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, and the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the 2004 Regulations"), which govern the conduct of clinical trials of medicinal products for human use. The amendments make provision for the establishment and operation of the statutory version of the Early Access to Medicine Scheme (EAMS) – there has previously been a non-statutory version of the Scheme. The EAMS has the purpose of giving patients with life threatening or seriously debilitating conditions access to medicinal products that are either not authorised or not authorised for that use.

Subject to various exceptions, medicines for human use may only be sold or supplied if they have been granted a marketing authorisation by the licensing authority (which is either, or both, of the Secretary of State and the Minister of Health in Northern Ireland). These Regulations add to those exceptions dedicated arrangements that allow unlicensed medicines to be placed on the market in the United Kingdom if they are supplied as part of the EAMS. The core functions of the licensing authority in relation to the EAMS are set out in the new regulation 167C of the 2012 Regulations, and include a licensing authority power to issue EAMS scientific opinions in respect of medicinal products. This opinion allows the EAMS scientific opinion holder to supply the product within the United Kingdom without a marketing authorisation, subject to the conditions that may be attached by the licensing authority to the opinion, as well as to the statutory conditions set out in the new regulations 167E to 167G. The new regulation 167D of the 2012 Regulations makes provision in respect of EAMS scientific opinions ceasing to have effect.

The new regulation 167E of the 2012 Regulations contains the statutory conditions with regard to the ordering, manufacture and distribution of unlicensed EAMS medicinal products, whilst also providing for licensed medicinal products to be supplied as part of the EAMS where this is done to ensure the ongoing availability of products, with the agreement of the licensing authority. The requirements in respect of unlicensed medicinal products are similar in effect to those included in regulation 167 of the 2012 Regulations in relation to special medicinal products, and similarly take as their starting point Article 5(1) of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**1**). The new regulation 167F of the 2012 Regulations prohibits the advertisement of EAMS medicinal products, although this does not preclude promotion of the Scheme itself – and the new regulation 167G of the 2012 Regulations thereafter sets out pharmacovigilance obligations in respect of EAMS medicinal products, such as the reporting by the EAMS scientific opinion holder of changes to the risk-benefit balance of the product. The new regulation 167H of the 2012 Regulations deals with data collection, but also makes clear that patient consent to data collection is not, and must not be made, a requirement of access to an EAMS medicinal product as part of the EAMS (regulation 8).

A number of consequential changes are made to the 2012 Regulations and the 2004 Regulations. In particular, requirements relating to the manufacture, importation and distribution of EAMS medicinal products are integrated within the existing framework of requirements for the manufacture, import and distribution of medicinal products under the 2012 Regulations and the 2004 Regulations, so that holders of authorisations for the purposes of those Regulations will be able to carry out the activities that they are authorised to perform in relation to licensing medicinal products,

(**1**) OJ L 311, 28.11.2001, p.67, to which there have been amendments which are not relevant.

special medicinal products and investigational products in relation to EAMS medicinal products as well – and the conditions for their licences or authorisations to manufacture, import or distribute are modified to support this (regulations 5 to 7, 13, 17 and 18). There are also consequential changes to licensing authority functions (regulations 3, 10 and 11), in relation to classification of EAMS medicinal products (regulation 12), to definitions provisions (regulations 4 and 16), and to sanctions provisions (regulation 9). There is also a transitional provision which provides that EAMS medicinal products that were the subject of EAMS scientific opinions issued before these Regulations came into force are to be regulated as if the arrangements with regard to the sale or supply of, or the pharmacovigilance for, EAMS medicinal products set out in these Regulations had not been made – pending the renewal of that scientific opinion or it ceasing to have effect (regulation 19).

A Regulatory Triage Assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be proportionate. These Regulations are not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.