'Children and Adolescents'
Asthma Therapy

Example for EU regulations for medical devices and combination medicinal products'

Pretoria 9th October 2014

Birka Lehmann

Asthma in Children

WORLD HEALTH ORGANIZATION
EUROPE

ENHIS
EUROPEAN ENVIRONMENT AND HEALTH INFORMATION SYSTEM

B1

Prevalence of asthma and allergies in children

FACT SHEET NO. 3.1 · MAY 2007 · CODE: RPG3_Air_E1

The prevalence rates of symptoms of asthma and allergic rhinoconjunctivitis in children aged 6–7 years and 13–14 years

The summary gives an overview on the prevalence of asthma and allergic rhinoconjunctivitis symptoms in children as found in the International Study of Asthma and Allergies in Childhood (ISAAC) *(1)*.

KEY MESSAGE

ISAAC found that asthma and rhinoconjunctivitis symptoms cause a significant burden of disease and that the prevalence of both is rising in European children. Allergic and asthmatic symptoms are associated with, among other things, indoor and outdoor air quality.

In 1999–2004, asthma prevalence in children across the European study centres varied from less than 5% to over 20%. Policies that promote early identification of the disease, ensure adequate treatment and, in particular, improve air quality, help to reduce this burden.

Slide 2

B1 Mitsinga, Efi, 2011/11/03

Paediatric Investigation Plans

- Beclometasone dipropionate / formoterol fumarate dihydrate:
  Pressurised inhalation, solution; Inhalation powder

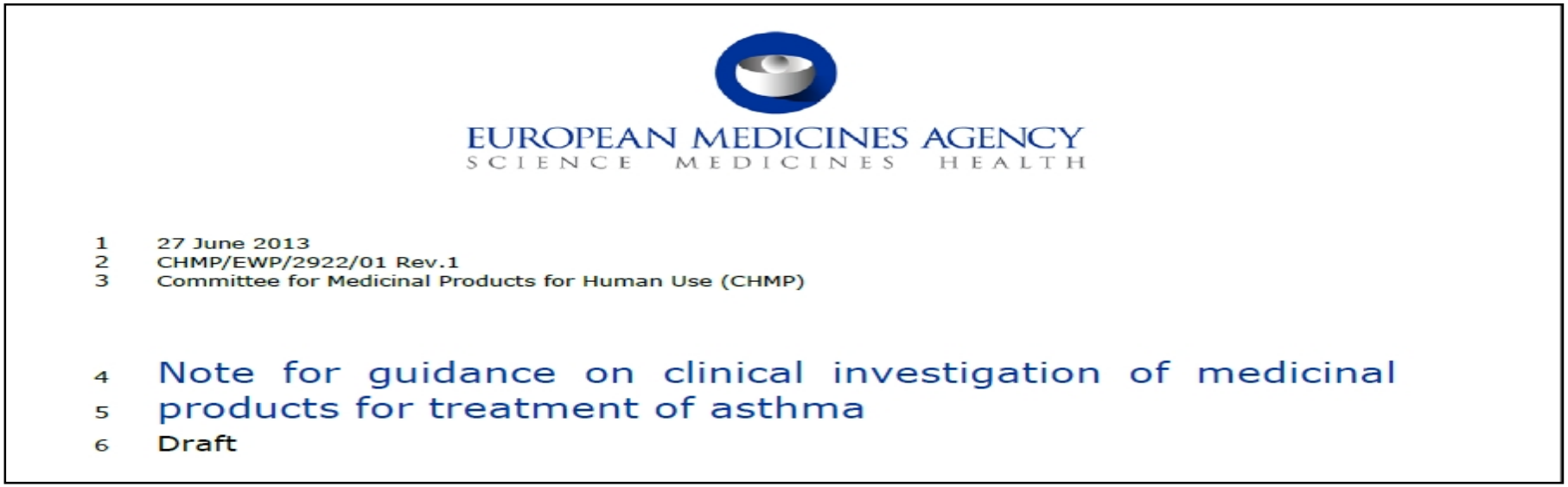
- Benralizumab/Lebrikizumab/Dupilumab
  Solution for injection Subcutaneous use
- Mepolizumab
  Powder for solution for injection / infusion: Intravenous use, Subcutaneous use
- Budesonide
  Nebuliser suspension

- Fluticasone propionate / formoterol fumarate
  Pressurised inhalation, suspension: Inhalation use

- Indacaterol (acetate) / mometasone (furoate)
  Inhalation powder; Hard capsule: Inhalation use

- Lumacaftor / ivacaftor
  Film-coated tablet; Age appropriate oral solid formulation: Oral use

- Mometasone furoate, Formoterol fumarate dihydrate
  Pressurised metered dose inhaler (MDI) with HFA-227 as propellant, suspension: Inhalation use



- **..when using inhalers, inhalers technique and adherence to treatment and time of dosing should ne optimised. This is particularly important for children**

7.5. Selection of inhalation delivery devices

Particular attention should be paid to the effects of age on the adequate function of inhalation delivery devices.

For children under 4 years of age corticosteroid and bronchodilator therapy should be routinely delivered via a **pressurised metered-dose inhaler (pMDI)** and a **specific named spacer device** for use with the particular pMDI and with a **facemask** where necessary.

For children aged 4 years and older a dry powder inhaler (DPI) may be considered although special attention should be paid on whether children aged 4 to 6 years have the ability to use the device appropriately. Therefore, characterisation of **flow rate dependency** in the range of flows/pressure drops of the patient populations in whom the DPI is to be used should be presented.

• It is important to use an inhaler device which is appropriate for the age group concerned.

• Both the child and the caregiver should be trained to use the inhalation devices correctly. Patients should demonstrate their inhalation technique, and relevant instructions and corrections should be provided at every visit.

Nebulizer/Inhaler

Children < 6 years:

- Nebulizer
- pressurized Metered-Dose Inhaler (pMDI)
- Spacer/Mask

Box 6-7. Choosing an inhaler device for children 5 years and younger

Age	Preferred device	Alternate device
0–3 years	Pressurized metered-dose inhaler plus dedicated spacer with face mask	Nebulizer with face mask
4–5 years	Pressurized metered-dose inhaler plus dedicated spacer with mouthpiece	Pressurized metered-dose inhaler plus dedicated spacer with face mask or nebulizer with mouthpiece or face mask

Children > 6years:

- pMDI or Dry Powder Inhaler (DPI)

Inhaler
&
Legal Requirements

Fixed combination =

inhaler & medicinal product = Directive 2001/83/EC

Non fixed combination =

for the medical devices
= Directive 93/42/EC

for the medicinal product
= Directive 2001/83/EC

} **Consultation procedure**

EUROPEAN COMMISSION
DG ENTERPRISE and INDUSTRY
Directorate F, Unit F3 "Cosmetics and medical devices"

MEDICAL DEVICES: Guidance document
-
Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative

MEDDEV 2. 1/3 rev 3

GUIDELINES RELATING TO THE APPLICATION OF:
THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES
THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

Foreword

The present Guideline is part of a set of Guidelines relating to questions of application of EC Directives on medical devices. This guideline is not legally binding, since only the European Court of Justice can give an authoritative interpretation of Community law. It has been elaborated by an expert group including experts from Member States' Competent Authorities, the Commission' services, as well as industry trade associations. It is therefore intended that the document will provide useful guidance which should assist common positions to be taken throughout the European Union. Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions.

