SCOTTISH STATUTORY INSTRUMENTS

2015 No. 91

NATIONAL HEALTH SERVICE

The National Health Service (Cross-Border Health Care) (Scotland) Amendment Regulations 2015

Made - - - -	*27th February 2015*
Laid before the Scottish Parliament - - - -	*2nd March 2015*
Coming into force - -	*31st March 2015*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**) and all other powers enabling them to do so.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the National Health Service (Cross-Border Health Care) (Scotland) Amendment Regulations 2015 and come into force on 31st March 2015.

(2) These Regulations extend to Scotland only.

Amendments to the National Health Service (Cross-Border Health Care) (Scotland) Regulations 2013

2.—(1) The National Health Service (Cross-Border Health Care) (Scotland) Regulations 2013(**2**) are amended as follows—

(a) in regulation 2 (interpretation) after the definition of "the Directive" insert—

> "Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to medicinal products for human use(**3**);";

(b) after regulation 5 (NCP: information about treatment in another Member State) insert—

(**1**) 1972 c.68. Section 2(2) was amended by the Scotland Act 1998 Act (c.46) ("the 1998 Act"), Schedule 8, paragraph 15(3) (which was amended by section 27(4) of the Legislative and Regulatory Reform Act 2006 (c.51) ("the 2006 Act")). Section 2(2) was also amended by section 27(1)(a) of the 2006 Act and by the European Union (Amendment) Act 2008 (c.7), Schedule, Part 1. The functions conferred upon the Minister of the Crown under section 2(2), insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act.

(**2**) S.S.I. 2013/292.

(**3**) OJ L 311, 28.11.2001, p.67.

"**NCP: information about prescriptions intended to be used in another Member State**

5A.—(1) The NCP must make available to patients information about the elements, specified in the Schedule, to be included in a prescription which is—

(a) issued in one Member State; and

(b) intended to be used in another Member State."; and

(c) insert the following as the Schedule to the Regulations—

"SCHEDULE Regulation 5A

Elements that must be included in a prescription issued in a Member State other than the Member State where it is intended to be used

1. The patient's—

(a) surname(s);

(b) first name(s) (written out in full); and

(c) date of birth.

2. The date on which the prescription is issued.

3. The prescribing professional's—

(a) surname(s);

(b) first name(s) (written out in full);

(c) professional qualification;

(d) direct contact details including—

(i) email address;

(ii) telephone or fax number with the appropriate international prefix;

(iii) work address;

(iv) Member State in which the professional works; and

(v) signature (either written or electronic depending on the medium chosen for issuing the prescription).

4. The details of the prescribed product, including where applicable the—

(a) common name as defined by Article 1 of Directive 2001/83/EC;

(b) brand name if—

(i) the prescribed product is a biological medicinal product as referred to in point 3.2.1.1.(b) of Annex 1 (Part 1) to Directive 2001/83/EC; or

(ii) the prescribing professional deems it medically necessary for that product to be dispensed and, in that case, the prescribing professional's reasons justifying the use of the brand name;

(c) pharmaceutical formulation (such as tablet, solution etc.);

(d) quantity;

(e) strength as defined in Article 1 of Directive 2001/83/EC; and

(f) dosage regimen.".

St Andrew's House,
Edinburgh
27th February 2015

SHONA ROBISON
A member of the Scottish Government

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Cross-Border Health Care) (Scotland) Regulations 2013 ("the 2013 Regulations").

They implement in Scotland Article 4 of Commission Implementing Directive 2012/52/EU of 20th December 2012, laying down measures to facilitate the recognition of medical prescriptions issued in another Member State. The 2013 Regulations implement in Scotland provisions of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

Regulation 2 inserts a new regulation 5A and a Schedule into the 2013 Regulations which places a duty on the National Contact Point (NHS 24) to ensure that information is made available to patients on the elements required to be included in prescriptions which are issued in one Member State and intended to be used in another Member State. The matters which must be included are set out in the new Schedule.

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.