From: [redacted]
To: GAMBS Hubert (GROW)
Cc: [redacted] GROW TFIS
Subject: Fwd: Vaccines Europe document for DG Grow TF : 1- pager + Annex (COVID manufacturing narrative)
Date: mardi 9 mars 2021 17:00:34
Attachments: image002.jpg
image003.jpg
image004.jpg

Dear Hubert,

Thank you very much for your response and feedback.

I would like to use the opportunity to bring to your attention that four companies (AstraZeneca, J&J, Novavax and Pfizer/BioNTech) have recently informed Vaccines Europe that they are facing major challenges with the implementation of labelling/packaging requirements for their COVID-19 vaccine.

According to all feedback received, some labelling/packaging requirements are adding a lot of complexity, especially as the supply of COVID-19 vaccines relies on complex networks with multiple sites involved. This complexity may delay vaccine availability.

For instance, some Member States are requesting paper patient information leaflets in their national language(s) even though they are not listed in Question 2 of the Q&A posted by EMA. Implementation of serialisation and traceability elements (e.g. stickers or specific vaccination cards) are also highly challenging and requires complex planning, coordination and tracking systems.

Although flexibilities have been granted by EMA, exemptions have to be negotiated on a case-by-case basis and justified, which is time and resource consuming for companies. These exemptions are limited in time, which means that companies have to dedicate resources for the development and implementation of new requirements while there is still a lot of uncertainty on supply scenarios.

For instance, one company reports that it was granted temporary exemptions for elements on the printed artworks until end May 2021 and therefore updates to the artworks will be required soon after launch.

Vaccine Europe would appreciate if the Task Force could take into consideration these feedbacks and work with DG Santé and EMA on further extending labelling flexibilities and ensuring broader alignment of Member States.

I remain at your disposal if anything addressed above requires further explanation.

Kind regards

[redacted]

[redacted]

[redacted]

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Website www.vaccineseurope.com

Transparency Register ID: 53073567234-18

EFPIA - European Federation of Pharmaceutical Industries and Associations

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1050 Brussels (Belgium)

---------- Forwarded message ---------
From: **GAMBS Hubert** <Hubert.Gambs@ec.europa.eu>
Date: Sun, 28 Feb 2021 at 11:35
Subject: RE: Vaccines Europe document for DG Grow TF : 1- pager + Annex (COVID manufacturing narrative)
To: [redacted]@vaccineseurope.eu>
Cc: [redacted]@gsk.com>, [redacted]@vaccineseurope.eu>, [redacted]@ec.europa.eu>, [redacted]@ec.europa.eu>, [redacted]@ec.europa.eu>, [redacted]@ec.europa.eu>, [redacted]@ec.europa.eu>, GROW-TFIS@ec.europa.eu <GROW-TFIS@ec.europa.eu>

Dear [redacted],

Thank you very much for your email and the attached documents setting out the position of Vaccines Europe and your members. I agree that establishing direct contacts between the task force and the vaccine companies will offer advantages and am happy to implement such an approach. It will guarantee the confidentiality of the information provided and speed up the process to obtain input on bottlenecks in the production or other relevant vaccine-related issues. Hence, the functional mailbox of our task force should serve GROW-TFIS@ec.europa.eu as an entry for all such correspondence.

Internally we have already assigned members of the task force to cover individual companies.

With regard to some issues, which fall under the remit of our colleges in DG SANTE, we have received the following information:

DG SANTE highly appreciates your recognition of the work of our SANTE and EMA colleges to accelerate development, assessment and approval over the past year. As regards your proposal for regulatory flexibility, DG SANTE would like to stress that according to the current legislation developers of medicinal products centrally authorised in the EU must ensure that the labelling, packaging and product leaflet of the product is translated in all Member States' languages (Article 63 of Directive 2001/83/EC). As you know, in the context of the pandemic, it was recognised that flexibility in the labelling and packaging requirements would facilitate the rapid deployment of COVID-19 vaccines at the large scale required for vaccination campaigns. For this purpose, the Commission, together with the Member States, agreed on a number of flexibilities for COVID-19 vaccines. In addition, specific flexibilities have been granted to individual vaccines, including no serialisation and facilitation of batch release by OMCLs. The Commission and Member States have facilitated development significantly within the existing legal framework in relation to labelling requirements and are committed to continuing to do so.

Regarding the accelerated approvals of variations to regulatory dossiers, EMA and the Commission have put in place a system for the acceleration of post-approval variations of existing marketing authorisations in order to approve fast changes such as the inclusion of new manufacturing sites and the adaptation of authorised vaccines to new variants. On the latter, EMA published on 25 February a guidance on a (smaller) set of data needed for the adaptation of the vaccines to new variants:

https://www.ema.europa.eu/en/regulatory-requirements-vaccines-intended-provide-protection-against-variant-strains-sars-cov-2

Furthermore, the Commission has prepared a proposal for a change in the Commission 'variations' Regulation No 1234/2008. In March, the Commission intends to adopt a targeted amendment of the this regulation, to put in place a fast and streamlined approval process for any adaptations of authorised vaccines to variants. In practice,

companies will have to submit far less data then before.

I am looking forward to continuing our fruitful cooperation.

Kind regards,

Hubert

Hubert GAMBS
Deputy Director-General

European Commission
Directorate-General Internal Market, Industry, Entrepreneurship and SMEs

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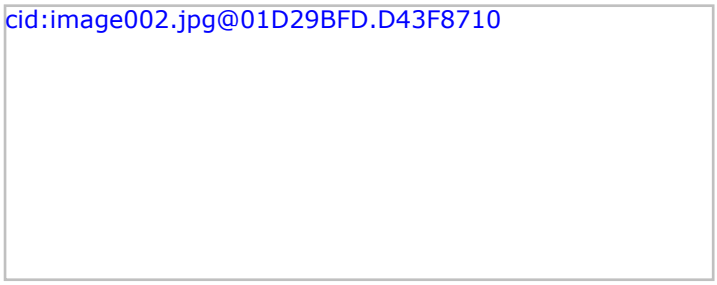

From: [redacted]@vaccineseurope.eu>
Sent: Wednesday, February 24, 2021 11:12 PM
To: GAMBS Hubert (GROW) <Hubert.Gambs@ec.europa.eu>; GROW TFIS <GROW-TFIS@ec.europa.eu>
Cc: [redacted]@gsk.com>; [redacted]@vaccineseurope.eu>
Subject: Vaccines Europe document for DG Grow TF : 1- pager + Annex (COVID manufacturing narrative)

Dear Hubert, all

Once again we would like to thank the Commission for the initiative of the Task Force for Industrial Scale-up of COVID-19 vaccines, which we believe will

help step up the industrial production of vaccines and enhance coordination between major players in COVID19 vaccine manufacturing in order to achieve this.

Considering the importance to address the short term needs of COVID-19 vaccine manufacturers, we would like to propose, via the attached document, additional structural proposals to ensure agile responses. We also join Vaccines Europe narrative on COVID-19 vaccine manufacturing, which we hope will help understanding the specificities and complexities of COVID19 vaccine manufacturing as well as identifying which bottlenecks need support from the Task Force.

[redacted] and I remain at your disposal for any question you may have and on the best way to move forward.

Looking forward to hearing back from you.

Kind Regards

[redacted]

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For more information related to COVID-19 see: https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-response-to-coronavirus/