The present guideline provides non-exhaustive lists of examples of medical devices, accessories to medical devices and medicinal products. Further examples may be found in the manual on borderline and classification in the Community Regulatory framework for medical devices, published on the European Commission website.[1] Particular attention should be paid to borderline cases between medical devices and herbal medicinal products. This issue may be further developed in this guidance in the near future.

Note: This document is a revision of an earlier document published in July 2001 as MEDDEV 2.1/3 rev 2. Some of the examples given in the MEDDEV 2.1/3 rev 2 have not been included in the present Guideline. These examples will be further elaborated in the above mentioned manual on borderline and classification in the Community Regulatory framework for medical devices.
This guidance incorporates the changes introduced by the Directive 2007/47/EC. [2] These changes have to be applied as of 21 March 2010.

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[1] http://ec.europa.eu/consumers/sectors/medical-devices/documents/borderline/index_en.htm

[2] OJ L 247 , 21.09.2007

BfArM
Bundesinstitut für Arzneimittel und Medizinprodukte

Über das BfArM▾ Arzneimittel▾ Medizinprodukte▾ Bundesopiumstelle▾ Forschung▾ Service▾

Konsultationsverfahren

STARTSEITE → ARZNEIMITTEL → ARZNEIMITTELZULASSUNG → ZULASSUNGSVERFAHREN → NATIONAL → KONSULTATIONSVERFAHREN

Consultation procedure

Für Medizinprodukte, die einen arzneilichen Bestandteil mit ergänzender Wirkung enthalten, ist ein Konsultationsverfahren vorgesehen. Im Rahmen dieses Verfahrens wird der Arzneimittelanteil nach arzneimittelrechtlichen Kriterien von einer Arzneimittel-Zulassungsbehörde bewertet. Sofern ein entsprechendes Verfahren auf Antrag einer Benannten Stelle beim BfArM durchgeführt wird, erfolgen die administrative Abwicklung und die inhaltliche Bearbeitung durch die für Arzneimittel zuständigen Abteilungen. Auskünfte erteilt das Fachgebiet 11 "Validierung". Das Konsultationsverfahren für Medizinprodukte, die ein Plasmaderivat im Sinne der Richtlinie 89/381/EWG enthalten, ist bei der europäischen Arzneimittelbehörde EMA durchzuführen.

› Hinweise zur Durchführung von Konsultationsverfahren und Einreichung von Unterlagen für Medizinprodukte mit die Wirkung des Produktes ergänzendem Arzneimittelanteil

› Der Antrag auf Konsultation unter Berücksichtigung der Empfehlung der MEDDEV 2.1/3 rev.2 B3

› Ablauf eines Konsultationsverfahrens beim Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

Service

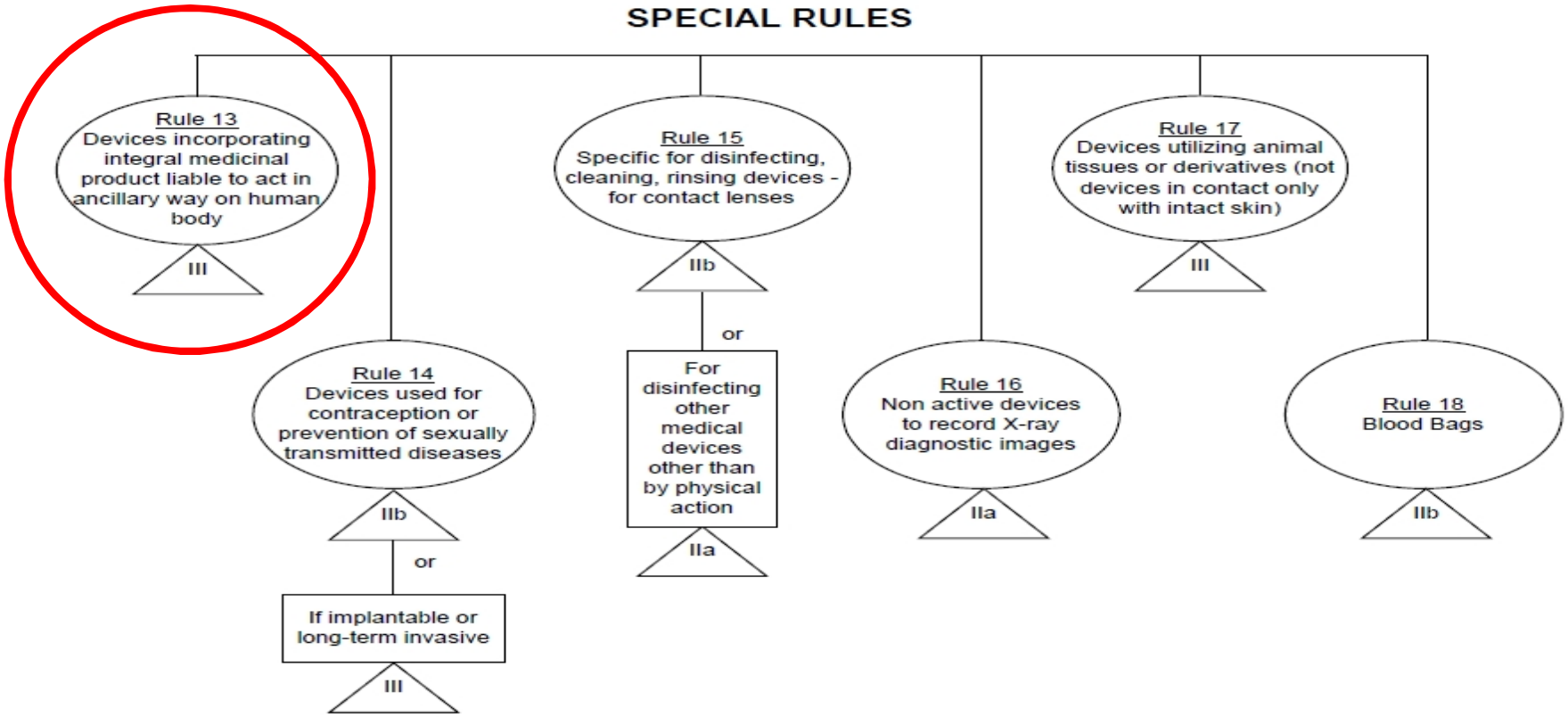
› Bekanntmachungen Arzneimittelzulassung

› Formulare Arzneimittelzulassung

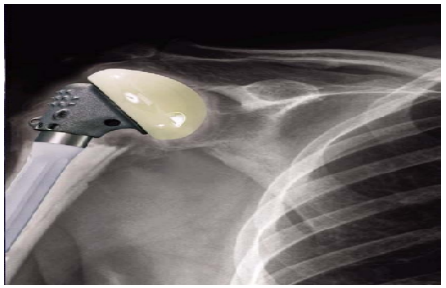
› FAQ Arzneimittelzulassung

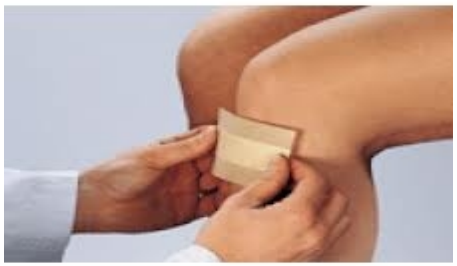
MEDDEV 2.1/3 rev.3

Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative



Medical Devices





European Union

Medical Devices

- Legislation in force
- Proposal for new legislation

MEDICAL DEVICES

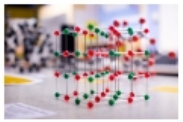
Search


Competitiveness


Regulatory framework


Specific areas of development


Market surveillance and vigilance


Scientific and technical assessment


Other related policies


Dialogue between interested parties


International Cooperation

Medical devices

The role of medical devices in healthcare is essential.

