STATUTORY INSTRUMENTS

2023 No. 314

MEDICINES
FEES AND CHARGES

The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023

Made - - - -	*9th March 2023*
Laid before Parliament	*10th March 2023*
Laid before the Northern Ireland Assembly - -	*10th March 2023*
Coming into force - -	*1st April 2023*

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) and 6(1)(a) of the Medicines and Medical Devices Act 2021(**1**), 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.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023.

(2) These Regulations come into force on 1st April 2023.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

2. The Medicines (Products for Human Use) (Fees) Regulations 2016(**2**) are amended in accordance with regulations 3 to 26.

(**1**) 2021 c. 3.
(**2**) S.I. 2016/190; relevant amending instruments are S.I. 2019/775(as amended by S.I. 2020/1488).

Amendment of regulation 4

3. In regulation 4 (fee for scientific advice: application for, or variation to, EU marketing authorisation)—

(a) in paragraph (a), for "£2,201" substitute "£2,421",

(b) in paragraph (b), for "£2,763" substitute "£3,039",

(c) in paragraph (c), for "£3,061" substitute "£3,367",

(d) in paragraph (d), for "£3,624" substitute "£3,986", and

(e) in paragraph (e), for "£4,487" substitute "£4,936".

Amendment of regulation 5

4. In regulation 5(1) (fee for scientific advice: classification of a medicinal product)—

(a) in sub-paragraph (a), for "£2,763" substitute "£3,039", and

(b) in sub-paragraph (b), for "£3,624" substitute "£3,986".

Amendment of regulation 6

5. In regulation 6 (fee for advertising advice), for "£2,201" substitute "£2,421".

Amendment of regulation 7

6. In regulation 7(1) (fee for pharmacovigilance advice)—

(a) in sub-paragraph (a), for "£3,624" substitute "£3,986", and

(b) in sub-paragraph (b), for "£3,061" substitute "£3,367".

Amendment of regulation 8

7. In regulation 8 (fee for advice on labelling or leaflets), for "£2,201" substitute "£2,421".

Amendment of regulation 9

8. In regulation 9 (fee for regulatory advice), for "£2,763" substitute "£3,039".

Amendment of regulation 10

9. In regulation 10(1) (fee for advice for other purposes), for "£4,451" substitute "£4,896".

Amendment of regulation 12

10. In regulation 12(1) (fees for applications for authorisations, registrations, licences or certificates etc.), after "a broker's registration", insert ", an application under the Early Access to Medicines Scheme".

Amendment of regulation 14

11. In regulation 14 (fee for applications for additional copy certificates), for "£68" substitute "£75".

Amendment of regulation 15

12. In regulation 15 (fees for applications for certificates and copy certificates by exporters of medicinal products)—

(a) in paragraph (1)(a), for "£152" substitute "£167",

(b) in paragraph (1)(b), for "£68" substitute "£75", and

(c) in paragraph (3), for "£34" substitute "£37".

Amendment of regulation 19A

13. In regulation 19A(**3**) (fees for certification of plasma master files)—

(a) in paragraph (1), for "£8,309" substitute "£9,140",

(b) in paragraph (2)(a), for "£277" substitute "£344", and

(c) in paragraph (2)(b), for "£734" substitute "£1,308".

Amendment of regulation 19B

14. In regulation 19B(**4**) (fee for certification of vaccine antigen master files), for "£8,309" substitute "£9,140".

Amendment of regulation 19C

15. In regulation 19C(**5**) (fees for assessment of post-authorisation safety studies)—

(a) in paragraph (2)—

(i) in sub-paragraph (a), for "£734" substitute "£1,308",

(ii) in sub-paragraph (b), for "£8,309" substitute "£9,140",

(iii) in sub-paragraph (c), for "£734" substitute "£1,308", and

(b) in paragraph (3)—

(i) in sub-paragraph (a), for "£734" substitute "£1,308",

(ii) in sub-paragraph (b), for "£8,309" substitute "£9,140", and

(iii) in sub-paragraph (c), for "£734" substitute "£1,308".

