SCHEDULES

SCHEDULE 8

Material to accompany an application for a UK marketing authorisation

PART 1

General requirements

[F1 18. Where—

(a) in the case of a UKMA(NI) or a UKMA(UK), an application for authorisation for the medicinal product to be placed on the market is under consideration in one or more member States—

(i) a list of the member State or States concerned, and

(ii) in relation to each such application, a copy of the summary of the product characteristics, and the package leaflet, proposed by the applicant;

(b) in the case of a medicinal product for sale or supply in Great Britain, an application for authorisation for the medicinal product to be placed on the market is under consideration in a country other than the United Kingdom, or by the EMA, notification of that fact.**]**

F1 Sch. 8 para. 18 substituted (31.12.2020) by S.I. 2019/775, regs. 1, **50(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(b)**)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Paragraph 18.