



Appropriate use of plasma products

(Coordinators: H.E. Heier, T. Burnouf, V. De Angelis, M. El Ekiaby)

Residential Course

Zagreb (Croatia), 14-18 November 2012

(in cooperation with:

EDQM/Council of Europe,

IPFA - International Plasma Fractionation Association,

WFH - World Federation of Hemophilia)

Wednesday, 14/11/2012 *Evening: Arrival at the Hotel*

Thursday, 15/11/2012 *Morning: Introduction. Plasma collection and fractionation in Europe*

- 8,00 - 8,30 **Opening of the course** (Coordinators). **Presentation of participants**
 8,30 - 8,45 Stressing the need of professional and clinical education in the field of plasma products (IPFA, U. Rossi, coordinators)
 8,45 - 9,15 Plasma collection and fractionation in Europe: overview of the present situation (V. De Angelis)
 9,15 - 10,00 Modern plasma fractionation and viral inactivation/removal procedures (T. Burnouf) 10,00 Coffee-break
 10,30 - 11,00 Plasma collection and fractionation in Croatia (S. Marković)
 11,00 - 11,45 Preparation of plasma meeting requirements for contract or domestic fractionation (T. Burnouf)
 11,45 - 12,30 Plasma supplier qualification, Audits and Plasma Master File (C. Parés) 12,30 Lunch

Thursday, 15/11/2012 *Afternoon: Plasma products: biological, technical and quality specifications*

- 14,00 - 15,00 Impact of epidemiology and screening strategies on plasma safety (M. Nübling)
 15,00 - 15,30 Quality management for mastering plasma-derived production (R. Verdeguer)
 15,30 - 16,00 Batch release (A. Blausenhauer-Borderau) 16,00 Coffee-break
 16,30 - 17,00 Implications and experience with the EU GMP Annex-14 (Manufacture of Medical Products Derived from Human Blood or Plasma) update (C. Parés)
 17,00 - 18,30 General discussion of sessions 1 and 2: 19,30 Dinner

Friday, 16/11/2012 *Morning: Clinical use of plasma products in haemostatic disorders*

- 8,00 - 8,30 Clotting factor concentrates: evidence-based usage and pharmacoeconomics (M. Makris)
 8,30 - 9,00 Clinical and practical aspects of indications and administration of blood products in inherited bleeding disorders (L. Walterová)
 9,00 - 9,30 The WFH vision of Treatment for All (M. El Ekiaby)
 9,30 - 10,00 Clinical and practical aspects of indications and administration of blood products in acquired bleeding disorders (L. Walterová) 10,00 Coffee-break
 10,30 - 11,00 Clotting factor concentrates: methods for monitoring adverse events in clinical practice (M. Makris)
 11,00 - 11,45 Presentation of clinical cases
 11,45 - 12,30 Discussion 12,30 Lunch

Friday, 16/11/2012 *Afternoon: Clinical use of plasma products in anaesthesiology and surgery*

- 14,00 - 14,40 Plasma, Colloid or Saline: what is the evidence in Anaesthesia and Critical Care? (D. Thomas)
 14,40 - 15,20 The use of plasma and plasma products in the treatment of acute bleeding (H. E. Heier)
 15,20 - 16,00 Pre-operative preparation of patients for elective surgery (D. Thomas) 16,00 Coffee-break
 16,30 - 17,00 Pooled SD-pathogen inactivated FFP as an alternative to regular FFP (T. Krusius)
 17,00 - 17,30 General principles of evidence-based medicine (D. Thomas)
 17,30 - 18,00 Presentation of clinical cases
 18,00 - 18,30 Discussion 19,30 Dinner

Saturday, 17/11/2012 *Morning: Clinical use of plasma products in metabolic and immunological disorders*

- 8,00 - 8,40 Mechanisms and prevention of alloimmunisation in pregnancy (J. Kjeldsen-Kragh)
 8,40 - 9,10 The use of high doses immunoglobulins in different childhood haemopathies (M. Janković)
 9,10 - 9,40 Replacement with high-dose immunoglobulins after bone marrow transplantation in children with onco-haematological diseases (D. Longoni)
 9,40 - 10,10 Primary immunodeficiency disorders: diagnosis and treatment (J. Kelečić) 10,10 Coffee-break
 10,40 - 11,10 Adverse reactions related to plasma components (D. Šarlija)
 11,10 - 11,40 Therapeutic needs for rare diseases: the necessity of national and international networks (B. Bembi)
 11,40 - 12,10 Presentation of clinical cases and country reports
 12,10 - 12,30 Discussion

Saturday, 17/11/2012 *Afternoon: Organisational, educational and "political" aspects of distribution and use of plasma products in Europe*

