BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group BIO: Biological and Biotechnological Products

SUMMARY MINUTES

A meeting of this Expert Advisory Group was held via MS Teams on Friday 11th September 2020 commencing at 10:00 AM and continuing in the afternoon.

Present: Dr P Varley (Chair), Dr A-M Brady (Vice Chair), Mr S Gill, Dr B Patel, Mr L Randon, Dr R Thorpe, Dr C Burns, Dr A Kippen, Dr B Cowper, Dr E Amirak, and Dr L Tsang.

Apologies: Dr W Zunic, Dr V Loh and Mr P Sheppard.

In attendance: Mr A Gibb, Mr R Smith, and Mr P Crowley.

Dr T Rudd and Dr K Nordgren from NIBSC attended the meeting as invited experts for the items under minute 363 and 369 respectively.

356 Introductory remarks

Welcome
The Chair welcomed everyone to the meeting including new member: Dr E Amirak. The Chair noted that Dr G Kemp is currently on parental leave and that Mr P Crowley will be covering BIO duties in his absence.

Declaration of Interests
Members were reminded to declare specific interests as they arose during the meeting and to inform the Secretariat of any changes to their interests throughout the year.

Use of Teams
Mr R Smith gave a brief outline of how to use MS Teams functionality during the meeting.

357 General Matters **BIO(20)01**

Organisational updates
The Secretariat informed members that a new Chair of the Agency, Stephen Lightfoot, had been appointed. He succeeds Prof Sir Michael Rawlins GBE, Kt who has been the Chair of the Agency Board since December 2014. Stephen has been a Non-Executive Director of the Agency since September 2015.

The Secretariat informed members of the British Pharmacopoeia's response to the COVID-19 pandemic.

The Secretariat also informed members that the British Pharmacopoeia Commission will be recruiting new members to replace those whose terms are coming to an end which included the EAG BIO Chair who informed the group that he wished to remain a part of EAG BIO.

I MINUTES

358 The minutes and summary minutes of the meeting held on 13th September 2019 were confirmed.

II MATTERS ARISING FROM THE MINUTES

359 The following matters arising from the meeting held on 13th September 2019 were noted.

Oxytocin Injection (minute 346 refers) Secretariat was to investigate the addition of an acetate test in the Identification section of the Ph. Eur. API monograph for a future revision.

III EAG BIO STRATEGY

360 General Update BIO(20)02

The Secretariat updated members on the ongoing implementation of the MHRA's strategy for pharmacopoeial quality standards for biological medicines.

361 Update on the progress of WP ATMP BIO(20)03

Members were informed that Dr Jacqueline Barry had been approved as the Chair of the Working Party due to her extensive experience within the sector, her contribution to the development of the Accelerated Access Collaborative and the high engagement and support for the role of standards in supporting quality and innovation in the ATMP sector.

The Secretariat informed members about progress of the working party this year. The proposed way of working had been implemented since the first WP ATMP meeting and has seen the establishment of two subgroups each comprised of approximately six external expert members who focus on producing documentary guidance for their respective topics.

362 Update on the progress of BIO-DPS WP BIO(20)04

The BP Working Party: Alternative Approaches for documentary and physical standards for biotechnological products (WP BIO-DPS) had been established in 2018 to deliver an Agency commitment to explore the potential value of performance and class-based concepts in assuring the quality of biological medicines and enabling and supporting innovation.

A key aim for this group was to establish if performance or class based concepts allow greater flexibility throughout the product lifecycle including facilitation of changes in analytical technologies.

IV MONOGRAPHS IN PROGRESS

363 Heparin Injection BIO(20)05

The draft monograph would be included in a future publication, subject to resolution of any outstanding points

V MONOGRAPH REVISIONS

364 Low Molecular Weight Heparin BIO(20)06

Members were informed of recent amendments to the overarching European Pharmacopoeia text for Low-Molecular Weight Heparins (0828). The following amendments were made to Dalteparin Sodium Injection, Enoxaparin Sodium Injection, and Tinzaparin Sodium Injection monographs:

- The number of theoretical plates was deleted from the system suitability section.

- The following sentence was added to the Assay section *"Provided the equivalence with the below methods is demonstrated, the volumes below can be adjusted in order to use automated methods."*

VII WORK PROGRAMME AND EUROPEAN PHARMACOPOEIA

365 Work Programmes: BP and Ph. Eur. Biologicals Update BIO(20)07

BIO monographs included in the BP2021
Members were informed that three revised and one omitted BIO monographs had been included in the BP2021. The edition was published on August 1st and will be implemented on 1st January 2021. The monographs had all been discussed at the 2019 meeting of EAG BIO.

366 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.

367 Analytical Quality by Design Update BIO(20)08

The EAG had been provided an update on the Analytical Quality by Design (AQbD) project in 2019. Since this time, a full stakeholder consultation had been carried out and an official report produced by the MHRA.

Following the Consultation, the AQbD Working Party had been involved in a series of workshops to aid the digestion of the information gained from the consultation and to guide the Secretariat on the next steps for this project and the formation of the response. This response had released on the 11th August and was available at the following link: https://www.gov.uk/government/consultations/consultation-on-the-application-of-analytical-quality-by-design-aqbd-principles-to-pharmacopoeial-standards-for-medicines.

A major part of the Agency strategy would be to build capabilities across the Agency to drive forward regulatory science surrounding AQbD. This would include engagement and collaboration with all stakeholders and key global partners to collectively develop and implement these concepts as standard approaches throughout industry.

368 European Pharmacopoeia: Pharmeuropa BIO(20)09

Relevant comments were highlighted to members. BIO members were also encouraged to comment on BIO related monographs.

369 Texts adopted at the 165th, 166th, and 167th Sessions BIO(20)10

Lists of the documents relevant to the Group that had been adopted at the EPC over the past year were provided to members for information. Monographs related to the EAG BIO group were highlighted.

370 Adoption of Test for Bacterial Endotoxins using BIO(20)11

The European Pharmacopoeia had adopted a new general chapter titled "Test for Bacterial Endotoxins using Recombinant Factor C" at their 165th session which had been published in July 2020 with an effective date of 1st January 2021. The standard described how a bacterial endotoxin test (BET) using Recombinant Factor C (rFC) should be performed as an alternative to the classical LAL Assay and complemented the existing BET standards. It was noted that although the standard

was new, reference to rFC BET had been included in guidance in the European Pharmacopoeia since 2016 and stakeholders had been able to use a rFC BET as an alternative Assay in agreement with national competent authorities. One of the key drivers for the new standard was to reduce reliance on the supply of limulus amebocyte lysate (LAL) from horseshoe crabs.

The Ph. Eur. BET working group had prepared the text following a comprehensive review of available data on the equivalence of rFC to traditional LAL based BET which included a report from the PMDA endorsing this. Posted in Pharmeuropa 31.1 between January and April 2019, comments received were supportive.

371 European Pharmacopoeia – Biologics Update BIO(20)13

The BP Secretariat provided updates on work relevant to the work of the EAG to members.

Groups of Experts: Informal reports BIO(20)12

Informal reports, relevant to the work of the EAG, from UK representatives to Ph Eur Groups of Experts were shared with members.

VIII ANY OTHER BUSINESS

Date of next meeting: to be arranged.

List of Acronyms/Synonyms for use by BP Secretariat

Acronym/Synonym	Name
BAN	British Approved Name
BIO-DPS WP	Alternative Approaches for Documentary and Physical Standards for Biotechnological Products Working Party
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
MAB WP	Monoclonal Antibody Working Party
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