SCHEDULE

Regulation 4

AMENDMENTS TO OTHER ENACTMENTS

1. In the Medicines (Pharmacy and General Sale Exemption) Order 1980(**1**) in article 1 (citation, commencement and interpretation), in paragraph (2)—

(a) in the definition of "Community marketing authorization" after "Regulation (EEC) No. 2309/93" insert "or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency",

(a) after the definition of "cosmetic" insert the following definition—

> ""Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**2**), Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use", and

(b) in the definition of "United Kingdom marketing authorization" after "Schedule 6 to those Regulations" insert "or an authorization granted by the licensing authority in accordance with Article 126a of Directive 2001/83/EC".

2. In the Medicines (Applications for Grant of Product Licences – Products for Human Use) Regulations 1993(**3**), in regulation 1 (citation, commencement and interpretation), in paragraph 2, in the definition of "the 2001 Directive", after "as amended", insert "by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".

3. In the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**4**), in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of " authorised medicinal product", after "Council Regulation (EEC) No 2309/93", insert "or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

(**1**) S.I. 1980/1924; relevant amending instrument is S.I. 2000/1919.
(**2**) OJ No. L33, 8.2.2003, p.30.
(**3**) S.I. 1993/2538; relevant amending instruments are S.I. 2002/236 and S.I. 2003/2321.
(**4**) S.I. 1995/449.

4. In the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996(**5**), in regulation 3 (exemptions from requirement to carry out risk assessments), in paragraph (2)(c), after "Council Regulation (EEC) No 2309/93", insert "or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

5. In the Prescription Only Medicines (Human Use) Order 1997(**6**), in article 1 (citation, commencement and interpretation), in paragraph (2)—

(a) in the definition of "Community marketing authorization", after "Council Regulation (EEC) No. 2309/93", insert "or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency", and

(b) in the definition of "United Kingdom marketing authorization" after "Schedule 6 to those Regulations" insert "or an authorization granted by the licensing authority in accordance with Article 126a of Directive 2001/83/EC";

6. In the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000(**7**) in regulation 2 (interpretation), in paragraph 1—

(a) after the definition of "branded health service medicine" insert the following definition—

> ""Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use";

(b) in the definition of "marketing authorisation"—

(i) for sub-paragraph (a), substitute the following—

> "(a) by the competent authority of the United Kingdom in accordance with Directive 2001/83/EC and includes an authorisation granted by the competent authority in accordance with Article 126a of Directive 2001/83; or", and

(ii) in sub-paragraph (b), after "Evaluation of Medicinal Products" insert "or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

7. In the Genetically Modified Organisms (Contained Use) Regulations 2000(**8**) in regulation 3 (application), in paragraph (3) (a) (ii), after "Council Regulation (EEC) No 2309/93", insert "or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community

(**5**) S.I. 1996/1106.
(**6**) S.I 1997/1830; relevant amending instrument is S.I.2000/1917.
(**7**) S.I. 2000/123; relevant amending instruments are S.I. 2002/236 and S.I. 2004/3224.
(**8**) S.I 2000/2831.

procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

8. In the Biocidal Products Regulations 2001(**9**) in regulation 3 (application), in paragraph (1)(b), after "Evaluation of Medicinal Products", insert "or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

9. In the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**10**) in regulation 15 (exempt activities), after "Regulation (EEC) 2309/93", insert "or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

10. In the Medical Devices Regulations 2002(**11**), in regulation 2 (interpretation), in paragraph (1), in the definition of "Directive 2001/83", after "human use" insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".

