



Country indicators

Population (000s)*	11'104	Life expectancy at birth (years) ^a	80	World Bank income group ^b	High
Internet users (%) ^y	82.2%	Per capita total health expenditure (PPP Int \$) ^d	4320	GNI per capita (US\$) ^e	46'290



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.fagg-afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/legislation/index.jsp; http://www.iph.fgov.be/ClinBiol/bckb33/activities/competent_authority/_dowR14_11_2001dispositifsmedicauxIVD.pdf ; http://www.iph.fgov.be/ClinBiol/bckb33/activities/licence/_down/03_12_1999.pdf

Language(s): Français et Néerlandais

MOH responsible for health technology policy implementation: Agence Fédérale des Médicaments et des Produits de Santé pour les dispositifs médicaux et les dispositifs médicaux implantables actifs et l'Institut Scientifique de Santé Publique - Section de Biologie clinique pour les dispositifs médicaux de diagnostic in vitro



Regulatory agency

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

Name of principal institution: Agence Fédérale des Médicaments et des Produits de Santé

Web site: <http://www.fagg-afmps.be>

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National health technology assessment unit

Unit/department: Health Care Knowledge Center (KCE)

Web site: <https://kce.fgov.be/>

Contact: —

Email: info@kce.fgov.be



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:

Unit/department: —

Web site: —

Contact: —

Email: —

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.gmdnagency.org/>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.fagg-afmps.be/fr/> and <http://www.iph.fgov.be>

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://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:131:0017:0030:fr:PDF>

Medical device incorporation comments^λ:

Dans chaque Arrêté royal d'application se trouvent des exigences par rapport à la distribution et/ou la délivrance des dispositifs médicaux (docs: coord_tcm291-26685.pdf and tcm291-27069.pdf).

Décision de la Commission 2002/364/EC portant spécifications techniques communes des dispositifs médicaux de diagnostic in vitro



World Health Organization

http://www.who.int/medical_devices



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: —

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes, but it is only a recommendation

Unit: Institut National d'Assurance Maladie Invalidité - INAMI

Web site: —

Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués. Les dispositifs médicaux implantables et invasifs à long terme doivent se trouver dans ce listing de l'INAMI pour pouvoir être facturés par l'hôpital aux patients. La liste est disponible sur internet via le lien suivant: <https://www.riziv.be>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

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
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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	n/a	n/a	n/a	n/a
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^λ:

L'AFCN est en train de réviser les inventaires des dispositifs médicaux émettant des rayonnements ionisants présents en Belgique. Cet inventaire provient en partie de données fournies par les Organismes Agréés (AV Controlatom, TechniTest, ...). COCIR (European Coordination Committee of the Radiological, Electromedical and Medical IT Industries) peut également fournir des informations utiles (internationales, y compris pour la Belgique - données 2008 : http://www.cocir.org/uploads/documents/-609-new_members_ws_-_del_3_-_cocir_age_profile_17_june_2009.pdf) sur les dispositifs...



Contacts

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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