

*Draft Regulations laid before Parliament and the Northern Ireland Assembly under section 47(3) and (6)(c) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament and the Northern Ireland Assembly.*

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DRAFT STATUTORY INSTRUMENTS

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**2022 No. 000**

**MEDICINES**

**The Human Medicines (Amendments Relating to the  
Early Access to Medicines Scheme) Regulations 2022**

*Made* - - - - **\*\*\***  
*Coming into force* - - **\*\*\***

The Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland, make the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(a) to (e), (h) to (k), 5(1)(b), 6(1)(b) and 43 of the Medicines and Medical Devices Act 2021<sup>(1)</sup>, after having considered the matters in section 2(2) to (4) of that Act.

The Secretary of State and the Department of Health in Northern Ireland have carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 47(3) and (6)(c) of that Act, a draft instrument was laid before Parliament and the Northern Ireland Assembly and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.

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<sup>(1)</sup> 2021 c. 3. The powers in section 2(1) of the Medicines and Medical Devices Act 2021, and in the provisions that relate to it, are exercisable by the “appropriate authority”. See section 2(6) of that Act, which contains the definition of “appropriate authority” that is relevant to the powers being exercised.