11. In the Genetically Modified Organisms (Deliberate Release) Regulations 2002(**12**), in regulation 15 (exempt activities), in paragraph (e), after "Commission Regulation EC No. 649/98", insert "or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

12. In the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (*Rheoliadau Organeddau A Addaswyd Yn Enetig (Eu Gollwng Yn Fwriadol) (Cymru) 2000*) (**13**) in regulation 16 (exempt activities) (*gweithgareddau esempt*),in paragraph (e), in the English text, after "Commission Regulation EC No. 649/98", insert "or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency" and in the Welsh text, after "Reoliad y Comisiwn EC Rhif 649/98" insert "neu Reoliad (EC) Rhif 726/2004 Senedd Ewrop a'r Cyngor sy'n gosod gweithdrefnau'r Gymuned ar gyfer awdurdodi a goruchwylio cynhyrchion meddyginiaethol at ddefnydd pobl ac anifeiliaid a sefydlu Asiantaeth Meddyginiaethau Ewrop".

13. In the Food Supplements (England) Regulations 2003(**14**), in regulation 3 (scope of regulations), in paragraph (2), after "human use", insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on

(**9**) S.I. 2001/880.
(**10**) S.I. 2002/541.
(**11**) S.I. 2002/618.
(**12**) S.I. 2002/2443.
(**13**) S.I. 2002/3188.
(**14**) S.I.2003/1387.

the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".

14. In the Food Supplements (Scotland) Regulations 2003(**15**) in regulation 3 (scope of regulations) in paragraph (2), after "human use", insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".

15. In English text of the Food Supplements (Wales) Regulations 2003(**16**)(*Rheoliadau Ychwanegion Bwyd (Cymru) 2003*)(**17**), in regulation 3 (scope of regulations) in paragraph (2), after "human use", insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use". In the Welsh text of the Regulations, in regulation 3 (scope of regulations) in paragraph (2), after "i bobl eu defnyddio", insert "fel y"i diwygiwyd gan Gyfarwyddeb 2002/98/EC Senedd Ewrop a'r Cyngor sy'n gosod safonau ansawdd a diogelwch ar gyfer casglu, profi, prosesu, storio a dosbarthu gwaed a chydrannau gwaed dynol , Cyfarwyddeb y Comisiwn 2003/63/EC sy'qn diwygio Cyfarwyddeb 2001/83/EC ar god y Gymuned ynglŷn â chynhyrchion meddyginiaethol i bobl eu defnyddio, Cyfarwyddeb 2004/24/EC Senedd Ewrop a'r Cyngor sy'n diwygio, o ran cynhyrchion meddyginiaethol llysieuol traddodiadol, Gyfarwyddeb 2001/83/EC ar god y Gymuned ynglŷn â chynhyrchion meddyginiaethol i bobl eu defnyddio a Chyfarwyddeb 2004/27/EC Senedd Ewrop a'r Cyngor sy'n diwygio Cyfarwyddeb 2001/83/EC ar god y Gymuned ynglŷn â chynhyrchion meddyginiaethol i bobl eu defnyddio".

16. In the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**18**) in paragraph 43 of Schedule 6 (restrictions on prescribing by supplementary prescribers), in sub-paragraph (6), after "human use", insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".

17. In the Medicines for Human Use (Clinical Trials) Regulations 2004(**19**), in regulation 2 (interpretation), in paragraph (1)—

(**15**) S.I.2003/278.
(**16**) S.I. 2003/1719.
(**17**) S.I. 2003/1719.
(**18**) S.I. 2004/478.
(**19**) S.I. 2004/1031.

(a) in the definition of "Directive 2001/83/EC" after "as amended" insert "by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use",

(b) in the definition of "marketing authorization", in paragraph (c), after "Council Regulation (EEC) 2309/93", insert "or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

18. In the General Product Safety Regulations 2005(**20**) in regulation 33 (duty to notify), in paragraph (10)(b), after "human use", insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".

19. In Schedule 13 to the Enterprise Act 2002(**21**), for paragraph 11 substitute the following—

"**11.** Articles 83 to 100 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use as read with—

(a) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, the code, and

(d) Directive 2004/27/EC of the European Parliament and of the Council also amending the code.".

(**20**) S.I. 2005/1803.
(**21**) c.40; relevant amending instrument is S.I. 2003/1374.