STATUTORY RULES OF NORTHERN IRELAND

2015 No. 130

HEALTH AND PERSONAL SOCIAL SERVICES

The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015

Made - - - -	*6th March 2015*
Coming into operation	*27th March 2015*

The Department of Health, Social Services and Public Safety(**1**), makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**2**).

The Department of Health, Social Services and Public Safety is a Department designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to cross-border health care(**3**).

Citation and commencement

1. These Regulations may be cited as The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015 and shall come into operation on 27th March 2015.

Amendments to the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013

2.—(1) The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013(**4**) are amended as follows.

(2) After regulation 5 (National Contact Point: Information about treatment in another member State) insert—

"**National Contact Point: 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—

(**1**) Formerly the Department of Health and Social Services; See S.I. 1999/283 (N.I. 1) Article 3(6)
(**2**) 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1) and by the European Union (Amendment) Act 2008 (c.7), section 3(3) and Part 1 of the Schedule
(**3**) S.I. 2009/2743
(**4**) S.R. 2013 No. 299

(a) issued in one member State, and

(b) intended to be used in another member State.".

(3) Add the following Schedule—

"SCHEDULE Regulation 5A

Elements that must be included in prescriptions intended to be used in another member State

1. The patient's—
   (a) surname,
   (b) first names, and
   (c) date of birth.
2. The issue date of the prescription.
3. The prescribing professional's—
   (a) surname,
   (b) first names,
   (c) professional qualification,
   (d) direct contact details including—
      (i) email address, and
      (ii) telephone or fax number with the appropriate international prefix,
   (e) work address,
   (f) member State in which the professional works,
   (g) signature (either written in ink 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 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ("Directive 2001/83/EC")(**5**),
   (b) brand name if—
      (i) the prescribed product is a biological medicinal product, as defined 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.".

(**5**) OJ No L311, 28.11.2001, p.67. Directive 2001/83/EC was last amended by Directive 2012/26/EU (OJ No. L299, 27.10.2012, p. 1).

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 6th March 2015

Mark Lee
A senior officer of the Department of Health,
Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health Service (Cross-Border Health Care) Regulations (Northern Ireland) 2013 ("the 2013 Regulations") to implement Article 4 of Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another member State. The 2013 Regulations themselves implement the 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(2) amends the 2013 Regulations so as to introduce a duty on the national contact point (which in Northern Ireland is the Regional Health and Social Care Board) 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 elements which must be included are specified in the Schedule which is added to the 2013 Regulations by regulation 2(3).

An impact assessment has not been prepared for these Regulations as no, or no significant impact on the public, private or voluntary sectors is forseen.