

**BRITISH PHARMACOPOEIA COMMISSION**

**Working Party ATMP: Advanced Therapy Medicinal Products**

**SUMMARY MINUTES**

A meeting of the working party was held via Zoom teleconference on Tuesday 14<sup>th</sup> April 2020.

**Present:** Jacqueline Barry (Chair), Elsa Abranches, Ian Rees, Janet Glassford, Alison Niewiarowska, Clare Blue, Franz Schnetzinger, Cristina Trento, James Norton, James Towler, Jasbir Rattu, Len Pattenden, Roy Cowell, Victoria Robertson, Moïra François, Ryan McCoy, Isobel Searing, David Caulfield, James Pound, Alistair Gibb, Ryan Smith.

**Opening Remarks**

**Welcome** The Chair welcomed all members to the meeting. Members introduced themselves and gave brief overviews of their background experience in relation to the work of the working party during the breakout session rather than the plenary session due to timing constraints and the large group size.

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

**Objectives** A brief outline of the objectives of the working party was described to the group by the Chair.

**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. No conflicts of interest were identified.

**2. Overview**

**ATMP(20)02**

Background about the Agency's consultation on Strategy for Pharmacopoeial public quality standards for biological medicines was presented by the Secretariat. This work was supported

## **Working Party on Advanced Therapy Medicinal Products**

by a Cross-agency group involving MHRA Licensing Department, NIBSC and the British Pharmacopoeia. The Working Party for Advanced Therapy Medicinal Products (WP ATMP) had been established as a result of the strategic work programme.

### **3. Workshop and Discussion**

**ATMP(20)03**

It was noted that this work was endorsed by people at the highest levels within the Agency. WP ATMP members were split into three groups to discuss topics that have been identified as priority areas for producing guidance. Several potential topic areas were discussed within breakout groups and flow cytometry and vector copy number were highlighted as priority areas. There was agreement that physical standards need to be relevant over a long period of time whereas documentary standards have the advantage of being editable when necessary. It was generally thought that the topic areas were very broad, and any documentary guidance would need to be clearly defined in terms of scope before the work began.

### **4. Ways of working**

It was suggested to the group that a subgroup was formed for each topic to provide documentary guidance. Each subgroup would be led by a member of the WP ATMP and include external experts.

An aspirational goal of having a draft guidance for flow cytometry and viral copy number was proposed to be ready within three months for the next WP ATMP meeting.

Volunteers were requested from the group to lead and/or support the subgroups, they were asked to correspond via e-mail if they did not wish to volunteer in the meeting.