Amendment of regulation 19E

16. In regulation 19E(2)(**6**) (fee for assessment of periodic safety update reports)—

(a) in sub-paragraph (a), for "£890" substitute "£979", and

(b) in sub-paragraph (b), for "£445" substitute "£490".

New regulation 19EA

17. After regulation 19E, insert—

(**3**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**4**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**5**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**6**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).

"**Fee for assessment of clinical trial annual safety reports**

19EA. The fee payable by a sponsor who submits an annual safety report to the licensing authority under regulation 35(1)(b) of the Clinical Trials Regulations is £248.".

Amendment of regulation 21

18. In regulation 21(1) (fees for notification of changes and reports for broker's registrations), for "£257" substitute "£283".

Amendment of regulation 22

19. In regulation 22(1) (fees for notification of changes and compliance reports for active substance registrations), for "£257" substitute "£283".

Amendment of regulation 27

20. In regulation 27 (fees for renewals of certain manufacturer's licences)—

(a) in paragraph (1), for "£178" substitute "£196", and

(b) in paragraph (3), for "£295" substitute "£325".

Amendment of regulation 41

21. In regulation 41 (fees for applications for membership and certificates)—

(a) in paragraph (1), for "£117" substitute "£129", and

(b) in paragraph (2), for "£62" substitute "£68".

Amendment of regulation 42

22. In regulation 42(1) (fee for a review upon oral representations or a person appointed hearing), for "£10,000" substitute "£11,000".

Amendment of Schedule 1

23. In Schedule 1 (general interpretation provisions), in paragraph 1(**7**) (interpretation), in the appropriate place insert—

""*Early Access to Medicines Scheme*" has the meaning given in regulation 8(1) of the Human Medicines Regulations;".

Amendment of Schedule 2

24.—(1) Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates) is amended as follows.

(2) In paragraph 1(**8**) (interpretation)—

(a) after the definition of "active ingredient from a new source", insert—

""*EAMS scientific opinion*" has the meaning given in regulation 8(1) of the Human Medicines Regulations;", and

(b) after the definition of "Phase IV trial", insert—

(**7**) Amended by S.I. 2019/775 (as amended by S.I. 2020/1488).

(**8**) Paragraph 1 of Schedule 2 was amended but the amendment is not relevant to these Regulations.

""*Promising Innovative Medicines designation*" means a designation issued by the licensing authority under the Early Access to Medicines Scheme in accordance with regulation 167C(2)(a) of the Human Medicines Regulations;".

(3) In paragraph 24(5)(**9**) (marketing authorisations), in the second column (fee payable) of the table (fees for marketing authorisation applications)—

(a) in item 1 (major application)—

(i) in entry (a), for "£29,732" substitute "£32,705",

(ii) in entries (b) to (d), for "£62,421" substitute "£68,663",

(iii) in entry (e), for "£18,437" substitute "£20,281",

(iv) in entry (f), for "£62,421" substitute "£68,663",

(v) in entry (g), for "£18,437" substitute "£20,281",

(vi) in entry (h), for "£92,753" substitute "£102,028",

(b) in item 2 (complex application)—

(i) in entries (a) to (c), for "£17,330" substitute "£19,063",

(ii) in entry (d), for "£10,443" substitute "£11,487",

(iii) in entry (e), for "£17,330" substitute "£19,063",

(iv) in entry (f), for "£10,443" substitute "£11,487",

(v) in entry (g), for "£25,643" substitute "£28,207",

(c) in item 3 (standard application)—

(i) in entries (a) to (c), for "£6,350" substitute "£6,985",

(ii) in entry (d), for "£5,783" substitute "£6,361",

(iii) in entry (e), for "£6,350" substitute "£6,985",

(iv) in entry (f), for "£5,783" substitute "£6,361",

(v) in entry (g), for "£9,402" substitute "£10,342",

(d) in item 4 (simple application), in entries (a) to (f), for "£2,564" substitute "£2,820",

(e) in item 5 (parallel import licence applications)—

(i) in entry (a), for "£1,792" substitute "£1,971",

(ii) in entry (b), for "£6,663" substitute "£8,722",

(iii) in entry (c), for "£18,180" substitute "£19,998", and

(f) in item 6 (change of ownership application), for "£442" substitute "£486".

(4) In paragraph 25(1) (fees where application includes reclassification)—

(a) in sub-paragraph (a), for "£11,992" substitute "£33,003", and

(b) in sub-paragraph (b), for "£8,162" substitute "£8,978".

(5) In paragraph 27(**10**) (joint development)—

(a) in sub-paragraph (2)—

(i) in paragraph (a)(i), for "£17,330" substitute "£19,063",

(ii) in paragraph (b)(i), for "£6,350" substitute "£6,985",

(iii) in paragraph (c)(i), for "£17,330" substitute "£19,063",

(**9**) Table inserted by S.I. 2019/775 and amended by S.I. 2020/1488.
(**10**) Amended by S.I. 2019/775(as amended by S.I. 2020/1488).

(iv) in paragraph (d)(i), for "£6,350" substitute "£6,985", and

(b) in sub-paragraph (3)(a)(i), for "£6,350" substitute "£6,985".

(6) In paragraph 28(**11**) (application for multiple authorisations)—

(a) in sub-paragraph (2)—

(i) in paragraph (a)(i), for "£17,330" substitute "£19,063",

(ii) in paragraphs (b)(i) and (c)(i), for "£6,350" substitute "£6,985",

(b) in sub-paragraph (3), in paragraphs (b)(i) and (c)(i), for "£6,350" substitute "£6,985", and

(c) in sub-paragraph (4)(b), for "£734" substitute "£1,308".

(7) In paragraph 28A(**12**) (application by pre-assessment of modules)—

(a) in sub-paragraphs (1)(a) to (c), for each "£23,188.25" substitute "£25,507", and

(b) in sub-paragraphs (2)(a) to (c), for each "£4,332.50" substitute "£4,766".

(8) In paragraph 30(1) (manufacturer's licences and authorisations)—

(a) in paragraph (a), for "£183" substitute "£201",

(b) in paragraph (b), for "£344" substitute "£378", and

(c) in paragraph (c), for "£3,143" substitute "£3,457".

(9) In paragraph 31 (wholesale dealer's licences)—

(a) in sub-paragraph (1), for "£1,803" substitute "£1,983",

(b) in sub-paragraph (2), for "£902" substitute "£992", and

(c) in sub-paragraph (5), for "£399" substitute "£439".

(10) In paragraph 32 (broker's registrations)—

(a) in sub-paragraph (1), for "£1,803" substitute "£1,983", and

(b) in sub-paragraph (2), for "£399" substitute "£439".

(11) In paragraph 33 (active substance registrations)—

(a) in sub-paragraph (1)—

(i) in paragraph (a), for "£3,143" substitute "£3,457",

(ii) in paragraph (b), for "£1,803" substitute "£1,983", and

(b) in sub-paragraph (2), for "£399" substitute "£439".

(12) In paragraph 34 (clinical trial authorisations)—

(a) in sub-paragraph (a), for "£3,060" substitute "£3,366", and

(b) in sub-paragraph (b), for "£225" substitute "£248".

(13) In paragraph 35(1) (traditional herbal registrations), in the second column (fee payable) of the table (fee for application for traditional herbal registration), in entry 5 (change of ownership application), for "£442" substitute "£486".

(14) After paragraph 35, insert—

"**Early Access to Medicines Scheme fees**

35A. The fee payable under regulation 12(1)(a) in connection with an application submitted under the Early Access to Medicines Scheme of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

(**11**) Amended by S.I. 2019/775(as amended by S.I. 2020/1488).
(**12**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).

