MDR: It's all about planning!

EyeOn Idealab

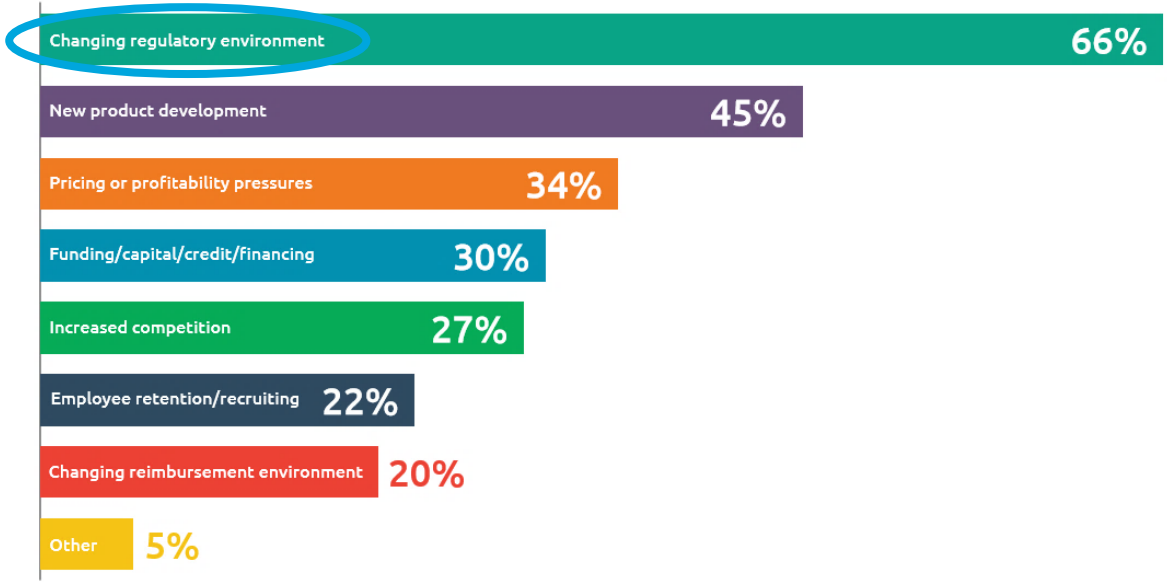
November 13, 2018

Sheraton Airport Zaventem, Belgium

Content

- Understanding the Medical Device Regulation
- Elements on supply chain planning impact

Key challenges for the Medical Device Industry



www.medtecheurope.org

Why MDR?

eyeon
YEARS AHEAD

First 2 articles:

*(1) Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union **regulatory framework for medical devices**, other than in vitro diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.*

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.

First 2 articles in summary:

- regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation;
- ensure the smooth functioning of the internal market;
- a high level of protection of health for patients and users;
- taking into account the small- and medium-sized enterprises that are active in this sector.

Why MDR?

- Scandals (e.g. PIP implants) demonstrated weaknesses in the system;
- Oversight of Notified Bodies insufficient;
- Post-Market safety monitoring lacking;
- Transparency and traceability of devices not sufficient;
- Further globalization;
- New types of products introduced;
- No consensus between competent authorities.

Medical Devices

MEDICAL DEVICE

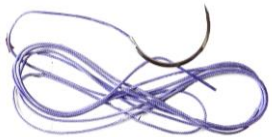
'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and
- which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

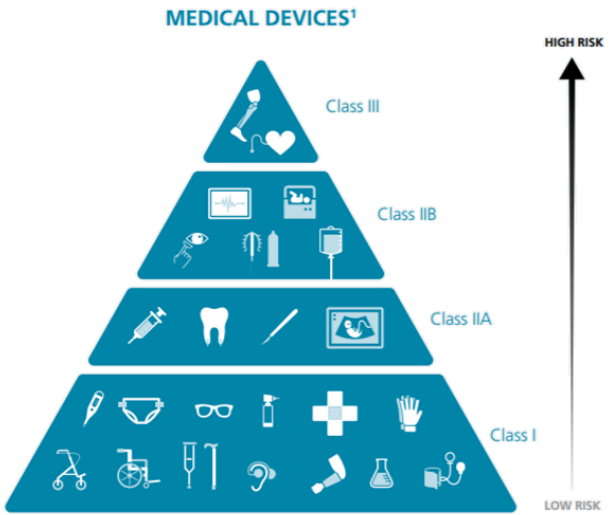
The following products shall also be deemed to be medical devices:
- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

ACCESSORY

An article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).



Risk Classes



The classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking into account of the potential risks associated with the devices.

The classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device

- **Class I** (low/medium risk)
- **Class IIA** (medium risk)
- **Class IIB** (medium/high risk)
- **Class III** (high risk)

Scope

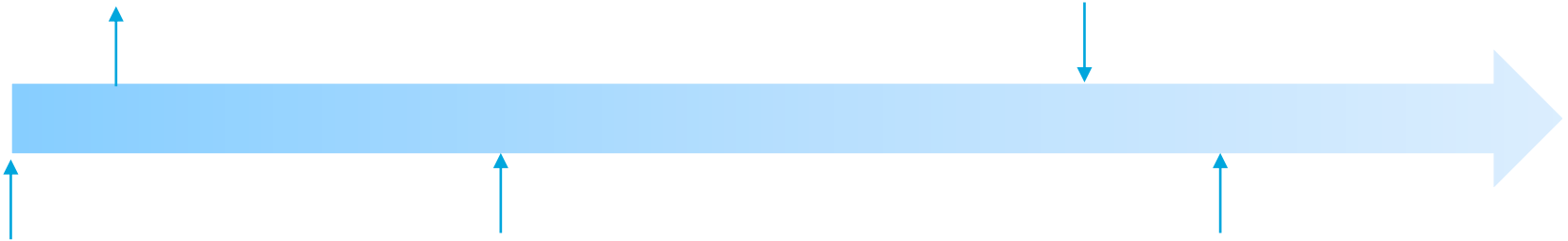
MDD applicable in EEA:

- Members EU
- Norway
- Iceland

Directives accepted in:

- Liechtenstein
- Switzerland
- Turkey

Time line



May 26, 2017
Date of Entry into Force (DEF).
MDR into force with 3 years transition period.

May 27, 2024
All MDD CE certificates, even with valid expiry date, will become void

May 5, 2017
Date of publication (DoP)
Publication in
Official Journal

May 26, 2020
Date of Application (DoA).
End of transition period.

- All Notified bodes will be de-notified
- All MDD CE certificates will expire (however expiry date)
- All requirements related to post-market surveillance, market surveillance, vigilance, etc. will become valid for all economic operators.
- Certificates with an expiry date (max 5 years) remain valid till end of expiry date, or May 27, 2024 (no significant changes in design and intended purpose possible anymore after this date under MDD CE certificate).

May 27, 2025
Devices already placed on the market, can be even made available or put into service for an additional year + 1 day .
(1 year extra to clear the supply chain)

Economic operators

- Manufacturer
- Authorized Representative
- Importers
- Distributors

New: In MDR also responsibilities for these Supply Chain operators

- (M.A.I.D.)

Manufacturer definitions

Before moving to the manufacturer's responsibilities under MDR, first some terms are explained.

- **Clinical Evaluation**

A systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits of the device when used as intended by the manufacturer.

- **PMS**

All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market, or put into service for the purpose of identifying any need to immediately apply any necessary corrective and preventive actions.

- **Eudamed**

Electronic system for registration of devices, UDIs, economic operators, notified bodies, certificates, clinical investigations, vigilance and post-market surveillance, market surveillance. Manufacturer need to register and keep up-to-date (manual or with automatic interfaces) this information in the Eudamed database.

Manufacturer definitions

- **UDI (DI+PI)**

UDI information must be placed on the label and/or package of medical devices. The UDI produced for a device comprises an **UDI-DI** (device identifier – specific to a manufacturer and a device) and an **UDI-PI** (production identifier – identifies unit of a device production). The UDI-PI identifies specific production series of a device (batch, serial number etc.). The UDI plays a key role in the communication with the Eudamed database.

UDI information assigned to medical devices would have to be tracked by manufacturers, authorized representatives, importers and distributors. So economic operators would need to modify their QMS to ensure information is not lost but stored in a proper, systematic way.

- **Vigilance reporting**

Vigilance is the reporting of serious incidents and fied safety corrective actions by manufacturers to the relevant competent authorities. Manufacturers also have to report trends in expected undesirables side effects and incidents that are not classified as serious. Vigilance is a reactive processes. It is described in MDR which timescales for reporting need to be applied depending on the severitry of the serious incident.

Manufacturer (1)

The manufacturer will need to ensure:

