

From: [REDACTED]
Sent: 08 February 2021 16:30
To: [REDACTED]
Cc: [REDACTED] (EMA); [REDACTED]@pei.de;
[REDACTED]@pei.de; [REDACTED] (SANTE);
[REDACTED]@efpia.eu; SANTE PHARMACEUTICALS B5
Subject: RE: Letter on packaging and labelling flexibilities for COVID-19 therapeutics

Dear Mr. [REDACTED]

Thank you for your query. The consultation between EMA and the Commission has been initiated and still on-going. We expect it to conclude before the end of month and will be able provide you with responses to your proposal then.

Kind regards,

Unit "Medicines: policy, authorisation and monitoring"



European Commission
DG Health and Food Safety

This message represents solely the views of its author and can not be regarded as the official position of the Commission. It is intended solely for the person to whom it is addressed and may contain confidential information. If you have received this message in error, please notify me as soon as possible.

From: [REDACTED]@efpia.eu>
Sent: Wednesday, February 3, 2021 8:46 PM
To: SANTE PHARMACEUTICALS B5 <SANTE-PHARMACEUTICALS-B5@ec.europa.eu>
Cc: [REDACTED] (EMA); [REDACTED]@ema.europa.eu>; [REDACTED] (SANTE); [REDACTED]@ec.europa.eu>; [REDACTED]
Subject: Re: Letter on packaging and labelling flexibilities for COVID-19 therapeutics

Dear Sir/Madam,

When do you estimate the consultation with EMA will be finalised?

Best regards,

On Mon, 11 Jan 2021 at 09:18, SANTE-PHARMACEUTICALS-B5@ec.europa.eu
<SANTE-PHARMACEUTICALS-B5@ec.europa.eu> wrote:

Our reference: [sante.ddg1.b.5\(2021\)198389](#)

Dear Mr [REDACTED]

Thank you for your letter dated 9 December 2020 on packaging and labelling flexibilities for COVID-19 therapeutics, requesting that those regulatory flexibilities granted for COVID-19 vaccines across the EU (and detailed in the Q&As on labelling flexibilities for COVID-19 vaccines published by EMA 27 November 2020) are extended to COVID-19 therapeutics.

We would like to inform you that your request is currently being processed and that we are planning to discuss it with the Agency. We will therefore be in a position to provide you with a reply as soon as this consultation with EMA is finalised.

Unit “Medicines: policy, authorisation and monitoring”



European Commission

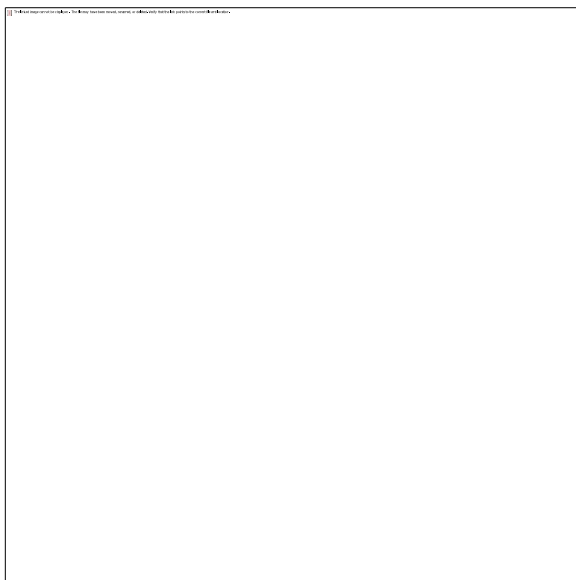
DG Health and Food Safety

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EFPIA - European Federation of Pharmaceutical Industries and Associations
Leopold Plaza Building, Rue du Trône 108, B-1050 Bruxelles
Tel: [REDACTED]

[REDACTED] [@efpia.eu](mailto:[REDACTED]@efpia.eu)



[More info on Corona virus](#)