6-7 MARCH 2019
IPFA 4th Asia Workshop on
Plasma Quality and Supply

IPFA 4th ASIA WORKSHOP ON PLASMA QUALITY AND SUPPLY

HANOI, VIETNAM, 6-7th MARCH 2019

SCIENTIFIC PROGRAMME, AS PER 4 FEBRUARY 2019

Day I: Wednesday 6 March

09.00 hrs Session 1: Opening and setting the scene

The Opening Session provides the opportunity for the Workshop host (NIHBT) to invite an appropriate official from their government or other institution to formally open the meeting and welcome the delegates. The keynote presentation will offer an overview of plasma fractionation and necessary considerations for the preparation and supply of PDMPs – including a global perspective. The session will also provide a summary of the current status and goals for PDMP/plasma supply for the host country and surrounding region. The opening session will aim to set the scene for discussion throughout the workshop.

- Opening
  - Opening and welcome (IPFA) (10 mins)
  - Formal opening
- Keynote – Setting the scene - Prof T. Burnouf, Taipei Medical University (Taiwan) (30 mins)
- Current status of plasma/PDMP supply in the region including overview of developments in the SE Asia region/Vietnam – T.B.A., Drug Administration Vietnam (Vietnam) (20 mins)

10.15 – 10.45 Coffee Break

10.45 hrs Session 2: Meeting patient needs

The local and global healthcare demand for PDMPs must always recognize and be driven by patient needs. Resources available to meet this need will vary from country and this session will provide an overview on the current and future supply of essential PDMPs from the local perspective of some key patient groups and healthcare providers in Vietnam and the wider region. Session 2 will therefore provide an opportunity to identify successes and challenges in meeting patient needs.

- Haemophilia: a WFH perspective – Dr A. Srivastava, WFH (India) (15 mins)
- Haemophilia: treatment in Vietnam – Dr M. Nguyen Thi, Hemophilia Center NIHBT (Vietnam) (15 mins)
- Immunodeficiency – Dr H. Le, Vietnam National Children's Hospital (Vietnam) (20 mins)
- Appropriate use of Albumin in Japan – Dr T. Kohno, Osaka Medical College (Japan) (20 mins)

12.15 – 13.45 hrs Lunch

13.45 hrs Session 3: Development of quality systems for blood establishments

The quality, safety and efficacy of PDMPs is critically dependent on the quality of plasma collected for fractionation. These quality requirements are the subject of strict regulation and control by fractionators. The development and implementation of appropriate 'quality systems' is therefore an essential prerequisite for organisations involved in blood/plasma collection. This session will identify the key principles of modern quality systems, experience of the importance of management attitude and culture in blood establishments to achieve sustainable quality systems and the experiences and progress in Vietnam in meeting these requirements.

- Establishing the essential principles of quality systems/GMP for blood/plasma collection (20 mins) – Ms V. Armstrong, VA Armstrong (Australia) (20 mins)
- Developing a culture of quality in blood establishments – Dr P. Flanagan, NZBS (New Zealand) (20 mins)
- Status of quality management systems in Vietnam – Mr Q. Phan Huu, NIHBT (Vietnam) (20 mins)

15.00 – 15.30 hrs Coffee Break

15.30 hrs Session 4: Quality Management

Quality Management Systems are underpinned by detailed technical requirements and effective regulation. This session will outline specific international requirements for 'plasma for fractionation' which are enforced by fractionators and regulatory authorities. The arrangements for the enforcement and monitoring of blood/plasma quality and safety requirements in Vietnam will be described as well as the experiences and progress from

neighbouring countries in meeting international quality and regulatory standards.
An understanding of the importance of quality systems and its essential contribution to an increased national and global supply of plasma for fractionation and PDMPs is a key feature of this workshop. Sessions 3 and 4 of the programme will facilitate discussion on the actions necessary to increase plasma supply and increase patient access to PDMP therapies.

