

The supply of plasma-derived medicinal products in the future of Europe

Second edition

23-24
April 2024
Rome, Italy

HOTEL RIPA

Via degli Orti di Trastevere, 3

The scientific event involves both national and international key actors of the field. The main objectives are to share and discuss experiences on current pivotal topics related to Plasma-Derived Medicinal Products. In addition, a focus on the new forthcoming EU legislation relating to Substances of Human Origin and Pharmaceuticals will be presented together with its implications at national and European level.

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PROGRAMME - DAY 1

08:30 **REGISTRATION**

09:30 **Welcome address**

O. Schillaci, *Minister of Health*

S. Van Der Spiegel, *Health Innovation Sector, DG Santé, European Commission*

P. Russo, *Italian Medicines Agency*

R. Bellantone, *Italian National Institute of Health*

10:00 **Introduction**

V. De Angelis, *National Blood Centre, 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. Iijima**

12:00 **Perspectives from Africa - F. Moftah**

12:15 **Spain - L. Larrea**

12:30 **Latvia - S. Akuličs**

12:45 **Questions & Answers**

13:00 **LUNCH BREAK**

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

Chairpersons: R. Forde, P. O'Leary

14:00 **SUPPLY Project in a nutshell - P. O'Leary**

14:20 **Recommendations on**
Plasma collection and processing best practices - A. De Fijter
Plasma collection and PDMPs management - V. De Angelis
Informed and appropriate prioritisation at 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, S. Sasongko, J.B. Thibert

Intro on Ethical implications in

15:30 **Donors and patients regarding plasma supply - J. B. Thibert**

15:40 **Donor retention and recruitment strategies - M. Clement**

15:50 **Donor protection - K. van den Hurk**

16:00 **Patient protection - S. Sasongko**

16:10 **Panellists**

Y. Maryuningsih, *WHO*

K. Magnussen, *FIODS-IFBDO*

A. Simonetti, *CIVIS*

M. Pergent, *IPOPI*

F. Willersinn, *PLUS*

P. Tiberghien, *EBA*

17:00 **CLOSING REMARKS - V. De Angelis**

END OF THE DAY 1

PROGRAMME - DAY 2

SESSION 3 - SHORTAGES OF MEDICINES AND INSIGHTS ON PDMPs AVAILABILITY

Chairpersons: A. Farrugia, E. McGrath

09:00 **CHESMEN, Coordination and Harmonization of the Existing Systems against Shortage of Medicine - European Network**
Joint Action in a nutshell - D. Di Giorgio

09:15 **Identification of the root causes of observed medicines shortages** - L. Marrero

09:30 **Identification of best practices to address medicines shortages** - M. Tovornik

09:45 **Digital information exchange for monitoring and reporting medicines 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 - AVAILABILITY OF PDMPs AND TIMELY ACCESS TO THERAPIES**

Chairpersons: A. Farrugia, E. McGrath

12:00 **Introduction**

12:15 **Panellists**
F. Borgese, *Kedrion*
O. Schmitt, *CSL Behring*
S. González Orti, *Grifols*
A. Walshe, *Takeda*

12:40 **Open discussion**

13:00 **LUNCH BREAK**

SESSION 4 - AN OVERVIEW OF THE NEW AND UPCOMING EU LEGISLATION ON SUBSTANCES OF HUMAN ORIGIN 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** - A. Rodiadis

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	<i>State Agency of Medicines of the Republic of Latvia</i>
Ferdinando Borgese	<i>Kedrion Biopharma</i>
Fabio Candura	<i>Italian National Blood Centre, National Institute of Health</i>
Michel Clement	<i>University of Hamburg, Germany</i>
Vincenzo De Angelis	<i>Italian National Blood Centre, National Institute of Health</i>
Aránzazu de Celis Miguélez	<i>Ministry of Health, Spain</i>
Annemieke de Fijter	<i>Sanquin, The Netherlands</i>
Domenico Di Giorgio	<i>Italian Medicines Agency</i>
Dragoslav Domanovic	<i>European Blood Alliance</i>
Gabriele Ebenstein	<i>Federal Institute for Drugs and Medical Devices, Germany</i>
Albert Farrugia	<i>University of Western Australia</i>
Richard Forde	<i>European Directorate for the Quality of Medicines & HealthCare, Council of Europe</i>
Santiago González Orti	<i>Grifols</i>
Sylvain Grenier	<i>Canadian Blood Services</i>
Matthew Hotchko	<i>Marketing Research Bureau, U.S.A.</i>
Ta-Ke Iijima	<i>Japan Blood Products Organization</i>
Klaus Kruttwig	<i>European Medicines Agency</i>
Luis Larrea	<i>Valencian Community Blood Transfusion Centre, Spain</i>
Johanna Linnolahti	<i>Finnish Medicines Agency</i>
Karin Magnussen	<i>International Federation of Blood Donor Organizations</i>
Laura Marrero	<i>Spanish Agency of Medicines and Medical Devices</i>
Yuyun Maryuningsih	<i>Health products Policy and Standards Department, World Health Organization</i>
Ellen McGrath	<i>Health Products Regulatory Authority, Ireland</i>
Faten Moftah	<i>Africa Society for Blood Transfusion</i>
Peter O'Leary	<i>European Blood Alliance</i>
Martine Pergent	<i>International Patient Organisation for Primary Immunodeficiencies</i>
Joanne Pink	<i>Australian Red Cross</i>
Patrick Robert	<i>Marketing Research Bureau, U.S.A.</i>
Antonios Rodiadis	<i>Directorate-General for Health and Food Safety, European Commission</i>
Syeldy Sasongko	<i>European Hematology Association</i>
Oliver Schmitt	<i>CSL Behring</i>
Alice Simonetti	<i>Committee of Voluntary Italian Blood Donors Associations/Federations</i>
Jean-Baptiste Thibert	<i>French Blood Establishment of Britany</i>
Pierre Tiberghien	<i>European Blood Alliance</i>
Melita Tovornik	<i>Agency for Medicinal Products and Medical Devices of the Republic of Slovenia</i>
Maarten Van Baelen	<i>Plasma Protein Therapeutics Association</i>
Katja van den Hurk	<i>Sanquin, The Netherlands</i>
Stefaan Van der Spiegel	<i>Directorate-General for Health and Food Safety, European Commission</i>
Marieke van der Werf	<i>European Centre for Disease Prevention and Control</i>
Miguel Angel Vesga Carasa	<i>Basque Centre for Transfusions and Human Tissues, Spain</i>
Leni von Bonsdorff	<i>International Plasma and Fractionation Association</i>
Alan Walshe	<i>Takeda</i>
Frank Willersinn	<i>Platform of Plasma Protein Users</i>

Scientific Director
Vincenzo De Angelis

Scientific Secretarial
Fabio Candura, Livia Cannata,
Lucia De Fulvio, Anna Palmieri

Organizational Secretarial
Laura Di Marco, Silvia Giannetti,
Francesca Martini, Maria Simona Massari,
Cinzia Scagliarini, Giacomo Silvioli

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