STATUTORY INSTRUMENTS

2010 No. 1620

HEALTH CARE AND ASSOCIATED PROFESSIONS

The Pharmacy Order 2010 (Approved European Pharmacy Qualifications) Order 2010

Made - - - - 28th June 2010

Laid before Parliament
Laid before the Scottish
Parliament - - - 5th July 2010

Coming into force - - 27th September 2010

At the Council Chamber, Whitehall, the 28th day of June 2010 By the Lords of Her Majesty's Most Honourable Privy Council

Their Lordships make the following Order of Council in exercise of the powers conferred by article 21(1)(b) and (3) of the Pharmacy Order 2010(1) as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(2).

This Order makes provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to their Lordships that it is necessary for the reference to Directive 2005/36/EC of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications(3) to be construed as a reference to that Directive as amended from time to time.

⁽¹⁾ S.I.2010/231

^{(2) 1972} c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51) and amended by S.1.2007/1388.

⁽³⁾ OJNo. L255, 30.09.2005 p22, as amended by Council Directive 2006/100/EEC of 20th November 2006, OJ No. L363 of 20.12.2006, p141; Commission Regulation 1430/2007 EC of 5th December 2007, OJ No. L320 of 1.12.2007 p3; Commission Regulation 755/2008 EC of 31st July 2008, OJ No. L205 of 1.8.2008 p10; Regulation 1137/2008 EC of the European Parliament and of the Council of 22nd October 2008, OJ No. L311 of 21.11.2008 p1; and Commission Regulation 279/2009 of 6th April 2009, OJ No. L93 of 7.4.2009 p11.

PART 1

Introductory

Citation, commencement and interpretation

- 1.—(1) This Order may be cited as the Pharmacy Order 2010 (Approved European Pharmacy Qualifications) Order 2010 and comes into force on 27th September 2010.
 - (2) In this Order—
 - "appropriate European diploma" has the meaning given in article 2; and
 - "reference date", in relation to a relevant European State, means the date specified in relation to that State in the column entitled "Reference date" in Annex V, point 5.6.2 of the Directive.
- (3) References in this Order to "competent authority" have effect only in relation to the practise of pharmacy by pharmacists.
- (4) References in this Order to any provision of the Directive are references to that provision of the Directive as amended from time to time.

Appropriate European diplomas

- **2.**—(1) Appropriate European diplomas are designated as being approved qualifications for the purposes of entry in Part 1 of the Register.
- (2) Subject to article 7, the following diplomas are "appropriate European diplomas" for the purposes of paragraph (1)—
 - (a) a diploma listed in Annex V, point 5.6.2 of the Directive which has been granted in a relevant European State after its reference date and which is evidence of training commenced after that date, provided that that diploma is accompanied, where appropriate, by the certificate listed in relation to that State in the column of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma"; or
 - (b) any diploma which—
 - (i) subject to article 3, has been granted in a relevant European State before its reference date or which is evidence of training commenced before that date but completed on or after that date,
 - (ii) subject to article 4, was awarded by the competent authority of, or which is evidence of training started in, the territory specified in column (b) of the table in the Schedule before the date specified in the corresponding entry in column (a) of that table,
 - (iii) subject to article 5, is evidence of training commenced before 3 October 1990 and undertaken in the territory of the former German Democratic Republic, or
 - (iv) subject to article 6, does not fall within paragraphs (i) to (iii) and is not listed in Annex V, point 5.6.2 of the Directive but which is a diploma in pharmacy granted in a relevant European State on or after its reference date.

Conditions relating to diplomas, whether listed or not, awarded in respect of training before a relevant European State's reference date

- 3. A diploma to which article 2(2)(b)(i) applies is only an appropriate European diploma if—
 - (a) in the case of a diploma listed in Annex V, point 5.6.2 of the Directive—
 - (i) the Registrar is satisfied (by means of a certificate from the relevant competent authority or otherwise) that the diploma guarantees that the holder's training satisfied

- the requirements of Article 44 of the Directive (requirements for pharmacists' training), and
- (ii) the diploma is accompanied, where appropriate, by the certificate listed in relation to the relevant European State in which the diploma was awarded in the column of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma";
- (b) in the case of a diploma which is not listed in Annex V, point 5.6.2 of the Directive, the diploma is accompanied by a certificate from the competent authority of the relevant European State in which the diploma was awarded which certifies that the diploma—
 - (i) is evidence of training which satisfies the requirements of article 44 of the Directive, and
 - (ii) is treated by the competent authority of the relevant European State in which it was awarded as equivalent to a diploma listed in relation to that State in Annex V, point 5.6.2 of the Directive,

and the certificate is made available to the Registrar; or

(c) whether or not the diploma is listed in Annex V, point 5.6.2 of the Directive, the competent authority of a relevant European State has certified that the holder has, in a relevant European State, been effectively and lawfully engaged in the practice of an activity open to pharmacists in that State for at least three consecutive years during the five years preceding the date of the certificate, and the certificate is made available to the Registrar.

