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

edqm

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

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

RESILIENCE

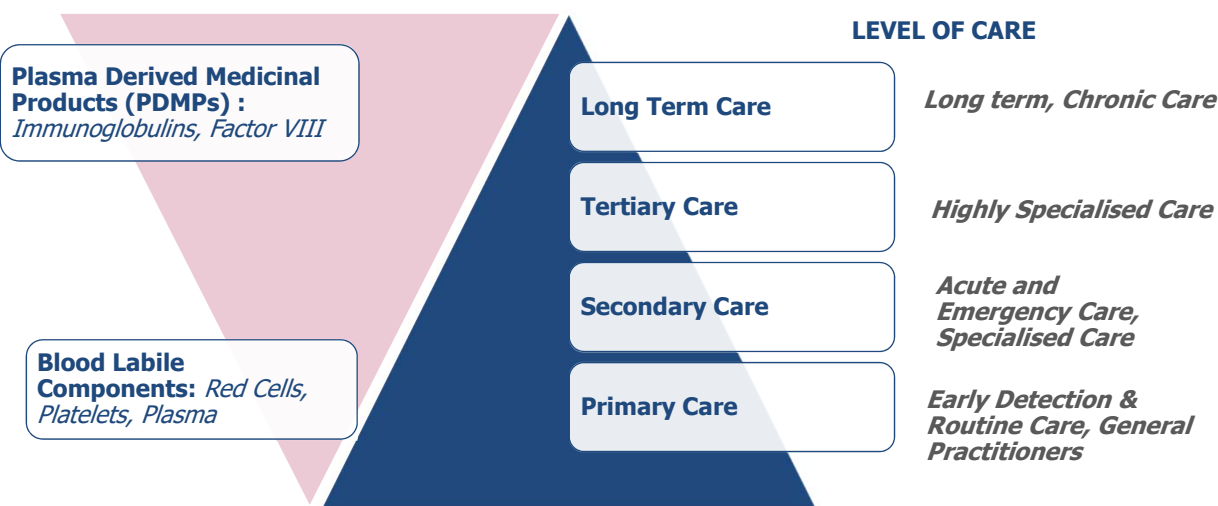FLEXIBILITY INTO PLANNING — WITHSTAND SHOCK — ADAPT TO CHANGE — PURSUE YOUR GOAL — ANTICIPATE RISK — PROTECT WEAK SPOTS

@ROI

EDQM supporting initiatives to help European BEs to have more resilient and sustainable blood systems

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

29 October 2020

Marie-Laure Hecquet
Head of Substances of Human Origin Section,
EDQM/Council of Europe
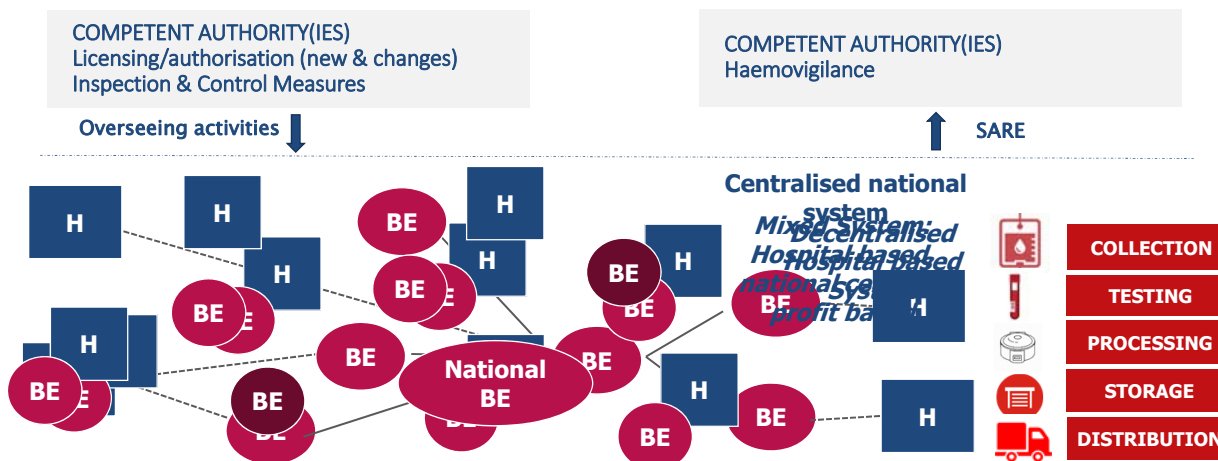
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BLOOD TRANSFUSION IN A HEALTHCARE SYSTEM

Plasma Derived Medicinal Products (PDMPs) :
Immunoglobulins, Factor VIII

Blood Labile Components: *Red Cells, Platelets, Plasma*

LEVEL OF CARE

Long Term Care — *Long term, Chronic Care*

Tertiary Care — *Highly Specialised Care*

Secondary Care — *Acute and Emergency Care, Specialised Care*

Primary Care — *Early Detection & Routine Care, General Practitioners*

NATIONAL BLOOD SYSTEMS – A GREAT VARIABILITY OF SYSTEMS

>1400 Blood Establishments in Europe

COMPETENT AUTHORITY(IES)
Licensing/authorisation (new & changes)
Inspection & Control Measures

COMPETENT AUTHORITY(IES)
Haemovigilance

Overseeing activities

SARE

Centralised national system

Mixed system: Hospital based national centres

Decentralised hospital based non profit banks

H

BE

National BE

COLLECTION

TESTING

PROCESSING

STORAGE

DISTRIBUTION

A CHANGING ENVIRONMENT

Changing suppliers market place

Emerging Risks, disease e.g. COVID-19

Changing/emerging regulation (e.g. IVD, GDPR) & Coherence with other legislation (e.g.pharmaceutical)

New technologies (e.g. AI) and innovation

Quality System

Demographic changes: donors and professionals

RISK MANAGEMENT

CHANGE MANAGEMENT

EVOLUTION OF SYSTEMS - PAST DECADE

PRO-ACTIVE

REACTIVE

Quality Management System

Quality Assurance

Quality

Product

Processes

Organisation

Product

Processes

Organisation

Product

Processes

Product

- Procedures

- Quality policy & objectives
- Leadership
- Personnel implication
- Customers focus & interested parties
- Continuous Improvement

- Product requirements
- Quality control

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- Strategic planning
- Cost-effectiveness and productivity
- Resilience/sustainability

RESILIENCE MODEL – Adapted to Blood Systems
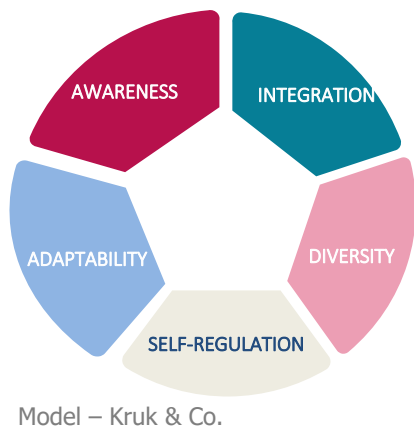
Model – Kruk & Co.

ADAPTABILITY
Be able to operate under changing conditions, rebounds from crisis
► QMS & Contingency/Emergency planning ► EDQM

AWARENESS
Detect risks/threats before they arise.
Know its own capacity to react/own resources
► QMS & Contingency/Emergency planning ► EDQM

DIVERSITY
Reliance on multiple suppliers, diverse health professionals
► QMS ► EDQM

SELF-REGULATION
Capacity to have own policies to mitigate risks/contain crisis
Flexible regulatory framework ► EC & EDQM
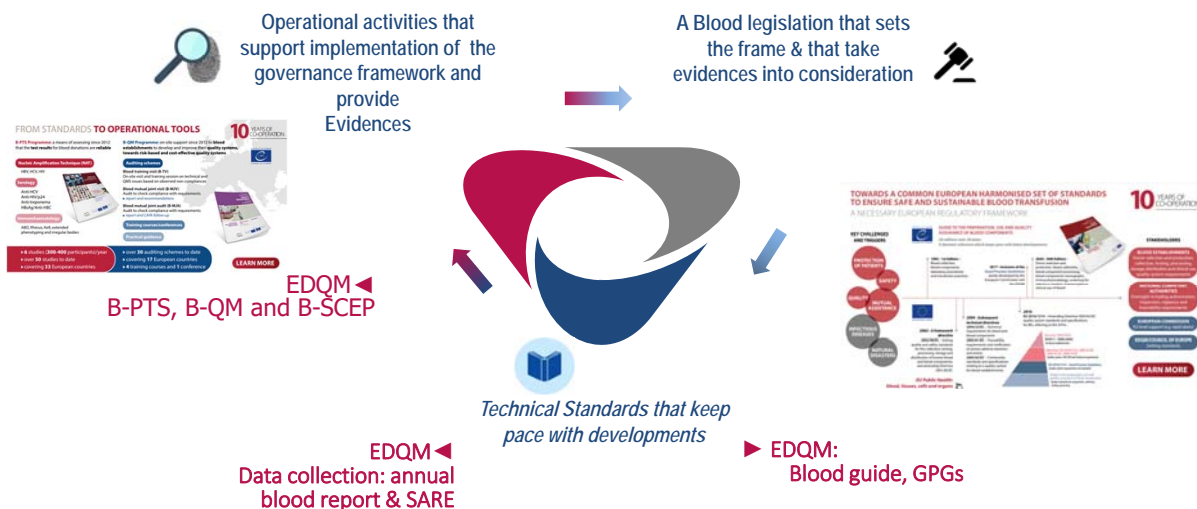► QMS ► BEs

INTEGRATION
Regulatory framework
► EC & EDQM
Collaborate/coordinate with others
► European Blood Alliance

EDQM ACTIVITIES COMPLEMENTARY TO EC ACTIVITIES

Operational activities that support implementation of the governance framework and provide Evidences

A Blood legislation that sets the frame & that take evidences into consideration

EDQM ◄
B-PTS, B-QM and B-SCEP

EDQM ◄
Data collection: annual blood report & SARE

Technical Standards that keep pace with developments

► EDQM:
Blood guide, GPGs

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AS IS THE BLOOD GUIDE & GPGs ....

► **That keeps pace with developments**

► **if referred to in the EU legislation**

► **Sustainable Regulatory framework**

ARE THE BLOOD QUALITY ACTIVITIES........

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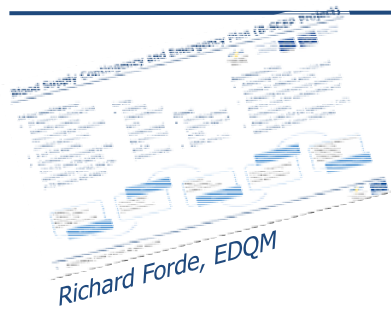
Richard Forde, EDQM

► While the EC provides the **framework**: Regulatory framework and funding instruments for EU & candidate, neighbouring & partner countries

► **EDQM Blood quality activities: continuous** support to BEs to **implement** requirements, **adapt their systems** to a changing environment and respond to **risks & crisis** ► **resilience and sustaining** results & systems

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THINKING BEYOND

- **Regulatory Framework**
- **Quality System driven by Risk Management & Change Control**
- **Resilience and Sustainability**

Cost-efficiency?

FIGURE I: Value in Healthcare

THANK YOU

KS6 Replace Dollare by Euro....
KEITEL Susanne; 26/10/2020

Thank you for your attention

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