Fees for Early Access to Medicines Scheme applications

Column 1	*Column 2*
Kind of Application	*Fee payable*
1. Promising Innovative Medicine (PIM) designation	£3,986
2. EAMS scientific opinion for new medicinal products	£25,643
3. Renewal of an EAMS scientific opinion for new chemical or biological medicinal products	£12,821
4. EAMS scientific opinion for new indications	£8,309
5. Renewal of an EAMS scientific opinion for new indications	£4,154”

(15) In paragraph 38 (marketing authorisations)—

(a) in the second column (fee payable) of Table 1(**13**) (fees for applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008)—

(i) in entries 1(a) and 1(b), for “£277” substitute “£344”,

(ii) in entry 1(c), for “£2,493” substitute “£2,742”,

(iii) in entry 1(d), for “£7,693” substitute “£8,462,

(iv) in entry 2(a), for “£277” substitute “£344”,

(v) in entry 2(b), for “£496” substitute “£1,255”,

(vi) in entry 2(c), for “£2,703” substitute “£2,973”,

(vii) in entry 2(d), for “£7,883” substitute “£8,671”,

(b) in the second column (fee payable) in Table 2 (fees for applications for variations of marketing authorisations falling within the scope of Chapter IIa of Commission Regulation (EC) No 1234/2008 and of marketing authorisations in force in Great Britain)—

(i) in entry 1, for “£277” substitute “£344”,

(ii) in entry 2, for “£734” substitute “£1,308”,

(iii) in entry 3, for “£8,309” substitute “£9,140”,

(iv) in entry 4, for “£25,643” substitute “£33,003”,

(v) in entry 5, for “£622” substitute “£684”,

(vi) in entry 6, for “£1,652” substitute “£1,817”,

(vii) in entry 7, for “£9,010” substitute “£9,911”,

(viii) in entry 8, for “£26,276” substitute “£28,904”, and

(c) in the second column (fee payable) in Table 3 (fees for reclassification variation applications)—

(i) in entry (a), for “£11,992” substitute “£33,003”,

(ii) in entry (b), for “£8,162” substitute “£8,978”.

(16) In paragraph 40(1) (reclassification of marketing authorisations), for “£734” substitute “£1,308”.

(17) In paragraph 42(1) (variation of parallel import licence)—

(**13**) Table substituted by S.I. 2019/775(as amended by S.I. 2020/1488).

(a) in paragraph (a), for "£11,992" substitute "£33,003",

(b) in paragraph (b), for "£8,162" substitute "£8,978", and

(c) in paragraph (c), for "£357" substitute "£393".

(18) In paragraph 43 (manufacturer's authorisations and licences)—

(a) in sub-paragraph (a), for "£257" substitute "£283", and

(b) in sub-paragraph (b), for "£514" substitute "£565".

(19) In paragraph 44 (variation of manufacturer's authorisations and licences), for "£257" substitute "£283".

(20) In paragraph 45 (wholesale dealer's licences), for "£486" substitute "£535".

(21) In paragraph 46 (variation of wholesale dealer's licence), for "£257" substitute "£283".

(22) In paragraph 47 (variation of a broker's registration), for "£257" substitute "£283".

(23) In paragraph 48 (variation of an active substance registration), for "£257" substitute "£283".

(24) In paragraph 49(1) (clinical trial authorisations) for "£225" substitute "£248".

(25) In paragraph 53(a)(ii) (multiple reclassification variation applications), for "£734" substitute "£1,308".

(26) In paragraph 54 (a set of changes)—

(a) in sub-paragraph (1)—

(i) in paragraph (a), for "£518" substitute "£570",

(ii) in paragraph (b), for "£328" substitute "£361", and

(b) in sub-paragraph (2), for "£186" substitute "£205".

(27) In paragraph 56(**14**) (renewal of a marketing authorisation)—

(a) in sub-paragraphs (a) and (b), for "£747" substitute "£822", and

(b) in sub-paragraph (c), for "£9,682" substitute "£10,650".

(28) In paragraph 57(2)(**15**) (renewal of multiple marketing authorisations)—

(a) in sub-paragraphs (a)(i) and (a)(ii), for "£747" substitute "£822",

(b) in sub-paragraph (b)(i), for "£9,682" substitute "£10,650", and

(c) in sub-paragraph (b)(ii), for "£747" substitute "£822".

