How Companies can make the relevant changes to comply

Sandra Welch

NAMSA

Medical Device Directives

- After 20 years of broadly accepted success, Medical Device Directives are in line for a major overhaul due to:
  - Huge leaps in technology, number of Member States (MS) almost doubled
  - Application of Directives different across MS while Regulation is mandatory to all MS.
  - Some have been advocating a more prescriptive regime
- Been under review for the last 4 years
- Main thrust - patient safety & free movement of goods

NAMSA

What's going to change for the companies?

NAMSA

Proposed Regulations

- Proposals formally issued on 26 Sept 2012
- Proposals discussed again in European Parliament & Council – latest draft April 2014
- General med device & active implantable Regulation has a transition time limit of 3 years
- Aim is to provide an overview of some of main changes proposed within the Medical Device and Active Implantable device single Regulation

NAMSA

What's going to change for the companies?

- **Regulation instead of Directive**
  - Directives are adopted in each Member State (MS) legislation so there are different interpretations of it.
  - Regulations are mandatory and not transposed, so are issued in all MS exactly as written.

A Regulation will mean a consistent interpretation across Europe.

NAMSA

Chapters I - X

Chapter I	Scope and definitions	Articles 1 – 3
Chapter III	Identification & traceability of devices, registration of devices Eudamed	Articles 23 - 27
Chapter VI	**Clinical evaluation and clinical investigations**	**Articles 49 - 60**

NAMSA

Chapters I – X (cont)

- Chapter VII Vigilance & market surveillance — Articles 61 - 75
- Chapter VIII Co-operation between MS, MDCG, EU ref labs — Articles 76 - 83
- Chapter IX Confidentiality, data protection — Articles 84 – 87

NAMSA

What's going to change for the companies?

- **Within the manufacturer's organisation a 'qualified person' should be responsible for regulatory compliance**
  - There is a prescribed list of what a Qualified Person needs to do
  - It differs from the requirements of a QPin the EU legislation for medicinal products.

What's going to change for the companies?

- **Devices will have a Unique Device Identification (UDI) which allows traceability**
  - UDI will comprise:
    - a device identifier specific to a manufacturer and a device model;
    - A production identifier that identifies data related to the unit of device production

NAMSA

What's going to change for the companies?

- **Manufacturers/authorised representatives and importers must register themselves and the devices they place on the EU market in a central European database;**

NAMSA

What's going to change for the companies?

- **Manufacturers of high-risk devices to make publicly available a summary of safety and performance with key elements of the supporting clinical data;**

UDI + Manufacturers Registry + Summary will allow the creation of a database *European Databank on Medical Devices (Eudamed)*

NAMSA

What's going to change for the companies?

The MDR will:

- provide a high level of transparency through the EUDAMED database
- do away with diverging national registration requirements which have emerged over recent years and which have significantly increased compliance costs for economic operators.
- contribute to reducing the administrative burden on manufacturers.

NAMSA

What's going to change for the companies?

- **Implant Card**
  - The manufacturer of an ID shall provide an implant card to the particular patient who has been implanted with the device.
  - This card shall contain the following information written in a way that is readily understood by a lay person:
    - the information allowing identification of the device (UDI);
    - any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;
    - any information about the expected lifetime of the device and any necessary follow-up.

NAMSA

What’s going to change for the companies on what concerns Clinical Investigation/Evaluation

NAMSA

Annexes I – XVI (cont)

- Annex XIII Clinical evaluation and post-market clinical follow-up
- Annex XIV Clinical Investigations
- Annex XVI Correlation table; 93/43EEC & 90/385 EEC

NAMSA

Definitions

- Concept of a sponsor for CI's is to be introduced

- Definition 38

  "Sponsor" means an individual, company, institution or organisation which takes responsibility for the initiation and management of a CI (conduct or financing). Wider definition than current ISO 14155

- *Where the sponsor is not in the EU, a contact must be established in the European Union.*

NAMSA

Clinical Evaluation & Investigations

(Chapter VI)

- Before Commencing, every Clinical Investigation must be registered in an electronic system, which the commission will set up - Art 53
- Application for a CI:
  - ✓ *Sponsor shall procure an identification number from the electronic system*
  - ✓ *No personal data of subjects participating in clinical investigations shall be publically available*
  - ✓ *Only parts of the database will be publically accessible - Art 52*

NAMSA

Registration of Clinical Investigation

(Art 52)

Information required for the database

a) Identification no of CI

b) Name & contact details of sponsor; if applicable his contact person in EU

c) Name & contact details of legal person responsible for investigational device, if different from sponsor

d) Description of investigational device

e) Description of comparator

f) Purpose of CI

g) Status of CI

Within 1 week of any change, the sponsor shall update data in electronic system

NAMSA

Co-ordinating Member State

(Art 58)

- Where a CI is to be carried out in more than one MS, a single application may be submitted through the electronic system
- Applicant shall propose one MS as co-ordinating MS
- Concerned MS have **6 days (14)** to agree with another MS who will co-ordinate the investigation
- In case of disagreement, Commission will decide

NAMSA

Application
(Annex XIV)

- Health & Safety will be assessed centrally, but ethical aspects will still be considered separately by each MS
- Within **3 days (6)**, MS shall notify the Sponsor if the CI falls within the scope of this Reg & if application is complete – Art 58
- Sponsor has **6 days** to comment or complete application
- **35 days (60)** after application, Sponsor can proceed

NAMSA

Clinical Investigations

(Annex XIV)

- Application form
- Investigator's Brochure
- Clinical Investigation plan
- Other Information
- Other Sponsor's obligations

- Much text taken from ISO 14155; hence it will thus be mandated once in MDR

NAMSA

Post Market Clinical Follow Up

(Annex XIII)

Clinical investigations with devices authorised to bear CE marking

- "Post market clinical follow up investigation"
- Sponsor shall notify MS at least **30 days** prior to commencement if submit subjects to additionally invasive or burdensome procedures
- If substantial modifications to a CI needed, notify MS
- Sponsor may implement substantial modifications **30 days** after notification, unless MS refusal

NAMSA

Clinical investigations

(Art 57)

- If Sponsor has halted CI on safety grounds, inform MS within **15 days** of temporary halt
- Sponsor shall notify MS(s) at end of a CI. Notification to MS(s) within **15 days** of overall end of CI
- Within **1 year** from end of CI, Sponsor shall submit to MS(s) a CI report

NAMSA

Clinical Evaluations & PMCF

(Annex XIII)

- Requirement for a clinical evaluation report specifically mentioned

Part A – Clinical evaluations

- In the case of implantable devices and Class III devices, demonstration of equivalence with a device **shall not be** considered sufficient justification for not collecting clinical data

  ie an investigation is warranted

Part B – PMCF

- Continuous process to update clinical evaluation
- PMCF plan & what it should contain

NAMSA

Enabling/Implementing Acts throughout Regulation

- Numerous enabling/implementing acts throughout the Regulation – enables Commission to establish rules which implement an aspect of the regulations in a harmonised way across the EU

Examples:

- Background statement 25)
  - Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting ….should be incorporated into the enacting provisions of this Regulation to enhance legal certainty

NAMSA

Summary

A lot of changes are expected to happen with impact on the medical device life cycle.

This changes will allow greater transparency and uniformity across Europe for the Medical Device industry.

NAMSA®

THANK YOU

NAMSA®