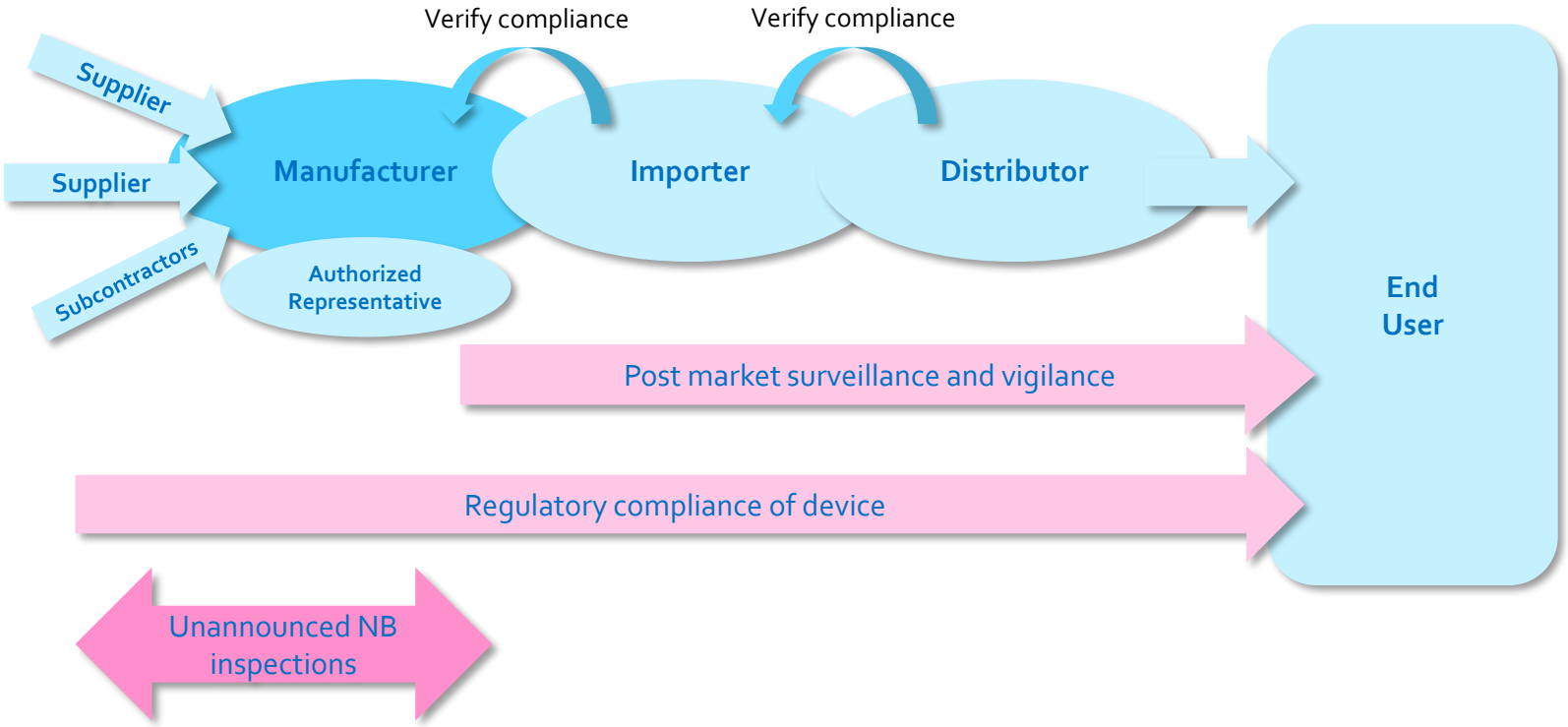
- **MDR requirements**: General safety and performance requirements are met;
- **Classification:** the device had been correctly classified against the correct MDR risk classification criteria;
- **Clinical evaluations** are executed according to the defined requirements (including Post Market Clinical Follow up - PMCF);
- **Clinical evidence:** the increased requirements for clinical evidence are met;
- **Technical documentation** is according to the requirements, up to date, and always available for conformity assesments;
- **DoC:** Draw up a EU declaration of conformity when compliance has been demonstrated following the applicable conformity assessment;
- **Labelling and technical documents** are compliant with the requirements.

Manufacturer (2)

The manufacturer will need to ensure:

- **UDI**: To comply with the obligations relating to UDI (Unique Device Identifier);
- **Responsible:** There is person responsible for regulatory compliance;
- **Supply chain responsibility:** Economic operators in the supply chain are complaint (responsibility of manufacturer to validate);
- **Financial coverage:** Sufficient financial coverage is in place (insurance for product liability);
- **Vigilance reporting:** The new vigilance reporting timescales are met;
- **Risk management:** A proper system for risk management is implemented;
- **Safety update report:** An annual periodic safety update report is created;
- **Post market surveillance system:** A systematic procedure is in place to proactively collect and review information about devices in the market.
- ……..

Supply chain controls



Source: RAPS

Compliance Cost Estimates

- Rough estimate for the industrywide cost of compliance between 3,5 % and 5 % of revenues.

- MDR cost to industry of €17,5b, if a centralized pre-market authorization system is implemented excl. UDI compliance.

- UDI compliance and improvements in labelling & clinical performance data : estimated industry cost of €7,5b

Large differences are expected between companies.
For some operators only a small part of their portfolios will be affected.
For others, the compliance process may be applicable to nearly all product lines.

