STATUTORY INSTRUMENTS

2021 No. 1452

The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021

Amendments to Schedule 4 (standard provisions of licences under Part 3) Part 2 (manufacturer's licence relating to the import of medicinal products from a state other than an EEA State/Country other than an Approved Country for Import)

25. In Schedule 4, after paragraph 23, insert—

"**23ZA.** The licence holder in Great Britain must take all reasonable precautions and exercise due diligence to ensure that any information provided to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a product for human use which is supplied from Great Britain into Northern Ireland by virtue of regulation 167A handled, stored or distributed under the licence is not false or misleading in a material particular.".