

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 (“the 2012 Regulations”), which govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use. These Regulations extend to England and Wales and Scotland only.

Regulation 3 amends regulation 3A of the Human Medicines Regulations 2012, and regulation 4 amends regulation 19. These provisions currently cease to have effect on 1st April 2024, and this is extended to 1st April 2026. Regulation 3A of the 2012 Regulations ensures that all professionally justified acts of preparation and assembly of a coronavirus vaccine may be undertaken by or under the supervision of a doctor, nurse or pharmacist, at any location, without precipitating the need for a manufacturer's licence or marketing authorisation — provided those acts are done under NHS arrangements or arrangements as part of the medical services of His Majesty's Forces. It also allows for authorised medicinal products used for the reformulation of coronavirus vaccines (for example, diluents) to be re-assembled at the end of the medicines supply chain without the resultant products needing a marketing authorisation in order to be supplied. Regulation 19 provides for certain exemptions from the requirement to hold a wholesale dealer's licence, and paragraphs (4A) to (4C) of that regulation permit sharing of stocks of coronavirus and influenza vaccinations between vaccination centres without the need for such a licence.

Regulation 247A exempts from the requirements relating to the supply of medicines under regulations 214, 220 and 221, the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus (of any type), which is made under a national protocol relating to such supply. This regulation removes the requirement, in respect of Great Britain, that the supply or administration shall be made whilst a disease is, or is in anticipation of being imminently, a pandemic and a serious risk or potentially serious risk to human health. Regulation 247A will cease to have effect in Great Britain on 1st April 2026.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU, and is available on the www.legislation.gov.uk website.