THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

10 YEARS OF CO-OPERATION

European Commission & the EDQM/Council of Europe collaboration: Towards the future in the Blood sector

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

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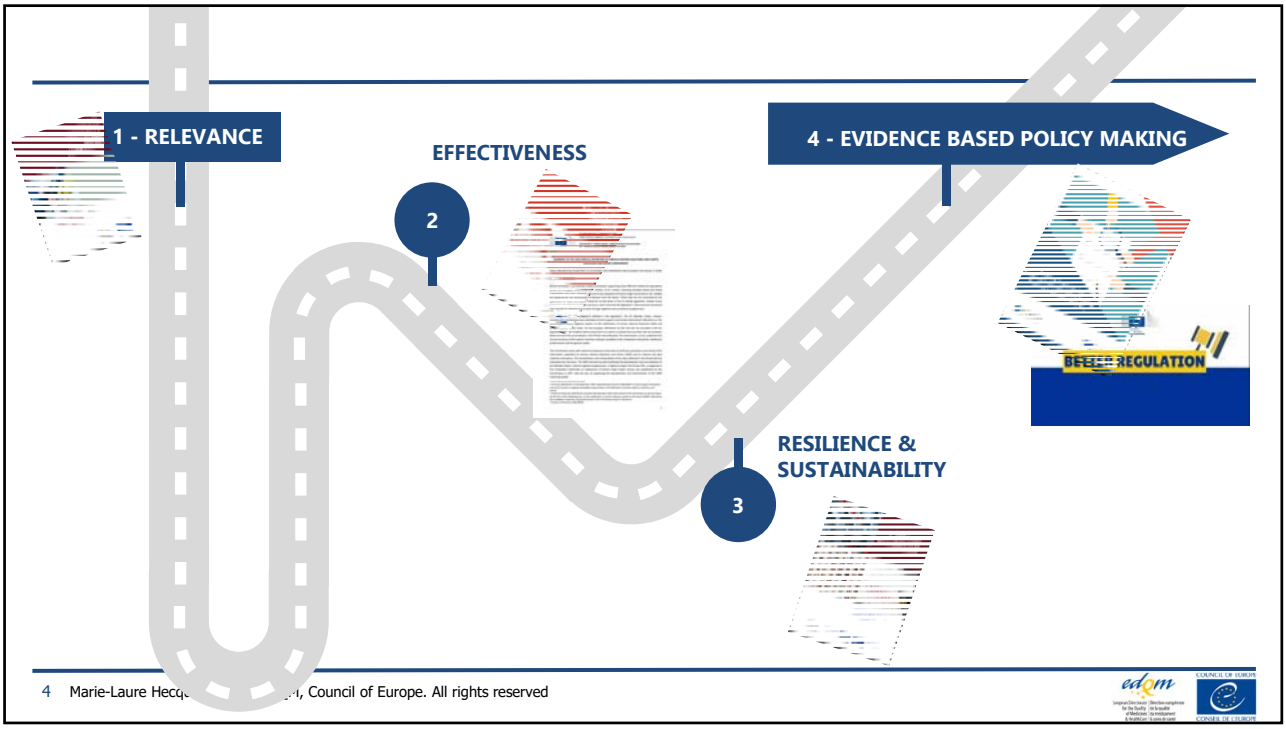
>>> The future is to be shaped by what we observe today <<<

Some considerations

Disclaimer: non exhaustive



1

RELEVANCE

A blood framework that should live the principle of 'keeping up with its time'

- The blood sector is a dynamic sector
- Risks are changing

►Ensuring Framework Keeps Pace with Developments (1)

Restructured

► Principles & Standards merged in a single chapter
► Monographs for components – harmonised specifications for the Q&S of blood components
► **Pharmacopoeial approach**
►**Good Practice Guidelines (GPGs)** reflect the most recent GMP applicable to BEs

Keep pace with scientific & technical developments

► Periodical revision: 2-3 years basis
► CD-P-TS subordinate body: GTS working group

Guy Rautmann, Secretary to CD-P-TS & GTS working group

►Ensuring Framework Keeps Pace with Developments (2)

Blood Guide 20th Edition
Distribution within CoE MSs and Worldwide within < 5 months

► > 4000 copies distributed
► More than for the 19th edition (over 3 years)

►Ensuring Framework Keeps Pace with Developments (3)

Level 1

Level 2

Level 3

Level 4 - Standard

Chapter 3 Collection of blood and components

3.2. **Premises for blood and blood component collection**

Collection of blood and blood components should take place in premises that assure the health and safety of donors and staff, support privacy during the donor assessment process, provide for appropriate clinical oversight of donors, prevent errors during the collection procedure and maintain quality and safety of the blood and blood components.

