

THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE FUTURE OF EUROPE

23-24 APRIL 2024

| DAY 1 |

08:30 REGISTRATION AND WELCOME COFFEE

09:30 Welcome address

O. SCHILLACI, MINISTRY OF HEALTH

S. VAN DER SPIEGEL, HEALTH INNOVATION SECTOR, DG SANTÉ, EUROPEAN COMMISSION

G. PALÙ, PRESIDENT OF THE ITALIAN MEDICINES AGENCY (*invited*)

V. DE ANGELIS, DIRECTOR, ITALIAN NATIONAL BLOOD CENTRE, ITALIAN NATIONAL INSTITUTE OF HEALTH

10:00 Introduction - R. BELLANTONE, PRESIDENT OF THE ITALIAN NATIONAL INSTITUTE OF HEALTH

SESSION 1 – COUNTRY EXPERIENCES ON PDMPs CONTINGENCY

Chairpersons: A. DE CELIS, D. DI GIORGIO

10:15 The global demand for PDMPs: current scenario and future trends – P. ROBERT

10:35 Italy - F. CANDURA

10:55 Australia - J. PINK

11:10 Canada - S. GRENIER

11:25 Coffee Break

11:45 Japan – T. IJIMA

12:00 Africa Society for Blood Transfusion – F. MOFTAH

12:15 Spain - L. LARREA

12:30 Latvia – S. AKULIČS

12:45 Questions & Answers

13:00 Lunch Break



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SESSION 2 – SUPPLY - STRENGTHENING VOLUNTARY NON-REMUNERATED PLASMA COLLECTION CAPACITY IN EUROPE

Chairpersons: S. VAN DER SPIEGEL, P. O' LEARY

- 14:00 SUPPLY Project in a nutshell – P. O' LEARY
- 14:20 Recommendations
- Plasma collection and processing best practices - P. VERHEGGEN
 - Plasma collection and PDMPs management - V. DE ANGELIS
 - Report enabling informed and appropriate prioritisation on national level – S. SASONGKO
- 14:50 Position Paper on PDMPs distribution - M. A. VESGA CARASA
- 15:00 Questions & Answers

15:30 ROUND TABLE - ETHICAL IMPLICATIONS FOR PATIENTS AND DONORS

Chairpersons: M. CLEMENT, K. VAN DEN HURK, J.B. THIBERT

Intro on Ethical implications in

- 15:30 Donors and patients regarding plasma supply
- 15:40 Donor retention and recruitment strategies and
- 15:50 Donor protection

16:00 *Panellists:*

WHO - YUYUN-MARYUNINGSIH; FIODS-IFBDO - K. MAGNUSSEN; CIVIS – A. SIMONETTI; IPOPI - M. PERGENT; Plasma Plus - F. WILLERSINN; EBA P. TIBERGHEN

- 17:00 Closing remarks – V. DE ANGELIS

End of the day 1

SESSION 3 – SHORTAGES OF MEDICINES AND INSIGHTS ON PDMPs AVAILABILITY

Chairpersons: A. FARRUGIA, HPRA (*invited*)

- 09:00 CHESSMEN JA in a nutshell - Coordination and Harmonization of the Existing Systems against Shortage of Medicine - European Network - D. DI GIORGIO
- 09:15 Identifying the root causes of observed shortages of medicines - L. MARRERO
- 09:30 Identification of best practices to address medicines shortages - M. TOVORNIK
- 09:45 Digital Information Exchange for Monitoring and reporting medicine shortages - G. EIBENSTEIN
- 10:00 Reducing the likelihood of medicines shortages via preventive and mitigation strategies - J. LINNOLAHTI
- 10:15 Monitoring and mitigating shortages of medicines and management of public health emergencies/major events – K. KRUTTWIG
- 10:30 Questions & Answers

10:45 *Coffee Break*

- 11:15 Perspectives from Asia – M. HOTCHKO
- 11:30 International Plasma and Fractionation Association – L. VON BONSDORFF
- 11:45 Plasma Protein Therapeutics Association – M. VAN BAELEN

