FRANCE

1. Country profile

Capital city	Paris
Total area	551 000 km²
Population	60 125 000
Density (habitants by km²)	109

Medical Devices market : 9 billion euros in 2002
In Vitro Diagnostics market : 1,24 billion euros in 2002 (1,04 billion euros for reagents and 0,20 billion for equipment).

2. Institutional framework

The Health administrative organisation in France has two level :

- A central level of administration with two institutions, the ministry of health and the French Health Products Safety Agency (Afssaps)
- A regional level with the ministry of health inspectorate.

The Ministry of Industry can intervene punctually on matters regarding customers protection and customs.

2.1. French Health Products Safety Agency (Afssaps)

The French Health Products Safety Agency was created in 1998 within a national context of strengthened health monitoring and control, with three mains missions : evaluation, inspection and testing.

The General Director is Doctor Philippe Duneton. He administers the Agency and is responsible for all safety decisions taken. Philippe Duneton is assisted in his duties by two boards : the Management Board which defines the general orientations of the Agency's administration strategy and the Scientific Board, which coordinates the global scientific strategy.

- **Protecting public health and guaranteeing health products safety**

Afssaps is the national authority responsible for all safety decisions relating to health products for human use and in particular medical devices, from their design, manufacturing to their marketing. It carries out three major missions: scientific and technical evaluation; laboratory control and advertising control; inspection of manufacturers. The Agency also coordinates all vigilance activities.

- **Decisions taken in the name of the State**

When a risk/danger is likely to occur following the use of a product (adverse event, quality default, …) or when a non compliance with a regulation requirement is detected, enforcement powers come into force. Therefore, decisions taken may be the following:

- product or activity suspension
- product or activity ban
- restrictions of use
- product consignation

All these decisions are taken in the name of the State in respect to the contradictory procedure. All decisions are discussed and motivated. In this policing context, the Agency calls for internal and external expertise for any scientific investigation. It either conducts its own inspections or relies on external inspection bodies.

Nine committees and four scientific expert groups participate in the evaluation process and give scientific advice to the Director General. In the medical devices area, the committees are :

- National Committee for Medical Devices Vigilance
- Committee In Charge Of Advertising Control Relating To Other Products That Present Health Allegations
- Viral Safety Expert Group
- Expert Group for Medical Devices clinical trials
- National Committee for In Vitro Diagnostic Medical Devices (final stage)

Other committees directly depend on the Ministry of Health and Social Security whose secretariat is carried out by Afssaps. In particular :

- Transparency Committee (in the area of reimbursement)

2.1.1. Medical Devices Evaluation Directorate (DEDIM)

The medical devices evaluation division is in charge to ensure the medical safety of medical devices (MD) and in vitro diagnostic medical devices (IVDMD).

The missions of evaluation are mainly *a posteriori*, i.e. after the products have been placed on the market by the manufacturers with the CE marking.

- *Market surveillance*
  - the examination of the declarations of the manufacturers and the development of market surveillance by checking the CE technical file (ex: MD used for the preparation blood products);
  - Introduction of new class IIb and III devices as well as the active implantable medical devices after communication to Afssaps by the manufacturer or the distributor (decree 2002-1221of September 30, 2002);

- Re-evaluations of risk / benefit ratio in certain categories of products (ex : Aortic endografts, Silicone filled breast implants, devices for endocoronary brachytherapy HIV diagnosis, Glycemia dosage devices).

- *The matériovigilance and the réactovigilance*

These activities relate to the evaluation of the incidents and risks of incidents reported within the framework of vigilances (materiovigilance for the MD, reactovigilance for the IVD). This evaluation can lead to decisions of suspension or restrictions of use by the general manager; proposed by the DEDIM

However, some evaluations take place a priori:

- The medical devices of animal origin which must be authorized by Afssaps after review from the group of viral safety; before there are put on the market (These procedure will end after French transposition of the BSE/TSE Directive)

- The clinical trials declared in accordance with the law of December 1980 on the protection of the people subject to biomedical research;

- *Designation of Notified Bodies and implementing measures*

The division participates with the Inspection and Establishment Division in the initial evaluation and surveillance of the French notified body i.e. : the G-Med.

Lastly, the DEDIM implements complementary regulations:

- quality control of the analyses of medical biology,

- quality control of the biomedical equipment.