Conditions relating to old diplomas granted in respect of training commenced in the former Czechoslovakia, the former Soviet Union or the former Yugoslavia

- **4.** A diploma to which article 2(2)(b)(ii) applies is only an appropriate European diploma if—
 - (a) the competent authority of the relevant European State specified in the appropriate row of column (c) of the table in the Schedule has certified that the diploma has, on its territory, the same legal validity as regards access to the practice of pharmacy as the diploma listed in Annex V, point 5.6.2 of the Directive in respect of their State;
 - (b) that competent authority has also certified that the holder of the diploma has, in the relevant European State specified in the appropriate row of column (c) of the table in the Schedule, been effectively and lawfully engaged in the practice of an activity open to pharmacists in that State for at least three consecutive years during the five years preceding the date of that certificate; and
 - (c) the certificate is made available to the Registrar.

Conditions relating to old diplomas granted in respect of training commenced in the former German Democratic Republic

- 5. A diploma to which article 2(2)(b)(iii) applies is only an appropriate European diploma if—
 - (a) the diploma entitles its holder to practise pharmacy throughout the territory of Germany on the same conditions as those that apply to the holder of a diploma listed in Annex V, point 5.6.2 of the Directive in respect of Germany; and
 - (b) the competent authority in Germany has certified that the holder of the diploma has been effectively and lawfully engaged in the practice of an activity open to pharmacists in Germany for at least three consecutive years during the five years preceding the date of that certificate, and the certificate is made available to the Registrar.

Conditions relating to new diplomas

- **6.** A diploma to which article 2(2)(b)(iv) applies is only an appropriate European diploma if the competent authority of the relevant European State that has awarded it has certified that the diploma—
 - (a) is evidence of training that satisfies the requirements of article 44 of the Directive, and
 - (b) it is treated by that competent authority as equivalent to a diploma listed in Annex V, point 5.6.2 of the Directive in respect of that State; and
 - (c) the certificates are made available to the Registrar.

Justified doubts

- 7. A diploma is only an appropriate European diploma if—
 - (a) in a case where the Council (including its Registrar) has justified doubts about the authenticity of the evidence of the diploma made available to the Council and has required the relevant competent authority's confirmation of the authenticity of the evidence, the relevant competent authority has confirmed the authenticity of the evidence;
 - (b) in a case where the Council (including its Registrar) has justified doubts about whether the holder of the diploma has completed training which satisfies the requirements of Article 44 of the Directive, and has required of the relevant competent authority confirmation of completion of such training, the relevant competent authority has confirmed completion of such training; and
 - (c) in a case where the Council (including its Registrar) has justified doubts concerning training received in a relevant European State other than that in which the diploma was awarded, and has required confirmation of the relevant competent authority in accordance with Article 50(3) of the Directive, the relevant competent authority has provided confirmation in accordance with that article.

Judith Simpson Clerk of the Privy Council

SCHEDULE

Article 2(2)

TABLE IN RESPECT OF RECOGNITION OF TRAINING IN THE FORMER CZECHOSLOVAKIA. THE FORMER SOVIET UNION OR THE FORMER YUGOSLAVIA

Table

Column (a)	Column (b)	Column (c)
1 January 1993	Former Czechoslovakia	Czech Republic
1 January 1993	Former Czechoslovakia	Slovakia
21 August 1991	Former Soviet Union	Latvia
20 August 1991	Former Soviet Union	Estonia
25 June 1991	Former Yugoslavia	Slovenia
11 March 1990	Former Soviet Union	Lithuania

EXPLANATORY NOTE

(This note is not part of the Order)

This Order provides for the approval of certain European pharmacy qualifications by reference to the framework for mutual recognition in Directive 2005/35/EC. Although that Directive does not currently apply to Switzerland, this Order makes anticipatory provision for the recognition within Great Britain of pharmacy qualifications awarded in Switzerland as well as provision for the recognition of those pharmacy qualifications awarded in the EEA States other than the United Kingdom. Recognition of the qualifications is subject to specified conditions, which include a procedure for confirming the authenticity of qualifications where there are justified doubts.

Appropriately qualified pharmacists are entitled to be entered in Part 1 of the register established and maintained by the General Pharmaceutical Council under article 19 of the Pharmacy Order 2010 (S.I.2010/231) and so practise as pharmacists in Great Britain, provided their fitness to practise is not impaired and they have paid the appropriate fees.

This Order, and the Pharmacy Order 2010 under which it is made, contain the legislative measures necessary for implementing Council Directive 2005/36/EC concerning the co-ordination of provisions laid down by law, regulation and administrative action in respect of certain activities in the field of pharmacy and the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy. The legislative measures implementing this Directive in Great Britain were previously partly set out in the Pharmacists and Pharmacy Technicians Order 2007 (S.I.2007/289) which has been revoked by Schedule 4 to the Pharmacy Order 2010.