EN P-001634/2021 Answer given by Ms Kyriakides on behalf of the European Commission (30.4.2021)

The Commission's Notice of 25 January 2021 gives flexibilities under the current EU pharmaceuticals legislation for the countries affected by Brexit to ensure the continuity of supply in the short term¹. It is for the companies to make the necessary changes to ensure compliance and in the supply chains to avoid any disruption of the markets as well as for the Member States concerned to implement the Commission Notice, including finding alternative supplies whenever necessary.

As for the long term, the Pharmaceutical Strategy for Europe² foresees a number of actions to ensure patients' access to medicines, including in smaller and less wealthy markets. For instance, the Commission will propose to revise the pharmaceutical legislation to enhance security of supply and address shortages through specific measures. These include stronger obligations for supply and transparency, earlier notification of shortages and withdrawals, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages. The Commission is working with the European Medicines Agency (EMA) and Member States, with the engagement of marketing authorisation holders, on addressing the root causes of deferred market launches.

Finally, the Strategy foresees non-legislative actions on aspects of national competence, like on pricing. In particular, the Commission will promote and support cooperation between national authorities in the areas of pricing, payment and procurement policies to share knowledge and exchange best practices to help Member States to take decisions on pricing and reimbursement and ultimately improve the affordability, cost-effectiveness of medicines and health system's sustainability.

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0125(01)&from=EN

² https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN