Global Growth in Product Environmental Compliance Requirements

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Introduction: **Vinay Goyal**

Working as Product Stewardship Project Engineer/Manger for over 15 years

Responsible to implement various product environmental requirements e.g. RoHS, WEEE, REACH, Packaging, Battery, related to new EU Medical Device Regulation etc.

- ASQ Fellow
- Serving as the Chair of Section 0701
- Membership Chair of Section 0702 and
- Chair of 11th Southern California Quality Conference in November 2018.
- Adjunct faculty at North Orange County Community College.

Disclaimer

- This presentation has nothing to do with my past and current employers and their internal practices
- This is a general presentation based on presenter's good faith interpretations
- Most of the Product Stewardship (Product Environmental Compliance) requirements are legal in nature and subject to interpretation
  - Depending on your products
  - Applications etc.
- Please seek help and guidance from your legal counsel

Basic Requirement

- What is Product Stewardship or Product Environmental Compliance Requirements
- In layman's terms –
  - Substances in your Part, Product, Packaging
- Substances are either:
  - Banned – cannot be used in the product Example – Mercury in Thermometer
  - Restricted – Should not be exceeding over the threshold limit - RoHS
    - Pb should not be more than 0.1% or 1000 ppm
    - Cd should not be more than 0.01% or 100 ppm
  - Or Require Disclosure : If you have in your product, disclose it

Basic Requirement

- Difference between an EU Directive and a Regulation
  - 3 Kinds of Legislative Acts
    - Proclamation
    - Directive
    - Regulation
- What is CE Marking
  - Some directives and Regulations are CE marking directive and regulations
  - If they apply to your product partially or fully, your product **must be compliant to all applicable directives and Regulations** before you can place a CE marking
  - CE marking is like a **PASSPORT** to place on the EU marking

Basic Requirement

- Applies to
  - Manufacturer
  - Importer
- Do not take it lightly
- Due to Globalization of SCM - when designing a product, make sure it is compliant to all local and **preferably GLOBAL** PS/PEC compliance requirements

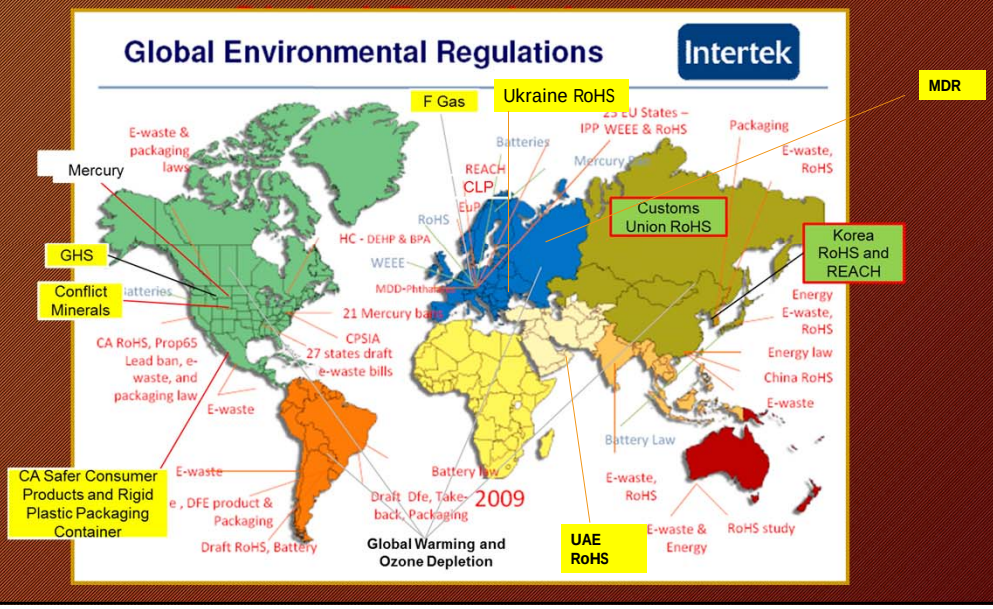
Basic Requirement

- Why they are restricted:
  - Human Health
    - Allergic, Carcinogenic, Mutagenic and Reproductive Toxin (CMR)
    - Long term Health Impact – BPA, DEHP
  - Environmental
    - Landfills
    - Water
    - Air
  - Sustainability – replenish
    - Global warming, 4Rs – Reduce, Reuse, Recover, Recycle

Product Environmental Compliance Requirements

- Constantly growing and changing
- To stay competitive in today's market, manufacturers "must" consider environmental compliance as one of the key marketing elements
- "You can run but cannot hide" - Ignoring the issue is not an option, as the consequences could be devastating to your business due to regulatory non-compliance, blocked shipments, costly redesigns, corrections, recalls and bad press.

If not all, majority of the regulations either apply to most commercial and Medical Device companies or they will be in the future.