(29) In paragraph 57A(**16**) (capital fee for conducting a major safety review)—

(a) in sub-paragraph (a), for "£51,286" substitute "£56,415",

(b) in sub-paragraph (b), for "£59,595" substitute "£65,555",

(c) in sub-paragraph (c), for "£67,904" substitute "£74,694", and

(d) in sub-paragraph (d), for "£76,213" substitute "£83,834".

(30) In paragraph 57B(4)(**17**)—

(a) in the second column (fee payable where the licensing authority carries out a full assessment) of the table (fees for testing of samples)—

(i) in entry 1(a), for "£180" substitute "£198",

(ii) in entry 1(b), for "£215" substitute "£237",

(**14**) Amended by S.I. 2019/775.
(**15**) Amended by S.I. 2019/775(as amended by S.I. 2020/1488).
(**16**) Inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**17**) Amended by S.I. 2019/775 (as amended by S.I. 2020/1488).

(iii) in entry 1(c), for "£230" substitute "£253",

(iv) in entry 2, for "£1,660" substitute "£1,826",

(v) in entry 3, for "£1,910" substitute "£2,101",

(vi) in entry 4, for "£2,340" substitute "£2,574",

(vii) in entry 5, for "£3,690" substitute "£4,059",

(viii) in entry 6, for "£6,410" substitute "£7,051",

(ix) in entry 7, for "£10,350" substitute "£11,385", and

(b) in the third column (fee payable where the licensing authority carries out a paper-based assessment) of the table—

(i) in entries 1(a), (b) and (c), for "£90" substitute "£99",

(ii) in entries 2 and 3, for "£305" substitute "£367",

(iii) in entry 4, for "£305" substitute "£992",

(iv) in entry 5, for "£677" substitute "£992",

(v) in entries 6 and 7, for "£677" substitute "£1,849".

Amendment of Schedule 3

25.—(1) Schedule 3 (fees for inspections) is amended as follows.

(2) In paragraph 2(1) (fees: general)—

(a) in paragraph (a), for "£2,655" substitute "£3,651", and

(b) in paragraph (b), for "£1,328" substitute "£1,825".

(3) In paragraph 5 (wholesale dealer's licence: general)—

(a) in sub-paragraphs (a) and (b), for "£1,936" substitute "£2,662", and

(b) in sub-paragraph (b), for "£968" substitute "£1,331".

(4) In paragraph 6(2) (wholesale dealer's licence: traditional herbal medicinal products)—

(a) in paragraph (a), for "£744" substitute "£1,023", and

(b) in paragraphs (b) and (c), for "£1,367" substitute "£1,880".

(5) In paragraph 7(3) (wholesale dealer's licences: inspection of short duration), for "£968", substitute "£1,331".

(6) In paragraph 8 (broker's registrations)—

(a) in sub-paragraph (1)—

(i) in paragraphs (a) and (b), for "£1,936" substitute "£2,662",

(ii) in paragraph (b), for "£968" substitute "£1,331", and

(b) in sub-paragraph (3), for "£582" substitute "£640".

(7) In paragraph 9 (active substance registrations)—

(a) in sub-paragraph (1)(a)—

(i) in sub-paragraphs (i) and (ii), for "£2,655" substitute "£3,651",

(ii) in sub-paragraph (ii), for "£1,328" substitute "£1,825",

(b) in sub-paragraph (1)(b)—

(i) in sub-paragraphs (i) and (ii), for "£1,936" substitute "£2,662",

(ii) in sub- paragraph (ii), for "£968" substitute "£1,331", and

(c) in sub-paragraph (3)—

(i) in paragraph (a), for "£792" substitute "£871",

(ii) in paragraph (b), for "£582" substitute "£640".

(8) In paragraph 10 (office-based inspections)—

(a) in sub-paragraph (a), for "£1,863" substitute "£2,562", and

(b) in sub-paragraph (b), for "£1,354" substitute "£1,862".

