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

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

27th – 29th October 2020

Preliminary Conference Outcomes

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

Outcomes and Recommendations

- **Webinar Format – challenges**
- **All presentations and recordings will be reviewed to ensure outcomes and recommendations are accurate and all speakers are well reflected**
- **Verified by the speakers / moderators of the session**
- **Presentations to be made available on website**
- **Proceedings to be published with outcomes and recommendation**

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

27th October 2020

Morning Session: 10 years of co-operation in the field of blood transfusion

Afternoon Session: The COVID-19 Pandemic – impact on the continuity of blood supply and lessons learnt

28th October 2020

Morning Session: Globalisation of the supplier market place – state of play – opportunities and issues in the blood sector

Afternoon Session: New Regulatory Environment for Medical Devices: State of Play, Opportunities and issues in the blood sector

29th October 2020

Morning Session: Changing Scope of Practice of Healthcare Professionals

Afternoon Session: Working Together to Support Blood Establishments and ensure continuity of supply towards the future

10 years of co-operation in the field of blood transfusion

Moderator: Richard Forde

Rapporteur: Stefaan Van Der Spiegel

Outcomes and Recommendations

- Occasion to mark 10 years of cooperation between the EDQM / CoE and the European Commission – working together with the common goal to improve the quality and safety of blood and other SoHO fields;
- Overview on the historic and current activities performed by the EDQM and EC in the field;
- Overview of the activities performed through cooperation projects between the EDQM / CoE and EC in SoHO field;
- BTC Legislation evaluation – impact assessment for the revision of the legislation;
- VUD itself was not a major issue identified in the legislation evaluation, but compensation and donor protection measures will become relevant for the revision of the legislation;
- Legislation to be future proof – dynamic in its implementation;
- EDQM work to be considered in the impact assessment of the revision

The COVID-19 Pandemic – impact on the continuity of blood supply and lessons learnt

Moderator: Sheila MacLennan

Rapporteur : Ina Bjorg Hjalmarsdottir

Key Outcomes / Recommendations

An overview of the COVID-19 pandemic and the effect on the blood, tissue and organ supply.

- The importance of ongoing risk analysis, contingency planning and effective triage in dealing with the pandemic.
- The importance of collaboration between countries and between different bodies, as with COVID-19 convalescent plasma.
- The importance of sharing information within and between BE and others.
- The importance of an adaptable quality management system and change control.
- Focus on customers and stakeholders is needed.
- Effect on staff, opening hours, locations, donors etc.
- Some positive changes in the use of information technology (remote inspections, teleconferencing, e-learning).

Strengths	Weaknesses
• QMS efficient in managing COVID 19; • Collaboration and experience sharing between countries; • Communication between regulatory authorities and BE; • Regulatory flexibility; • Communication from ECDC – Rapid Risk Assessments / recommendations for supply	• Still things to be learned about SARS-CoV-2; • Impact on Staff shortages • Lockdowns preventing donation • Reduced capacity at donation centres; • Reduced availability of donation sites
Opportunities	**Threats**
• Share best practice on risk analysis, contingency planning; • Established continuity plans for BEs / national level; • Continued exchange through forums; • Training / guidance in specific areas; • COVID19 Convalescent Plasma;	• Continued restrictions due to pandemic leading to loss in donors; • Decrease in blood stocks; • Interruption to critical supplies / services;

Globalisation of the supplier market place – state of play – opportunities and issues in the blood sector

Moderator: Stephane Begue
Rapporteur: Karen Byrne

Strengths	Weaknesses
• Standardised Procurement Regulations which aim to provide transparency and fairness; • BE collaboration in procurement joint ventures which can improve quality outcomes; • Experience sharing in supplier audits, blood bag validation; • Supplier Audit Framework;	• Balance between technical and financial requirements; • Ambiguity and inconsistencies in procurement and validation practices within BE's; • Insufficient communication between suppliers, BE's and regulators; • Changing scenarios requiring quick responses – disruption of supplies; • Insufficient Business Continuity Planning; • Insufficient resources to perform activities;
Opportunities	**Threats**
• Enhance collaboration across BE's in procurement procedures; • Implementation of lean business continuity plans; • Improved guidance and training in procurement - in particular contract management and managing non conformances; • Development of strategies for managing a changing scope of practice;	• EU Regulations – one size fits all; • Public Procurement - bureaucratic and not always a supporting tool; • Geographic issues (e.g. location, natural disasters); • Financial Constraints; • Tender failures/non compliance lead to issues such as implementation delays which could impact patients; • Supplier Issues (Parent and Local); • Customer perception - Reputation and relationships; • Continued restrictions due to pandemic leading to loss in donors;

Globalisation of the supplier market place – state of play – opportunities and issues in the blood sector

Key Outcomes and Recommendations:

