## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Human Medicines Regulations 2012 ("the HMRs"), which govern the arrangements throughout the United Kingdom for the manufacture, importation and marketing of medicinal products for human use. Regulation 3 of the HMRs contains exemptions from the manufacturing and product licensing requirements of the HMRs that relate to the manufacture or assembly of medicines by doctors, dentists, nurses and midwives at the final stage of the medicines supply chain – and related to those exemptions, there are provisions of regulation 3 that deal with the packaging, labelling and leafleting requirements for the products covered by those exemptions.

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 ("the 2019 Regulations") made an amendment to an interpretation provision in paragraph (15) of regulation 3 that related to the repackaging, labelling and leafleting requirements in the case of products covered by a specified list of types of authorisations. Regrettably, because of a numbering error in the drafting of the amendment, introduced into the 2019 Regulations by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, the attempt to add "EU marketing authorisation" to the list of types of authorisations was ineffective. These Regulations correct that numbering error and restore the original drafting intention.

Consequential amendments are made to the provisions that contained the numbering error.