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STATUTORY INSTRUMENTS

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**2020 No. 189**

**DANGEROUS DRUGS, ENGLAND  
DANGEROUS DRUGS, SCOTLAND**

**The Controlled Drugs (Supervision of Management  
and Use) (Amendment) Regulations 2020**

*Made - - - - 26th February 2020*

*Laid before Parliament 28th February 2020*

*Coming into force in accordance with regulation 1(2)*

The Secretary of State in exercise of the powers conferred by sections 17(1) and (3)(b), 18 and 79(3) of the Health Act 2006(1) makes the following Regulations.

The Scottish Ministers have been consulted in accordance with section 24(6) of that Act.

**Citation and commencement**

1.—(1) These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020.

(2) These Regulations come into force as follows—

- (a) regulations 1 to 3 come into force on 30th March 2020; and
- (b) regulations 4 to 7 come into force on 1st April 2020.

**Amendment of the Controlled Drugs (Supervision of Management and Use) Regulations 2013**

2. The Controlled Drugs (Supervision of Management and Use) Regulations 2013(2) are amended as follows.

**Amendment of regulation 1**

3. In regulation 1 (citation, commencement, application and expiry), omit paragraph (3), and in its heading, for “, application and expiry” substitute “and application”.

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(1) [2006 c.28](#). Section 18 was amended by [S.I. 2013/602](#), article 26, and Schedule 2, paragraph 51(1), (2)(a), (b) and (c)(ii). Section 79 was amended by the Children and Families Act [2014 \(c.6\)](#), section 95(1), (5)(a), (b) and (c) and [S.I. 2018/644](#), article 42(1) and (3).

(2) [S.I. 2013/373](#), to which there are amendments not relevant to these Regulations.

## Insertion of regulation 1A

4. After regulation 1 (citation, commencement and application), insert—

### “Review

- 1A.**—(1) The Secretary of State must from time to time—
- (a) carry out a review of the regulatory provision contained in these Regulations; and
  - (b) publish a report setting out the conclusions of the review.
- (2) The first report must be published before 30th March 2025.
- (3) Subsequent reports must be published at intervals not exceeding 5 years.
- (4) Section 30(4) of the Small Business, Enterprise and Employment Act 2015<sup>(3)</sup> requires that a report published under this regulation must, in particular—
- (a) set out the objectives intended to be achieved by the regulatory provision referred to in paragraph (1)(a);
  - (b) assess the extent to which those objectives are achieved;
  - (c) assess whether those objectives remain appropriate; and
  - (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.
- (5) In this regulation, “regulatory provision” has the same meaning as in sections 28 to 32 of the Small Business, Enterprise and Employment Act 2015 (see section 32 of that Act).”.

## Amendment of regulation 2

5. In regulation 2(1) (interpretation)—
- (a) omit the definition of “NHS Protect”;
  - (b) in the definition of “regular force”, omit from “(that is” to the end of that definition; and
  - (c) for the definition of “reserve force”, substitute—
    - ““reserve force” means the Royal Fleet Reserve, the Royal Naval Reserve, the Royal Marines Reserve, the Regular Reserve, the Army Reserve, the Air Force Reserve or the Royal Auxiliary Air Force;”.

## Amendment of regulation 6

6. In regulation 6 (meaning of “responsible bodies”)—
- (a) in paragraph (b)—
    - (i) omit sub-paragraph (iii), and
    - (ii) in sub-paragraph (iv), omit “the Prescription Pricing Division of”; and
  - (b) in paragraph (c), for sub-paragraph (iii), substitute—
    - “(iii) Public Health Scotland<sup>(4)</sup>.”.

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(3) 2015 c. 26. Section 30 is amended by the Enterprise Act 2016, section 19(a) and (b) and the European Union (Withdrawal) Act 2018, section 23(5), Schedule 8, paragraph 36(a) and (b).

(4) Constituted by S.S.I. 2019/336.

### **Amendment of regulation 13**

7. In regulation 13 (monitoring, assessing, investigating and taking action in relation to relevant individuals)—

(a) in paragraph (3)—

(i) in sub-paragraph (a), for “ePACT” substitute “ePACT2”, and

(ii) in sub-paragraph (b), for “the Common Services Agency,” substitute “Public Health Scotland<sup>(5)</sup>,”;

(b) in paragraph (6), omit sub-paragraph (c); and

(c) in paragraph (7), in sub-paragraph (b)—

(i) in paragraph (iii), omit sub-paragraph (cc), and

(ii) in paragraph (iv), omit sub-paragraph (dd).

Signed by the authority of the Secretary of State for Health and Social Care.

26th February 2020

*Jo Churchill*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (the 2013 Regulations). The 2013 Regulations contain a sunset clause to provide that they expire on 31st March 2020. Regulation 3 removes this clause. Regulation 4 inserts new regulation 1A which introduces a requirement on the Secretary of State to carry out a statutory review of the 2013 Regulations and to publish a report of that review by 30th March 2025, and to then publish subsequent reports every 5 years. Regulations 5, 6 and 7 make miscellaneous amendments to regulations 2, 6 and 13 of the 2013 Regulations, to update definitions and references to bodies. In particular they reflect internal reorganisation of the National Health Service Business Services Authority, and the change of one of the responsible bodies in Scotland who are engaged in information activities that involve the management or use of controlled drugs, from the Information Services Division of the Common Services Agency to Public Health Scotland, who will also hold the Prescribing Information Systems for Scotland.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sector is foreseen.