From: [redacted] (SANTE)
Sent: vendredi 5 février 2021 16:12
To: [redacted] (SANTE)
Cc: [redacted] (SANTE)
Subject: FW: NIP - Discussion with EFPIA
Attachments: EFPIA issues for meeting with DG Sante (5 February 2021).docx

[redacted],

This is a brief report of the today's BREXIT meeting we had today with the EFPIA representatives: [redacted]
From Sante the participants were: [redacted].

The industry representatives welcome the EU-UK TCA and happy to have the annex on medicines, however they are disappointed to see that it does not include the batch testing. They also pointed out that the COM BREXIT notice is helpful however there are still technical issues as regards the implementation of the Notice that is challenging.

The technical issues raised were related to:

- The deletion of the UK batch release sites during 12-month phase-in period: Member states implementation of the Commission Notice (2021/C 27/08). –

To this DG SANTE explained the COM BREXIT Notice and informed that MS are also further discussing thiss aspects in the CMDh and there would be an update of the CMDh practical guidance. DG SANTE inquired how many sites and products are concerned? Industry informed that they do not have the information at hand, however they will further inquire this.

- Location of MAH for Marketing Authorisations which include Northern Ireland within their scope: clarification needed on implementation by end of 2020 in order to avoid delays in applications and subsequent supply of medicines.

DG Sante explained the framework rules and the explaiantions given in the previsous COM BREXIT guidances or EMA or CMDh practical guidances on this issues. DG Sante inquired how many products or sites are concerned? Industry could not reply to this question however they will further inquire about this and let us know. Industry underlined that they face challenges how to move the MAHs from GB.

- Lack of MHRA access to EMA Common Repository and CESP: duplication of effort/resources.

DG Sante explained the framework about the access given to the UK to the EU EMA Databases and the COM Decision is implementing the NI Protocol and took note of the issue raised by the industry.
In addition, industry raised the fact that beyond BREXIT they have experienced that the requirements for the import licenses requirements are not harmonized between MS.
DG Sante invited the industry to raise the issues with the MS or via the IWG stakeholders meetings. In case these issues relate to the customs issues then these should be discussed with the MS customs authorities or the DG Taxud.
As regards the application of the COM Brexit Notice, industry informed that the timeframe given until the end of 2021 is helpful, however there are some outstanding issues as practical issues related to the supply in the NI and QC testing. Industry is looking to find alternative supply routes to NI. Industry

inquired whether en extension could be possible, however from DG SANTE side we could not reply at such a political question at our technical level.

In case you would like to add something else, just let me know.

Thank you, best wishes,
[redacted]

From: [redacted] @efpia.eu>
Sent: Tuesday, February 2, 2021 3:02 PM
To: [redacted] (SANTE) <[redacted] @ec.europa.eu>
Cc: [redacted] @efpia.eu>; [redacted] (SANTE) <[redacted] @ec.europa.eu>
Subject: Re: NIP - Discussion with EFPIA

Dear [redacted],

Many thanks for taking time this coming Friday for a discussion with us! We have consulted our relevant expert groups to collect the most urgent outstanding issues, which you will find in the attached document. (I tried to regroup by topic). I hope this is helpful in advance of the meeting and we remain at your disposal for any questions you may have!

I have sent through the list of participants from our side to [redacted], who very kindly already sent the invitations out yesterday. I was wondering if you could confirm who will be attending from your side (besides Ms. [redacted] and yourself.)

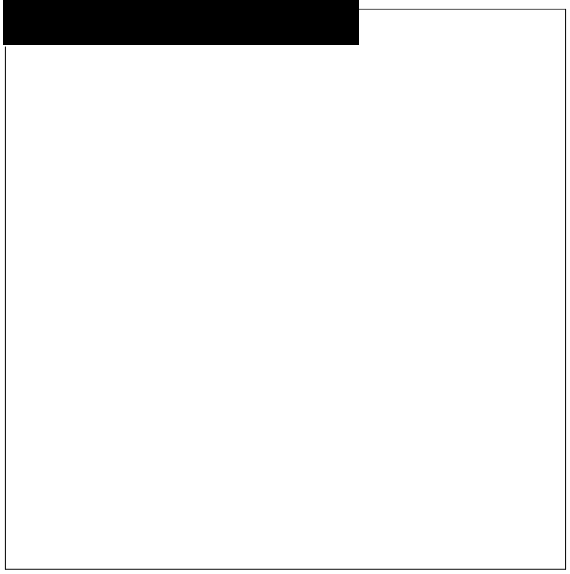
Thanks again and best regards,

[redacted]

[redacted]

EFPIA - European Federation of Pharmaceutical Industries and Associations
Leopold Plaza Building
Rue du Trône 108

B-1050 Bruxelles
[redacted]



On Tue, 19 Jan 2021 at 10:31, [redacted] <[redacted]@ec.europa.eu> wrote:

> Dear [redacted]
>
> Thank you for your email. [redacted] will organise a meeting.
>
> Kind regards,
>
> [redacted]
>
> **From:** [redacted]@efpia.eu>
> **Sent:** Tuesday, January 19, 2021 8:34 AM
> **To:** [redacted] (SANTE) [redacted]@ec.europa.eu>
> **Cc:** [redacted]@efpia.eu>
> **Subject:** NIP - Discussion with EFPIA

[redacted]

First of all, let me wish you a very happy New Year!

I would like to congratulate the EC team for successfully concluding an agreement with the UK on 24 December. As mentioned previously in Koen's emails towards the end of last year, we are still seeking to clarify some details around the NIP provisions, particularly regarding the 12-months phase-in period. Our members would need guidance in order to organise their internal processes accordingly.

We would be grateful for your time to have a discussion on this issue, hoping that your agenda allows for a meeting relatively soon.

Many thanks in advance and best,

[redacted]

[redacted]

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