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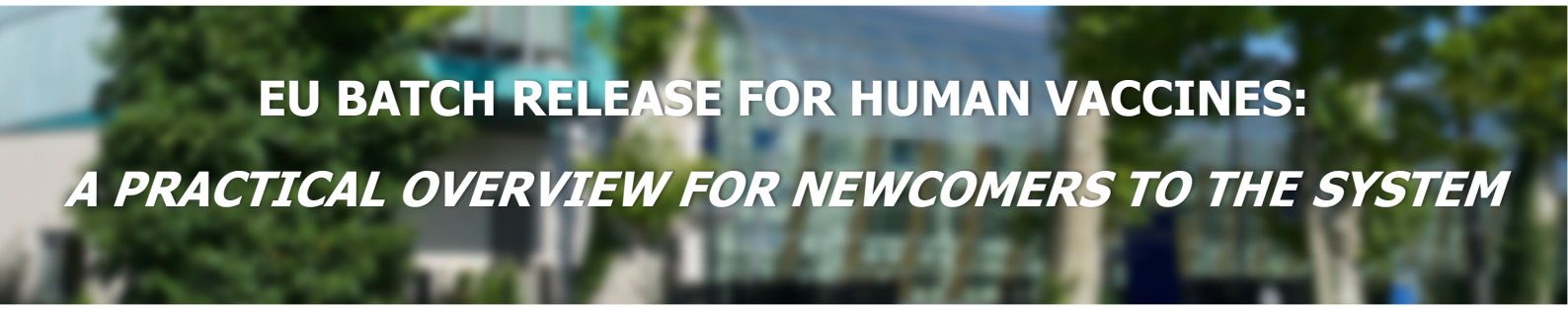

EU BATCH RELEASE FOR HUMAN VACCINES:

A PRACTICAL OVERVIEW FOR NEWCOMERS TO THE SYSTEM

09-10 November 2023, Strasbourg, France

Working language: English

Programme

08:45-09:30 | Registration

09:30-09:45 | Opening & Welcome Address

Michael Wierer, EDQM, Council of Europe

Session I: Regulatory Requirements & Framework

Moderator: Catherine Milne, EDQM, Council of Europe

09:45-10:15 | Marketing Authorisation Procedure for Vaccines in the EU

Volker Oeppling, Paul-Ehrlich-Institut, Germany

10:15-10:45 | Vaccines in the European Pharmacopoeia

Gwenael Cirefice, EDQM, Council of Europe

10:45-11:05 | Discussion

11:05-11:25 | *Coffee break*

Session II: OCABR Procedure

Moderator: Michael Wierer, EDQM, Council of Europe

11:25-12:15 | An overview of the European Official Control Authority Batch Release procedure and guidelines for vaccines: Outline of the procedure, key principles and tools

Catherine Milne, EDQM, Council of Europe

12:15-12:35 | Discussion

12:35-14:00 | *Lunch break*

Session III: Function and Role of Key Players

Moderator: Dieter Pullirsch, Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Austria

14:00-14:30 | Role of the Marketing Authorisation Holder in Official Control Authority Batch Release

Pete Mlynarczyk, Vaccines Europe

14:30-15:00 | Role of the OMCL in Official Control Authority Batch Release

François Cano, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), France

15:00-15:20 | Discussion

15:20-15:45 | *Coffee break*

Session IV: Quality Systems

Moderator: Geneviève Waeterloos, Sciensano, Belgium

15:45-16:15 | The OMCL Network: Quality Assurance and Mutual Joint Audit / Visit Schemes

Silvana Bellini, EDQM, Council of Europe

16:15-16:45 | Validation of methods for OCABR

Martijn Bruysters, National Institute for Public Health and the Environment (RIVM), the Netherlands

16:45-17:00 | Discussion

17:15 | Close of day

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Session V: Lessons Learned from COVID

Moderator: Catherine Milne, EDQM, Council of Europe

09:00-09:20 | OCABR network reaction to COVID-19 vaccine release and lessons learned

Hanna Sediri-Schön, Paul-Ehrlich-Institut, Germany

09:20-09:40 | Manufacturer perspective

Mark van Ooij, Vaccines Europe

09:40-10:00 | Perspectives of Coalition for Epidemic Preparedness Innovations (CEPI)

Anna Särnefält, Coalition for Epidemic Preparedness Innovations (CEPI)

10:00-10:20 | Discussion

10:20-10:40 | *Coffee break*

Session VI: 3Rs and Standardisation

Moderator: Martijn Bruysters, RIVM, the Netherlands

10:40-11:00| Replacement, Reduction and Refinement (3Rs): Network Strategies

Morgane Florens, Sciensano, Belgium

11:00-11:20 | Update on NC3Rs review of WHO guidelines

Elliott Lilley, NC3Rs

11:20-11:40 | EDQM contributions to the quality control of vaccines: Biological Standardisation Programme, Reference Standards and Preparations and PTS studies

Catherine Milne, EDQM, Council of Europe

11:40-12:00 | Discussion

12:00-14:00 | *Lunch break*

Session VII: Batch Release and OCABR beyond the EU

Moderator: François Cano, ANSM, France

14:00-14:30 | Overview of vaccine prequalification and monitoring

Carmen Rodriguez Hernandez, World Health Organization (WHO)

14:30-15:00 | Viewpoint from the manufacturer's perspective on Official Control Authority Batch Release beyond the EU

Philippe Juvin, Vaccines Europe

15:00-15:30 | Viewpoint from an EU OMCL's perspective

Geneviève Waeterloos, Sciensano, Belgium

15:30-16:00 | Discussion

16:00-16:05 | Closing Remarks

Michael Wierer, EDQM, Council of Europe

16:05 | Close of the training