News story: Pharmacopoeial biological standards assure the quality of biological medicines

In January 2017, MHRA launched a public consultation on pharmacopoeial quality standards for biological medicines.

The quality of biological medicines, which are an increasingly important part of healthcare worldwide, is assured by a regulatory framework which includes compliance to public quality standards. Documentary and physical standards work together to make sure biological medicines are of acceptable quality for use by patients.

The consultation posed specific questions to understand stakeholders' perspectives on biological medicines, how biological quality standards should be developed, what they should look like and how they can enable innovation, and how the Agency can best engage with users. The consultation was received positively by stakeholders and a wide range of responses were received representing trade associations, manufacturers, academia/researchers and peer organisations.

The responses were analysed by a cross-Agency group, and the key themes of value and innovation, Agency role, alternative approaches and unmet needs, collaboration and international engagement were drawn out:

- Value and innovation: in general, responses supported the value of standardisation as an important activity in ensuring the quality of medicines
- Agency role: the Agency, through its unique incorporation of the regulatory and standard setting functions (BP and NIBSC), is well placed to make an important contribution to the development of biological standards.
- Alternative approaches and unmet needs: alternative approaches and unmet needs identified by stakeholders were focussed on standards for biotechnologically produced proteins, raw materials and ATMPs.
- Collaboration: the opportunity to engage with the Agency on the draft strategy was commended and there was a clear desire for the Agency to continue to do this going forward, including offers of collaboration
- International engagement: consistent throughout the responses was the need for MHRA to engage with, and influence, the international regulatory and standard setting environment

The response document published today sets out how the Agency plans to incorporate the feedback we received from stakeholders into its strategy and the resultant work programme.

The work programme relates to key activities we are committed to undertaking to implement our strategy for pharmacopoeial standards for biological

medicines. The activities fall into 3 broad categories: standards development; engaging with users and building knowledge; our international peers. Key points are:

- Establishing three working parties with representatives from MHRA regulatory, British Pharmacopoeia, NIBSC and experts from industry and academia to explore alternative approaches, ATMPs and Raw materials
- A number of activities to continually engage stakeholders in the work including a 2018 symposium Maintaining our active roles and relationships internationally

We would like to thank all those who shared their views with us. If you have any further questions on the consultation response, please contact us on BiolStandards@mhra.gov.uk.