The diversity and innovativeness of this sector contribute significantly to enhance the quality and efficacy of healthcare.

Covering a wide range of products, from simple bandages to the most sophisticated life-supporting products, the medical devices sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities.

The EU's involvement concerns mainly the regulatory framework for market access, international trade relations and regulatory convergence, all aiming to ensure the highest level of patient safety while promoting the innovation and the competitiveness of this sector.

e-newsletter 05 June 2014

n effective, accessible and resilient health s

Latest updates

Restoring confidence in medical devices. Reporting on the success of the PIP Action Plan
Released 20 June 2014

New references of harmonised standards for Directive 93/42 on Medical Devices (OJ C149 of 16 May 2014)
Released 16 May 2014

More

Highlights


Commission Recommendation on a common framework for a UDI system of medical devices

26 September 2012 : Commission proposes new rules on medical devices and in vitro diagnostic medical devices

Evaluation of the European Databank on Medical Devices

Europe – legislation in force

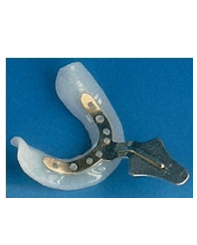
Legal framework consists of 3 directives:

- Directive 90/385/EEC regarding active implantable medical devices,
- Directive 93/42/EEC regarding medical devices
- Directive 98/79/EC regarding in vitro diagnostic medical devices.
  - Directive 2007/47/EC amending above mentioned directive in respect to technical revison

- Guidance documents MEDDEV (legally non-binding) = consensus statements and interpretative documents pursue the objective of ensuring uniform application of the relevant provisions of the directives within the EU.

Classification of Medicines

Medical Device



Any instrument, apparatus, appliance, material or other article, including the software necessary for its proper application, for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

The principal intended action...

- ...must not be achieved by pharmacological, immunological or metabolic means,
- ...but may be assisted in its function by such means

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 NOVEMBER 2001 ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE

Article 1

(2.) Medicinal product:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Article 2

1. This Directive shall apply to medicinalproducts for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

Presentation: ‚by function & by presentation‘

Europe – legislation in force

DIRECTIVE 93/42/EEC medical devices

Article 1

Definitions, Scope

(2) For the purposes of this Directive, the following definitions shall apply:
'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation or an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

- Note: It must be noted that for the purposes of determining whether a product falls within the definition of a medicinal product by function, the national authorities must decide on a case by-case basis, taking account of all the characteristics of the product, in particular ist composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of ist distribution, its familiarity to consumers and the risks which its use may entail.

Borderline and classification issues

Medical Devices Expert Group on Borderline and Classification

- List of Members of the MDEG on Borderline and Classification (188 KB)
- Manual on borderline and classification in the Community Regulatory framework for medical devices (338 KB)(version 1.16 of 07-2014)

Non-exhaustive list of judgements rendered by the European Court of Justice

- Cosmetic products sector
- Pharmaceutical sector
  - Definition of medicinal products (56 KB)
  - Other Pharmaceutical related issues

Other useful guidance

- Manual on the scope of application of the cosmetics Directive 76/768/EEC (64 KB)
- Guidance on the relationship between the GPSD and certain sector Directives with provisions on product safety
- Guidance on the demarcation between cosmetics Directive 76/768/EEC and medicinal products Directive 2001/83/EC (60 KB)
- MEDDEV Guidance
- EMEA recommendation on the procedural aspects and dossier requirements for the consultation to the EMEA by a Notified Body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device.

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members of a fully-equipped gym: let's put t

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Evaluation of the European Databank on Medical Devices

MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY

REGULATORY FRAMEWORK FOR MEDICAL DEVICES

Version **1.10** (08-2011)

Released 23 August 2011

Reference Annex IX Directive 93/42/EEC

Risk based approach – basic principles:

Class I - generally regarded as low risk
Class IIa - generally regarded as medium risk-
Class IIb - generally regarded as medium risk
Class III - generally regarded as high risk

EXAMPLE:
All non-invasive devices which come into contact with injured skin in:

- Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,
- Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,
- Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound

Class III All implantable devices and long-term surgically invasive devices to be used in direct contact with the heart, the central circulatory system or the central nervous system.

http://ec.europa.eu/health/medical-devices/index_en.htm

Medical Products & risk approach MEDDEV

Definition

- **Risk class** (I, IIa, IIb, III; depending on the vulnerability of the human body with respect to the use of the device) has to be determined (**rules**: Annex IX of MDD)
- Risk class defines the **modul(s)** that the manufacturer may use within the **conformity assessment** procedure
  - **Class I** The manufacturer is responsible for ensuring that their product complies with all the relevant essential requirements of the MDD and must draw up a written statement to this effect (self-declaration)

Notified Bodies:

- For medical devices belonging to class IIa, IIb, III = conformity assessment procedure = **certificate**

Manufacturer

CE-marks the device

CE

Regulatory framework

Legislation

Based on the New Approach, rules relating to the safety and performance of medical devices were harmonised in the EU in the 1990s. The core legal framework consists of 3 directives: Directive 90/385/EEC [158 KB] regarding active implantable medical devices, Directive 93/42/EEC [265 KB] regarding medical devices and Directive 98/79/EC [199 KB] regarding in vitro diagnostic medical devices. They aim at ensuring a high level of protection of human health and safety and the good functioning of the Single Market. These 3 main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47/EC [185 KB] .

Implementing measures

The Commission adopted several implementing measures based on the Medical Devices Directives. These measures concern medical devices manufactured utilising tissues of animal origin, the classification of certain medical devices and Common Technical Specifications for IVDs listed in Annex II of the IVD Directive.

Guidance

In addition, legally non-binding Guidance documents MEDDEV, consensus statements and interpretative documents pursue the objective of ensuring uniform application of the relevant provisions of the directives within the EU.

Revision of the regulatory framework

On 26 September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on medical devices and a Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices which will, once adopted by the European Parliament and by the Council, replace the existing three medical devices directives. The texts of the proposals and other related documents are available here.

e-newsletter 17 July 2014

gym: let's put those new machines to work!