Details about these regulations

- You can become an expert of these regulations in a very short time
- Hardest Part is – "Implementation" that may take months and years
- Why?
- They apply product life cycle management
  - Inception to end of useful life (Cradle to Grave)
  - Require Cross Functional Support
  - Marketing – Review – R&D – SCM (Document Control – Procurement – Manufacturing Operations, Shipping – Field Service – End of life obligations (Reuse, Recover, Recycle)
    - 3R – paying fee, periodic reporting, Format, Language, Hardcopy, e-filing etc.
- Today, I will be sharing about MDR

MDR Regarding Substances

Safety and Performance Requirement10.4, 10.5. 10.6, 14.7

Significant Differences

MDD

- Medical Device Directive (93/42/EEC) and the Active Implantable Medical Device Directive (90/385/EEC)
- 50+ Pages (MDD only)
- D=Directive: Legislation that sets out rules and must be transposed into national law to be effective

MDR

- REGULATION (EU) 2017/745
- 352 Pages (MDD + AIMD)
- R=Regulation: Mandatory Jurisdiction that is directly applicable and enforceable in all EU Member States

Will cover the Restricted Substances related to this Regulation

Substances 10.4

- RS requirements in MDR are:
  - Much longer than any Directive(s)
  - Much more specific than any Directives
- Substances are discussed
  - In the device
  - That are released
  - The most significant new text is the requirement for certain substances of concern that
    - Invasive devices (Implantable)
    - Devices administering/storing substances (IV Tubes, storage bags etc.)
- **Note: Four major routes of entry chemicals: Patient Contact** Inhalation (breathing), Absorption (skin contact), Ingestion (eating), Injection

Substances 10.4

- Unless justified concentration below 0.1 per cent by weight
  - CMR (carcinogenic, mutagenic, or toxic to reproduction)
  - Substances with endocrine-disrupting properties
  - References to substances categorized per
    - **EU Regulation 1272/2008 (Classification, Labelling and Packaging of Chemicals)**
    - **EU Regulation 1907/2006 (REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals)**
    - **EU Regulation 528/2012 (Market and Use of Biocidal Products)**
  - A justification **(10.4.2)** must be made if substances (for example: lead compounds, other heavy metals, phenols) are present above 0.1 per cent by weight in these device types

Substances 10.4

- **10.4.3 and 10.4.4** state EU Commission shall provide the scientific committee to prepare guidelines including a risk-benefit assessment of phthalates, CMR and endocrine-disrupting substance
  - **Phthalates are currently addressed in MDD ER 7.5**
- Manufacturers of devices having phthalates, CMR substances, or endocrine-disrupting substances must plan to meet the MDR requirements

Substances 10.4

- 10.4.5 addresses **labelling** requirements for devices which include substances as referred to previously, in concentrations above 0.1 per cent by weight
- This information must be disclosed on the label
- Specific information on treatment of vulnerable groups
  - Children and
  - Pregnant and Breastfeeding women

Must be included in the IFU

- This section is cross-referenced from the labelling requirement 23.2(f).

Substances 10.4

- The text and requirements for substances in the device, and especially substances of toxicological concern, are greatly expanded in the MDR
- A threshold and reference for substances of concern are now specifically defined, and considerations for justification are outlined if these substances are included in a medical device. Manufacturers should be aware of what substances are present in their devices.
- The specific requirements will further increase the need for careful characterization of device substances and materials going forward.

Substances 10.5 and 10.6

- 10.5: The risk of unintentional ingress/leakage is to be reduced as far as possible.
- 10.6: Risks related to particle size is a new requirement compared with the Directives
  - MDR states risks linked to the size and properties of particles should be reduced (exception if they come into contact with intact skin)
  - It is stated that 'special attention shall be given to nanomaterials (New requirement).
    - MDR Annex VIII, the risk is dependent on the level of internal exposure.
  - The new emphasis on nanomaterials will be very important for many devices were not a major concern under the Directives

Challenges

- Manufacturers have to proactively make sure their products are compliant to CMR, Endocrine Disruptive Substances, all referenced Regulations
- Manufacturer to assess during the entire development/change process
  - Products under your brand name
  - OEM products placed on the professional basis
    - Sub tier suppliers
- **Why:**
  - Customer RFPs – requester is not familiar with your product
  - Standard questionnaire
    - Don' t ask don't tell, also look for **Negative Declaration**

14.7: Design and manufacture for safe disposal

- Design and manufacture for safe disposal is a new requirement not found in either of the Directives
- Directives require the Instructions for Use (IFU) to include warnings about safe disposal
- MDR requires that devices are specifically designed and manufactured to
  - Facilitate their safe disposal
  - Safe disposal of any related waste substances by
    - User
    - Patient
    - Other person
- Manufacturers are required to actually identify and test procedures and measures for disposal of their devices and describe these procedures in the IFU

Questions

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- Ref: BSI White Paper
- https://www.bsigroup.com/meddev/LocalFiles/en-US/Whitepapers/bsi-md-whitepaper-uk-safety-performance-requirements.pdf

Medical Devices Regulation (MDR)

SPR/ER Cross-reference Mapping Guide

Low priority | Medium priority | High priority

Reference Number			
MDR SPR	MDD ER	AIMDD ER	Other Guidance
10.4	7.5	-	Regulation 1272/2008, Regulation 1907/2006, Regulation 528/2012
10.5	7.6	9	-
10.6	-	-	MDR Annex VIII Rule 19
14.5	14.1	9.1	-
14.6	10.2	-	-
14.7	-	-	-
15	10.1, 10.3	-	Directive 80/181/EEC
16.1a	11.1	-	-

SPR: General Safety and Performance Requirements
ER: Essential Requirements
MDD : Medical Device Directive; AIMDD: Active Implantable Medical Devices Directive

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