Clinical Trials Regulation

National Implementation

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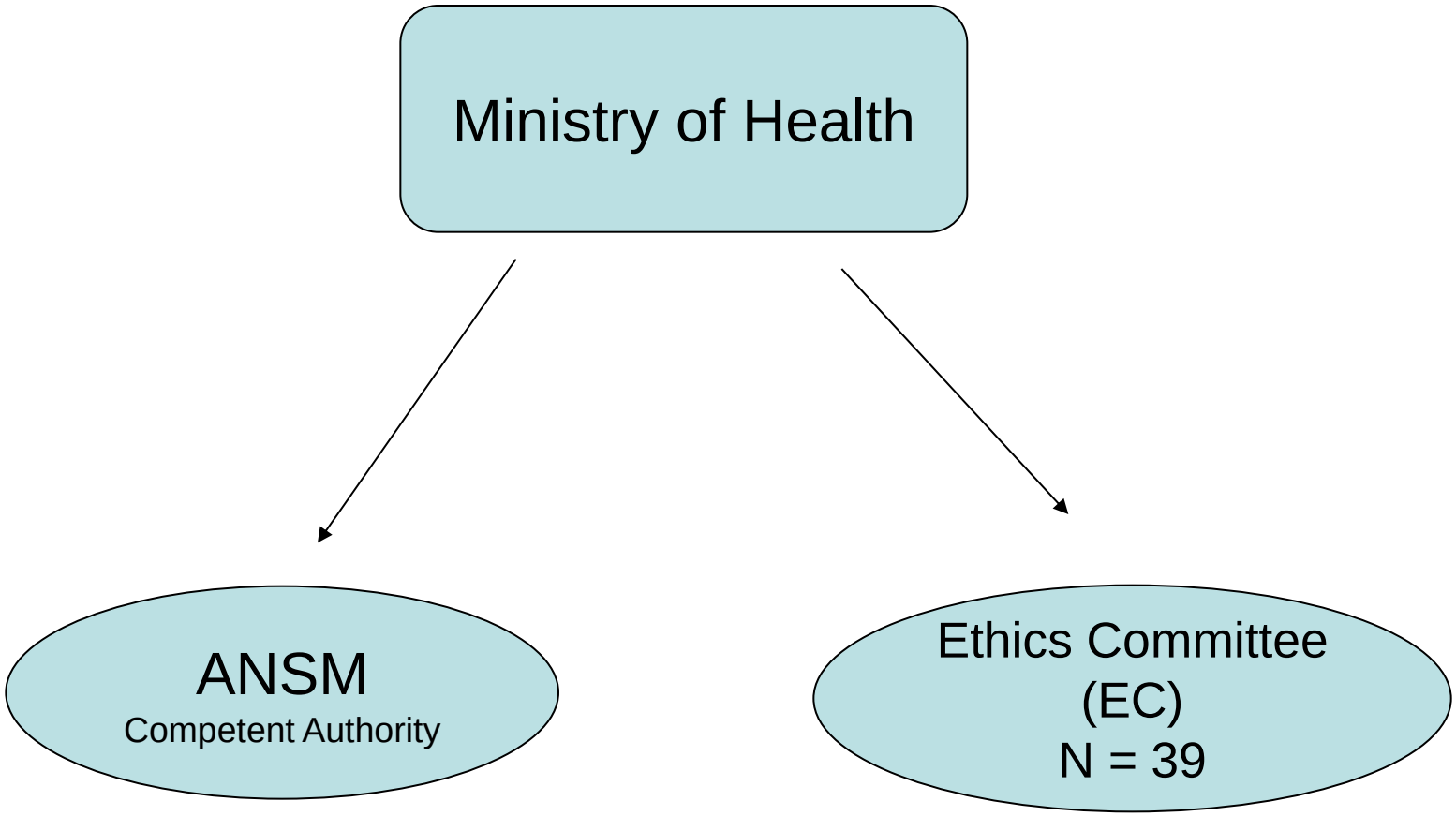
Ministry of Health
ANSM
Competent Authority
Ethics Committee
(EC)
N = 39

Context

ANSM missions :

« L'autorité compétente se prononce **au regard de la sécurité des personnes qui se prêtent à une recherche biomédicale**, en considérant notamment la sécurité et la qualité des produits utilisés au cours de la recherche conformément, le cas échéant, aux référentiels en vigueur, leur condition d'utilisation et la sécurité des personnes au regard des actes pratiqués et des méthodes utilisées ainsi que les modalités prévues pour le suivi des personnes ».