Latest updates

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COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

Article 1

Definitions

- ‘device’ means active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC or medical devices and their accessories as defined in Article 1(2) of Directive 93/42/EEC
- ‘conformity assessment body’ means a body which performs calibration, testing, certification and inspection activities under Article R1(13) in Annex I to Decision No 768/2008/EC of the European Parliament and of the Council
- ‘notified body’ means a conformity assessment body which has been notified by a Member State in accordance with Article 11 of Directive 90/385/EEC or Article 16 of Directive 93/42/EEC;
- ‘accreditation body’ means the sole body in a Member State that performs accreditation with authority derived from the State as laid down by Article 2(10) of Regulation (EC) No 765/2008;
- ‘designating authority’ means the authority(ies) entrusted by a Member State to assess, designate, notify and monitor notified bodies under Directive 90/385/EEC or Directive 93/42/EEC;
- ‘competent authority’ means the authority(ies) in charge of market surveillance and/or of vigilance for devices;

Responsibilities

Notified Bodies

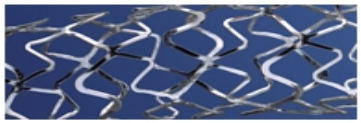
- certifier for active and non-active medical devices

National Competent Authorities

- Incident reports
- Clinical trials

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten





ZLG
ZLG founding agreement documents

medicinal products

medical devices
designation of conformity assessment bodies
documents

Welcome to the ZLG website

Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices

DOCUMENTS

> Answers and Conclusions EK-Med

BODIES

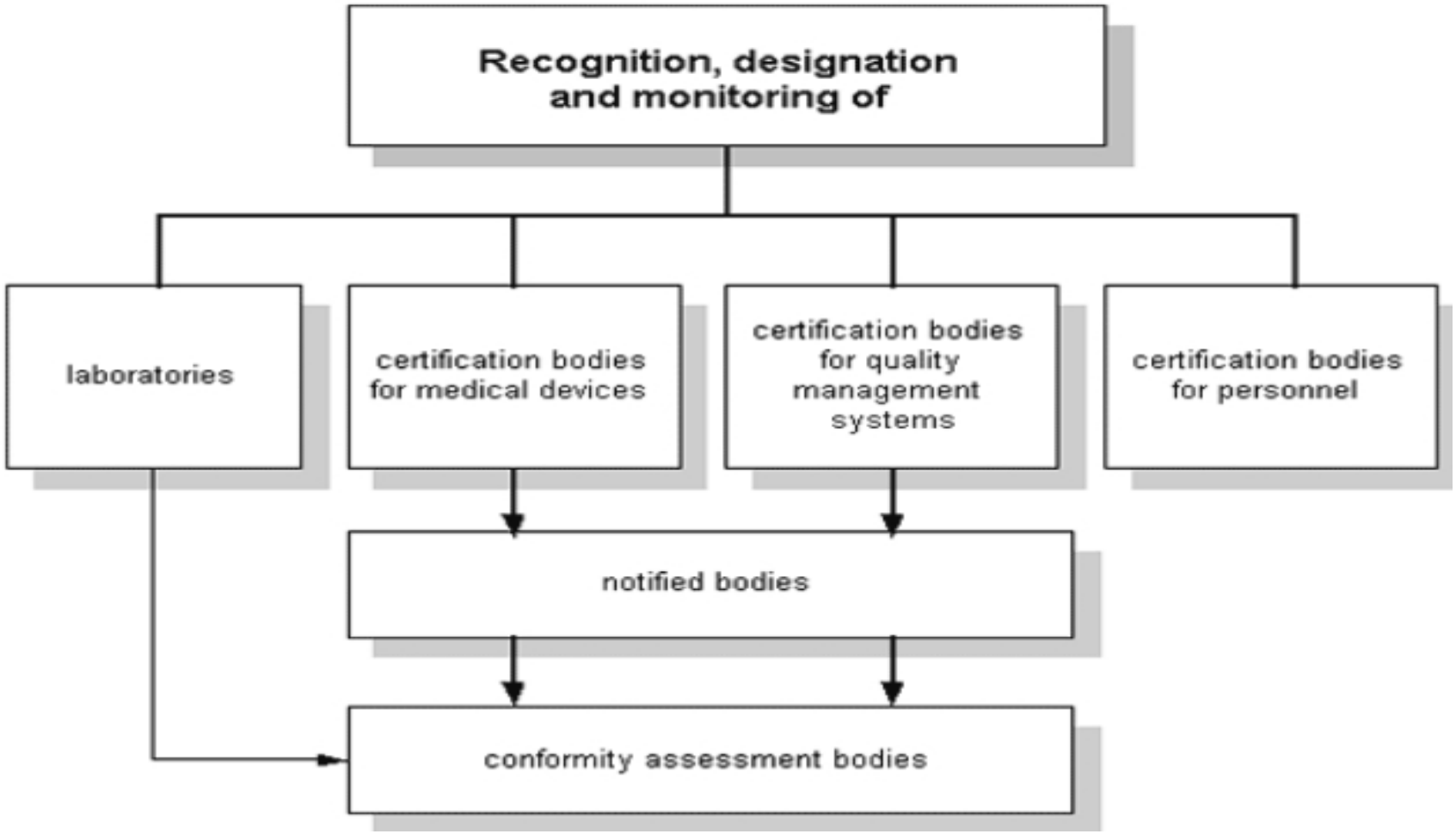
> Laboratories
> Notified Bodies
> Certification Bodies
> Conformity Assessment Bodies

CONTACT FORM

Do you have questions?
> Contact us.

Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices

The implementation of the MPG is within the responsibility of the Laender. In the area of medical devices the ZLG performs the tasks of the 16 Laender with regard to recognition and designation. This includes particularly the recognition and monitoring of testing laboratories and certification bodies in the area of medical devices and in vitro diagnostic medical devices.



Procedure for the designation of the notified body

- Conformity assessment body – application (- to become notified body)
- The designating authority of the Member State where the conformity assessment body is established shall assess that body
- Representatives of designating authorities of two other Member States shall, in coordination with the designating authority of the Member State in which the conformity assessment body is established and together with a representative of the Commission, participate to the assessment of the conformity assessment body.
- The Member State shall notify to the Commission its decision on the designation of a conformity assessment body … Information System.
- The validity of the designation shall be limited up to a maximum of five years.

Germany

- **Designating authority**

ZLG: Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices

ZLS: Central Office of the Federal States for Safety Engineering

- **Accreditation body**

DAkkS: Germany's National Accreditation Body

As government-appointed accreditation body - provide accreditation of conformity assessment bodies.

- **Competent Authority**

BfArM: Federal Institute for Drugs and Medical Devices (Devison 9)

BfArM

Incidents Report

- Risks reported on products already on the market received from operators (physicians, hospitals) - initation of a Risk assessment procedure - a recommendation for the manufacturer and/or the competent supervisory authority of the "Land". The legal instruments for implementing these recommendations lie with those authorities.

Clinical trials

- Authorisation of clinical investigations of medical devices (10/30 days)

Consultation – decision on classification

- Upon request by the competent authority of the "Land", a notified body, or the manufacturer, decides on the classification of individual medical devices and their demarcation from other products.