- *French Competent Authority*

Dr Jean-Claude Ghislain has delegation for representing the French Competent Authority (Afssaps) in the article 7 Regulatory Committee and in all committees and working parties set in place in the areas of MD and IVDMD.

Following national health monitoring measures taken by the Afssaps, the division have responsibilities to introduce for example safeguard clauses and acts as the point of contact for the Commission and for other Member States.

2.1.2. Inspection and Establishments Directorate (DIE)

The DIE is in charge of inspection activities and follow-up of the establishments of manufacture, distribution, importation and exportation for all healthcare products and in particular in medical devices areas. It manages the files relating to the whole of these establishments which are of its competence.

This division carries out an activity of monitoring and control of these establishments by field inspections. A special department is in charge of the inspection of the establishments in the field of the MD and IVDMD. This department acts in internal programs regarding for example sterility manufacturer and also to adress requests initiated by the DEDIM.

Lastly, the division has been involved in inspections of the French Notified body.

2.1.3. Laboratories and Testing Directorate (DLC)

The division acts as a supplier for testing activities in different laboratories within the Afssaps.

2.2. Ministry of Health, Family and People with disabilities (Ministère de la santé)

2.2.1. Central level

The Ministry has responsability for the establishment of the overall regulatory framework conditions regarding the manufacturing, clinical evaluation, distribution, vigilance, market surveillance in close collaboration with Afssaps. It is responsible for the transposition of Medical devices Directives.

2.2.2. Regional Level

At a regional level, Ministry of health inspectorate have competencies on the surveillance, by periodic inspections, on pharmacists, medical laboratories, hospitals established in their particular territory. He has power to stop infringements and to decide sanctions within their regional territory.

The Ministry of Health can act on request initiated by the Afssaps, for example in order to verify the completion of a recall.

3. Transposition of directives and implementing directives

3.1. Medical device

- Law n°94-43 of 18 January 1994 transposing medical device directives 90/385/EEC and 93/42/EEC
- Decree n°95-292 of 16 March 1995 regarding medical devices
- Decree n°96-62 of 15 January 1996 regarding vigilance on medical devices
- Decree n°2001-1154 of 5 December 2001 regarding maintenance and quality control obligations on particular medical devices
- Decree n°2002-1221 of 30 September 2002 regarding declaration of Class IIb and III class medical device before there are put into service
- Decree n° 2003-1106 of 20 November 2003 regarding to the transposition of Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices

3.2. In Vitro Diagnostic Medical devices

- Ordinance n° 2001-198 of 1er march 2001 on transposition of directive 98/79/EC

- Decree n° 2004-108 of 4 february 2004 regarding medical devices for in vitro diagnostics

4. Identification of services (ministry, agency…….) involved

4.1. Ministry of the Health, Family and People with disabilities

Ministère de la santé, de la famille et des personnes handicapées
Direction générale de la santé
8, avenue de Ségur
F-75350 Paris 07 SP
France

4.2. Agency

Agence française de sécurité sanitaire des produits de santé (AFSSAPS)
143/147 Boulevard Anatole France
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4.2.1. Direction de l'évaluation des dispositifs médicaux (DEDIM)

Mr Jean-Claude Ghislain

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5. Participants and contacts details in the various Commission Working Groups

Group	Name	Organisation	e-mail
MDEG	Jean-Claude Ghislain Alain Prat	Afssaps	Jean-claude.ghislain@Afssaps.sante.fr
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NBOG	Isabelle Tordjman Alain Prat	Afssaps	Isabelle.Tordjman@Afssaps.sante.fr Alain.prat@afssaps.sante.fr
Standardisation	Björn Fahlgren	Afssaps	bjorn.fahlgren@afssaps.sante.fr

6. Participation in GHTF

GHTF Steering Committee	Jean-Claude Ghislain
GHTF Ad hoc Clinical Task Force	Jean-Claude Ghislain
GHTF Study group 3 : Quality Management System	Alain Prat

7. Participation in the standardisation process

Gérard Berthier and Björn Fahlgren are involved in the standardisation process. For example, the following working items are followed : quality management system, risk management.

