# SCHEDULES

## SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

# PART 19

## Insertion of Schedule 2A (insertion of new Schedule 8C (material to accompany an application for a UK marketing authorisation under the unfettered access route))

**190.** After Schedule 2 (insertion of new Schedule 8B (modifications of Annex I to the 2001 Directive)) insert—

"SCHEDULE 2A Regulation 51A

Insertion of new Schedule 8C (Material to accompany an application for a UK marketing authorisation under the unfettered access route)

**1.** After Schedule 8B to the Human Medicines Regulations 2012, insert—

"SCHEDULE 8C Regulation 50(1)

Material to accompany an application for a UK marketing authorisation under the unfettered access route

**1.** A copy of the application submitted in connection with the granting of the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.

**2.** A copy of all material submitted in support of the application for the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.

**3.** A copy of the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.".".

**Commencement Information**

**I1** Sch. 2 para. 190 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

**Changes to legislation:**
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 19.