DEUTSCH PRESS CONTACT

BfArM
Federal Institute for Drugs and Medical Devices

About us▾ Medicinal Products▾ Medical Devices▾ Federal Opium Agency▾ Research▾ Service▾

About us

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) is an independent federal higher authority within th ...
▸ More

- Medicinal Products
- Federal Opium Agency
- Medical Devices
- Research

Federal Institute for Drugs and Medical Devices

Risk information on medicinal products

2014.03.20
Recommendation in relation to the recall of the intragastric balloon Heliosphere ...
Recall of the intragastric balloon Heliosphere Newtech -Newtech 720.
› more

2013.03.12
IV extension sets with multiple ports and vented caps
BfArM informs about the potential risk of air embolism when using IV extension sets with multiple ports and vented caps
› more

Risk information on medical devices

2013.08.27
Weld control of the hoist Omnilift G2
Weld control of the hoist Omnilift G2 of the former manufacturer Weiner Innovative Medizintechnik
› more

2012.09.28
FlowMedical PTA-CATH 5,0 x 100 Angioplasty Catheter of the manufacturer itm ...
The recommendation that the Angioplasty Catheter FlowMedical PTA-CATH 5,0 x 100 of the manufacturer itm FlowMedical GmbH should not be used anymore is cancelled by BfArM
› more

Reporting risks to the BfArM

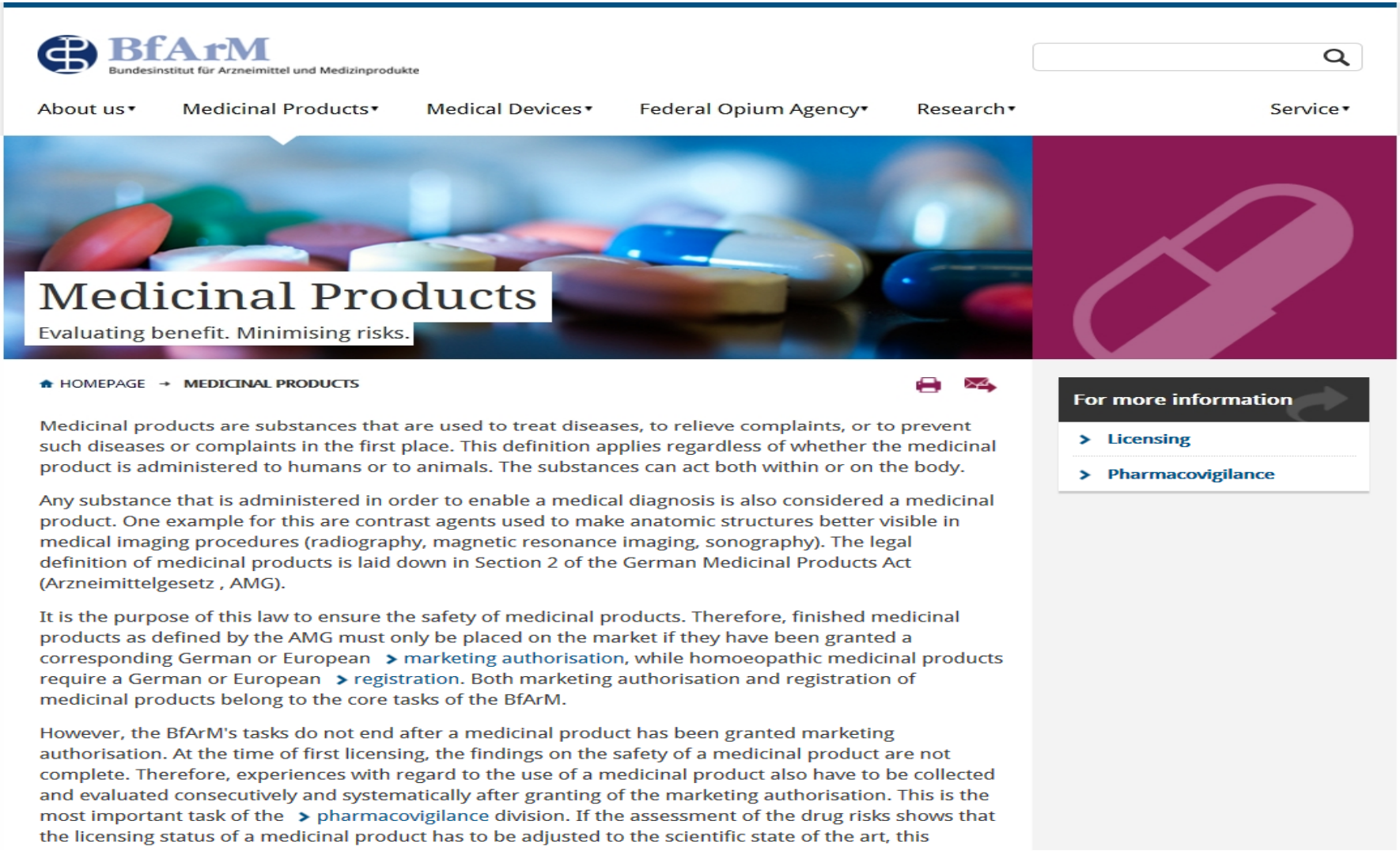
Medicinal Products
- Healthcare professionals
- General public and patients

Medical Devices
- Incident report
- Recall report
- SAE report

Advice Procedures

› Advice Procedures

Further information: www.bfarm.de/EN



BfArM
Bundesinstitut für Arzneimittel und Medizinprodukte

About us · Medicinal Products · Medical Devices · Federal Opium Agency · Research · Service

Medicinal Products

Evaluating benefit. Minimising risks.

HOMEPAGE → MEDICINAL PRODUCTS

Medicinal products are substances that are used to treat diseases, to relieve complaints, or to prevent such diseases or complaints in the first place. This definition applies regardless of whether the medicinal product is administered to humans or to animals. The substances can act both within or on the body.

Any substance that is administered in order to enable a medical diagnosis is also considered a medicinal product. One example for this are contrast agents used to make anatomic structures better visible in medical imaging procedures (radiography, magnetic resonance imaging, sonography). The legal definition of medicinal products is laid down in Section 2 of the German Medicinal Products Act (Arzneimittelgesetz , AMG).

It is the purpose of this law to ensure the safety of medicinal products. Therefore, finished medicinal products as defined by the AMG must only be placed on the market if they have been granted a corresponding German or European > marketing authorisation, while homoeopathic medicinal products require a German or European > registration. Both marketing authorisation and registration of medicinal products belong to the core tasks of the BfArM.

However, the BfArM's tasks do not end after a medicinal product has been granted marketing authorisation. At the time of first licensing, the findings on the safety of a medicinal product are not complete. Therefore, experiences with regard to the use of a medicinal product also have to be collected and evaluated consecutively and systematically after granting of the marketing authorisation. This is the most important task of the > pharmacovigilance division. If the assessment of the drug risks shows that the licensing status of a medicinal product has to be adjusted to the scientific state of the art, this

For more information

> Licensing

> Pharmacovigilance

Information on Risks

- Field Corrective Actions
- BfArM Recommendations
- Scientific Review

Clinical Trials MD / Performance Evaluations

- Advice Procedures
- Information on submission of a request for authorisation of a clinical trial or a performance evaluation
- Information on submission of a request for waiving the authorisation of a clinical trial or a performance evaluation

Legal Framework

Market Access

Vigilance System

Service

- Forms Medical Devices

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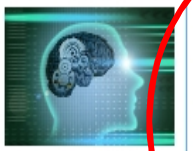
MEDICAL DEVICES


Competitiveness


Regulatory framework


Specific areas of development


Market surveillance and vigilance


Scientific and technical assessment


Other related policies


Dialogue between interested parties


International Cooperation

Medical devices

The role of medical devices in healthcare is essential.

The diversity and innovativeness of this sector contribute significantly to enhance the quality and efficacy of healthcare.

Covering a wide range of products, from simple bandages to the most sophisticated life-supporting products, the medical devices sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities.

