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## STATUTORY INSTRUMENTS

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# 2012 No. 1916

## MEDICINES

### The Human Medicines Regulations 2012

<i>Made</i>	- - - -	<i>19th July 2012</i>
<i>Laid before Parliament</i>		<i>24th July 2012</i>
<i>Coming into force</i>	- -	<i>14th August 2012</i>

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972<sup>M1</sup>, having been designated for the purposes of section 2(2) of that Act in relation to medicinal products<sup>M2</sup> and to measures in the veterinary and phytosanitary fields for the protection of public health<sup>M3</sup>. They do so in exercise also of the powers conferred by sections 87(1), 88(1) and (2), 91(2), and 129(1), (2) and (5) of the Medicines Act 1968<sup>M4</sup>, having consulted such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations in accordance with section 129(6) of that Act.

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#### **Modifications etc. (not altering text)**

- C1** Instrument modified (10.5.2013) by [The National Health Service \(Pharmaceutical Services\) \(Wales\) Regulations 2013 \(S.I. 2013/898\)](#), **reg. 2(5)**

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#### **Marginal Citations**

- M1** 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act 2006 (2006 c.51) and section 3(3) of and Part 1 of the Schedule to the [European Union \(Amendment\) Act 2008 \(2008 c.7\)](#). Section 2(5) was amended by section 41(1) of and Part 1 of Schedule 6 to the [Northern Ireland Constitution Act 1973 \(1973 c.36\)](#).
- M2** S.I. 1972/1811.
- M3** S.I. 1999/2027.
- M4** 1968 c.67.

### Changes to legislation:

The Human Medicines Regulations 2012, Introductory Text is up to date with all changes known to be in force on or before 18 April 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

[View outstanding changes](#)

### Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 11 para. 1(1)(d)-(f) inserted by [S.I. 2019/775 reg. 63\(2\)\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by [S.I. 2019/1385 Sch. 1 para. 10\(4\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by [S.I. 2019/1385 Sch. 1 para. 10\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by [S.I. 2019/1385 Sch. 1 para. 10\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by [S.I. 2019/1385 Sch. 1 para. 5](#) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by [S.I. 2019/775 reg. 57\(2\)](#) (This amendment not applied to legislation.gov.uk. Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)
- reg. 53(2)-(2C) substituted for reg. 53(2) by [S.I. 2019/775 reg. 58\(3\)](#) (This amendment not applied to legislation.gov.uk. Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by [S.I. 2019/1385 Sch. 1 para. 6\(2\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 173(e) inserted by [S.I. 2017/1322 Sch. 4 para. 2\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by [S.I. 2017/1322 Sch. 4 para. 2\(3\)\(c\)](#) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by [S.I. 2017/1322 Sch. 4 para. 2\(3\)\(g\)](#) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)