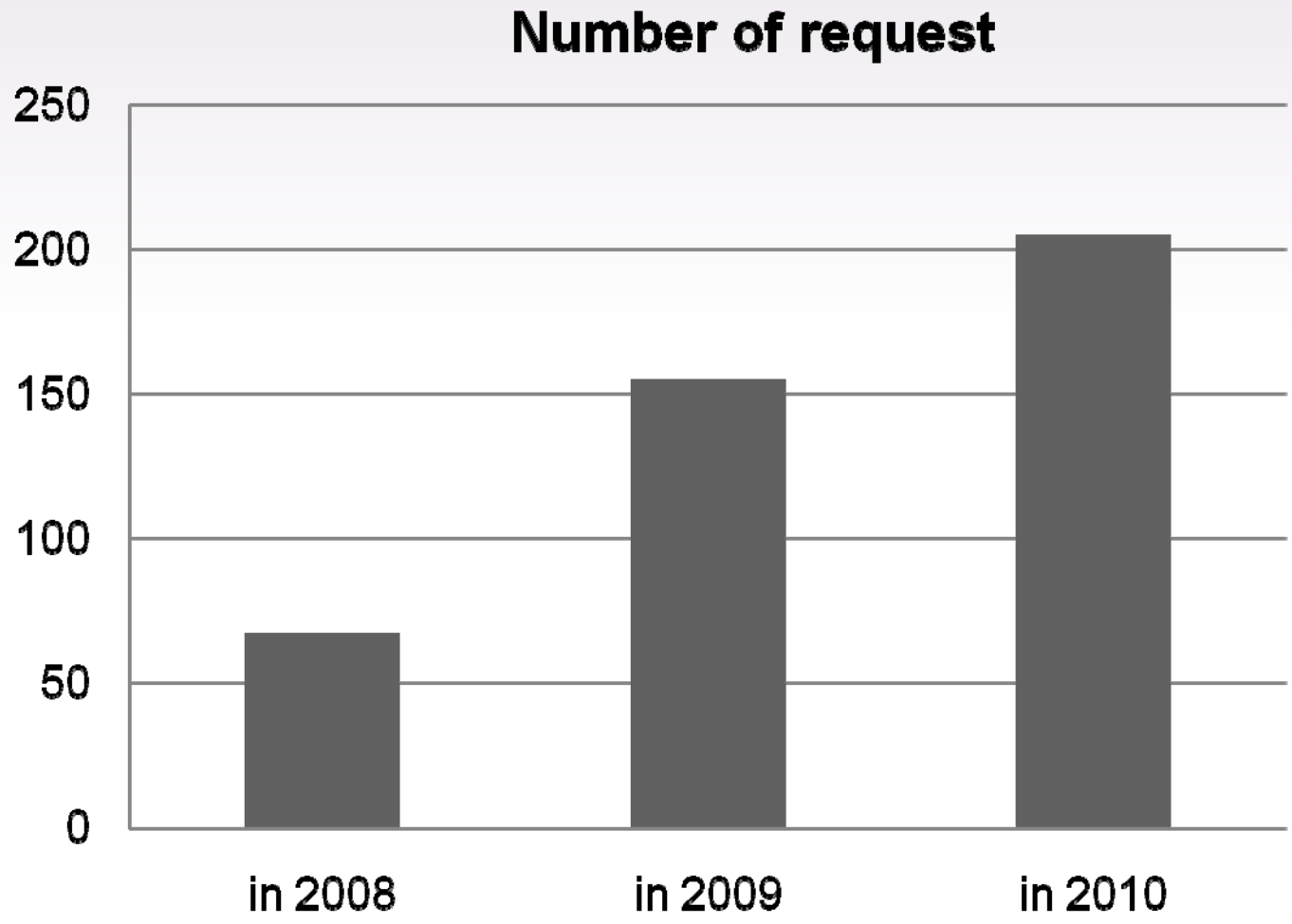

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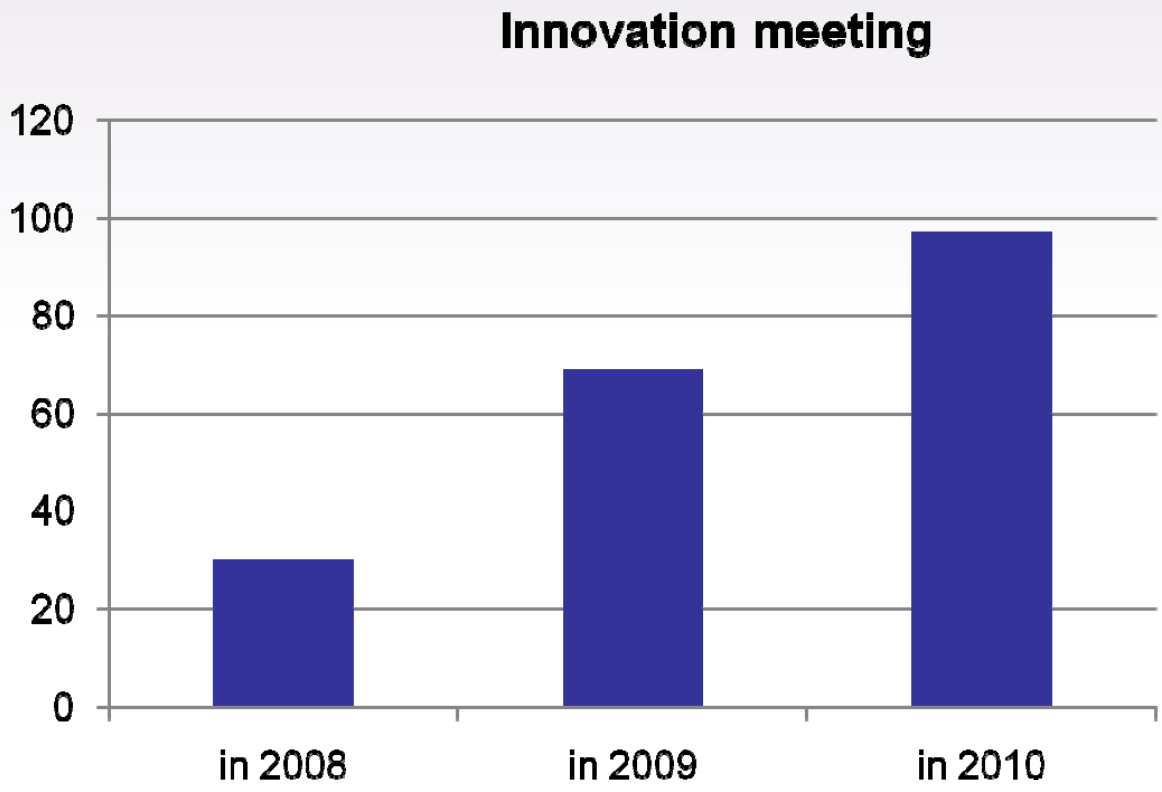

+ 80 scientific advice / Year

Information and Contacts : Afssaps.fr

Dedicated web pages on Afssaps.fr

- Procedure and request form
- But also links
  - To the most important guidelines (EMA, OMS, MEDDEV),
  - Eu and National Regulations,
  - Afssaps specifics documents / Guidelines / FAQ
  - Notice to applicant

Newsleter dedicated innovation

- In order to inform as soon as possible of change in regulation (national and EU), new guidelines, workshops etc

Workshops/training sessions dedicated to SME / academics structures

….Merci