

# 2<sup>ND</sup> WORKSHOP ON THE CHARACTERISATION OF HEPARIN PRODUCTS

Symposium organised by the European Directorate for the Quality of Medicines & HealthCare (Council of Europe), United States Pharmacopeia and the National Institute for Biological Standards & Control

**19-20 June 2008, EDQM, Strasbourg, France**

Duration: 1½ days, Working language: English

## PROGRAMME

**19 June 2008**

Registration: 12h00 onwards

**13h00 Welcome and Introduction: S. Keitel, EDQM**

### SESSION 1

#### CONTAMINATION OF HEPARIN – CURRENT SITUATION AND PERSPECTIVES

**Chair: D. Abernethy, USP**

##### **Presentation of situation**

##### **Data from the field – market surveillance – batch results**

*13h10* European Control Authorities/ OMCL – synoptic view point from the Network by EDQM (J-M. Spieser)

*13h25* **Summary of recent events** (A. Al-Hakim, FDA)

##### **Reaction from the licensing authorities**

*13h55* EU: AFSSAPS (P. Lechat), BfARM (M. Wittstock, J. Norwig)

*14h30* Japan: MHLW (D. Koga)

*14h45* Australia: TGA (L. Kelly)

##### **Possible solutions for the future – view points from industry and academia**

*15h00* APP (P. Soon-Shiong)

*15h15* Baxter (G. Goestl)

*15h30 – 16h00* **Coffee break**

*16h00* Leo Pharma (C. Petersen)

*16h15* Sandoz (H. Binder)

*16h30* Sanofi-Aventis (C. Houiste)

*16h45* Gland Pharma Ltd (V. Chidambaram Subramanian/ R.K. Penmetsa)

*17h00* Loyola University (J. Walenga)

##### **Pharmacopoeias – plans for revision**

*17h15* European Pharmacopeia (E. Charton)

*17h30* Japanese Pharmacopeia (D. Koga)

*17h45* United States Pharmacopeia (T. Morris)

*18h00* **Open discussion of Session 1** (End: 19h00)



**20 June 2008**

**SESSION 2**

**GLOBAL HARMONISATION**

**Chair: E. Gray/B. Mulloy, NIBSC**

**8h30 Pietro Bianchini: an appreciation of his life and work (G. Mascellani, Opocrin)**

**Are current pharmacopoeial methods adequate for quality control of unfractionated heparin?  
What new methods might be considered and why?**

**8h40 Characterization of UFH samples from the past decade (P. Shaklee, BioCascade Inc)**

- Physico-chemical characterisation
  - **9h00** FDA perspective on heparin – characterization and analytical considerations (A. Al-Hakim, FDA)
  - **9h20** Possible “expander” contaminants of heparin (B. Mulloy, NIBSC)
  - **9h30** NMR spectroscopic evaluation of heparin for pharmacopoeial purposes (U. Holzgrabe, Institut für Pharmazie und LMC, B. Diehl, Spectral Service GmbH)
  - **9h45** Advanced techniques suitable for commercial heparin and LMM heparin characterization (G. Torri, Istituto di Ricerche Chimiche e Biochimiche “G. Ronzoni”),
  - **10h00** Qualitative and quantitative NMR analysis of heparin and contaminants (I. McEwen, MPA)

**10h15 – 10h45 Coffee break**

- **10h45** Electrophoretic method to separate and quantify contaminant in heparin (T. Freudemann, Sandoz)
- **11h00** Quantification of dermatan sulfate in heparin (R. Lecky, Leo Pharma)

**Open discussion: what is “pure” heparin? Should the criteria be global?**

**Harmonisation of methods for estimation of potency**

**11h30** Replacement of the 5<sup>th</sup> IS for unfractionated heparin (E. Gray, NIBSC)

**11h35** A general chromogenic substrate based heparin assay (C. Jackson, Hemosaga Inc)

**11h50** The development of a plasma free, chromogenic, anti-factor IIa pharmacopoeial assay for UFH (K.B. Johansen, Zealand Pharma)

**12h05** Harmonisation of pharmacopoeial methods? (K.B. Johansen, Zealand Pharma and E. Gray, NIBSC)

**12h20** Open discussion

**13h00 – 14h30 Lunch**

### SESSION 3

#### LOW MOLECULAR WEIGHT HEPARIN

Chair: J-M. Spieser, EDQM

##### Unfractionated heparin as starting material for LMW heparins

Are current compendial methods for unfractionated heparin adequate to control quality of LMW heparins? Additional characterisation tests:

*14h30* PCR to control origin of species (P. Anger, Sanofi-Aventis)

*14h45* Open discussion

##### Characterisation of LMW heparins

*15h25* Low molecular weight heparin characterisation: past and current views (C. Viskov, Sanofi-Aventis)

*15h45* Laser light scattering characterization of LMMH; comparison of molecular weight distribution methods (G. Gratzl, Ben Venue Laboratories)

***16h00 – 16h30 Coffee break***

Compendial aspects: is current monograph specification of LMM heparins sufficient to control the quality of both innovator and biosimilar products?

*16h30* United States Pharmacopeia (A. Szajek)

*16h45* European Pharmacopoeia (P. Jongen, RIVM BMT)

*17h00* Japanese Pharmacopoeia (N. Kawasaki)

*17h15* Need for harmonisation. Comparison of pharmacopoeial methods: Discussion

***17h45 Open Discussion*** (S. Keitel)

*18h30* Conclusion