From:	Cuddy Brendan <brendan.cuddy@ema.europa.eu>
To:	<brendan.cuddy@ema.europa.eu>
Cc:	<industry@ema.europa.eu>
Subject:	Request for information: Potential for disruption in manufacturing of aseptically produced medicines
Date:	Thursday October 28, 2021 1:01 PM
Attachments:	

Dear Colleague,

We are contacting you because the Agency has been informed of the potential for disruption in manufacturing of aseptically produced medicines due to significant difficulties in obtaining Single Use System components (sterile components).

The Agency wants to gain a better understanding what the causes are, how widespread this issue is for manufacturers in the EU, and what mitigation measures industry is putting in place . In particular we would appreciate if you could further information on the impact on availability of (critical) medicines.

In order to determine what regulatory measures could be appropriate in this situation it would be necessary to substantiate that:

- they would be able to resolve or at least substantially mitigate the issue (i.e. if it is use of alternative systems, that alternatives are available);
- the risks involved are considered acceptable and outweighed by the benefits of avoiding shortages/not delaying availability and for mitigating risk;
- Any deviations from normal requirements would be as minimal as possible

We would be grateful if you could provide any further information by 15th November so that this topic could be discussed further by the GMDP IWG and subsequently by the EU SPOC Network for shortages. Please reply directly to me and please copy the Industry mail box in copy to this message.

I would also like to take this opportunity to draw your attention to a forthcoming matchmaking event organised by DG Grow at the end of November, with a preparatory webinar on 9th November. The matchmaking event aims to inter alia accelerate "The production of disposable materials (e.g. single use systems), ingredients and raw materials required for the manufacture of medicinal products". We would be very grateful if you could inform your interested stakeholders of this event.

Many thanks in advance,

Dear Madam, Sir,

You are warmly invited to participate in the European Commission's **Second Virtual Matchmaking Event on COVID-19 Therapeutics on 29-30 November.**

This event aims to accelerate:

- The development of new and repurposed medicines for COVID-19 therapeutics, i.e. medicines specifically developed for an indication in treatment of COVID-19, at all stages of COVID-19 disease;
- The development of medicines used to treat the symptoms of COVID-19;
- The production of disposable materials (e.g. single use systems), ingredients and raw materials required for the manufacture of medicinal products.

It also aims to mobilise the EU pharma manufacturing capacity for the production of medicines to treat or prevent COVID-19.

The event is organised by the European Commission in partnership with the **Council of European BioRegions (CEBR)**, the **European Cluster Alliance (ECA)** and the European Cluster Collaboration Platform.

Companies interested in participating in the event must complete the registration form by **18 November 2021 (23h59 CEST).**

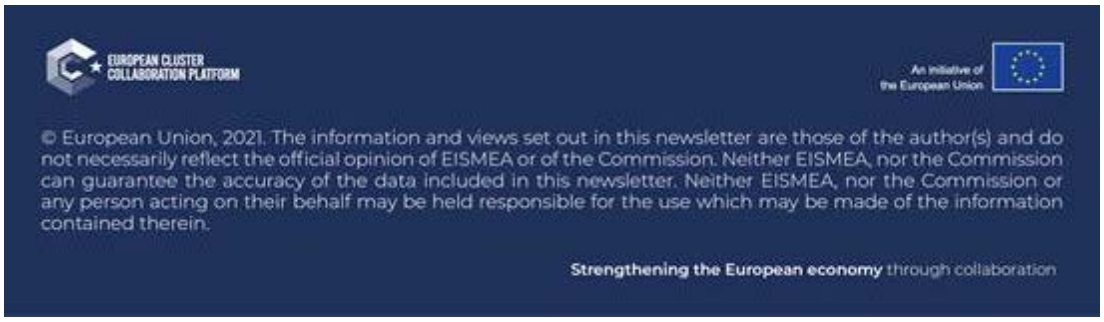
Register now

Please also share the registration link with your network.
A preparatory webinar will take place on 9th November.

We look forward to seeing you there. Should you have any questions do not hesitate to contact us.

Best regards,

The events' team



Many thanks in advance for your assistance.

Brendan Cuddy
Lead Scientific Officer.
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