- 14,00 - 14,30 Forces shaping the pattern of consumption of plasma products in the industrialised world (H. E. Heier)
 14,30 - 15,00 Organisation and requirements for a contract fractionation programme (T. Burnouf)
 15,00 - 15,30 Minipool plasma fractionation in blood establishments and national Service Centres (M. El Ekiaby)
 15,30 - 16,00 Monitoring the appropriate use of plasma products (V. De Angelis) 16,00 Coffee-break
 16,30 - 17,00 Epidemiological data on use of plasma products (T. Krusius)
 17,00 - 17,45 Improving access to blood products in developing countries (A. Padilla)
 17,45 - 18,30 **Closing discussion and conclusion of the course** 20,30 Social dinner

Sunday, 18/11/2012 *Morning: Departure from the Hotel*

Course venue: Meeting room of the Four Points by Sheraton, Panorama Zagreb Hotel, where participants will be hosted (see below)

Hotel accommodation at: Four Points by Sheraton, Panorama Zagreb Hotel, Trg Krešimira Čosića 9, 10000 Zagreb, Croatia

Tel.: +385/1/365.83.33; Fax: +385/1/309.26.57; e-mail: fourpoints.zagreb@fourpoints.com;

Website: <http://www.hotel-fourpointspanorama.com/>

FACULTY MEMBERS

Thierry Burnouf (co-Coordinator), Professor, Taipei Medical University (TMU), Taipei, Taiwan; Director Human Protein Process Sciences, Lille, France; **Vincenzo De Angelis** (co-Coordinator), Director, Transfusion Medicine Dept., Azienda Ospedaliero-Universitaria, Udine, Italy; **Magdy El Ekiaby** (co-Coordinator), Shabrawishi Hospital, Giza, Egypt; WFH Board Member 2010-2012; Member ATMC Executive Committee; **Hans Erik Heier** (co-Coordinator), Professor Emeritus, Transfusion Medicine, University of Oslo; formerly Medical Director, Blood Bank of Oslo, Oslo University Hospital, Oslo, Norway; ISBT President 2002-2004; **Bruno Bembí**, Director, Regional Coordinator Centre for Rare Diseases, University Hospital, Udine, Italy; **Aurore Blausenhauer-Borderau**: International Pharmaceutical Affairs, LFB-Biomédicaments, Les Ulis, Courtaboeuf, France; **Momcilo Janković**, Responsible, Paediatric Day Hospital Unit, S. Gerardo Hospital, Monza; Paediatric Clinic, University of Milano-Bicocca, Milano, Italy; **Jadranka Kelečić**: University Hospital Center Zagreb Department of Pediatrics Division of Clinical Immunology, Allergology and Respiratory Disease, Zagreb, Croatia; **Jens Kjeldsen-Kragh**, Senior Consultant, Clinical Immunology and Transfusion Medicine, University and Regional Laboratories Skåne, Lund, Sweden; **Tom Krusius**, Medical Director, Finnish Red Cross Blood Transfusion Service, Helsinki, Finland; **Daniela Longoni**, Responsible Bone Marrow Failure Unit, Bone Marrow Transplant Centre, S. Gerardo Hospital, Monza; Paediatric Clinic, University of Milano-Bicocca, Milano, Italy; **Michael Makris**, Reader in Haemostasis and Thrombosis, University of Sheffield, Sheffield, Great Britain; **Stribor Marković**, Head of Quality Control, Institute of Immunology Inc., Zagreb, Croatia; **Micha Nübling**, Head, Molecular Virology, Paul-Ehrlich-Institut, Langen, Germany; **Ana Padilla**, Programme Manager, Blood Products and other Biological Products Quality and Safety: Medicines, Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland; **Carles Parés**, Head, Suppliers Certification, Biomat, S.A., Grifols, Barcelona, Spain; **Umberto Rossi**, ESTM President, Milano, Italy; **Dorothea Šarlija**, Quality Manager, Croatian Institute of Transfusion Medicine, Zagreb, Croatia; **Dafydd Thomas**, Consultant in Intensive Care Medicine and Honorary Clinical Tutor, Welsh Blood Service and ABMUHB, Morriston Hospital, Swansea, Wales, Great Britain; **Robert Verdeguer**, Head of Quality, LFB-Biomédicaments, Les Ulis, Courtaboeuf, France; **Lenka Walterová**, Head, Dept. of Clinical Haematology, Liberec Regional Hospital, Liberec, Czech Republic; Member National Transfusion Committee, Ministry of Health, Czech Republic.

