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ARES (2019)

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Dear Sir/Madam,

Thank you for your letter of 17 May 2019 addressed Director-General Anne Bucher and me on shortages of medicines. I would also like to thank you for the constructive meetings on 1st and 22 July to discuss this important issue. Shortages of medicines are a serious problem that affect many patients across the EU and represent a threat to the wellbeing of all citizens. For this reason, the availability and accessibility of medicines is a priority for the Commission.

According to EU legislation, other than in exceptional circumstances, marketing authorisation holders must inform Member State authorities at least two months before they withdraw their product from the market either permanently or temporarily, including the reasons for the withdrawal.¹ There is also an obligation of continuous supply to cover the needs of patients once a medicine is placed on a specific EU market.²

The Commission has published a summary of Member States' measures to ensure continuous supply, including national measures addressing shortages following a meeting with Member States on 25 May 2018.³ A paper on the obligation of continuous supply to tackle shortages was also agreed with Member States at the May meeting.⁴ In addition, my services are closely following an HMA-EMA task force that is working to develop and coordinate actions to address shortages and availability of medicines.

¹ Article 23a of Directive 2001/83/EC

² Article 81 of Directive 2001/83/EC

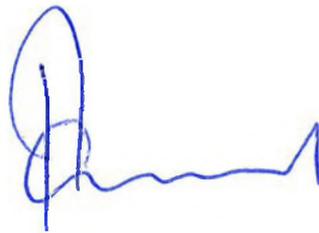
³ https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_summary_en.pdf

⁴ https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd01_en.pdf

I take note of your request to ***start an investigation into the factors leading to medicines shortages to provide clear and transparent information on the root causes of these problems, including on responsible entities and affected population groups, to healthcare professionals, patients and the general public.***

Let me reiterate that I take the problem of shortages very seriously. I believe multiple actions, as well as the involvement and commitment by all stakeholders are needed to address this very complex problem. It will be for the next Commission to decide on next steps.

Yours sincerely,

A handwritten signature in blue ink, consisting of a large, stylized initial 'A' followed by a series of connected loops and a final vertical stroke.