STATUTORY INSTRUMENTS

2015 No. 139

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

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

Made - - - -	*4th February 2015*
Laid before Parliament	*11th February 2015*
Coming into force - -	*27th March 2015*

The Secretary of State, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 (**1**), makes the following Regulations.

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to the National Health Service(**2**).

Citation, commencement and extent

1.—(1) These Regulations may be cited as the National Health Service (Cross-Border Healthcare) (Amendment) Regulations 2015 and come into force on 27th March 2015.

(2) These Regulations extend to England and Wales only.

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

2.—(1) The National Health Service (Cross-Border Healthcare) Regulations 2013(**3**) are amended as follows.

(2) After regulation 4 (NCP: information about treatment in another member State) insert—

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

4A. 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

(**1**) 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a), and by the European Union (Amendment) Act 2008 (c.7), section 3(3) and Part 1 of the Schedule.
(**2**) S.I. 2001/3495.
(**3**) S.I. 2013/2269.

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

(3) Insert the following Schedule—

"SCHEDULE

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 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")(**4**),

(b) brand name if—

(i) the prescribed product is a biological medicinal product, as defined in point 3.2.1.1. (b) of Annex I (Part I) 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."

(**4**) 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).

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

4th February 2015

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations amend the National Health Service (Cross-Border Healthcare) Regulations 2013 ("the 2013 Regulations") to implement in England and Wales, 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 in England and Wales 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 amends the 2013 Regulations so as to introduce a duty on the national contact point (which in England is the National Health Service Commissioning Board and in Wales is the Welsh Ambulance Services National Health Service Trust) 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 inserted into the 2013 Regulations.

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