To:

Cc:

Subject: Meeting with representatives of AdvaMed, 28 October
Attachments: AdvaMed - MTE joint statement for the TTC.pdf, 26102022_MDR implementation_Urgent Need for Legislative Action.pdf

and I met last Friday (28 October) with representatives of the Advanced Medical Technology Association, AdvaMed [redacted] and [redacted] at their request. They wanted both to introduce themselves to [redacted] and to raise two issues of concern of the US industry – market access difficulties in China and implementation of the EU Medical Devices Regulation.

On the various problems in China, they noted that they were working closely with MedTech Europe and had prepared a shared analysis of market access barriers (attached, although I expect you’ve seen this before). They hoped that there would be a further mention of the issue in the joint declaration to be agreed at TTC3, as a way to maintain its visibility. They also wanted to explore what might be the next concrete steps to put pressure on China – was the EU raising the matter bilaterally? could the EU take this up under the International Procurement Instrument? (In this context, it would be good to know from you if there have been any contacts with MedTech over a possible IPI complaint, and what is the evidence level threshold to be met for an IPI investigation to be launched. Is there any guidance or presentational material we can share with AdvaMed or other US stakeholders?)

On the EU Medical Devices Regulation (745/2017), AdvaMed shared the attached industry letter of 26 October, co-signed by a large number of MedTech companies, including ones from the EU, calling for legislative action to extend the validity of existing Medical Devices Directive and Active Implantable Medical Devices Directive Certificates, allow conditional and/or temporary MDR certification, and abolish the MDR Article 120(4) “warehousing” deadline. The letter is addressed to the Czech Deputy Prime Minister and Minister of Health, but has also been shared with EU Member State Health Ministers, certain MEPs and Commissioners Breton, Gabriel and Kyriakides.
The AdvaMed representatives underlined that at the present rate of product approvals, and with insufficient EU certification bodies to handle the work, there was no way industry could comply with EU regulatory requirements in time. This would force reputable US companies to exit the EU market.

I would recall that the Medical Devices Regulation is something that is regularly raised by US industry (including in EVP Dombrovskis' meeting with the US Chamber of Commerce last month). Thanks in advance for sharing the latest LTT – that would be very useful for us!

with best wishes