From: [redacted] (TRADE)
Sent: jeudi 1 octobre 2020 12:07
To: [redacted] (EMA); VGTO ([redacted]; [redacted]@efpia.eu'; [redacted]@novonordisk.com'; [redacted]@danskerhverv.dk'; [redacted]@efpia.eu'; [redacted]@efpia.eu'; [redacted]@efpia.eu'; [redacted]@efpia.eu'; [redacted] (SANTE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (SANTE)
Cc: [redacted] EEAS-TOKYO); [redacted] (EEAS-TOKYO)
Subject: Meeting 28-09-2020 between European Commission, Danish Chamber of Commerce and Novo Nordisk
Attachments: Meeting with the EU Commission 28092020 VGTO_STPE_Bremerskov.pptx

Dear participants,

Once again, I would like to thank you for attending the meeting on Monday. We hope that the discussion allowed to shed some light on the issue amongst all present participants.

I take this opportunity to summarize the discussion and outline the next steps. I also attach the presentation kindly shared by [redacted]

Summary of the discussion:

- EFPIA, the Danish Chamber of Commerce and Novo Nordisk raised concerns about repeated unnecessary and duplicate paper based and possibly on-site inspections by the Japanese competent health authorities (MHLW/PMDA), notably in Denmark but possibly also in other MS.

- In order to ensure follow up and also with the view to identify practices that would qualify as violations of the MRA, the Commission reiterated its request to industry to share concrete examples of duplication of approval procedures and excessive demands.

- Based on the description of the situation by the participants of the meeting, there seems to be different assessment/inspection practices between the regulators of the two parties. This could explain the claim by the industry of an absence of reciprocity and the important request of additional documents during a Japanese paper-based inspection in comparison with Danish inspection.

- Industry has provided the attached presentation to be shared with the Japanese authorities (PMDA, etc.) through the kind assistance of Kishioka-san, liaison officer at EMA who will liaise with MHLW/PMDA and will discuss the matter based on concrete examples. [redacted] explained during the meeting that the text of the MRA was clearly restricted to on-site inspections (Article 2 d of the sectoral annex). As for the objective of the paper based inspection, he explained that even when a GMP certificate by MRA partner exists, it may link to a potential difference in the scope of “GMP inspection” and the role of assessors/inspectors. The paper based inspection is a “product-based inspection ” which includes the assessment of the control of a specific product in addition to other aspects such as equipment, utilities and facilities, and system.

-MHLW/PMDA will look into the elements provided in the attached presentation and pget back to the Commission with additional comments. Based on the information provided above by MHLW/PMDA and additional information on the concrete examples the industry has been asked to provide, the Commission will then determine the best way of proceeding in order to try to respond to the industry's concerns.

Best regards,

[redacted]

[redacted]

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