

Naik, Nikita

**From:** David Schaefer [REDACTED]  
**Sent:** Wednesday, February 21, 2024 2:19 PM  
**To:** Naik, Nikita; Hall-Jordan, Luke  
**Cc:** John Hong; Lorraine Cancro; Bruce Cox; Curtis Rhyne  
**Subject:** GSK feedback on action taken during our last call - extraordinary circumstances

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Nikita and Luke,

Our team came up with the following list of other events that we thought could also cause an urgent need of additional allowances to make Metered Dose Inhalers for US patients besides a pandemic (as we pledged to provide during our call earlier this year):

- Manufacturer that makes MDIs outside of US (off shore) leaves the US market by choice or other reason (manufacturing plant damage, labor dispute)
- Major recall or suspension of production of alternative (non-MDI) emergency asthma treatments prompting increase in MDI demand
- Change in preferred products from PBMs or state Medicare programs to patients
- FDA compliance or enforcement actions that reduce generic availability that impacts MDI market dynamics
- Significant increase in respiratory infections in general population (e.g., RSV, COVID)
- Decrease in availability of Active Pharmaceutical Ingredient or device component for one or more MDI manufacturers causing a supply shortage

From this list, we had a thought that it could be summarized in the following way:

A global pandemic, public health emergency, or other healthcare system need

**Healthcare system need:** Circumstances where increase in demand may occur because of a change in market conditions that otherwise would not be included in rates of growth calculated in paragraph (c) (1) (i.e., other supplier exits market)

We hope this information is useful.

Also, please keep us in mind if you'd like to discuss any upcoming changes with a stakeholder. We're happy to be a sounding board.

Regards,



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