Principle

3.2.1. **General requirements**

STANDARDS

3.2.1.1. Premises including mobile sites must be located, constructed, adapted and maintained to suit the activities to be carried out. They must enable work to proceed in a logical sequence so as to minimise the risk of errors and must allow for effective cleaning and maintenance in order to minimise the risk of contamination (Directive 2005/62/EC Annex 3.1).

Standard EU Directive

3.2.1.2. Blood collection must be carried out in an area intended for the safe withdrawal of blood from donors and which is equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation.

Standard Blood Guide

► The new structure of guide – clearer distinction between "minimum standards' and 'recommendations' which makes it ready to become a dynamic reference in the EU legislation

► Ensuring Framework Keeps Pace with Developments (4)

BLOOD ESTABLISHMENTS

BLOOD COMPONENTS

EU Blood Legislation

2002/98/EC, 2005/62/EC,
2004/61/EC, 2004/33/EC

Good Practice Guidelines (GPG)

CoE Blood Guide

PLASMA MANUFACTURERS

PDMPs

EU Pharmaceutical Legislation

Good Manufacturing Practices (GMP)

European Pharmacopoeia

2

EFFECTIVENESS

Data & practices monitoring: Collecting well and to the point, and 'Comparing Apples with Apples'

► Ensuring data are accurate, comparable & meaningful

Common and harmonised methodology among CoE/EU countries

► Same definitions
► Various types of data, what data, what level and sources of data and for what purpose
► Compatibility and comparability
► Mandatory and optional data set
► Sense making & decision making

Accurate & meaningful data for the sake of public health

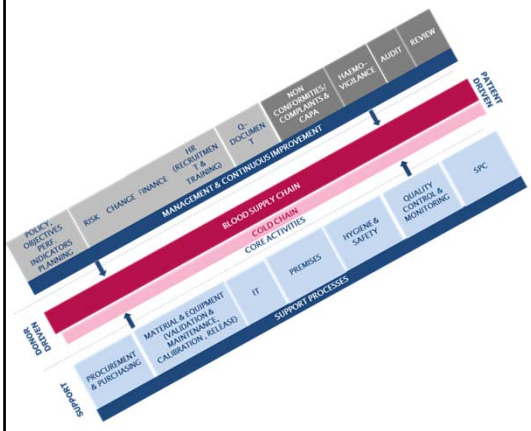
► Needs versus demands for blood components and plasma
► Optimal use : 'ecologic use' of precious resources
► Avoid dependency & ensure self-sufficiency

3

RESILIENCE & SUSTAINABILITY

Provisions & their implementation: flexible as to enable BEs to have Q-systems that speak risks & that are cost-effective

► Ensuring blood systems are resilient & sustainable (1)



Supporting BEs to constantly adapt to their environment

► Assessments tools & advising/guiding BEs **(B-QM programme, B-PTS studies, B-SCEP projects)**
- ► Measures taken are commensurate to the risks
- ► Costs are commensurate to the risks
- ► Benchmarking
- ► Preparedness
- ► Setting the ground for mutual recognition of system in case of global crisis ?
- ► Setting the ground for mutual recognition of audit suppliers ?

