

External Affairs Working Party Meeting Minutes – 17th September

Apologies – None received.

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

Ollie Mitchell (OM) addressed the previous meeting minutes and no actions needed the group's attention.

BIVDA Current Activities and Issues – Doris-Ann Williams

- Doris-Ann addressed the launch of the future medical devices Consultation by MHRA, saying that BIVDA received advance warning of its release, there are 10 weeks left until response deadline. BIVDA is working on an industry response to be led by the Regulatory Affairs Working party sub-group on UKCA marking.
- On a further note to Consultations, at least one more webinar will be held on the laboratory evaluation Consultation on COVID-19 Antigen & Molecular test laboratory validation testing. This is to be held by BIVDA and ABHI jointly.
- Regarding the Diagnostics Strategy, there is a strong emphasis on IVDs coming out through the discussions. There have been three workshops hosted by BIVDA, MediLinks and ABHI on different aspects. BIVDA hosted the webinar on 'Access and Adoption by the NHS'. Next week, there is a roundtable on the Strategy on Thursday, which Doris-Ann will be attending. The Strategy is not a policy document itself, but a gathering of information to push a funding bid into the Comprehensive Spending Review to secure investment in diagnostics.
- AMR, Long COVID and Sepsis are being rolled into one type of issue, as Long COVID has a lot of similarity with post-Sepsis conditions (people experience infection post-Sepsis and be affected for up to seven years).
- Regarding the Blood Collection Tube issue, BIVDA is reassured by BD that it is 'business as usual' now. It was a combination of issues that led to the problem, and certain lessons on Procurement arrangements are to be taken from the supply issues.
- BIVDA is proposing to join the Royal College of Radiologists and the Royal College of Pathologists' steering group on a new APPG for Diagnostics. This will be a positive step, with industry supporting the professions to raise awareness of the importance of diagnostics.
- Helen stated that regarding COP26, there will be activity from BIVDA

BIVDA Activity Update – Helen Dent

- HD presented the upcoming activities based on the strategic-operational Workplan for 2021. The core programme is derived from the Chairs Meeting at BIVDA.
- There are 24 x Public Programmes which are of importance to BIVDA, including Accelerated Access Collaborative, implementing of the Life Sciences Vision and GIRFT which are relevant to NICE.
- The slides presented the Strategic Pillars from September to December 2021. Market Access, External Affairs, Membership and Organisation are the strategic pillars.
- These cover market access, external affairs, membership and the organisation. BIVDA is currently recruiting a new Policy Officer and Regulatory Affairs Manager, as well completing a PR project, working towards COP26 and there remain two Policy Papers to be completed and released.

AOB: There were no AOB's from the attendees.

The next External Affairs Working Party will take place from 10.30am – 11.30am on Friday 22 October.

END