Sources : E&Y, 2017; industry group Eucomed

Content

- Understanding the Medical Device Regulation
- Elements on supply chain planning impact

MDR on MD&D Supply Chains

Supply Execution & Logistics

- E2E Supply Chain transparency will become increasingly important, as manufacturers must show that they are in control of their supply and distribution chains;
- Tracking and tracing of unique articles throughout the E2E supply chain is required;
- Extensive adjustments of information systems and production lines are needed to implement the Unique Device Identification (UDI) and other new labeling requirements.

Supply Chain Planning

- The Product Life Cycle Management (PLM) is drastically impacted as old and new products will need to be phased out and phased in.
- Forecasting/demand management will need to be able to handle pre-MDR and MDR approved products;
- Monitoring and management of inventories of pre-MDR and MDR registered products;

Main focus Idealab

Product Life Cycle Management (PLM) - Elements to consider

- Transparency on the regulatory process for phase in and phase out is drastically impacted as timing depends on a lot of factors, such as (non limitative list)

  - Planning and timing PLC is driven by readiness of regulatory tech files. Tech file needs to be complete and reviewed before certification / filing can start.
  - Expiration dates of current CE Marking Certificates
  - Availability of clinical data
  - Availability of Notified Bodies
  - UDI readiness
  - Expiration dates of devices
  - Inventories including consignment stocks
  - Production readiness
  - ....

  The phase in and phase out process will likely require a monthly or weekly validation cycle, a specific workflow and a risk management process to mitigate shifts in timing and risk factors

Demand Planning

- Forecasting/demand management will need to be able to handle pre-MDR and MDR approved products

- Elements to consider (non limitative list):
  - Availability of forecast data on country level will gain importance to manage the demand planning process
  - Alignment with timing compliance readiness will need to be managed in the forecast for the different distribution channels. Sales involvement needs to be intensified. Demand planning effort will increase.
  - Forecast aggregation levels will likely need to be reviewed to manage complexity
  - Readiness of forecast tooling : forecast data will at least double during transition period

Supply Planning

- PLC process, changes in the regulatory process and its pre-requisites and expect amount of changes in the forecast will drive supply planning and impact production readiness

- Elements to consider (non limitative list):
  - Impact of MDR pre-requisites on supply planning (fe. UDI)
  - Compliance agreements & audits for external supply. Find alternatives for non-complaint economic operators in the value chain
  - Capacity and production planning & scheduling will become more complex due to SKU growth during transition period. Supply planning effort will increase
  - Required modifications in supply planning tooling
  - Planning with required production line changes for compliance

Inventory Planning

- Monitoring and management of inventories (warehouse inventories, assembly /kit/ FG inventories, consignment inventories, etc.) of pre-MDR and MDR registered products

- Elements to consider (non limitative list):

  - Efficient implementation of the MDR regulations while maintaining service levels and minimizing write offs. This is not an inventory optimisation exercise.

  - Dealing with & interpreting of consignment stock is a specific challenge

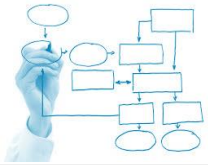
  - Inventory at external suppliers is an element that is likely to be managed wrt. manufacturing & supplier liabilities.

Other MDR Planning Enablers

- Decision making / S&OP
- E2E reporting
- Issue management and reporting
- Evaluation process, pace and plan integration
- Risk management process, organisation & tooling
- Workflow organisation & tooling
- Tool capabilities wrt increase of data capturing
- Maintenance of scenario's (if required, depending on complexity)
- Resourcing & effort throughout the compliance and planning process
- Master data maintenance and changes in process & tooling

Building blocks for effective MDR transition planning

Regulatory process & organisation



REGULATORY PROCESS & WORKFLOW

SC process

EFFECTIVE PHASE IN & OUT

RISK MANAGEMENT

INVENTORY MANAGEMENT

Enablers

FIT FOR USE TOOLS

PLANNING SKILLS & PROJECT RESOURCING

EyeOn bv
Croylaan 14
5735 PC Aarle-Rixtel
The Netherlands
Tel.: +31 (0)88-8830000
mail@eyeon.nl
eyeon.nl

EyeOn Amsterdam
Vijzelstraat 68-72
1017 HL Amsterdam
The Netherlands
Tel.: +31 (0)88-8830000
mail@eyeon.nl
eyeon.nl

EyeOn Belgium
De Keyserlei 58-60 B19
B-2018 Antwerp
Belgium
Tel.: +32 (0)3 304 95 13
mail@eyeon.eu
eyeon.nl

EyeOn Switzerland
Aeschenvorstadt 71
CH-4051 Basel
Switzerland
Tel.: +41 61 225 4230
mail@eyeon.eu
eyeon.nl

Forecast Services
Croylaan 14
5735 PC Aarle-Rixtel
The Netherlands
Tel.: +31 (0)88-8830000
forecastservices@eyeon.nl
forecastservices.com