



## Country indicators

|                                 |        |   |      |                                      |        |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)*              | 64'291 | Life expectancy at birth (years) <sup>a</sup>                 | 82   | World Bank income group <sup>b</sup> | High   |
| Internet users (%) <sup>y</sup> | 81.9%  | Per capita total health expenditure (PPP Int \$) <sup>d</sup> | 4260 | GNI per capita (US\$) <sup>e</sup>   | 43'460 |



## National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.sante-sports.gouv.fr/les-dispositifs-medicaux.html>

Language(s): Français

MOH responsible for health technology policy implementation: Direction Générale de la Santé et Direction Générale de l'Offre de Soins



## Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministère du travail, de l'emploi et de la santé

Web site: <http://www.sante.gouv.fr/>

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## National health technology assessment unit

Unit/department: Haute Autorité de Santé

Web site: <http://www.has-sante.fr>

Contact: Jean-Patrick SALES

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## National health technology management units

National health technology unit(s): Yes

**DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:**

Unit/department: —

Web site: —

Contact: —

E mail: —

**OTHER:** Conformité des dispositifs médicaux aux normes de sécurité sanitaire

Unit/department: AFSSAPS Agence française de sécurité sanitaire des produits de santé

Web site: <http://www.afssaps.fr>

Contact: Jean-Claude GHISLAIN

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**OTHER:** —

Unit/department: —

Web site: —

Contact: —

Email: —



## Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For regulatory purposes

Nomenclature system name: — Web site: [http://www.legifrance.gouv.fr/affichCode.do;jsessionid=3DA99E555FOAB933E0B91227088DB46C.tpdjo04v\\_3?idSectionTA=LEGISCTA000006190738&cidTexte=LEGITEXT000006072665&dateTexte=20100330](http://www.legifrance.gouv.fr/affichCode.do;jsessionid=3DA99E555FOAB933E0B91227088DB46C.tpdjo04v_3?idSectionTA=LEGISCTA000006190738&cidTexte=LEGITEXT000006072665&dateTexte=20100330)



## Medical device incorporation

**PROCUREMENT**

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

**DONATIONS**

Policy or guideline: No

Web site: —

**TECHNICAL SPECIFICATIONS**

Technical specifications to support procurement or donations: Yes

Web site: <http://www.ameli.fr/professionnels-de-sante/fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/consultation-et-telechargement-de-la-lpp.php>

Medical device incorporation comments<sup>λ</sup>: —



## Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments<sup>λ</sup>: —



## Lists of medical devices

### LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments<sup>λ</sup>:

Lists available: Yes

Unit: Ministère chargé de la santé et de la sécurité sociale

Web site: —

La liste des dispositifs médicaux et prestations pris en charge par l'assurance maladie est accessible à l'adresse suivante: <http://www.ameli.fr/professionnels-de-sante/fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/consultation-et-telechargement-de-la-lpp.php>

### NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.ameli.fr/professionnels-de-sante/fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/consultation-et-telechargement-de-la-lpp.php>

Web site - procedures: —

### NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

|        |                       |                           |          |                                    |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



## Healthcare facility

|                     | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post         | n/a           | n/a            | n/a   | n/a                            |
| Health centre       | n/a           | n/a            | n/a   | n/a                            |
| District hospital   | n/a           | n/a            | n/a   | n/a                            |
| Provincial hospital | n/a           | n/a            | n/a   | n/a                            |
| Regional hospital   | n/a           | n/a            | n/a   | n/a                            |



## Medical equipment

|                                      | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging           | 325           | 326            | 651   | 10.126                           |
| Computerized Tomography Scanner      | n/a           | n/a            | n/a   | n/a                              |
| Positron Emission Tomography Scanner | n/a           | n/a            | n/a   | n/a                              |
| Nuclear medicine                     | n/a           | n/a            | n/a   | n/a                              |
| Mammograph*                          | n/a           | n/a            | n/a   | n/a                              |
| Linear accelerator                   | n/a           | n/a            | n/a   | n/a                              |
| Telecobalt unit (Cobalt-60)          | n/a           | n/a            | n/a   | n/a                              |
| Radiotherapy                         | n/a           | n/a            | n/a   | n/a                              |

\* Density per 1,000,000 females aged from 50-69 old.

## Additional information and comments<sup>λ</sup>:

Dans cette enquête, nous avons mentionnées la HAS et l'ANSM qui sont deux agences qui sont chargées:

HAS: Agence d'évaluation des dispositifs médicaux, ANSM : Agence nationale de sécurité du médicament qui est chargée de la sécurité sanitaire des dispositifs médicaux



## Contacts

### FOCAL POINT

Name: Geraldine Bonnin

Position title: Chargée de mission

Department: Bureau international Santé et protection sociale, Delegation aux affaires européennes et internationales, Ministère des Affaires sociales et de la santé

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Postal address: 14 avenue duquesne, 75350 Paris 07 SP

### WHO representative:

Name: —

Email: —

### WHO health products focal point:

Name: —

Email: —

Telephone: —

\* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at [www.who.int/medical\\_devices/countries/full\\_text.xls](http://www.who.int/medical_devices/countries/full_text.xls)