8. Relevant websites

8.1. Ministry of the Health, Family and People with disabilities

http://www.sante.gouv.fr

8.2. French Agency

http://www.afssaps.sante.fr/
Registration in Afssaps mailing list at : http://afssaps.sante.fr/htm/2/lstdif/inddif.htm

8.3. National professional manufacturer association

- Medical devices : syndicat national de l'industrie des technologies médicales (SNITEM)

http://www.snitem.fr

- In Vitro Diagnostic Medical devices : Syndicat de l'industrie invitro (SFRL)

http://www.sfrl.fr/

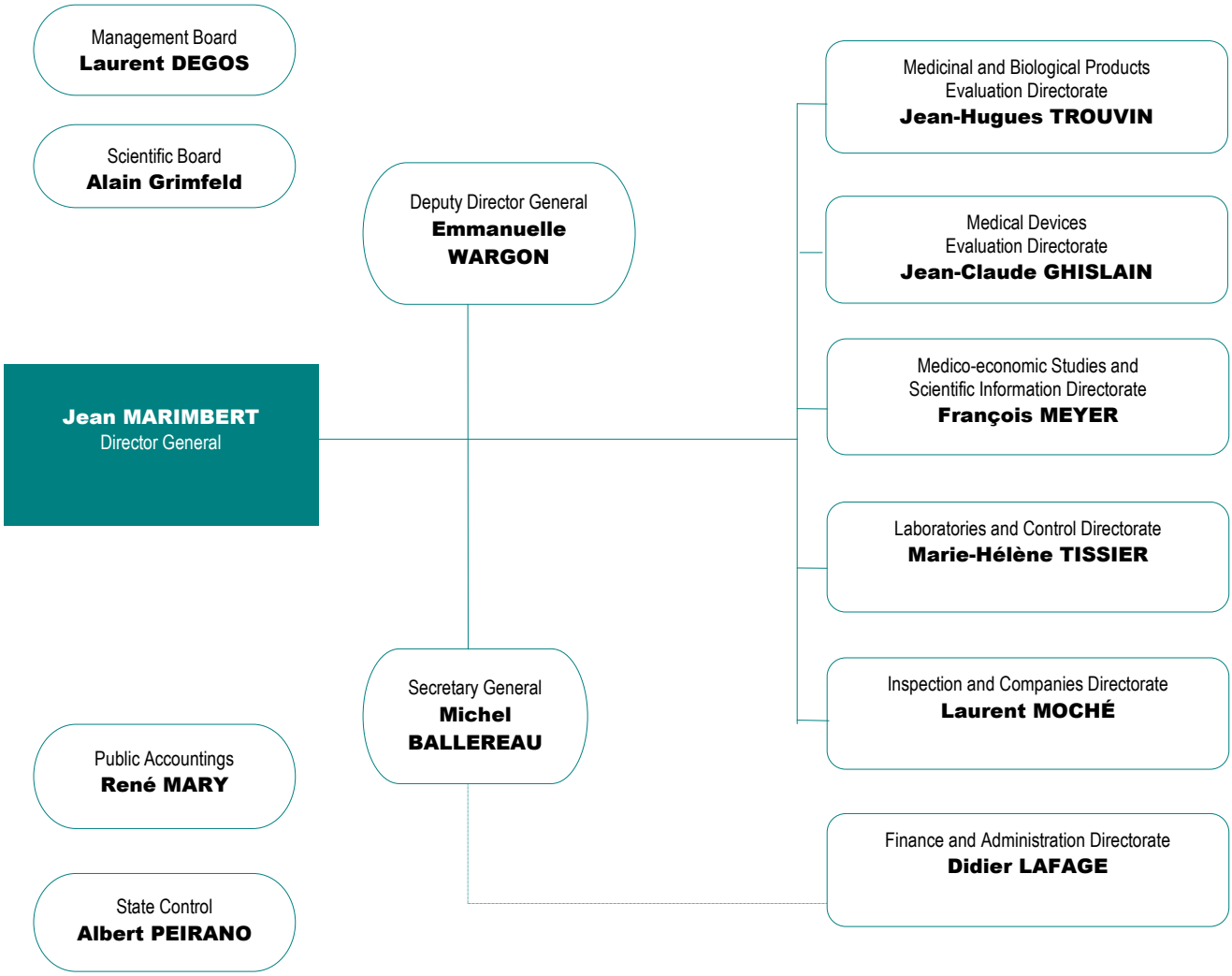
9. Projects and co-operation between current and future Member States or EFTA countries.