- Specific requirements for plasma for fractionation – Mr S. Mérrien, LFB (France) (20 mins)
- Current status of blood/plasma product regulation in Vietnam – T.B.A., Drug Administration Vietnam (Vietnam) (20 mins)
- Experience from Indonesia of quality management / GMP programmes – Dr R. Nur Aditya, Central Blood Transfusion Services (Indonesia) (20 mins)
- Panel Discussion

Day II: Thursday 7 March

09.00 hrs Session 5: Manufacturers' Session

IPFA Workshops are supported by industry sponsors. Their participation and key contribution to healthcare developments are gratefully acknowledged. Category A sponsors are invited to participate in the scientific programme through presentations which describe their interest and role in supporting the goals of national and regional healthcare providers.

- Abbott Diagnostics (20 mins)
- Merck (20 mins)
- Roche Diagnostics
  Partnership with Roche - your pathway to operational efficiency and compliance – Mr T. Hardiman (USA) (20 mins)

10.15 – 10.45 hrs Coffee Break

10.45 hrs Session 6: Epidemiological Considerations and Donor Screening Strategies

It is widely recognized and understood that the safety of blood transfusion and PDMPs is critically dependent on an understanding of the epidemiology of infectious diseases transmissible by blood and necessary strategies to prevent disease transmission by blood and plasma products. The

epidemiology of current and potentially emerging infectious diseases in the region will be discussed together with a consideration of donor selection and screening strategies to safeguard the safety of blood transfusion and to meet international regulatory standards for plasma for fractionation.
Data from Vietnam and the surrounding region will be presented and cost effective strategies for donor selection and screening considered.

- Overview of donor epidemiology in the region and impact on blood/plasma collection – Dr Y-Y. Chen, Taipei Blood Foundation (Taiwan) (20 mins)
- Overview of donor epidemiology in Vietnam and impact on blood/plasma collection – Dr N.T.L. Ahn, National Institute of Hygiene Epidemiology (Vietnam) (20 mins)
- Emerging TTIs – Dr S. Lam, Health Sciences Authority (Singapore) (20 mins)
- Screening strategies – Mr J. Vincini, NRL (Australia) (20 mins)

12.15 – 13.45 hrs Lunch

13.45 hrs Session 7: Strategies for National/Regional Supply of PDMPs

PDMPs are included in the WHO list of essential medicines. The global supply of these medicines has grown substantially but is highly dependent on commercial plasma collection and supply from the US. This dependency creates risks for PDMP supply outside of the US and it is acknowledged that a secure and affordable supply for other regions requires an increase in plasma and PDMP supply independent of the US. Options for such "Strategic Independence" require increased national/regional collection of plasma for fractionation together with arrangements for its fractionation locally into PDMPs or via Toll Manufacturing agreements with international fractionators. Consideration of such options for national/regional supply will be discussed and experiences of national fractionation and toll manufacture in the region shared with delegates.

- Practical considerations for fractionation and/or Toll Manufacturing programme – Dr Tsuda, JBPO (Japan) (20 mins)
- Strategic independence of PDMPs in Thailand – Dr U. Charoonruangrit, The Thai Red Cross Society (Thailand) (20 mins)
- Experiences from Malaysia of toll manufacturing programmes – Dr N. Abu Amin, National Blood Centre (Malaysia) (20 mins)
- Panel Discussion

15.15 hrs Session 8: Donor Recruitment and Plasma Collection

National strategies and programmes for donor recruitment to meet the national demand for blood and/or plasma collection will be presented from the region including Australia, Indonesia, Japan and Vietnam. Future actions necessary to meet increasing demand for PDMPs will be discussed.

- Australian experience – Mr S. Chesneau, ARCBS (Australia) (20 mins)
- Experience from Indonesia on establishing blood donor panels – Dr N.K. Ritchie, Jakarta Blood Services (Indonesia) (20 mins)
- Situation of blood donor motivation in Vietnam and potential in plasma donor recruitment – Dr Q. Ngo, NIHBT (Vietnam) (20 mins)
- Japanese experience – Dr K. Ikeda, Japanese Red Cross Society (Japan) (20 mins)

16.45 hrs Closure

17.00 hrs End of Workshop