EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations") in order to implement—

- Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products ("Directive 2011/62/EU");
- Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council ("the Implementing Regulation");
- an EU Corrigendum(**1**) which corrects an error in Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicines for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products ("the EU Corrigendum).

The majority of provisions in these Regulations introduce new provisions into the 2012 Regulations in relation to brokers, active substances and the sale of medicinal products at a distance in order to implement Directive 2011/62/EU. In particular—

- regulation 3 updates the general interpretation provisions to insert new definitions;
- regulations 4 to 6, 9 to 15, 17, 19 and 20 amend provisions relating to manufacturers or wholesalers of medicinal products, marketing authorisations and traditional herbal registrations;
- regulation 16 inserts new provisions relating to brokers of medicinal products and importers, manufacturers or distributors of active substances;
- regulation 28 inserts new provisions relating to the sale at a distance of medicinal products;
- regulation 30, 34 and 35 make consequential amendments related active substances;
- regulation 32 amends provisions so that brokers of medicinal products and importers, manufacturers and distributors of active substances can apply for certain decisions to be reviewed upon oral representations; and
- regulation 33 inserts a new Schedule in relation to information requirements for registration in relation to active substances.

Regulations 21, 23 and 25 amend the 2012 Regulations in order to provide sanctions for breaches of obligations and requirements imposed by the Implementing Regulation in relation to pharmacovigilance activities and regulation 22 makes consequential changes to remove duplication of obligations.

Regulations 18 and 24 make amendments to ensure that cross-references to Regulation (EC) No 726/2004 that were amended by the EU Corrigendum are correctly reflected in the 2012 Regulations.

(**1**) OJ No L 201, 27.7.2012, p138.

Regulations 7, 26 and 27 insert new provisions into the 2012 Regulations that enable physiotherapist independent prescribers and podiatrist independent prescribers to mix, sell or supply certain types of prescription only medicines.

Regulation 8 amends the 2012 Regulations so that where a licence holder wishes to make oral representations to the licensing authority a fee is payable by the licence holder.

Regulations 29 and 31 amend the 2012 Regulations to ensure that regulations related to inspections, sampling and seizure and the review of provisions can be applied in relation to new provisions for brokers, the importation, manufacture and distribution of active substances and the sale of medicines to the public at a distance.