The EU's involvement concerns mainly the regulatory framework for market access, international trade relations and regulatory convergence, all aiming to ensure the highest level of patient safety while promoting the innovation and the competitiveness of this sector.

e-newsletter 05 June 2014

:ive, accessible and resilient health systems

Latest updates

The new version of the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices is available

Released 01 September 2014

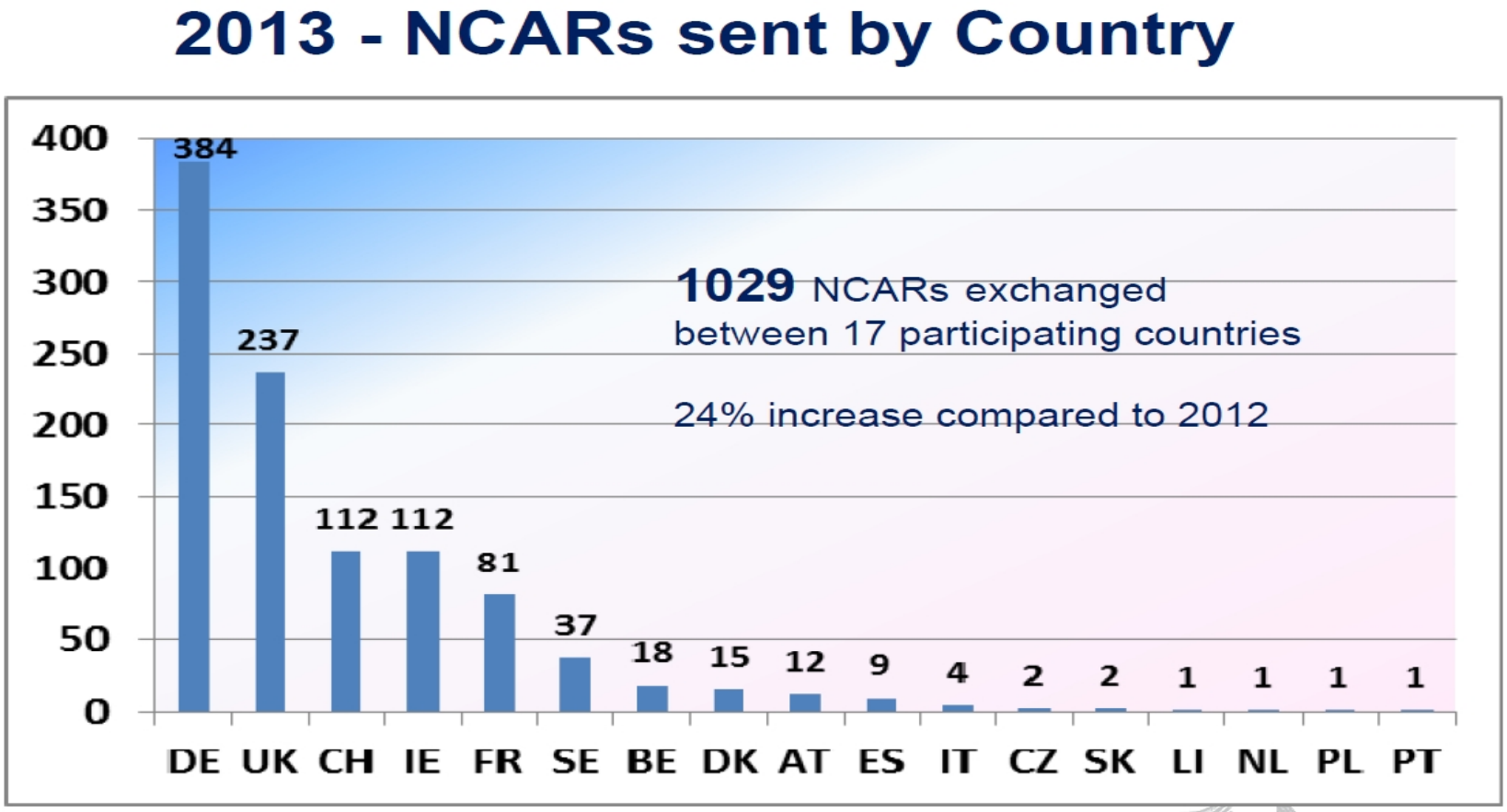
More

Highlights


Commission Recommendation on a common framework for a UDI system of medical devices

26 September 2012 : Commission proposes new rules on medical devices and in vitro diagnostic medical devices

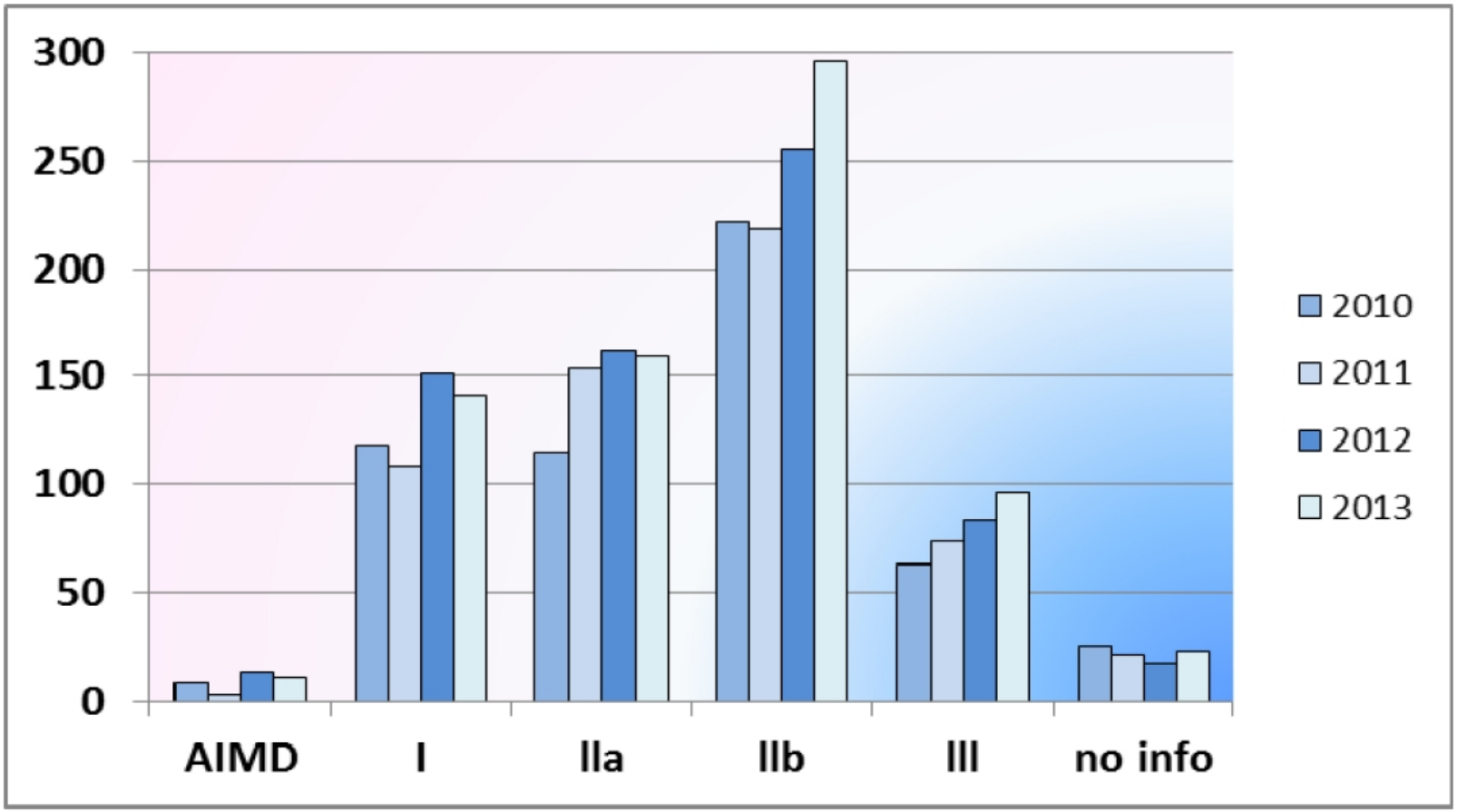
Adverse incidents are evaluated and, where appropriate, information is disseminated in the form of a National Competent Authority Report (NCAR)