Amendment of Schedule 4

26.—(1) Schedule 4 (periodic fees for licences) is amended as follows.

(2) In paragraph 5 (marketing authorisations), in column 2 (fee payable) of the table (periodic fees for holding a marketing authorisation)—

(a) in entry 1, for "£9,710" substitute "£10,681",

(b) in entry 2, for "£307" substitute "£338",

(c) in entry 3(a), for "£9,710" substitute "£10,681",

(d) in entry 3(b)(i), for "£2,428" substitute "£2,671",

(e) in entry 3(b)(ii), for "£1,211" substitute "£1,332",

(f) in entries 3(b)(iii), (c) and (d), for "£307" substitute "£338", and

(g) in entries 3(e) to (h), for "£76" substitute "£84".

(3) In paragraph 6 (marketing authorisation: where Part 2 of the Act applies), for "£307" substitute "£338".

(4) In paragraph 7 (marketing authorisation: derivatives)—

(a) in sub-paragraph (a), for "£9,710" substitute "£10,681", and

(b) in sub-paragraph (b), for "£6,554" substitute "£7,209".

(5) In paragraph 11(1) and (2) (manufacturer's licences or manufacturing authorisations), for "£468" substitute "£515".

(6) In paragraph 12 (wholesale dealer's licences)—

(a) in sub-paragraph (1), for "£288" substitute "£317", and

(b) in sub-paragraph (2), for "£172" substitute "£189".

(7) For paragraph 15(1), substitute—

"(1) The additional amount referred to in paragraphs 11(3) and 14 in relation to any fee period is—

(a) the fee specified in the entry in column 2 of Table 1 (additional periodic fee in connection with notices for imported special medicinal products) corresponding to the estimated number of special import notices for that fee period specified in column 1, and

(b) the fee specified in the entry in column 2 of Table 2 (additional periodic fee in connection with the number of different special medicinal products imported) corresponding to the estimated number of different special medicinal products imported for that fee period specified in column 1.

Table 1

Additional periodic fee in connection with notices for imported special medicinal products

Column 1	*Column 2*
Number of special import notices	*Additional amount*
1 to 20	£70
21 to 100	£350
101 to 1,000	£2,400
1,001 to 5,000	£12,000
5,001 to 20,000	£30,000
20,001 to 50,000	£60,000
50,001 to 100,000	£120,000
100,001 or more	£200,000

Table 2

Additional periodic fee in connection with the number of different special medicinal products notified for import

Column 1	*Column 2*
Number of different special medicinal products notified for import	*Additional amount*
1 to 5	£100
6 to 10	£200
11 to 20	£400
21 to 50	£1,000
51 to 100	£2,000
101 to 200	£4,000
For each additional 100 special medicinal products notified for import above 200	£2,000”

(8) After paragraph 15(2), insert—

“(3) For the purposes of this paragraph, the estimated number of different special medicinal products notified for import for any fee period shall be the number notified in writing to the licence holder by the licensing authority before the start of that fee period as the number of such notices which the authority estimate will be given by the holder during the fee period.”.

(9) In paragraph 16 (traditional herbal registrations), for “£76” substitute “£84”.

Signed by authority of the Secretary of State for Health and Social Care

Will Quince
Minister of State,
9th March 2023 Department of Health and Social Care

Sealed with the Official Seal of the Department of Health in Northern Ireland 8th March 2023

L.S.

Cathy Harrison
A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190).

The Medicines (Products for Human Use) (Fees) Regulations 2016 make provision for the fees payable in relation to authorisations, licences, certificates and registrations in respect of medicinal products for human use, including those under the Human Medicines Regulations 2012 and the Medicines for Human Use (Clinical Trials) Regulations 2004.

The fee amounts specified in these Regulations represent an increase in the existing fees of 10% or more and are set in line with a consultation response issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 31 January 2023. A summary of the consultation responses and the Government's response to the consultation are published on the MHRA's website (www.mhra.gov.uk).

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.