Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community

PART THREE

SEPARATION PROVISIONS

TITLE I

GOODS PLACED ON THE MARKET

Article 45

Making available of information in relation to past authorisation procedures for medicinal products

1 The United Kingdom shall, upon a reasoned request from a Member State or the European Medicines Agency, make available without delay the marketing authorisation dossier of a medicinal product authorised by a competent authority of the United Kingdom before the end of the transition period, where that dossier is necessary for the assessment of a marketing authorisation application in accordance with Articles 10 and 10a of Directive 2001/83/EC or Articles 13 and 13a of Directive 2001/82/EC.

2 A Member State shall, upon a reasoned request from the United Kingdom, make available without delay the marketing authorisation dossier of a medicinal product authorised by a competent authority of that Member State before the end of the transition period, where that dossier is necessary for the assessment of a marketing authorisation application in the United Kingdom in accordance with the United Kingdom's legislative requirements, to the extent that those legislative requirements replicate the circumstances of Articles 10 and 10a of Directive 2001/83/EC or Articles 13 and 13a of Directive 2001/82/EC.