- Understanding organisational requirements to ensure a clearly defined strategic procurement process in place
- Achieve the right balance between technical and financial requirements
- Cost should not be the main driver
- Importance of collaboration in the areas of Procurement, Joint Audit Venture* and Continuity arrangements
- Risk mitigation to achieve compliant and transparent tender processes which are timely, fit for purpose and captured within the Quality Management System
- Importance of supplier relationships and contract management **
- Benefits of supplier audits/evaluation to reduce any potential risks
- Proactive approach to improving supplier communication, in particular with critical suppliers
- Early identification of non conformances to improve quality outcomes
- Business continuity instils confidence and trust in our customers and provides a framework which prevents and mitigates risk to service continuity
- Lean approach to business continuity reduces variation within our control, provides robust continuity planning with critical suppliers, improved supply chain lead times, increased agility and can support surge capacity

- * Poll results 80% in favour of joint audit ventures
- ** Poll results 62% would like further guidance in contract management

New Regulatory Environment for Medical Devices: State of Play, Opportunities and issues in the blood sector

Moderator: Stephen Vardy
Rapporteur: Margarida Amil

Strengths	Weaknesses
• Improve safety of patients and donors • Cross country collaboration;	• Insufficient communication between suppliers, BE's and regulators; • Resources required to perform appropriated validation (including IT systems); • Guidance, definitions, product classification, e.g. blood bags sets, anticoagulants, clinical validation requirements still not clear or missing • Impact on BEs and its responsibilities on implementing still not very clear
Opportunities	**Threats**
• Communication between regulatory authorities, suppliers, notified bodies and BEs, in particular to implement the required changes to improve safety of patients and donors • Communication between pre market and pos market • Relevance of information -Post Market Clinical Follow-up, in particular for clinical validation	• Impact of regulations – EU, National, Brexit, on suppliers, manufacturers, Bes, CA • Onerous validation requirements; • Time needed to prepare the expected huge amount of required documentation and evaluation; • Time needed to perform clinical validation; • Difficulties to get new products better than the existing without compromising the blood supply. • Availability of MD

New Regulatory Environment for Medical Devices: State of Play, Opportunities and issues in the blood sector

Key outcomes and Recommendations:

- Impact on
  - Classification of blood bags (clarifications needed?) - Class IIb to Class III
  - Clinical evaluation – "manufacturer shall specify and justify the level of clinical evidence" – applicable to devices class III – exceptions are defined
  - Phtalate in medical devices (DEHP) – impact on Blood Bags – continuity of blood supply;
  - Concerns MD e.g. software will be classified as medical device – and the consequences on BE's;
  - In-house methods/reagents are no longer exempt – consequence for BE's;
  - Reagent red cells is an *in vitro* medical device - classification and exceptions are defined;
  - Regulatory clarification still required; Pragmatic approach required

Is DEHP a concern for transfusion activities ?

- All manufacturers are working on alternatives
- A concerted action between manufacturers, blood establishments, users and EC to reduce wastage of efforts and resources: Cooperation, Standardization and Recognition to guarantee that:
- The whole transfusion chain must be validated
- The safeguard of the blood supply, and that the DEHP-free products should be 'not significantly inferior' (e.g. shelf life, critical defect rate) compared to DEHP-containing products

Health Professionals, Changing the cope of practice: State of play, opportunities and issues in the blood sector

Moderator – Craig Spalding

Rapporteur – Marielle Van Roosmalen

Strengths	Weaknesses
• QMS efficient in managing change of scope in practice • Experience sharing is very usefull; • Nurses challenge the work of the MDs • Open and mature discussion with CA • Protective regulations • Better interpretation and application of EU law • Member states have own power in regulating health professions • Good educational programmes • Building evidence that risks to donor and blood components can be mitigated and remain equal	• Difficulties in recruiting health care professionals • No harmonisation between and within countries • Migration • Salary noncompliant • differences in qualification requirements for health professional exist between countries, impeding their recognition • To narrow medical role for MDs • Relying on decision making algorithms
Opportunities	**Threats**
• New challenges for health professionals • More appropriate work distribution • Data/evidence showing no impact on donor safety • Strategies for managing a changing scope of practice for healthcare professionals; • Harmonisation within a country • Pandemic trigger to act because need for urgent change • Change scope of practice more resources/MDs for other health sector • Finding the right balance between stakeholders	• Pandemics having a direct impact on the availability of health professional > need for fast response But also challenge in situation of real pressure you have to act! • Protectionism of medical body • Sustainability of health professions in the blood field • Insufficient valuing and protecting • Continuity of blood supply in countries where the legislation is not permissive to change in the scope of practice • To strict national legislation

Health Professionals, Changing the cope of practice: State of play, oppurtunities and issues in the blood sector

Key outcomes and Recommendations:

Change in scope of practice due to:

- difficulties in hiring certain categories of health professionals with the required qualification
- demographic changes among health professionals
- Justification for restricting staff movement at National level - requires to be proportionate and justified – backed up by substantial data to show impact)
- Creation of nurses curriculum in the blood field – Support from EDQM ?
- Use of QMS for the implementation of the changing scope of healthcare professionals - Model
- Polls data collected – no more an emerging issue but more commonplace

Thank you for your attention

Richard Forde

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