

External Affairs Working Party Meeting Minutes – 18 March

Apologies – Gregg Quinn and Jo Martin

Doris-Ann Williams (DAW) read out the Competition Law notice to attendees.

Working Party Chair Ollie Mitchell (OM) addressed the previous meeting notes and no actions needed the group's attention.

Guest Speaker presentation from Dr John Tyson, Head of the Innovation Lab at the Integrated COVID Hub North East:

- Dr John spoke about the Innovation Lab's work in response to COVID and their ambitions to support of the UK's IVD industry
- The Innovation Lab was created following the pandemic with the aim of establishing a comprehensive and accessible biobank, futureproofing diagnostics, being 'pandemic-ready' for the future, and forging partnerships to accelerate the development and adoption of next-generation diagnostics.
- Utilising their four laboratories, the Innovation Lab has helped the development of diagnostic tests by providing samples and other assistance for both early and late-stage projects
- They have chiefly worked to 'test tests' by analysing their sensitivity and usability among others, as well as assisting with regulatory submissions
- These include LFTs, point-of-care PCR tests, central lab PCR tests and antibody tests
- Their data expertise can be applied to all IVDs, not just COVID tests
- A key advantage of their being part of a hospital is their ability to collect, bank, store and provide samples for new diagnostic tests – mainly sourced from lab samples, hospital inpatients and community samples
- 66 company engagement, 23 projects and 20,000 banked samples in the past year
- Majority of work is UK-based but deal with international companies too, including those as far afield as China and Australia
- Established a rapid response variant of concern testing team to identify different strains. Also monitored air and waste water to try to identify new variants and pathogens

Guest Speaker presentation from Stevan Cirkovic, Senior Policy Lead (MedTech Regulation) at DHSC:

- Stevan spoke at greater length about the proposed legislation regarding mandatory reporting of industry payments to increase transparency and accountability
- The Cumberlege Review called for manufacturers to publish details of payments to teaching hospitals, research institutions and clinicians
- Intended to effectively model the US Sunshine Act, following patient group consultations
- The legislation aims to: improve patient and public trust in professionals, ensure clinicians make decisions independently from payments, and protect and enhance the standing of the UK Life Sciences Sector
- This is included in the Health and Care Bill and Stevan and his team are working on a public consultation which will be released in the coming months

- The proposed legislation (Clause 81) also stipulates that companies can be exempt from the stated requirements if the equivalent information is published elsewhere via an alternative reporting system
- DHSC are still deciding the scope of reporting and are currently conducting a data protection impact assessment
- Stevan opened the floor to attendees to give feedback about the proposed legislation and pose any questions
- Following a question, Stevan confirms that payment reporting would apply to both individuals and organisations subject to consultation
- Stevan stated that these regulations would probably be implemented in March 2023, with a transition period in 2024 and reporting only starting in 2025, with no retrospective reporting planned
- Stevan urged attendees to respond to the public consultation to ensure that business operationality is successfully maintained while reporting is undertaken
- Doris-Ann stated that BIVDA could, if helpful, provide an industry response to the proposed legislation by mid-April

Summary of current BIVDA activities – Doris Ann-Williams

- BIVDA attended the IBMS Congress in Birmingham, providing an excellent forum for stakeholder and member engagement
- DAW, Michael and Ben attended the APPG for Life Sciences, led by Daniel Zeichner MP, and included presentations from Diagnostics in the Real World and AstraZeneca
- DAW attended a reception held by the APPG for Medical Research and Academy for Medical Science for COVID Research during the Pandemic. It was another great opportunity to engage with high-profile figures such as Jenny Harries
- DAW regretted that Louise Wood from NIHR is leaving her job, acknowledging that she will be a hard person to replace and has always been a good ally
- DAW met with Earl Howe, current Deputy HoL Leader, at the aforementioned reception and will explore the Health and Care Bill with him in the future
- DAW had a meeting regarding the next stage of the Diagnostics Strategy. The DS has been moved into the MedTech Directorate and will be published in the summer as a separate piece of the Medical Technology Strategy. A trade association led roundtable on the subject will occur next week
- The DS team has previously been repurposed to focus on clearing the backlog, therefore BIVDA will engage with them to ensure testing is a key part of their strategy
- Jack Attard from DHSC will be in attendance at the AGM to provide a fuller explanation of the DS to attendees
- BIVDA were due to have a bilateral meeting with June Raine and the senior management team at MHRA which was cancelled. DA wrote a note expressing extreme disappointment and now has another date set in the diary. This is particularly important as MHRA are losing many talented individuals with diagnostics expertise, much to DA's alarm

AOBs – none

Action:

DA and/or Helen to discuss the proposed legislative changes and their impact at the MedTech trade association forum

Next meeting date:

The next External Affairs Working Party will take place at **9:30-10:30 on Friday 15th April**. [Register here.](#)