

**BRITISH PHARMACOPOEIA COMMISSION**

**Working Party ATMP: Advanced Therapy Medicinal Products 2<sup>nd</sup> Meeting**

**SUMMARY MINUTES**

A meeting of the working party was held via MS Teams teleconference on Wednesday 19<sup>th</sup> August 2020.

**Present:** Jacqueline Barry (Chair), Isobel Searing, Elsa Abranches, Alison Niewiarowska, Clare Blue, Franz Schnetzinger, James Norton, James Towler, Jasbir Rattu, Len Pattenden, Victoria Robertson, Moira Francois, Ryan McCoy, John Campbell, Ilaria Santeramo, Stephen Vinter, Beata Surmacz-Cordle, and Archie Lovatt.

**In attendance:** Alistair Gibb and Ryan Smith.

**Apologies from:** Yuan Zhao, Anna Nowocin, Kimberley Gilmour, Cristina Trento, and James Pound

**Opening Remarks**

**Welcome** The Chair welcomed all members to the meeting. New members introduced themselves and gave brief overviews of their background experience in relation to the work of the working party subgroups.

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

**1. General Matters**

ATMP(20)01

**Duties of members** Members had been provided details of their duties as experts on a British Pharmacopoeia (BP) Working Party (WP). These had been taken from volume one of the BP.

**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.

**Declaration of Interests** Prior to the meeting all members had submitted a declaration of interest form. The Chair asked members to declare any interests at the start of the meeting and prior to the relevant agenda item

**2. Progress Report**

ATMP(20)04

Members were reminded of the agreed upon way of working and updated on the membership of the subgroups including the scientific leads and informed about the frequency of meetings.

A snapshot of the work produced by each subgroup was shared with WP ATMP, the material was discussed later in the meeting during the subgroup presentations.

The proposed way of working had been implemented and the Secretariat indicated good progress had been made by each subgroup thus far. It was outlined that to be able to meet the

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diverse requirements set for the guidance, the way of working needed to be nimble and flexible.

### **3. Flow Cytometry and Vector Copy Number Discussion and Feedback Session**

Presentations were given by the scientific leads of the flow cytometry and vector copy number subgroups. The presentations lasted approximately 45 minutes each and were broken up into several sections. Each presentation was followed by discussion from the group members, recommendations were made, and potential oversights highlighted. The scientific leads of the subgroup agreed to take the discussion points back to the next subgroup meetings for the final decision.

### **4. Next Steps for the WP ATMP**

Secretariat plans for the external review process were made known to WP ATMP. Key stakeholders were outlined and potential routes to publication explored.

The potential establishment of a third subgroup was also discussed with a focus on the capacity to support such work and what topic should be prioritised if additional work was possible.

### **5. Advanced Therapy Collaborations**

ATMP(20)05

The Secretariat spoke about how the Agency had recently engaged more broadly regarding ATMPs. It was said that several meetings had been held throughout late spring and summer with key stakeholders. These meetings focussed on understanding the work one another had carried out and recognising potential opportunities for collaboration.