BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group BIO: Biological and Biotechnological Products

SUMMARY MINUTES

A meeting of the Expert Advisory Group was held at 151 Buckingham Palace Road, Victoria, London SW1W 9SZ on Friday 17th November 2017.

Present: Dr P Varley (*Chair*), Dr A M Brady *(Vice Chair)*, Dr L Tsang, Dr C Burns, Mr S Gill, Dr B Patel, Mr L Randon, Dr A Thomas, Dr R Thorpe, Dr E Griffiths.

Dr J Cook contributed to the meeting by teleconference for items BIO(17)03 and BIO(17)04.

In attendance: Mr A Gibb, Dr A Gardiner, Dr K Radi, Mr J Pound, Dr A Gleadle.

Apologies for absence were received from P Sheppard and Dr T Sesardic.

Opening Remarks

Welcome The Chair welcomed everyone to the meeting, in particular new Secretariat member Dr Radi, British Pharmacopoeia group manager J Pound and British Pharmacopoeia Commission lay member Dr Gleadle. Members introduced themselves and gave brief overviews of their background experience in relation to the work of the EAG.

Professor Derek Calam OBE CBE Members had been saddened to learn of the death of Professor Derek Calam, a former Chair of the BP Commission and member of EAG BIO.

The group observed a minutes' silence in remembrance of Professor Calam.

Comments had been received from Dr M Wadhwa and these were taken into consideration during the discussions and decisions of the relevant agenda items.

Confidentiality Members were reminded of the confidential nature of the papers, discussions and minutes of the meeting.

Declaration of Interests The Chair asked members to declare any interests at the start of the meeting and prior to the relevant agenda item.

Mr Randon and Dr Patel declared an interest in one or more agenda items and appropriate action was taken.

307 General Matters BIO(17)01; Annex 1

Emergency exit The emergency evacuation procedure was confirmed.

BIO membership list Members were asked to inform the Secretariat of any changes to their contact details. The current contact details were circulated for checking at the meeting.

I MINUTES

308 The minutes of the meeting held on 7th November 2016 were confirmed.

II MATTERS ARISING FROM THE MINUTES

309 A list of matters arising from the minutes of the meeting of EAG BIO held on 7th November 2016 had been provided. A copy is attached.

III EAG BIO STRATEGY

310 Agency Strategy for Pharmacopoeial Biological Standards BIO(17)02; Annex 1

A verbal update on the progress made towards implementation of the strategy and a summary of the public response document and strategic work programme was presented by the Secretariat.

The Secretariat used workshops to capture members' experience and opinions on three topics relating to the strategic work programme; Standards development, Engaging with users and building knowledge and International Peers.

IV MONOGRAPHS IN PROGRESS

311 Biphasic Insulin Aspart Injection BIO(17)03

The draft monograph would be included in a future BP publication, subject to comments from manufacturers.

312 Biphasic Insulin Lispro Injection BIO(17)04

The draft monograph would be included in a future BP publication, subject to comments from manufacturers.

313 Gastro-resistant Pancreatin Capsules BIO(17)05

Following advice from EAG PCY, and further investigation by the Secretariat, the group agreed that the dissolution methodology should not be included in the monograph; instead the production section should be retained.

Monograph title change At the previous meeting the change of the monograph title from 'Pancreatin Capsules' to 'Gastro-resistant Pancreatin Capsules' had been endorsed. The change would be implemented for the BP2019.

POST-MEETING NOTE: EAG PCY and the British Pharmacopoeia Commission agreed that monographs titles should no longer contain split standard terms, and therefore the title 'Pancreatin Gastro-resistant Capsules' would be used in BP2019 (PCY minute 490 and BPC minute 174 respectively).

314 Desmopressin Preparations BIO(17)06

The Secretariat reported that the two desmopressin BPCRS which were being established were now available for customers to purchase, and some had been sold. The Laboratory reports relating their establishment were had been agreed by the group's Chair and Vice Chair and has been made available for members to review.

V REVISION OF MONOGRAPHS

315 Heparin Flush Solution BIO(17)07

Identification Investigation of whether an additional identification method should be included in the monograph had been undertaken. Members agreed the identification requirements within the monograph were sufficient and no further ID test would be included.

Sodium The Secretariat reported that the previously included Sodium test had been found unsuitable by manufacturers. The Secretariat had revised the monograph to include a titration test for Sodium and the group endorsed the publication of the revision in the BP2019, subject to stakeholder comment

316 Interferon beta-1a Injection BIO(17)08

NIBSC and the BP had collaboratively produced an Interferon Beta-1a oxidised peptide BPCRS to aid the analyst in identifying the oxidised form of the 34-45 amino acid fragment produced in the peptide mapping Identification test and limited in the test for Oxidised forms.

Monograph revision The Secretariat had revised the monograph to incorporate the new BPCRS. The group endorsed the publication of the revision in the BP2019, subject to stakeholder comment.