European Commission

AIMD and MD number of NCARs linked to risk class

Comparison: 2010-2013



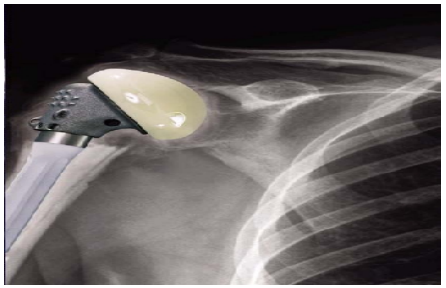
AMID = 90/385/EEC, MDD = 93/42/EEC

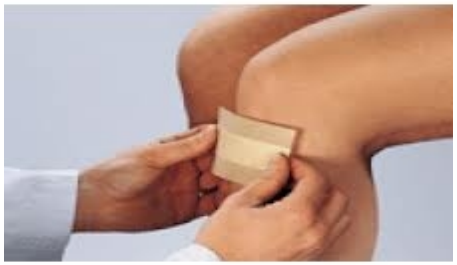
European Union

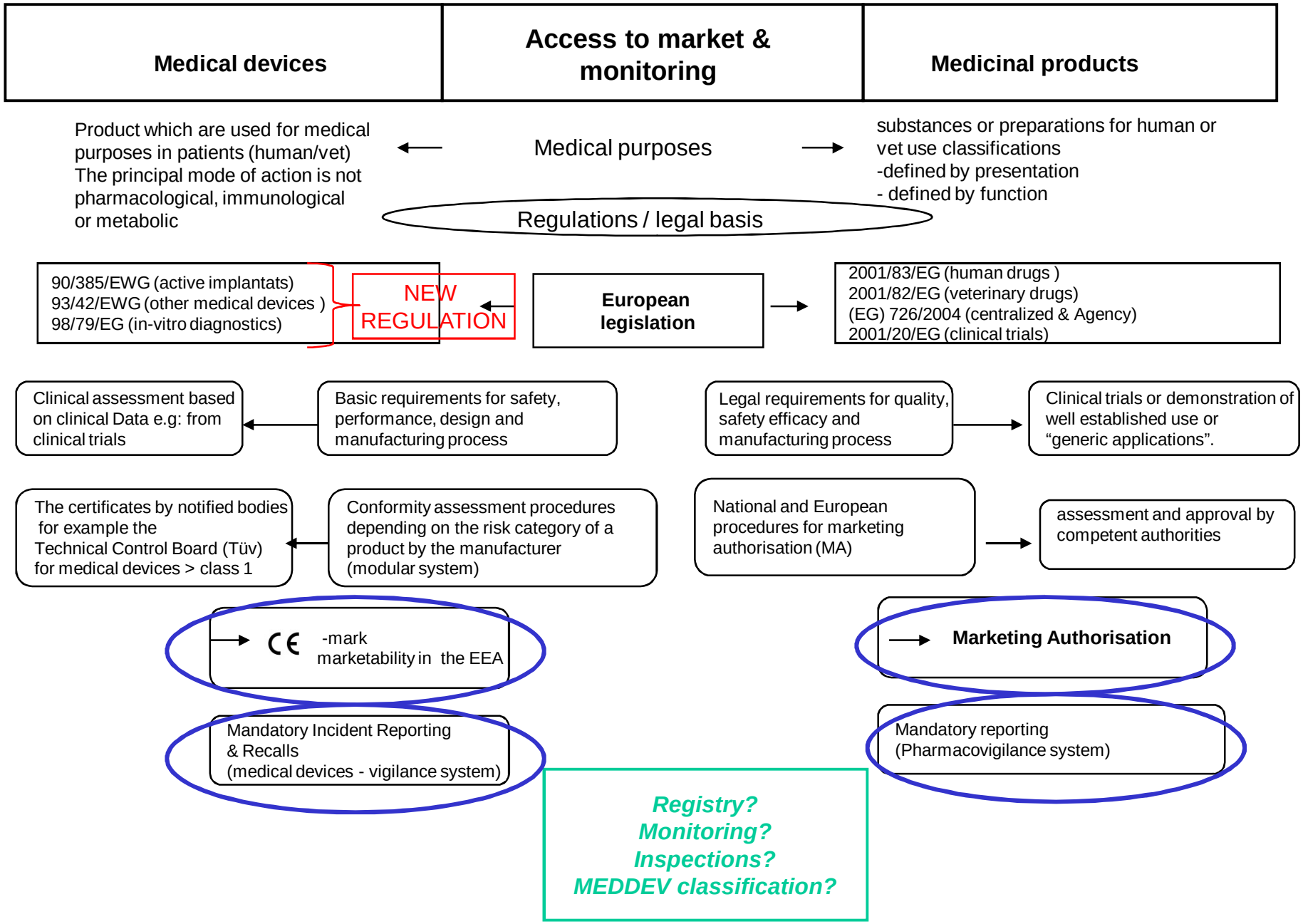
Medical Devices

- Legislation in force
- Proposal for new legislation

Medical Devices






Medical devices
Access to market & monitoring
Medicinal products
Product which are used for medical purposes in patients (human/vet)
The principal mode of action is not pharmacological, immunological or metabolic
Medical purposes
substances or preparations for human or vet use classifications
-defined by presentation
- defined by function
Regulations / legal basis
90/385/EWG (active implantats)
93/42/EWG (other medical devices)
98/79/EG (in-vitro diagnostics)
NEW REGULATION
European legislation
2001/83/EG (human drugs)
2001/82/EG (veterinary drugs)
(EG) 726/2004 (centralized & Agency)
2001/20/EG (clinical trials)
Clinical assessment based on clinical Data e.g: from clinical trials
Basic requirements for safety, performance, design and manufacturing process
Legal requirements for quality, safety efficacy and manufacturing process
Clinical trials or demonstration of well established use or "generic applications".
The certificates by notified bodies for example the Technical Control Board (Tüv) for medical devices > class 1
Conformity assessment procedures depending on the risk category of a product by the manufacturer (modular system)
National and European procedures for marketing authorisation (MA)
assessment and approval by competent authorities
CE -mark
marketability in the EEA
Marketing Authorisation
Mandatory Incident Reporting & Recalls
(medical devices - vigilance system)
Mandatory reporting
(Pharmacovigilance system)
Registry?
Monitoring?
Inspections?
MEDDEV classification?

