News story: Richard Pennycook appointed Lead Non-Executive Board Member

The Department for Education has announced today, Monday 23 October, the appointment of Richard Pennycook to the Board as Lead Non-Executive Board Member.

As the former CEO of The Co-Operative Group, Richard has first-hand experience in change management and staff engagement, and in creating a workplace driven by core values. This background makes Richard the ideal candidate to work with our leadership team on the Building Our Department Together programme, making our Department an even better place to work.

The Secretary of State for Education, Justine Greening, has appointed Richard to support her role as chair of the Board, and to engage with a wide range of people across the Department. He will work closely with the Permanent Secretary to ensure the Department is meeting its strategic priorities. He will also bring together the commercial and management expertise of our Non-Executive Board members to offer robust advice and challenge.

Richard Pennycook said:

> I am honoured to have been appointed as the Lead Non-Executive on the DfE Board. I look forward to taking on the challenge and to supporting the people who deliver some of our most important public services; including educating our children and young people and safeguarding those who are at risk.

Education Secretary Justine Greening, said:

> I am delighted that Richard has agreed to be our Lead Non-Executive. The Board plays a vital role in helping our Department to work efficiently and strategically. Richard's experience in driving change, creating a values-based culture and engaging with staff will be crucial in helping us to build our capability.

Permanent Secretary, Jonathan Slater, said:

> I'm looking forward to working closely with Richard to achieve our key objectives, in particular making the Department a great place to work for our staff. I know that our colleagues will join me in warmly welcoming Richard to the Department.

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.

Consultation outcome: Proposed Control of Mercury (Enforcement) Regulations

2017

Updated: Summary of responses and government response added.

We want to know what you think about how we plan to enforce controls on mercury in the UK. The controls will apply the requirements of EU Regulation 2017/852 on mercury.

We are interested in the views of those in industries that use mercury or deal with mercury waste, as well as those involved in dentistry. In particular, we would like to hear whether you view the approach proposed as being appropriate and proportionate.

This is a joint consultation led in England by Defra, the Department for Business, Energy and Industrial Strategy (BEIS), with input from the Department of Health. In the Devolved Administrations it has been led by the Scottish Government, the Welsh Government, the Department of Agriculture, Environment and Rural Affairs (Northern Ireland) and the Department of Health (Northern Ireland).

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