VI REPORTS AND CORRESPONDENCE

317 Dalteparin Sodium Injection BIO(17)09

A request had been received to remove the test for Clarity and colour of solution, and to instead include a statement within a 'characteristics' section. Members agreed that the monograph should be amended.

318 Low Molecular Weight Heparins BIO(17)10

ENOXAPARIN SODIUM INJECTION
DALTEPARIN SODIUM INJECTION
TINZAPARIN SODIUM INJECTION
HEPARIN INJECTION

The current Related Substances Test in the monograph for Heparin Injection and in monographs for preparations containing low molecular weight heparins were based on the Related Substances test of European Pharmacopoeia Heparin Sodium monograph. The Ph.

Eur. monograph had been revised in Supplement 9.3 to include a disregard limit for the Related substances test. The experts agreed that the monographs should be amended to include a disregard limit.

319 Erythropoietin Injection BIO(17)11

The Secretariat proposed to adopt the use of the Erythropoietin for physicochemical tests CRS and Erythropoietin for SEC system suitability CRS within the BP Erythropoietin Injection monograph. Whilst agreeing in principle to the proposal, members raised concerns about the suitability of the CRS standards for the test methods in the Injection monograph. It was concluded that the suitability of the methods should be assessed prior to progressing the revision further.

320 Interferon Alfa Monographs BIO(17)12

It had been highlighted that a cell line recommended in the BP Interferon Alfa-2a and Alfa-2b monographs was no longer available. The cell line used in the Potency assay was originally based on the Ph. Eur monograph method. The parent monograph had been updated in supplement 5.7 of the European Pharmacopoeia. Members agreed to revise the affected monographs to include the A-549 cell line as detailed in the Interferon Alfa-2 Concentrated Solution parent monograph.

VII WORK POGRAMME AND EUROPEAN PHARMACOPOEIA

321 Work Programmes: BP and Ph. Eur. Biologicals Update BIO(17)13; Annexes 1 to 5

New and revised BIO monographs included in the BP2017 The new and revised texts relating to the work of the EAG that had been included in the BP 2016 were noted, in particular, one new monograph, eleven technically revised monographs and one revised supplementary chapter.

Work Programmes The work programmes of the expert group, as well as the relevant European Pharmacopoeia expert groups had been included in the papers for the meeting.

322 Comments from the British Pharmacopoeia Commission BIO(17)14; Annex 1

Members noted that comments from the BP Commission had been sent to Strasbourg on proposals for new and revised Ph. Eur. texts included in Pharmeuropa Volumes 28.4, and 29.2

323 Comments Requested from Members on Draft Texts BIO(17)15

Members were reminded that comments on draft texts included in Pharmeuropa Volume 29.4 should be submitted by 31 December 2017 either by using the BP Website forum or contacting the Secretariat directly.

324 Texts adopted at the 156th, 157th and 158th Sessions BIO(17)16

Lists of the documents relevant to the Group that had been adopted at the 156th, 157th and 158th Sessions of the EPC were provided to members for information.

306 Groups of Experts: Formal reports BIO(17)17

The most recently available formal reports and summaries of decisions of Groups of Experts 6 and 15, and Working Parties BET, CTP, MAB and P4BIO had been made available to members electronically. Members noted that if they wished to receive previous reports the Secretariat should be informed.

VIII ANY OTHER BUSINESS

Date of Next Meeting: to be announced.

List of Acronyms/Synonyms for use by BP Secretariat

Acronym/Synonym	Name
BAN	British Approved Name
BP	British Pharmacopoeia
BP (Vet)	British Pharmacopoeia (Veterinary)
BPC	British Pharmacopoeia Commission
BPCRS	British Pharmacopoeia Chemical Reference Substance
BRP	Biological Reference Preparation
BSP	Biological Standardisation Programme
CHM	Commission on Human Medicines
CRS	Chemical Reference Substance
EAG	Expert Advisory Group
EDQM	European Directorate for the Quality of Medicines & HealthCare
EPBRP	European Pharmacopoeia Biological Reference Preparation
EPC	European Pharmacopoeia Commission
EPCRS	European Pharmacopoeia Chemical Reference Substance
EU	European Union
FIP	International Pharmaceutical Federation
FOI	Freedom of Information
GC	Gas chromatography
ISO	International Organisation for Standardisation
LC	Liquid chromatography
LD	Licensing Division
LGC	Laboratory of the Government Chemist, Teddington
LR	BP Laboratory Report
MHRA	Medicines and Healthcare products Regulatory Agency
NIBSC	National Institute for Biological Standards and Control
NOAH	National Office of Animal Health
NPA	National Pharmacopoeial Authority
OMCL	Official Medicines Control Laboratory
Ph. Eur.	European Pharmacopoeia
TGA	Therapeutic Goods Administration, Australia
TLC	Thin layer chromatography
UK	United Kingdom
UKD	United Kingdom Delegation [to the European Pharmacopoeia]
USP	United States Pharmacopeia