(Article R1123-29 du Code de la Santé Publique)

ANSM : organisation chart (since 12th october, 2012)

	Product Divisions →	Division for Medicines used in Oncology, Haematology, Immunology and Nephrology	Division for Medicines used in Cardiology, Endocrinology, Gynaecology and Urology	Division for Medicines used in Neurology, Psychiatry, Pain, Rheumatology, Pulmonology, ENT and Ophtalmology, plus Narcotics	Division for Medicines used in Infectious Diseases, Hepatogastroenterology, Dermatology and Rare Metabolic Diseases	Division for Generic, Homeopathic, Herbal Medicines	Division for Advanced Therapies, Products from Human Origin and Vaccines	Division for Diagnosis Medical Devices and Medical Devices Equipments	Division for Therapeutic Medical Devices and Cosmetics
Operating Divisions ↓									
Legal and Regulatory Affairs Division									
Evaluation Division									
Surveillance Division									
Inspection Division									
Laboratory Control Division									

Clinical trials : key figures

Number of clinical trials authorised by the French Medicines Agency (ANSM)	2011	2012	2013	2014
Medicinal products	704	705	899	821
Non Health Products	641	640	733	690
Medical devices	306	296	301	272
Cosmetology	nc [1]	nc [1]	5	3
Cell therapy	17	29	18	9
Gene Therapy	6	11	8	
Others [Labile blood products (LBP)], tissues, organs)	4	7	2	

[1] nc = not communicated

Evolution of CTA Phase I Medicinal Products

	2011	2012	2013	2014
Number of CTA authorized	704	705	899	821
Number of Phase I	25%	23%	15%	19 % 150/791 received on 30/11/14
Sponsors Dispatching				
Industrials	79%	87%	79%	77 % 116/150
Non Industrials	21%	13%	21%	23% 32/150

Objectives of the pilot phase

- **To facilitate the implementation of the CT regulation**
- **To define the different steps of the assessment process**
- **At every step of the instruction process, to identify suitable links between ANSM and EC**

⇨ Taking into account the requirements of the current regulation (European directive 2001/20/CE) in terms of deadlines

Current repartition of competences between ANSM and EC

	ANSM	EC
On the basis of the European Directive 2001/20/CE	Patient safety Scientific assessment (e.g. quality and safety of the products used in clinical trials)	Patient protection Information and consent / Recruitment methods / Exclusion Periods / Compensation Qualification of investigators / investigation sites Protocol : methodological aspects and ethic

Future repartition of competences between ANSM and EC (under discussion)

	ANSM	EC
On the basis of the European regulation	**Part I** Scientific assessment methodological aspects? (*)	**Part II** Patient protection Information and consent / Recruitment methods / Exclusion periods / Compensation Qualification of investigators / investigation sites Financial provisions

Impact of the implementation of the pilot phase

- **For sponsors**
  - Simplification of procedures : **Single Portal**
  - **Harmonisation** of assessments and practices between the member states (MS)
- **For EC**
  - **Harmonisation** of assessments and practices
  - Preparation of the implementation of the future CT regulation
  - Facilitation of links with the ANSM
- **For the ANSM**
  - Expanded scope of scientific assessment **? (m**ethodological aspects)
  - Finding of an organisational process regarding links between the ANSM and the ECs
  - Facilitation of relationships between with the ANSM and the EC actors

involved
involve

Governance

- **Steering Committee** : every two months meeting
- **Adhoc Subgroups** : validation, methodology assessment report, communication, IT systems, Key Performance Indicators / Metrics
- **Involving**
  - Sponsors (both industrial and academic)
  - Ethic Committees

Consensus

- **Scope**
  - Initial requests for clinical trial authorisation
    - Drugs only (with or without marketing authorisations)
    - Applying to every phase of development, all therapeutic areas
    - on a voluntary basis : both for sponsors (industrial and academic) and EC (13 / 39 currently)

- **Timeframe**
  - The pilot phase aims at simulating the different steps required by the European Regulation (validation, assessment, notification) in accordance with the current regulatory time limits stipulated in the European Directive 2001/20/CE *(60 days **with** questions and without clock stop)* *(see after)*

- **Parallel submission (ANSM and EC) of the CT dossier by the sponsor**

- **Definition of D0 :** reception of the entire application dossier by the ANSM and the EC

List of documents

- **French guideline to Applicants for CT dossiers under the Pilot Phase** describing :
  - The scope of the pilot phase
  - The instruction process with the deadlines
  - The link between the ANSM and the Ethic Committees

- **Assessment report of methodology**

- **Communication**
  - Press release : general information on European regulations and actions taken by the ANSM for the implementation of a pilot phase

Remaining issues

- Access to the European portal
- Language (especially for EC)
- Single notification
  - Format
  - Legal responsibility

Next steps

- **June 29, 2015 : Communication Day to all stakeholders (presentation of the organization of the pilot phase)**
- **September 2015 : Start of the pilot phase (week 40)**

Thank you for your attention

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