Press release

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EDQM and EC build on 10 years of co-operation to support a more sustainable blood supply and resilient blood sector

A conference celebrating 10 years of co-operation between the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the European Commission (EC) in the field of blood transfusion shed light on the challenges faced by blood establishments (BEs) in securing sustainable blood supplies and a resilient blood transfusion sector in Europe.

The conference, entitled "Keeping up with Reality and Quality: A Challenge for European Blood Establishments", provided a forum to assess the challenges arising from scientific, regulatory, societal and economic developments that impact the effectiveness of blood systems and BE quality systems. Speakers from BEs, competent authorities, suppliers of medical devices and equipment, blood professional associations and international organisations from all over Europe, reflected on ways forward to make blood systems more efficient, resilient and sustainable.

In particular, BEs stressed the serious impact of the COVID-19 pandemic on the continuity of blood supplies: lockdowns and staff shortages have reduced donations, as well as capacity at donation centres, making it necessary to activate emergency plans. This situation highlights the importance of preparedness, contingency planning and experience sharing, for which forums, such as the conference, may be useful.

Recent changes in regulatory requirements, such as in the EU Medical Device Regulation (MDR), the In Vitro Diagnostic Regulation (IVDR) and the REACH Regulation, are also having consequences for the blood sector. The prospective reclassification of blood bags and restrictions on phthalates (such as DEHP) in medical devices are compelling manufacturers to explore viable phthalate-free blood bag alternatives. This affects manufacturers and BEs with regard to clinical evaluation and re-validation of the entire blood chain, respectively. It was discussed that in implementing such requirements, the clinical benefits should outweigh the risks and consideration should be given to the increased costs for BEs and their suppliers in order for them to comply. The prospective classification as medical devices of computerised systems used in the blood sector is likely to have a similar impact.

The globalisation of the suppliers market and the effects of procurement regulations have revealed that BEs require training in procurement and tendering to become less reliant on individual suppliers. In particular, the need to facilitate the uptake of joint suppliers' audits in view of achieving economies of scale emerged. Participants also highlighted the crucial need to balance cost-efficiency against an uncompromising approach to safety and quality.

Difficulties in recruiting and retaining healthcare professionals were also covered. Plans for redeploying professionals to areas in need and making a change in the scope of practice may be a solution, but differences between countries in qualification requirements for healthcare professionals and related legislation remain a likely obstacle.

On the sidelines of the conference, Susanne Keitel, Director of the EDQM, explained: "The blood sector is a dynamic one that will continue to face challenges due to the ever-changing environment. While change can offer benefits for the quality and safety of blood components, it also comes with a risk for blood establishments and challenges their resources and capacity in fulfilling their objective of ensuring the continuity of blood supply". Dr Keitel called on

concerned parties "to work with decision makers on measures to mitigate risks, while securing the most beneficial outcomes in terms of public health".

The EC and EDQM will continue to provide initiatives and instruments to support BEs in achieving more resilient and sustainable systems. The two organisations, whose co-funded activities support BEs, also highlighted the importance of continuing their close collaboration in ensuring that the regulatory framework remains effective and evidence-based. Their 10 years of co-operation in the blood sector have laid the groundwork for a future-proof regulatory framework for substances of human origin (SoHO), as emphasised in the conclusions of the evaluation of EU blood, tissues and cells legislation.

The conference took place online from 27 to 29 October 2020. The recordings and programme of the conference are available at https://go.edqm.eu/BloodTraining, and the proceedings, comprising summaries of the sessions, discussion points and recommendations, will be published in 2021 and will serve as input for any future revision of EU blood, tissues and cells legislation.

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Note for the Editor: Further information is available on the internet site https://www.edqm.eu.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.1 The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 40 members of the European Pharmacopoeia Commission: *Austria, Albania, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.