

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

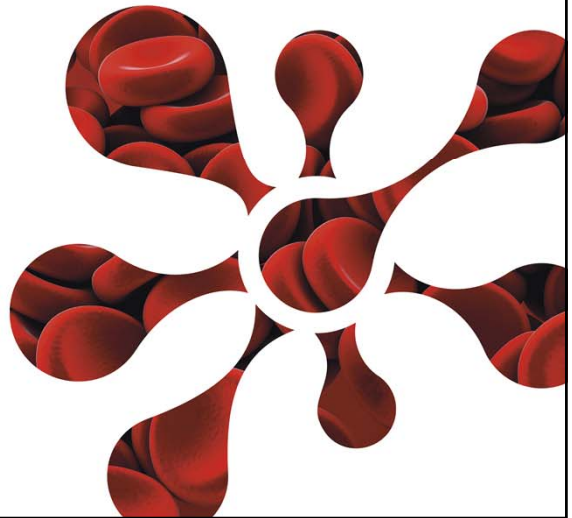
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Keeping up with Reality and Quality: A
Challenge for European Blood
Establishments Webinars

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**Blood Transfusion
Association**



Objectives of the presentation



1

Provide a brief overview of the complex regulatory environment of Blood Bag Sets;

2

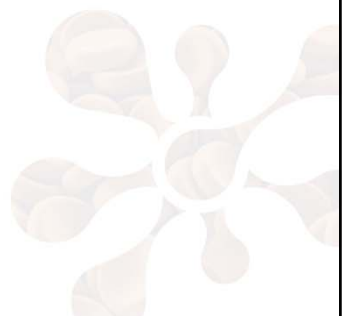
Present the challenges for suppliers in complying with the EU MDR and the corresponding impact;

3

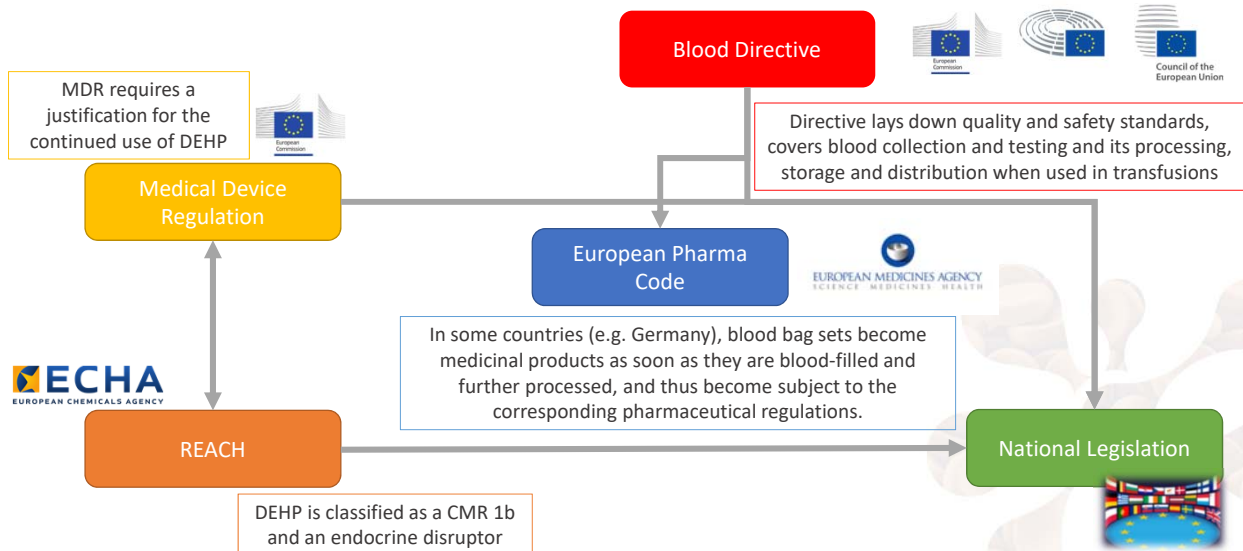
Present what has been done to prepare for the MDR;

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 - Guidance on classification remains unpublished by the Commission.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

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

- 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.



Impact of Brexit on medical devices

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.

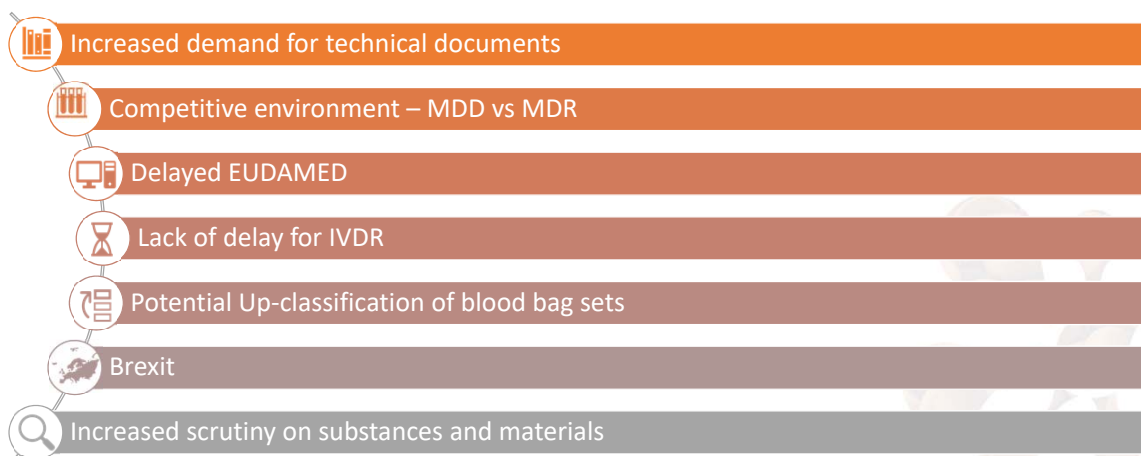
Business continuity

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



Conclusions

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



Thank you for your time and attention

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