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.

Press release: PM call with Prime Minister Abe: 23 October 2017

This morning the Prime Minister called Prime Minister Shinzo Abe of Japan to congratulate him on his success in the Japanese general election.

The Prime Minister and Prime Minister Abe discussed North Korea and agreed to continue to work with the international community to maintain pressure on the regime to cease its destabilising activity. They noted the role the UK played in the EU agreeing tough sanctions on North Korea last week.

The leaders reflected on the Prime Minister's successful visit to Japan in August and the positive impact it has had on UK-Japan relations. They looked forward to deepening ties between our two countries on trade, security and defence.

The Prime Minister also offered Prime Minister Abe her condolences on the impact and loss of life caused by Typhoon Lan.

News story: Making viral vectors for advanced therapies: apply for funding

Businesses can apply for a share of £16 million for manufacturing viral vectors for cell and gene therapy – part of the Industrial Strategy Challenge Fund.

Innovate UK has up to £16 million to invest in capital projects that support the growth of manufacturing capacity for viral vectors used in cell and gene therapies.

Commercial opportunities in advanced therapies

Advanced therapy medicinal products are emerging medicines that use cells, genes or engineered tissues to treat patients.

These therapies usually involve delivery of the treatment by a virus. The therapeutic gene is carried in a viral vector.

It is estimated that the global market for regenerative medicine and cell therapies could be more than $67 billion by 2020 and for gene therapy $11 billion by 2025. While the UK is at the forefront of research into these new therapies, there is a shortage of capacity for making viral vectors. We need to act to take advantage of the commercial opportunities.

The funding for this competition is under the government's Industrial Strategy Challenge Fund to develop first-of-a-kind technologies for the manufacture of medicines.

Encouraging public and private partnerships

Funding in this competition is for capital investment in equipment that can be used for making viral vectors. This can include refurbishment.

Projects must:

- advance UK ability to produce viral vectors for use in advanced therapies
- encourage partnerships between public and private organisations and maximise further investment

Successful projects are likely to include ones that:

- create infrastructure that fast-tracks research, development, production and commercialisation of viral vectors
- increase UK commercial capacity
- increase competitiveness of the lead business

Competition information

- the competition is open, and the deadline for registration is midday on 8 November 2017
- projects must be led by a business with a viral vector manufacturing facility, working alone or with partners
- we expect projects will range in size from total costs of £2 million to £6 million
- businesses can attract up to 50% of their project costs

Press release: Dstl analyst supports military in hurricane-hit Caribbean

Richard Hoyes, an operational analyst based at Portsdown West, deployed to the Caribbean to support the military following the devastation caused by Hurricanes Irma and Maria.

With just 3 days' notice Richard travelled to Barbados to join the military part of the Humanitarian Aid and Disaster Relief (HADR) Operations on the island. He provided operational analysis to the headquarters of the HADR Operations, focusing on how best to move people and freight across the many Caribbean islands with the aircraft available, and planning deployment of military force back to the UK.

Richard worked with the military, other government departments and civilian organisations. He said:

> The conditions in Barbados were very different to working in a lab, but it was highly rewarding to be part of supporting the aid of the islands. I felt my analytical experience was put to good use and I hope that I made a difference helping the islands get back on their feet.

Richard is just one of more than 30 members of Dstl staff who are trained and ready to deploy anywhere in the world in support of military operations. As part of Dstl's support to operations capability, Dstl has a pool of operational analysts and scientific advisers who can support the military at a moment's notice and even deploy on operations.

Dstl also has a 24-hour, 365-day 'reachback' capability, which provides rapid access to the breadth and depth of Dstl's capabilities in support of military operations. This could include anything from computer modelling and highly detailed scientific advice to a review of previous research studies for similar issues.

Press release: Minister for Europe opens Strategic Dialogue with Georgia

Minister for Europe and Americas, Sir Alan Duncan, will today [October 23]

welcome Deputy Prime Minister and Foreign Minister of Georgia, Mikheil Janelidze for the fourth round of the UK-Georgia annual strategic dialogue, known as the Wardrop Dialogue.

Deputy Prime Minister Janelidze's will also meet Foreign Secretary Boris Johnson before joining the Lord Mayor at Mansion House for talks on business links.

Georgian Defence Minister, Levan Izoria, is also visiting London to participate in the Dialogue and will meet Defence Secretary Sir Michael Fallon.

Relations between the governments of the UK and Georgia are at an all-time high. The dialogue will provide an opportunity to discuss continued co-operation on trade, defence, and mutual values, which underpin the strength of our ties.

Minister for Europe Sir Alan Duncan said:

> Our relations with Georgia are stronger than ever, and I'm delighted that Deputy Prime Minister Mikheil Janelidze visited London for the fourth round of our annual Wardrop Dialogue.
>
> The UK stands by Georgia in support of its territorial integrity, security, and ambitious reform agenda. This commitment is underlined by our Good Governance Fund, through which the UK helps Georgia to deliver necessary reforms, and reach its economic potential.
>
> As the UK leaves the European Union, we are ensuring our relationship with Georgia will continue to grow. Trade will be an important element and the Prime Minister's appointment of Mark Pritchard as our new Trade Envoy reiterates our optimism over the future of UK-Georgian trade.
>
> Not only is Georgia a role-model in the region for reform, democracy and human rights; they also play a pivotal role in the wider security of the region in the face of external pressures. We also support the positive role the EU plays in the region, which we expect to be reiterated at the Eastern Partnership Summit in Brussels in November.

Further information