EU economics

- 500,000 products (simple bandage to sophisiticated life-supporting devices)
- 25,000 companies – more than 500,00 employees = 80% SMEs

- Annual sales 2009 (EU&EFTA)
  - EUR 95 billion
    - Germany: 23,17billion (21 medical devices, 2.17 billion in vitro diagnostic medical devices)

Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices

Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Chapter I – Scope and Definitions;
Chapter II – Traceability, Registration and European databank;
Chapter III – Obligations of economic operators and CE-marking;
Chapter IV – Notified Bodies;
Chapter V – Classification and Conformity Assessment;
Chapter VII – Vigilance and Market surveillance;
Chapter VIII - Cooperation between Member States,
Medical Device Coordination Group, EU Reference Laboratories;
Chapters IX – Confidentiality, data protection, funding, penalties;
Chapter X – Final provisions

AND Annexes **I - XVI**

Proposal for a Regulation of the European Parliament and of the Council on medical devices

Scope and definitions

Article 1

Scope

1. This Regulation establishes rules to be complied with by medical devices and accessories to medical devices that are placed on the market or put into service in the Union for human use.

For the purposes of this Regulation, medical devices and accessories to medical devices shall hereinafter be referred to as ‘devices’.

Proposal for a Regulation of the European Parliament and of the Council on medical devices

Scope cont.'

2. This Regulation shall not apply to:

(a) in vitro diagnostic medical devices covered by Regulation (EU) […/…];

(b) medicinal products covered by Directive 2001/83/EC and advanced therapy medicinal products covered by Regulation (EC) No 1394/2007. In deciding whether a product falls under Directive 2001/83/EC or Regulation (EC) No 1394/2007 or under this Regulation, particular account shall be taken of the principal mode of action of the product;

(c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or used in accordance with the manufacturer's instructions, such blood products, plasma or cells, except for devices referred to in paragraph 4;

(d) cosmetic products covered by Regulation (EC) No 1223/2009;

(e) transplants, tissues or cells of human or animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable. However, human tissues and cells that are non-viable or are rendered nonviable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives;

(f) products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable, including living micro-organisms, bacteria, fungi or virus;

(g) food covered by Regulation (EC) No 178/2002.

Medical devices - responsibilites

Peer Review Assessment (Commission & MSs)

National authority responsible for notifed bodies

National accreditation body

Notified bodies

Conformatory assessment body

Medical Device Coordination Group (MDCG)

Proposal for a Regulation of the European Parliament and of the Council on medical devices

Annexes I – XVI

- Annex IV CE mark
- Annex VI Minimum requirements to be met by notified bodies
- Annex VII Classification Criteria (Rules 1 – 21)
  - Duration of use
  - Invasive and active devices
    - Classification (class I – III)
      - Class I = non-invasive devices
      - Class II = Invasive devices
        - » Class IIa = active devices (eg. in the theeth)
        - » Class IIb =
      - Class III = surgical invasive, implantable devices
      - & Special Rules
        - » Rule 13 = combination with medicinal product = Class III
        - » Rule 19 = incoperating or consiting of **nano**material = class III unless encapsulated…

Council discusses safety of medical devices

Meeting on 19 and 20 June in Luxembourg, the Employment, Social Policy, Health and Consumer Affairs Council looked at ways of improving the safety of medical and in vitro devices in the EU.

Medical devices

Ministers discussed ongoing work on changes to **the draft legislative package on medical devices and in vitro diagnostic medical devices**. The proposed law seeks to modernise the current rules to make sure that the devices are safe and can be traded across the EU. It aims to **step up scrutiny of products before they enter the market and tighten surveillance after they become available**. The draft legislation covers a broad range of products: from plasters and pregnancy tests to state-of-the-art pacemakers, X-ray machines and in vitro diagnostic products.

Ministers exchanged views on 3 issues:

- the designation and monitoring by EU countries of the so-called "notified bodies" in charge of certifying certain medical and in vitro devices before they enter the market
- the participation of businesses in the surveillance of the safety of devices placed on the market
- the responsibilities of the medical devices coordination group

Following the discussion, the Council asked its preparatory bodies to continue work in order to establish a Council position on the package.

Revision of the medical device directives

Ongoing revision

Proposals of the European Commission

On 26 September 2012, the European Commission adopted a package on innovation in health consisting of

- the Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals (52 KB)
- the Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (632 KB)
- the Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices (490 KB)

The adoption of the above documents was announced in a press release (70 KB). The key elements of the revision are summarised in a Citizens' Summary (37 KB) and in a questions and answers (79 KB) document.

The Commission proposals are accompanied by an impact assessment on the revision of the regulatory framework for medical devices that consists of

- an Executive Summary of the impact assessment (59 KB),
- Part I of the impact assessment addressing the systemic problems (443 KB) (e.g. oversight of Notified Bodies, post-market safety, transparency, governance) that are of a horizontal nature and apply to medical devices and in vitro diagnostic medical devices (IVDs) alike,
- Part II – Annex 1 (145 KB) that addresses specific issues relevant for medical devices other than IVDs [link] and Part II – Annex 2 (120 KB) that addresses specific issues relevant for IVDs,
- Part III – Appendices (437 KB) that contains supporting documents.

The proposals have been submitted to the European Parliament and the Council. In order to become binding Union law, Parliament and Council need to adopt the texts by ordinary legislative procedure. You find an overview of this procedure on the website of the European Parliament. You can follow the development of the legislative decision-making process on Pre-Lex or on the "Legislative Observatory" of the European Parliament.

Preparation of the European Commission's proposals

After the last amendment of Council Directives 90/385/EEC and 93/42/EEC by Directive 2007/47/EC (see below), the Commission considered a fundamental revision of the regulatory framework for medical devices necessary in order to ensure a high level of human health and safety, to ensure the smooth functioning of the internal market and to meet the growing expectations of European citizens while preserving its innovation-friendly approach.

e-newsletter 17 July 2014

gym: let's put those new machines to work!

Latest updates

Restoring confidence in medical devices. Reporting on the success of the PIP Action Plan
Released 20 June 2014

New references of harmonised standards for Directive 93/42 on Medical Devices (OJ C149 of 16 May 2014)
Released 16 May 2014

More

Highlights

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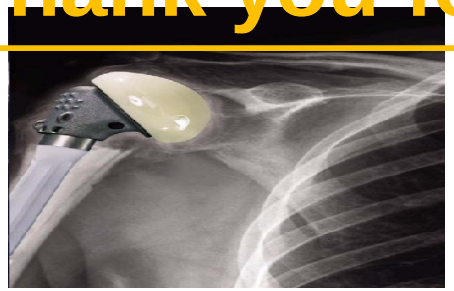
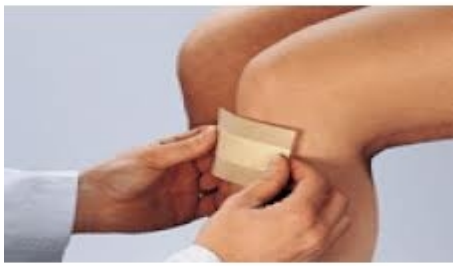
Evaluation of the European Databank on Medical Devices

Medical Devices

Thank you for your attention





- Back up slides

Ancillary medicinal substances

In this section you will find practical information and guidance documents for the consultation procedure to the European Medicines Agency by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device.

This page addresses the following topics, click on a link to go to the page: