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

10 Years of Cooperation

Between the European Commission & the EDQM/Council of Europe in the field of Blood

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

27 October 2020

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EDQM & EC COLLABORATION – In a Nutshell

Legal & Technical cooperation

Mutual Representation

Medicinal products

60 years of Collaboration (Legal & technical)

Subtances of Human Origin

10 years of Collaboration
Blood Transfusion

7 years of Collaboration
Tissues & Cells

A WIDE PORTFOLIO OF ACTIVITIES……

EDQM & EC COLLABORATION – Medicinal products

Legal cooperation

The EDQM is in charge of:

► **European Pharmacopeia (Ph.Eur):**
- Compendium of official standards, defining the quality of medicinal products and their components and the tests to be performed,
- Standards recognised as a scientific benchmark world-wide,
- referred into **the EU pharmaceutical legislation**

>>> *More than* **2400 monographs, 350 general texts**

► **Certification of suitability to the monographs of the Ph. Eur. :**
- confirms Ph.Eur monograph adequately controls the quality of a substance, CEP certificates part of MA dossiers
- Risk-based inspection of manufacturing sites and brokers/distributors holding CEP certificates
- referred into **the EU pharmaceutical legislation**

>>> ***5300 valid*** *certificates &* ***70 sites*** *covered by the annual programm /year worldwide*

EDQM & EC COLLABORATION – Medicinal products Cont.

Technical cooperation

The EDQM is in charge of:

Funded by the European Union and the Council of Europe
EUROPEAN UNION
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Implemented by the Council of Europe

► **Biological Standardisation Programme (BSP)**:
- Standardisation of methods and reference standards for biological medicinal products *e.g. vaccines*
- Inclusion into the Ph.Eur

>>> more 160 BSP projects since 1991

► Network of **Official Medicinal Control laboratories (OMCL Network)**, independent control from the manufacturers:
- Work sharing and mutual recognition of test results
- Market surveillance testing programme for centrally authorized products

>>> More than 600 Centrally Authorised Products, nearly 220 External Quality assessment scheme and more than 190 audits.

► **Official Control Authority Batch Release (OCABR):** testing results for biological medicinal products of **1** MS are mutually recognized by **all** Member States
- - Procedures and guidelines

>>> more than 24500 lots released (Vaccines, plasma pool &PDMPs) by 15 OMCLs

EDQM & EC COLLABORATION – Substances of Human Origin

The EDQM is in charge of:

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Technical cooperation

► **Development of Technical Standards that reflect latest scientific and technical developments in the fields**
- The Tissues & Cells Guide,
- The Good Practices Guidelines for Blood Establishments,

► **Monitoring data and practices**
- Harmonisation of data collection (Tissues & Cells)
- Analysis of biovigilance data in the EU (Blood and Tissues & Cells)
- Post mortem blood testing (Tissues & Cells)

► **Trainings**
- Biovigilance best reporting practices (Blood and Tissues & Cells)
- Quality Management (Tissues & Cells)

EDQM & EC COLLABORATION – SoHO cont.

The EDQM is coordinating:

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Technical cooperation

► **Blood Quality Management (B-QM) programme for Blood Establishments**
- Auditing/assessment schemes
- Trainings/Conferences
- Practical Guidance

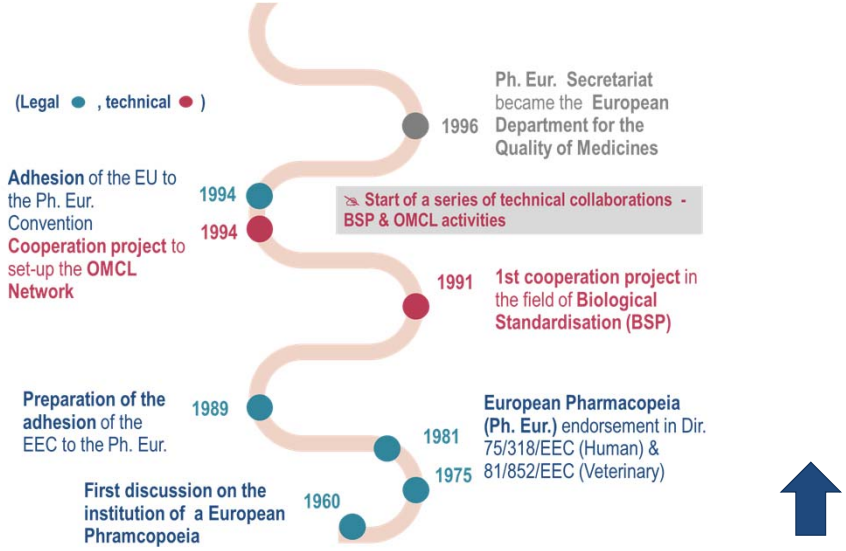
► **Blood Proficiency Testing (B-PTS) programme for Blood Establishments**
- Proficiency Testing scheme studies

► **Plasma Supply Management (PSM)**
- Ensuring plasma supply: Symposium & ensuing recommendations

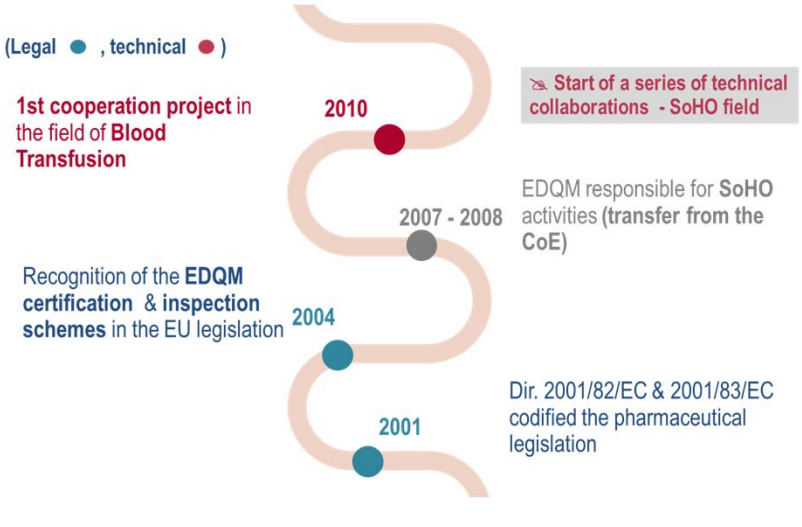
► **Blood Supply Contingency Emergency Planning (B-SCEP)**
- Provide an overview of interventions implemented by authorities to strengthen national & EU-level plans for continuity of blood supply under emergency situations

THE PATH TO GET THERE……..

EDQM & EC COLLABORATION – KEY MILESTONES

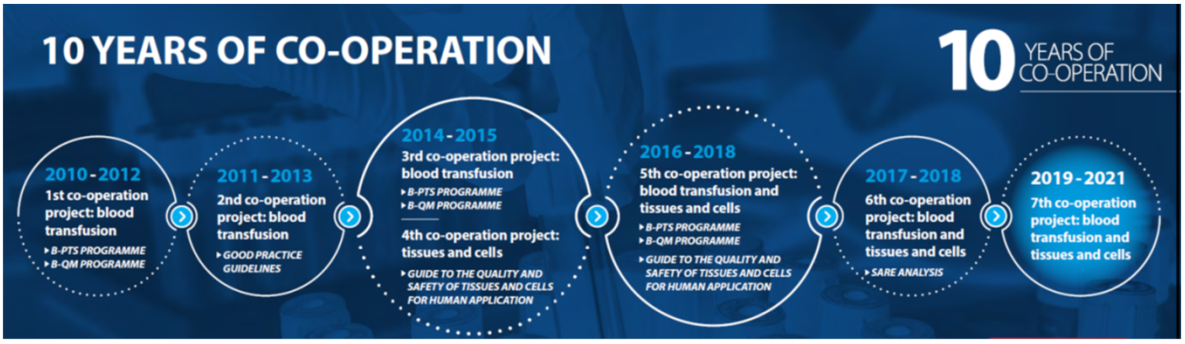


EDQM & EC COLLABORATION – KEY MILESTONES



IN SUM.....