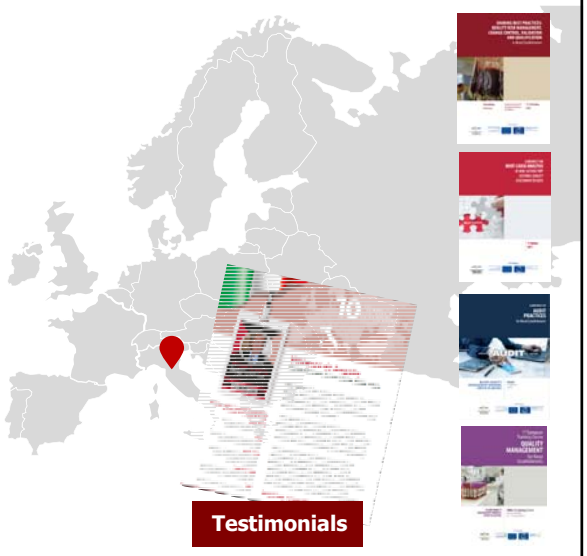
► Ensuring blood systems are resilient & sustainable (2)

► **55 B-PTS studies:** reliability of testing but also implicitly relevance on assays used by manufacturers

► **30 auditing/assessments schemes (B-MJVs/B-TVs)**
- **Product** & **process** approaches
- Audit focusing on **root causes** instead of last line of defence;
- Improve QMS but also **BEs** to change their **QM culture, rethink their process/system**;
- Raise awareness about **risk-based QM**;
- **Cost-effective QM** to decrease costs and burdens;
- Most common findings/issues faced by BEs:
  - **Risk management, contingency, change control; qualification/validation, changing market supplies**

► **Practical guidance (non –binding) to complement technical standards**

► **New project: Blood Supply Contingency and Emergency Planning (B-SCEP):** recommendations and model preparedness plan



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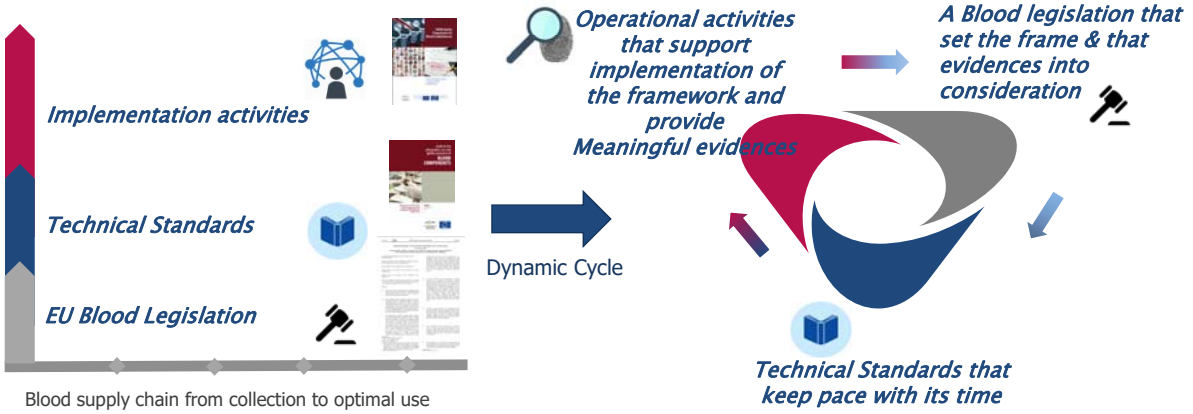
ENSURING EVIDENCE BASED POLICY MAKING

Evidences as part of the policy making cycle

► Ensuring Evidence based policy making



CONCLUDING REMARKS (1)

The Council of Europe/EDQM has **a leading role** in:

- establishing technical standards – *Blood Guide & GPGs-* that continuously keep pace with latest developments ► **Quality and safety** of blood components & **protection of** both the donors and patients,
- Supporting countries, through *operational activities,* in implementing EDQM standards and EU blood legislation,
- Providing timely state-of-the art *best practices,*
- Contributing to the development of evidence & risk–based legislation/policies - , evidenced collected as part of the *operational activities*

CONCLUDING REMARKS (2)

► Technical standards are **dynamic** tools that complement the EU legislation and support non-EU countries in ensuring the quality and safety of blood components,

► **Reservoir of comprehensive expertise** from blood establishments, authorities and European/international organisations,

► Large **geographical impact** that goes beyond the EU. It includes the EU candidate, neighbouring & partner countries and thus create a bridge for a pan blood European Framework

In further cooperating together, the CoE/EDQM & the EC should

- benefit from each others expertise and competences,
- make best use of existing resources, and,
- use their respective strengths to establish a **complementary & coherent legal framework** while recognising their respective role & competences

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Thank You

