BRITISH PHARMACOPOEIA COMMISSION

Working Party BIO-DPS: Alternative Approaches for Documentary and Physical Standards for Biotechnological Products.

SUMMARY MINUTES

A meeting of the Working Party was held at 10 South Colonnade, London E14 4PU on Wednesday 8th August 2019.

Present: Dr P Varley *(Chair)*, Dr A M Brady *(Vice Chair)*, Dr B Cowper, Dr V Ganeva, Dr B Rellahan, Mr C E Giartosio.

In attendance: Mr A Gibb, Mr J Pound, Dr G Kemp, Mr S Maddocks.

Apologies: Dr C Burns, Dr L Duhau, Dr M Wild, Dr A Ramzan, Dr L Randon.

Opening Remarks

Welcome The Chair welcomed everyone to the meeting and briefly stated the aims of the meeting. Members introduced themselves.

The Secretariat gave a brief general update of the MHRA and BP's activity since the last meeting in November 2018 and notified members of the planned public update on the MHRA's strategy for pharmacopoeial public quality standards for biological medicines.

9 General matters **BIO-DPS(19)01**

Emergency exit The emergency evacuation procedure was confirmed.

Duties of members Members had been provided details of their duties as experts on a British Pharmacopoeia Working Party.

Working Party membership The Working Party membership and contact details had been provided.

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

10 Minutes

The minutes and summary minutes of the meeting held on the 28th November were agreed.

11 Matters arising from the minutes

None.

12 Discussion Papers **BIO-DPS(19)02**

12.1 Progress review

The Secretariat presented an overview of the working party's progress. Members noted the considerable speed of the project and stated the importance of continued momentum.

12.2 WP AQbD update **BIO-DPS(19)03**

The Secretariat gave an overview of the MHRA study and consultation into applying Analytical Quality by Design concepts to pharmacopoeial standards. The importance of ensuring alignment of standards with regulatory authorities was noted – and the close collaboration during the project with MHRA colleagues including MHRA Licensing and Inspectorate staff was highlighted. The Secretariat noted that learnings from WP AQbD were being fed into the work of BIO-DPS.

12.3 Performance/Class-based standards **BIO-DPS(19)04**

Alternative standards were discussed including Performance, Capability, Structural Class and Functional Class based concepts.

Members discussed challenges with the current pharmacopoeial approach and described the potential benefits that alternative approaches could bring. Members also discussed the role that physical reference standards could play in an alternative standard and discussed whether the drafts standards should be mandatory or non-mandatory in nature.

12.4 Preliminary Laboratory work **BIO-DPS(19)05**

Members discussed preliminary laboratory work to facilitate a practical evaluation of the alternative approaches.

12.5 Draft Round Robin Laboratory Protocol **BIO-DPS(19)06**

Members discussed a potential plan to evaluate the alternative approaches in a multi-laboratory study, including the high-level objectives and resource required.

12.6 Agree next steps **BIO-DPS(19)07**

Members agreed to continue working with the Secretariat to further develop the alternative standards and plans for their evaluation.