Impact of MDR on the suppliers and their relations with Blood Establishments

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Keeping up with Reality and Quality: A Challenge for European Blood Establishments Webinars

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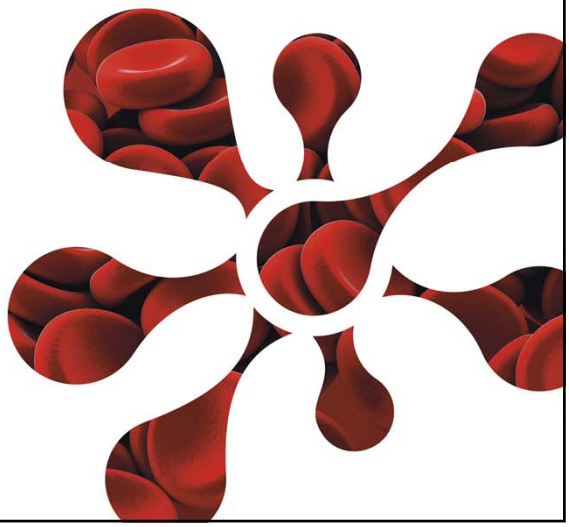
Blood Transfusion Association



Objectives of the presentation

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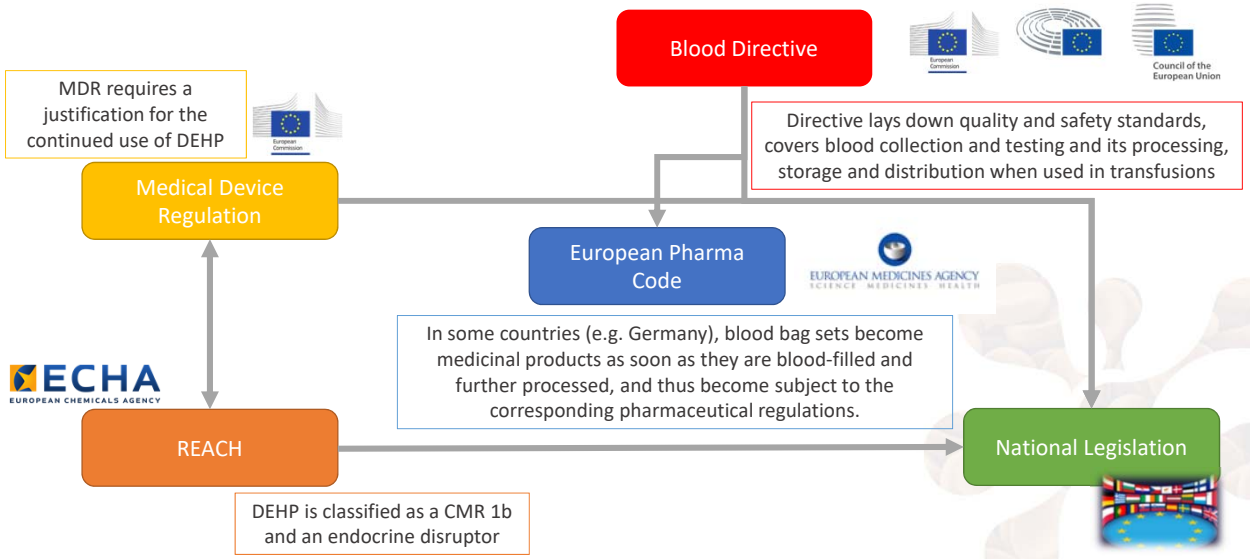
1. Provide a brief overview of the complex regulatory environment of Blood Bag Sets;
2. Present the challenges for suppliers in complying with the EU MDR and the corresponding impact;
3. Present what has been done to prepare for the MDR;
4. Impact of Brexit on medical devices.

Blood Bag Sets - A complex regulatory environment



Foreseen changes to MDR and challenges for suppliers

Technical documentation (TD) update	More scrutiny on substances and materials	Validity of MDD products	EUDAMED	IVDR
• A TD can include over 1,000 documents and 3,300 hyperlinks. • Dependent on Notified Bodies which need up to 9-12 months to review a TD. • TD to be updated every time there is a change to a product. • Guidance on classification remains un-published by the Commission.	• New labelling and justification requirements (e.g. BRA for the use of phthalates). • Require support from suppliers of raw materials.	• MDD products can still be marketed with a valid certificate • Push from BEs to become MDR compliant before the end of the MDD validity period through tender requirements exacerbates unnecessary competition.	• Delayed launch • Potentially multiple systems could be implemented by Competent Authorities in the interim period which require additional work. • Voluntary reporting through EUDAMED from December 2020 but reporting models remain unknown.	• Compliance with MDR by May 2021 but no extended timeline foreseen for IVDR. • Under IVDR most devices would require NB involvement. There are concerns that NBs will be designated on time.

Changes in classification of blood bag sets

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1. **Need for clarity –** The European Commission is still unable to communicate about the classification of certain products. As a result, the classification can be perceived differently by different Notified Bodies.
2. **Anticoagulants & storage solutions –** The vast majority of blood bag sets contain an anticoagulant & other storage solutions, which would be up-classified.
   - ➢ Considering the lack of guidelines, the entire industry needs to be ready for up-classification to Class III, as approximately 90% of blood bag sets would be classified as class III products.
3. **Scrutiny** – More scrutiny in relation to the technical documentation for class III products (Validation and Verification).
4. **Storage solutions & medicinal products –** Under an up-classification, NBs are considering that the storage solutions are medicinal products. Adds a level of complexity to this process.

Although an up-classification would result in a significant amount of work, each class requires considerable work even when the classification remains unchanged (e.g. technical documentation)

Benefit-Risk Assessment for the use of phthalates

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- The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) published **Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices** in June 2019.
- The Committee in charge of developing the guidelines consisted of 15 members including a Blood Establishment representative.
- SCHEER encourages manufacturers to generate high-quality data on such alternatives for CMR/ED phthalates in medical devices.
- The SCHEER guidelines state that the whole system should be reviewed rather than the individual components, specifically mentions blood bag sets.
- **Support is needed from the suppliers of raw materials**. They are required to be REACH compliant but not necessarily MDR compliant. When information is not provided or not available, testing is required to understand whether there are CMRs/EDs in a product. If so, a leachable testing would be necessary, which is work/cost intensive.


Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices

Final Version

Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

GUIDELINES

on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties

Scientific Committees

The SCHEER adopted this document at plenary meeting on 18 June 2019

Impact of Brexit on medical devices

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Divergence from the EU regulatory pathway

- With Brexit, the UK will create its own system of conformity standard (UKCA).
- NI will continue to follow the MDR.
- This will present many challenges in terms of e.g. synchronisation, timely access, proper supply

Registration of medical devices

- In the EU, medical devices will be registered through EUDAMED. Extra registration in the UK would duplicate the work for the manufacturers.

MDR requirements & Brexit requirements

- Each company will need to increase their efforts in order to meet the MDR requirements, and Brexit will likely exacerbate the increased workload.
- There may be a reduction in the availability of certain MDs in the UK/NI.

Business continuity

- The uncertainty of the future UK medical device regulation makes it uncertain what would be the regulatory requirements under the UKCA.

Conclusions

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These challenges could impact the availability of blood bag sets and, ultimately, blood supply in the EU

- Increased demand for technical documents
- Competitive environment – MDD vs MDR
- Delayed EUDAMED
- Lack of delay for IVDR
- Potential Up-classification of blood bag sets
- Brexit
- Increased scrutiny on substances and materials

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Thank you for your time and attention

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