12:00 OPEN DISCUSSION – INDUSTRY COMMITMENTS AGAINST SHORTAGES

Chairpersons: A. FARRUGIA, HPRA (*invited*)

- 12:00 Introduction
- 12:15 Plasma fractionation companies statements for comments for the audience
Panellists: Kedrion - F. BORGESE, CSL Behring – O. SCHMITT, Grifols SA – S.GONZALES, Takeda (*invited*)
- 12:40 Open discussion

13:00 *Lunch Break*

SESSION 4 – AN OVERVIEW OF THE NEW AND UPCOMING EU LEGISLATION ON SoHO AND PHARMACEUTICALS: PERSPECTIVES AND IMPLICATIONS

Chairpersons: D. DOMANOVIC, V. DE ANGELIS

- 14:00 EU - SoHO Legislation - S. VAN DER SPIEGEL
- 14:15 EU – Pharma Legislation – L. GESLIN (*invited*)
- 14:30 European Directorate for the Quality of Medicines - R. FORDE

- 14:45 European Centre for Disease Prevention and Control – M. VAN DER WERF
 15:00 European Medicines Agency - K. KRUTTWIG
 15:15 Discussion

15:45 **Closing remarks** – V. DE ANGELIS

16:00 **Closing of the Conference**

SPEAKERS AND CHAIRPERSONS

Sergejs Akuličs	State Agency of Medicines of the Republic of Latvia, Latvia
Fabio Candura	Italian National Blood Centre, National Institute of Health, Italy
Michel Clement	University of Hamburg, Germany
Vincenzo De Angelis	Italian National Blood Centre, National Institute of Health, Italy
Aránzazu de Celis Miguélez	Ministry of Health, Spain
Domenico Di Giorgio	Italian Medicines Agency, Italy
Dragoslav Domanovic	European Blood Alliance
Gabriele Ebenstein	Federal Institute for Drugs and Medical Devices, Germany
Albert Farrugia	University of Western Australia
Richard Forde	European Directorate for the Quality of Medicines & HealthCare, Council of Europe
Laure Geslin	Directorate-General for Health and Food Safety, European Commission
Sylvain Grenier	Canadian Blood Services, Canada
Matthew Hotchko	Marketing Research Bureau, U.S.A.
Ta-Ke Iijima	Japan Blood Products Organization, Japan
Klaus Kruttwig	European Medicines Agency
Luis Larrea	Valencian Community Blood Transfusion Centre, Spain
Johanna Linnolahti	Finnish Medicines Agency, Finland
Karin Magnussen	International Federation of Blood Donor Organisations
Laura Marrero	Spanish Agency of Medicines and Medical Devices, Spain
Yuyun Maryuningsih	World Health Organization
Faten Moftah	Africa Society for Blood Transfusion, Africa
Peter O' Leary	European Blood Alliance
Martine Pergent	International Patient Organisation for Primary Immunodeficiencies, Belgium
Patrick Robert	Marketing Research Bureau, U.S.A.
Syeldy Sasongko	European Hematology Association, The Netherlands
Alice Simonetti	Inter-associative Committee of Voluntary Italian Blood Donors Associations/Federations, Italy
Jean-Baptiste Thibert	French Blood Establishment, France
Pierre Tiberghien	French Blood Establishment, France
Melita Tovornik	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Slovenia
Maarten Van Baelen	Plasma Protein Therapeutics Association
Katja van den Hurk	Sanquin, The Netherlands
Stefaan van Der Spiegel	Directorate-General for Health and Food Safety, European Commission
Marieke van der Werf	European Centre for Disease Prevention and Control
Peter Verheggen	Sanquin, The Netherlands
Miguel Angel Vesga Carasa	Basque Centre for Transfusions and Human Tissues, Spain
Leni von Bonsdorff	International Plasma and Fractionation Association, Finland
Frank Willersinn	Alpha-1 Plus, Belgium

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