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From:
                      (SANTE)
Sent: Monday, September 23, 2019 3:33 PM
To: VINCIUNAS Arunas (CAB-ANDRIUKAITIS)
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Anne (SANTE) <
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Subject: BTO Report -Head of cabinet meeting with
                                                             and
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Abbott
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MEETING BETWEEN HEAD OF CABINET AND ABBOTT COMPANY

Date: 17 September 2019

Participants

Commission: A. Vinciunas (AV), (SANTE B4)

Abbott Company:

This was the first meeting with Abbott. gave a short introduction on the company:

- It focuses on medical devices, diagnostic, pharmaceuticals (emerging market) and nutrition;
- The EU is not a huge market for Abbott except for some manufacturers based in the Netherlands, Ireland, Spain and Denmark;
- Abbott is keen to export EU standards worldwide, in particular in food safety, and expressed the willingness to engage more at EU level.

Medical devices

- Abbott fully supports the medical devices and in vitro diagnostic medical devices regulations. It invested massively to be ready for implementation from May 2020 but expressed concerns and challenges on timelines. Other concerns are the current lack of alignment between EU and Turkish regulatory systems and the scope of the medical devices regulation (class I devices);
- AV explained the peculiar political momentum, the importance of avoiding any further delay in the implementation and the need for availability of Notified Bodies.
 AV confirmed that the Commission estimates that 20 Notified Bodies will be available by end of 2019 and reinsured Abbott that common efforts are being

- undertaken by the current Commission (DG GROW) and MS to monitor the situation and identify technical solutions.
- On Turkey, AV promised to come back to Abbott but suggested that it is for Turkey to adapt its legislation.

Brexit

- Abbott explained that one of their key region for operations is UK and Ireland (85% of liquid skim milk in Northern Ireland) and asked AV the impact that Brexit could have in a no-deal scenario and how they can secure their production (milk produced in NI, but treated in IE);
- AV explained that no guarantees can be given in case of no deal, and a lot will depend on reciprocal actions by the UK. However, the EU is working on contingency plans since the beginning of Brexit discussions to protect EU market.

HTA

- Abbott fully supports the HTA proposal for a regulation, asked to be updated on the current negotiations in Council and explained why they, together with MedTech, believe that medical devices should not be included in the scope of the HTA proposal;
- AV mentioned that progress is being made in Council but that there are still negative countries. AV explained that the mandatory uptake must be understood as an obligation to not duplicate requests to industries to submit the same data to undertake the same clinical analysis. AV stressed that the Finnish presidency will start discussions on the legal text of the most controversial articles (articles 7 and 8 of the Austrian proposal). Discussions on the scope are taking place in Council and specific characteristics of medical devices are acknowledged.

Nutrition

- Abbott is active in the fight against infant obesity and called for an EU regulatory framework. Also, Abbott express the need to revise EU regulation on chlorine;
- AV shared the concerns and invited Abbott to raise these issues with the forthcoming Commission.

Priorities of DG SANTE for the next months and forthcoming term

AV invited Abbott to read the Mission letter to Commissioner-designate Kyriakides
where the main priorities of DG SANTE are outlined (cancer, nutrition,
pharmaceuticals, e-health, supply of affordable medicines etc).

END