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 Wednesday 22nd September 2021 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, Dr V Loh, and Dr L Tsang.

Apologies: Dr A Pickett, Dr W Zunic.

In attendance: Mr A Gibb, Dr G Kemp and Mr R Smith.

372 Introductory remarks

Welcome
The Chair welcomed everyone to the meeting and noted Dr Kemp's return to supporting the work of EAG BIO.

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.

373 General Matters **BIO(21)01:**

Freedom of Information
Members were reminded that freedom of information requests should be referred to the Secretariat.

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

BIO membership list
Members were asked to inform the Secretariat of any changes to their contact details.

Organisational updates
The Secretariat informed members of notable MHRA/BP activity since the last meeting of EAG BIO.

I MINUTES

374 The minutes and summary minutes of the meeting held on 11th September 2020 were confirmed.

II MATTERS ARISING FROM THE MINUTES

375 The matters arising from the meeting held on 11th September 2020 were noted.

III EAG BIO STRATEGY

376 General Update BIO(21)02;

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

377 Update on the progress of WP ATMP BIO(21)03;

The Secretariat updated members on the progress of WP ATMP. New topics had been identified to be taken forward by new subgroups. These topics had been highlighted as most urgent and impactful by members of WP ATMP.

A public consultation for the flow cytometry guidance was held earlier in 2021, a short public consultation response document was published which summarised the recommendations from the consultation.

The vector copy number group had drafted guidance for public consultation which was available for comment until 27th September 2021.

378 Update on the progress of BIO-DPS WP BIO(21)04;

The Secretariat updated members on the progress of WP BIO-DPS including the ongoing laboratory study which was expected to be completed by the end of September 2021. The Secretariat noted that the results of the study will be evaluated and recommendations on the suitability of the alternative approaches to biological standards would be made to the British Pharmacopoeia Commission and the MHRA.

IV MONOGRAPHS

379 Serum Gonadotrophin Injection – for omission BIO(21)05;

The Ph. Eur. Serum Gonadotrophin drug substance monograph had been agreed for suspension by the European Pharmacopoeia Commission, therefore the BP Serum Gonadotrophin Injection monograph was considered unviable. Members agreed to omit the monograph.

Members questioned the impact on the Urofollitropin Injection monograph which also includes use of equine serum gonadotrophin IS. The Secretariat agreed to investigate.

380 Protamine Sulphate Injection - revision BIO(21)06;

Members were made aware that the European Pharmacopoeia drug substance monograph for Protamine Sulphate had been amended to include a second test to the Assay section. The Assay subsequently required a Protein content assay as well as the existing Potency assay.

Members agreed that the revised monograph was suitable as drafted but discussed whether adding the Protein content assay to the Protamine Sulphate Injection monograph would be beneficial.

381 **Supplementary Chapter IX Similar Biological Medicinal Products – revision/omission** **BIO(21)07;**

The Secretariat presented a paper that outlined revisions that were made to the text as result of the end of the Transition Period for the UK's exit from the EU, in addition to other minor updates resulting from changes to MHRA/BP policy. The Secretariat confirmed that the text had been published in BP 2022. The Secretariat noted the implementation of the MHRA's strategy for pharmacopoeial quality standards for biological medicines and changes to the biosimilar landscape since the first publication of Supplementary Chapter IX in BP 2012. Members were asked to comment on whether they thought the text should be retained as is, revised (if so, how?) or omitted.

Members indicated that the text still had value but noted the importance of considering the work of WP BIO-DPS in any revision of Supplementary Chapter IX. Members expressed a preference to wait for the conclusions of the current WP BIO-DPS project before embarking on a substantive revision.

382 **Veterinary Immunological Products Update** **BIO(21)08;**

Members were notified of a draft non-mandatory text outlining the minimum quality requirements for veterinary autogenous vaccines manufactured and / or administered in the UK. The text, likened to that of an unlicensed medicine for human use, was intended to be a Supplementary Chapter and reflected UK and Global requirements.

V **WORK PROGRAMME AND EUROPEAN PHARMACOPOEIA**

383 **Work Programme: BP Biologicals** **BIO(21)09;**

Members were informed that four revised BIO monographs had been included in the BP 2022. The edition was published on August 1st 2021 and would be implemented on 1st January 2022. The monographs included in BP 2022 had all been discussed at the 2020 meeting of EAG BIO.

Members were informed of the current EAG BIO work programme and were notified that current UK membership of Ph. Eur. Groups of Experts/Working Parties was available on pharmacopoeia.com or by request from the Secretariat.

384 **European Pharmacopoeia: Biologics update** **BIO(21)10;**

The BP Secretariat informed members of updates relevant to the work of EAG BIO, including the publication of draft standards from the Monoclonal antibodies Working party and the implementation of strategy to remove the rabbit pyrogen test from the Ph. Eur.

VI **ANY OTHER BUSINESS**

385 Members suggested that the BP should explore elaboration of standard for microbiome-based medicinal products.

386 The Chair stated that they would be stepping down after the meeting following the end of their term as a BP Commission member at the end of 2021. The Chair noted the excellent work that had developed from EAG BIO under their chairpersonship including WP BIO-DPS and WP ATMP.

Expert Advisory Group: Biologics and Biotechnological Products

List of Acronyms/Synonyms for use by BP Secretariat

Acronym/Synonym	Name
AAV	Adeno Associated Virus
APVMA	Australian Pesticides and Veterinary Medicines Authority
ATMP WP	Advanced Therapy Medicinal Products Working Party
AQbD	Analytical Quality by Design
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
CAR	Chimeric Antigen Receptor
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
MAH	Market Authorisation Holder

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
SC	Supplementary Chapter
SCB	Standards Coordinating Body for Regenerative Medicines
TGA	Therapeutic Goods Administration, Australia
TLC	Thin layer chromatography
UK	United Kingdom
UKD	United Kingdom Delegation [to the European Pharmacopoeia]
USP	United States Pharmacopeia
VMD	Veterinary Medicines Directive
WHO	World Health Organisation