

From: [REDACTED] <[REDACTED]@efpia.eu>
Sent: 12 October 2020 14:53
To: RYS Andrzej Jan (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Cc: [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]
Subject: Fwd: Kind request for a meeting - European Commission : Mr. Rys and [REDACTED]

Categories: Orange Category

Dear Andrzej, dear [REDACTED], dear [REDACTED],

Thank you again for our exchange of views of 2 October. We very much appreciated the opportunity to meet virtually, knowing how busy these times are.

The COVID-19 crisis has shown the importance of having a strong R&D innovation ecosystem and industrial assets in Europe enabling our region to immediately participate in the research and development of vaccines as well as ensure medicines' supply. We applaud the European Commission's considerable efforts to secure the provision of COVID-19 vaccines to Europe and we know that we must also consider how to build the sustainable capacity to fund R&D and infrastructure projects, capable of rapidly developing and manufacturing countermeasures to health emergencies from vaccines, to treatments to diagnostics. A public-private approach such as was necessary in effectively facing the COVID-19 crisis, seems to be the most appropriate approach.

In relation to the ongoing review of the Paediatric and Orphan Regulations, and as mentioned during our discussion, we wanted to inform you that EFPIA will soon release a public report which directly addresses two questions:

1. How do companies and their investors make decisions on whether to develop an OMP?
2. How would decisions to develop today's authorised OMPs have been affected if the incentives provided by the OMP Regulation had not been there?

We believe that this report will provide a useful complement to the Technopolis analysis that your services published on 11 August. **We would like to invite you to join a public discussion scheduled on 30 October and intended to discuss the two questions above.**

As per your suggestion, we have also followed-up with Mr. Ryan to have a dedicated call about future EU action to tackle antimicrobial resistance, as well as industry's efforts to stimulate R&D of new antimicrobials, via the newly launched [AMR Action Fund](#). We are looking forward to that discussion.

Please don't hesitate to contact us should you need any additional information and thank you again very much indeed for your time. We look forward to hearing back from you regarding your participation in the EFPIA event on 30 October.

Best wishes,



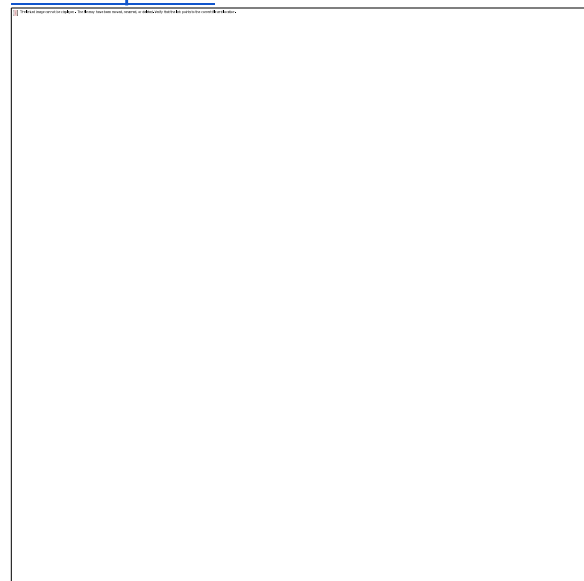
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For more information related to COVID-19 see: <https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-response-to-coronavirus/>

From: [REDACTED] <[REDACTED]@efpia.eu>
Sent: Tuesday, September 22, 2020 8:00 AM
To: RYS Andrzej Jan (SANTE) <[REDACTED]@ec.europa.eu>
Cc: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] <[REDACTED]@efpia.eu>; [REDACTED] <[REDACTED]@efpia.eu>; [REDACTED] <[REDACTED]@efpia.eu>; [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] <[REDACTED]@ec.europa.eu>
Subject: Re: Kind request for a meeting

Dear Andrzej,

Thank you so much and I look forward to hearing from you.

Very best,

[REDACTED]

[REDACTED]

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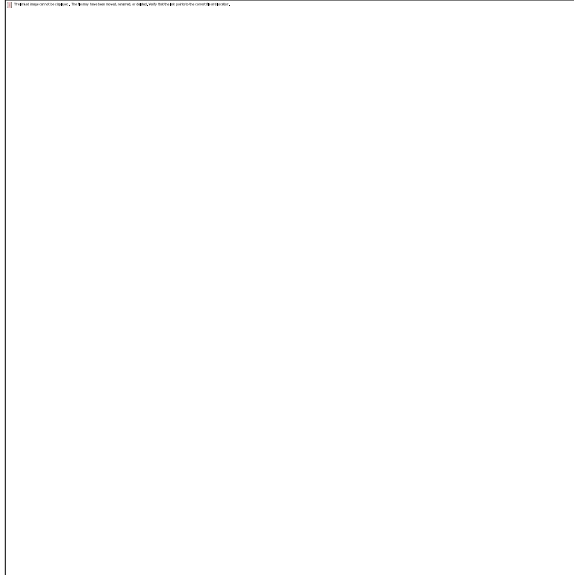
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For more information related to COVID-19 see: <https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-response-to-coronavirus/>

On Mon, 21 Sep 2020 at 19:05, [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)> wrote:

Dear [REDACTED]

We will try organize meeting asap, most probably next week.

Kind regards

Andrzej

From: [REDACTED] <[\[REDACTED\]@efpia.eu](mailto:[REDACTED]@efpia.eu)>

Sent: Monday, September 21, 2020 6:13 PM

To: RYS Andrzej Jan (SANTE) · [\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)

Cc: [REDACTED] (SANTE) [\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu); [REDACTED] (SANTE)

[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu); [REDACTED] <[\[REDACTED\]@efpia.eu](mailto:[REDACTED]@efpia.eu)>;

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

[\[REDACTED\]@efpia.eu](mailto:[REDACTED]@efpia.eu); [REDACTED] <[\[REDACTED\]@efpia.eu](mailto:[REDACTED]@efpia.eu)>

Subject: Kind request for a meeting

Dear Andrzej,

I hope this message finds you well.

We noted that in her recent State of the Union speech, the Commission President called for a stronger “European health union” and more competences for health at European level. At the same time we understand that the Pharmaceutical Strategy could be adopted on 24 November. Following the publication of the Commissions Roadmap and Public Consultation on the Pharmaceutical Strategy, we have requested a meeting with Commissioner Kyriakides in October.

Prior to a meeting with the Commissioner, we would like to request a meeting with you and your colleagues, to understand the potential consequences of the State of the Union proposals for the upcoming Pharmaceutical Strategy. The discussion on the Pharmaceutical Strategy highlights the relevance of activities that were already planned and that could address many of the real or perceived shortcomings of the European medicines regulatory framework in the short term. We see many of these areas as highlighted in the regulatory (science) strategies published by EMA or jointly by EMA/HMA, and we would be very to exchange views on how these are seen in the context and in support of the eventual implementation of the Pharmaceutical Strategy as well as the Staff Working Document on OMPs and Paediatrics.

I would be very grateful for the opportunity to meet with you and your colleagues either via digital means or in person to discuss these proposals in more detail and very much look forward to hearing from you.

Many thanks and best wishes,



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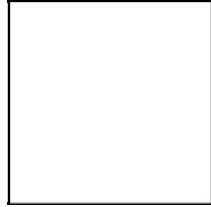


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