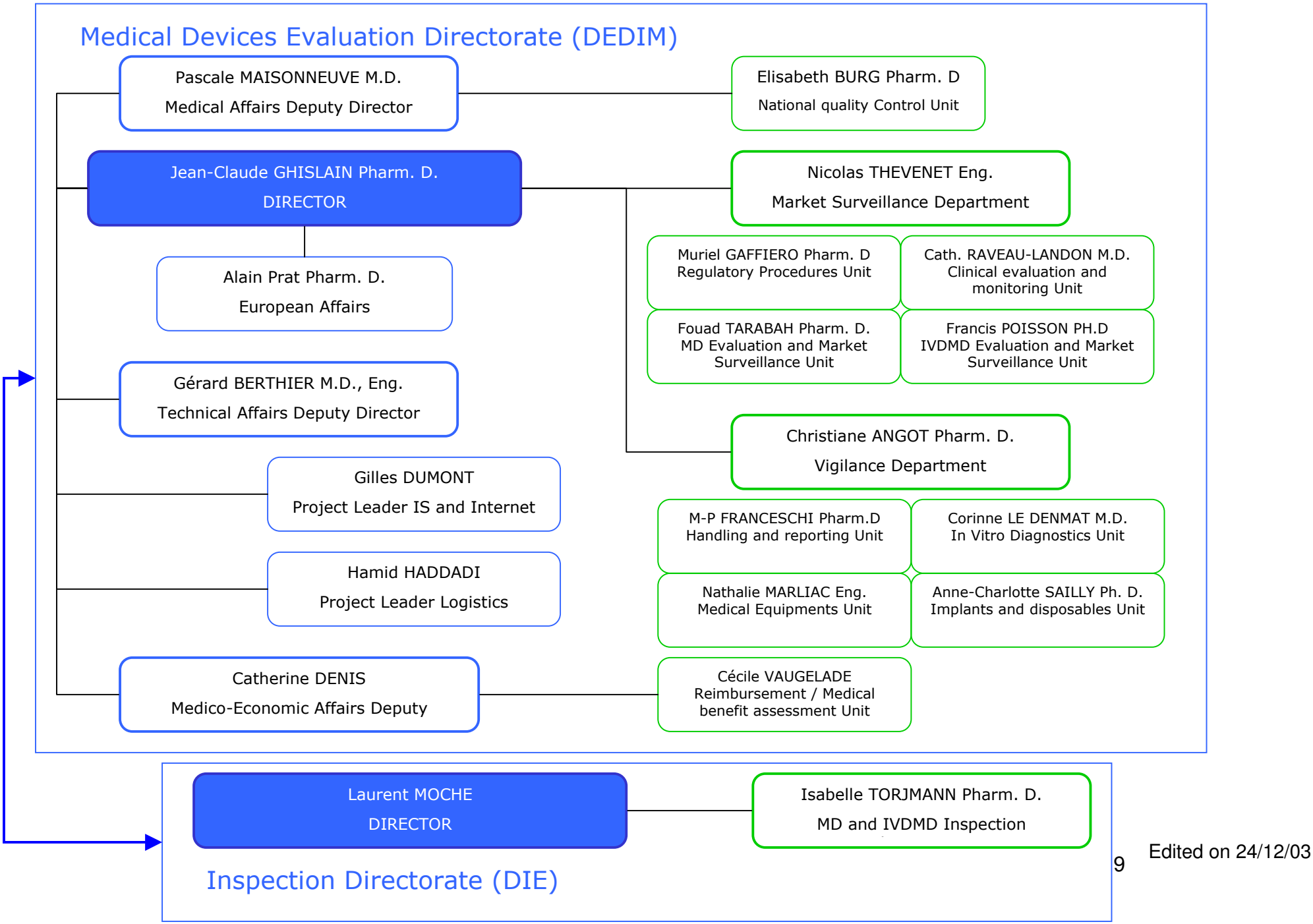
N/A

10. Number of staff involved in the implementation of directives (according to different areas: regulation, surveillance, Notified Bodies…)

Ministry 5 (lawyers), Afssaps 100 (Evaluation and vigilance 80, Inspection 20).

afssaps
Agence française de sécurité sanitaire des produits de santé





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