

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,
Giacomo Silvioli

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