PRACTICAL INFORMATION

Applications should ordinarily be sent **as soon as possible**. The deadline is **10/10/2012**. Applications may be accepted, in **extreme** cases, also after the deadline, following preliminary enquiry with the ESTM Secretariat. **Early application is strongly advisable** to ensure adequate hotel reservation. Notification of the registration with full practical information will follow in due course.

The fee of **985 Euro** (single room), or of **890 Euro** (shared double room, accepted only with the indication of the sharing participant), includes board and lodging from **Wednesday 14/11/2012 night** (dinner included) to **Sunday 18/11/2012 morning** (breakfast included), and covers accommodation at the hotel, the meals during the course, the Proceedings and other didactic material, the cost (travel, board and lodging) of the participation of teachers, and the ESTM organisational expenses for the preparation of the course.

Travel expenses are at the charge of participants.

Participants **from Zagreb**, not needing hotel accommodation (bed and breakfast), will pay a **reduced fee of 740 Euro**.

The registration fee includes a book of Proceedings of the course, to be distributed at the beginning of the course, and an attendance certificate, to be delivered at the end of the course.

The course shall be in English.

The course is submitted for **accreditation** to the Continuing Medical Education of the European Haematology Association (EHA/CME). Based on the experience of the previous ESTM courses, it is expected that the answer shall be given before the beginning of the course.

Accreditation by the Royal College of Pathologists of London (CME) is foreseen for British participants.

Payment of the registration fee should be made:

- through **bank transfer** to the "ESTM" (account n. **497/36561, Credito Valtellinese, C.so Magenta 59, 20123 Milano - Italy**; **IBAN code: IT 95 C052160161400000036561**; **SWIFT Code: BPCV IT 2S**): all bank expenses must be covered by the participant,
- or by **"non transferable" bank cheque in Euro** (for participants from the European Union), or **international cheque**, drawn to "ESTM" and sent by mail, together with the application form, to:
ESTM, Viale Beatrice d'Este 5, I-20122 MILANO, Italy - Tel. +39/02/58.31.65.15 - Fax +39/02/58.30.81.11.
- **on-line: www.estm.info --> What is on --> future courses** (The accepted credit cards are the following ones: Visa, Mastercard, Maestro and CartaSi. Please remember that CartaSi should be showing on the right-down side the Visa network or the Mastercard one).

Registrations without payment, or evidence of payment, will not be accepted.

The number of participants is foreseen in 100. In case the number of applications should exceed the number of available places, a selection of applications may be made on the basis of the chronological order of arrival and the judgement of the course coordinators.

The course is subject to cancellation, owing to causes beyond control, or in the unlikely case that the required minimum number of registrations should not be reached. In this case, a written notification of the cancellation will be sent to all registrants before the course, with full refund.

Requests of cancellation received up to 2 months before the beginning of the course entitle to a full refund. A charge of 25% will be made for requests of cancellation received between 60 and 30 days before, and of 50% between 29 days and 10 days before the beginning of the course. Cancellations received less than 10 days before the beginning of the course will not be reimbursed. All requests of cancellation must be done in written, signed and sent by fax and/or e-mail transmission. All reimbursements will be dealt with after the end of the course.

APPLICATION FORM

(to be filled and sent to the ESTM by fax ([+39/02/58.30.81.11](tel:+390258308111)) and/or e-mail (estm.secretariat@estm.info)).

Family name..... First name.....

Institute.....

Address..... Town..... Postal code.....

Country..... Tel..... Mobile tel.

Fax..... E-mail

I APPLY FOR PARTICIPATION

TO THE ESTM RESIDENTIAL COURSE (14-18 November 2012): "*Appropriate use of plasma products*"

☐ I include a copy of a **bank transfer** to the ESTM of
(all bank expenses must be covered by the participant)

- ☐ **985 Euro** (single room), or
- ☐ **890 Euro** (shared double room: accepted only with the indication of the sharing participant)
- ☐ **740 Euro** (participants from Zagreb, not needing hotel accommodation)

(account n. 497/36561, Credito Valtellinese, C.so Magenta 59, 20123 Milano - Italy; IBAN code: IT 95 C0521601614000000036561; SWIFT Code: BPCV IT 2S):

☐ I include a "non transferable" **bank cheque in Euro**
(for participants from the European Union),
or **international cheque**, drawn to "ESTM", of

- ☐ **985 Euro** (single room), or
- ☐ **890 Euro** (shared double room: accepted only with the indication of the sharing participant)
- ☐ **740 Euro** (participants from Zagreb, not needing hotel accommodation)

INFORMATION ABOUT ARRIVAL

☐ Means of transportation ☐ plane (flight number:) ☐ bus ☐ train ☐ car

Date Time

NOTES OR COMMENTS TO THE ESTM