EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations").

In particular, regulations 3 to 21 and 26 set out how parallel import licences are granted.

Regulations 22(a) and 23 amend provisions in the 2012 Regulations on the recognition of prescriptions issued by healthcare professionals in EEA States to make it clear that the rules also apply to prescriptions issued in Switzerland.

Regulations 22(b) and 27 insert a definition of "school" and amend Schedule 17 of the 2012 Regulations so that inhalers containing salbutamol can be supplied in schools in an emergency by persons trained to administer them to pupils who are known to require such medication.

Regulations 24 and 29 amend the requirements for advertisements for medicines that are aimed at persons qualified to prescribe or supply such products.

Regulation 24 enables advertisements for medicines available without a prescription to contain a website address where information on adverse reactions, precautions, contra-indications and methods of use can be found as an alternative to providing that information on the face of the advertisement.

Regulation 25 amends the 2012 Regulations to ensure that the new provisions on inhalers containing salbutamol are subject to review by the Secretary of State.

Regulation 28 amends the information that must be contained in the package leaflet that accompanies a medicine. Paragraph (2) corrects an error and paragraph (3) substitutes a general requirement to include text on adverse event reporting in place of a requirement to include prescribed text.

Regulation 29 enables advertisements to include relevant entries from the medicine's summary of product characteristics as an alternative to a summary of those entries.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on private, public or voluntary sectors is foreseen.