EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) ("the Withdrawal Act") in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c) and (d) of the Withdrawal Act) arising from the withdrawal of the UK from the European Union.

Regulation 2 and Schedule 1 amend the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) ("the Medicines Exit Regulations"). The Medicines Exit Regulations amend the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the Principal Medicines Regulations").

Paragraphs 2 and 3 amend regulations 15 and 17 of the Medicines Exit Regulations (amendment of regulations 18 and 19 of the Principal Medicines Regulations) to ensure that the requirements for a wholesale dealer's licence apply to hospitals importing human medicinal products directly from a country on an approved list, including for their own use (but not to those persons importing a medicine from such a country purely for administration to themselves or a member of their household).

Paragraph 4 amends regulation 47 of the Medicines Exit Regulations to ensure that the definition of "EU reference medicinal product" in regulation 48 of the Principal Medicines Regulations includes a medicinal product which was the subject of a marketing authorisation granted by the European Commission under Regulation (EC) No. 726/2004 which had been cancelled before exit day on grounds not relating to safety, quality or efficacy. Reference medicinal products are products in relation to which there was a full set of data supporting the application for the marketing authorisation for the product, and reliance may be placed on part of that data by subsequent applicants, for example applicants for marketing authorisations for generic versions of innovative products.

Paragraph 6 amends regulation 58 of the Medicines Exit Regulations so as to insert some missing words into regulation 53 of the Principal Medicines Regulations (biosimilar applications) relating to the time period for which biological reference medicinal products have to have been authorised before an abridged application may be made in reliance on the data supporting such reference products.

Paragraph 7 ensures that the amendments made to Schedule 11 to the Principal Medicines Regulations by regulation 63 of the Medicines Exit Regulations accommodate the process for seeking advice and making representations in relation to the new decisions conferred on the licensing authority by the Medicines Exit Regulations in relation to orphan (rare disease) medicines and paediatric medicines.

Paragraph 8 amends regulation 139(6) of the Medicines Exit Regulations (amendment of regulation 177 of the Principal Medicines Regulations) to include a definition of "signal" in relation to pharmacovigilance activities.

Paragraph 9 amends Schedule 6 to the Medicines Exit Regulations (insertion of Schedule 12A into the Principal Medicines Regulations) to provide for a definition of "signal evaluation" in paragraph 27 of inserted Schedule 12A in relation to periodic safety update reports.

Paragraph 10 amends Schedule 7 to the Medicines Exit Regulations (new Schedule 33A to the Principal Medicines Regulations - transitional provision in relation to EU Exit). The amendments—

(a) add the Republic of Korea to the list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day;

(b) ensure that the temporary exemption as to the location of an appropriately qualified person for pharmacovigilance (QPPV) applies to a holder of a UK marketing authorisation or traditional herbal registration granted before exit day, in respect of all UK marketing authorisations or registrations they hold for which there is the same QPPV; and

(c) provide a temporary exemption, subject to specified conditions, regarding the obligation to maintain and make available on request of the licensing authority a UK pharmacovigilance system master file covering all medicinal products for which the holder obtained a UK marketing authorisation.

Regulation 3 and Schedule 2 amend the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791) ("the Devices Exit Regulations"). The Devices Exit Regulations amend the Medical Devices Regulations 2002 (S.I. 2002/618) ("the Principal Devices Regulations").

Paragraph 2 makes minor amendments to regulation 3 of the Devices Exit Regulations, in particular to ensure that monographs of the European Pharmacopoeia, insofar as they relate to medical devices, are included as designated standards (i.e. standards which serve the same purpose as EU harmonised standards and which, if followed, will lead to the device being deemed to meet certain legislative requirements).

Paragraphs 3, 4 and 5 respectively make minor amendments to regulations 7A, 21A and 33A (inserted into the Principal Devices Regulations) to ensure that information provided by manufacturers, as part of the registration obligation, is updated if the information changes after the initial registration.

Paragraphs 6, 7 and 8 make minor amendments to the Devices Exit Regulations.

Paragraphs 9 and 10 make minor amendments to various regulations inserted into the Principal Devices Regulations by the Devices Exit Regulations. In particular these amendments ensure that devices which will be subject to the regulatory regime for the first time are required to comply with certain 'common specifications'.

Paragraph 11 makes minor amendments to Schedules 19 (technical documentation on post-market surveillance for in vitro diagnostic medical devices) and 24 (conformity assessment based on a quality management system) inserted into the Principal Devices Regulations.

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

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.