

# BRITISH PHARMACOPOEIA COMMISSION

## Working Party ATMP: Advanced Therapy Medicinal Products 5<sup>th</sup> Meeting

### SUMMARY MINUTES

A meeting of the working party was held at 13:00 via MS Teams teleconference on Friday 25<sup>th</sup> November 2022.

**Present:** Jacqueline Barry (Chair), Clare Blue, David Caulfield, Franz Schnetzinger, Ian Anderson, Ilaria Santeramo, Jasbir Rattu, Josefina Nilsson, Juan Miguel Sánchez Nieto, Jenny McIntosh, Monica Pianella, Paul Getty, Rickard Nordstrom, Rita Rego, Ryan McCoy, Tishwant Kanwarjit, Victoria Vanhoutte, and Zara Hannoun.

**In attendance:** Ryan Smith, Kajetan Rakowski, Louise Bisset, and Elena Razzano.

**Apologies from:** Chris Burns, Mark Lowdell, Vicky Smith, Archie Lovatt, Kimberly Gilmour, John Campbell, Janet Glassford, Peng Wang, Stephen Vinter, and Huimin Tao.

#### 1. General Matters

ATMP(22)03

Jacqueline Barry reminded members that any Freedom of Information requests should be forwarded to the BP team. Members were also reminded of the confidential nature of the documents related to this work, and not to share anything marked as “Official Sensitive” outside of the group.

Members were asked to inform the BP team if their contact details had changed. A general list of Duties of members was attached to the meeting papers for reference.

A link to the 2021 annual report of the Human Medicine Regulations advisory bodies was included in the papers. The report was published in July 2022 and included the BP Commission Annual Report.

#### 2. Progress Report

ATMP(22)04

Ryan Smith informed the members that the ATMP guidance for Flow cytometry and Vector copy number were made freely available online and a link was included in the papers. The guidance was well received by stakeholders.

**2.1 Empty Capsids for AAV products** – members were informed that the empty capsids for AAV products subgroup received input and endorsement from the MHRA Assessors and Clinical Investigations and Trials colleagues regarding the methods covered. The guidance was agreed to be separated into three parts: “Characterisation of the Particle Population in AAV products”, “Encapsidated DNA characterisation”, and “Post translational modification”.

Part one of the guidance had been posted for its public consultation. This forthcoming guidance was made to help industry select appropriate analytical methods by considering strengths and limitations of some example methods that are commonly applied. The consultation period was set to be open until the end of January 2023.

**2.2 T and NK cell potency assay** – members were informed that a pre-consultation draft of the guidance has been included on the Forum.

**2.3 Awareness raising activities** – members were informed that Clare Blue and Franz Schnetzinger, the scientific leads of the Vector Copy Number (VCN) and Empty Capsids subgroups respectively, presented to BioPhorum members about the BP guidance at the Cell and Gene Therapy CGT13 event.

### **3. Horizon Scanning for WP ATMP**

**ATMP(22)05**

Ryan Smith presented a summary of the cell and gene therapy-related work that five key stakeholders had been working on; these included European Pharmacopoeia, United States Food and Drug Administration, Standards Coordinating Body for Regenerative Medicines, BioPhorum, and International Organization for Standardization. The members were reminded of the six previously identified topics for ATMP guidance that have been discussed at the third WP ATMP meeting in April 2021, two of which were taken forward by the WP. All topics were given an update regarding their status and coverage by the WP or other stakeholders.

Discussion was held within the group on the topics presented in the paper and further topics were suggested.

### **4. Mural Board Discussion**

**Verbal/Interactive**

At the end of the meeting, experts were asked to consider the two earlier papers and make recommendations to the British Pharmacopoeia on the next topics to focus on producing guidance for. Experts were asked to add comments around challenges and opportunities of creating guidance to a “Mural Board”, there were four pre-proposed topics and a section for other topics to be recommended. The contents of that discussion board have been summarised below.

#### **Closing remarks**

Elena Razzano and Victoria Vanhoutte informed the group that they would be leaving their current roles. The BP team informed Elena and Victoria that should they wish to continue contributing to the BP WP ATMP they should pass on their new contact e-mails to [ryan.smith@mhra.gov.uk](mailto:ryan.smith@mhra.gov.uk). Ryan McCoy thanked both Elena and Victoria for their valuable contributions to the groups work.

The Chair thanked everyone and informed the group that the BP team would be in touch via email correspondence to arrange a 2023 meeting and gain endorsement on proposals on future work established during this meeting.