- Overall, more than **35 technical cooperation** projects run sucessfully
  - **7 technical cooperation projects in Blood Transfusion**



ACHIEVEMENTS IN THE FIELD OF BLOOD

BLOOD-PROFICIENCY TESTING SCHEME PROGRAMME

► **AIM: B-PTS** provides Blood Establishments (BEs) with an objective mean of assessing that the **testing results** for blood donations are **reliable**.

'Regular participation in a formal system of proficiency testing, such as an external quality-assurance programme'

EU Directive 2005/62/EC; Good Practice Guidelines ,Guide to the Preparation, Use and Quality Assurance of Blood Components

Nucleic Amplification Technique (NAT)

HBV, HCV, HIV

Serology

Anti-HCV
Anti-HIV/p24
Anti-treponema
HBsAg/Anti-HBC

Immunohaematology

ABO, Rhesus, Kell, extended phenotyping and irregular bodies

► **Since 2010: 6** studies (300-400 participants)/year, over **50** studies to date covering **33** European countries

BLOOD-QUALITY MANAGEMENT PROGRAMME

► **AIM: Assistance/Educational Programme** to help Blood Establishments in establishing, developing, improving comprehensive and integrated **Quality System**

'Quality System to be in place'

EU Directive 2005/62/EC; Good Practice Guidelines ,Guide to the Preparation, Use and Quality Assurance of Blood Components

Auditing schemes

Blood training visit (B-TV)
On-site visit and training session on technical and QMS issues based on observed non-compliances

Blood mutual joint visit (B-MJV)
Audit to check compliance with requirements
▸ *report and recommendations*

Blood mutual joint audit (B-MJA)
Audit to check compliance with requirements
▸ *report and CAPA follow-up*

Training courses/conferences

Practical guidance

► **Since 2010:** over **30** auditing schemes to date covering **17** European countries **5** training courses/conferences

GOOD PRACTICE GUIDELINES FOR BLOOD ESTABLISHMENTS

► **Compendia of** *Quality system standards and specifications of Directive 2005/62/EC, Quality system standards and Principles derived from the Guide to the Preparation, Use and Quality Assurance of Blood Components (17th edition), Quality system elements derived from the detailed principles of GMP*

► **Since 2017, integral part of the Blood Guide**

► **Directive (EU) 2016/1214/EC**: Members States to takes the GPG into account in implementing good practices based on the GMP

► **Advantages:**
- Dynamic reference (as is the European Pharmacopoeia in the EU Pharmaceutical legislation)>>> no need for regular update of the EU legislation;

PLASMA SUPPLY MANAGEMENT (PSM)

(1) ↘ Plasma supply

(2) ↗ Plasma need due to ↗ Plasma Derived Medicinal Products (PDMPs)

(3) Highly dependent on **US paid plasma** donors for PDMPs

Symposium , January 2019

- Quality & safety **standards for plasmapheresis** & Protection of **intense plasmapheresis donors**
- Reducing **dependence** on US imported plasma & use **plasma** to its full potential

Proceedings &

Consensus recommendations

Revision of the Blood Guide

'Blood Donor protection'

Concluding remarks

RESULTING LEGAL & TECHNICAL FRAMEWORK

	SUBSTANCES OF HUMAN ORIGIN (SoHO)			MEDICINAL PRODUCTS
				
Key EU legislation	*2010/45/EU* *2012/25/EC*	*2004/23/EC* *2006/17/EC* *2006/86/EC*	*2002/98/EC* *2004/33/EC* *2005/61/EC* *2005/62/EC*	*2001/82/EC* *2001/83/EC*
EDQM Standards	Organ Guide	Tissues & Cells Guide	Blood Guide Good Practice Guidelines	European Pharmacopoeia
EDQM activities supporting the implementation of EU legislation		Mapping practices, Trainings	Mapping practices, Quality management activities inc. auditing schemes, trainings, guidance and external quality assessment	Standardisation Marketing surveillance Mutual recognition

Thank you for your attention

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