Draft Regulations laid before Parliament and the Northern Ireland Assembly under section 47 of the Medicines and Medical Devices Act 2021 (c. 3), for approval by resolution of each House of Parliament and the Northern Ireland Assembly.

DRAFT STATUTORY INSTRUMENTS

2024 No.

MEDICINES

The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024

Made - - - -

Coming into force in accordance with regulation 1(2)

The Secretary of State in relation to England and Wales and Scotland and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland make these Regulations in exercise of the powers conferred by sections 2(1), 3(1)(n), 3(2)(a), (c) and (d) and 43(2) of the Medicines and Medical Devices Act 2021(**1**) ("the Act").

The Secretary of State and the Department of Health in Northern Ireland have carried out a public consultation in accordance with section 45(1) of the Act.

In accordance with section 2(2) to (4) of the Act, the Secretary of State's and the Department of Health in Northern Ireland's overarching objective in making these Regulations is safeguarding public health. The Secretary of State and the Department of Health in Northern Ireland have had regard to the matters specified in section 2(3) of the Act and consider that, where these Regulations may have an impact on the safety of human medicines, the benefit of making these Regulations outweigh the risks.

In accordance with section 47(3) and (6)(c) of the Act, a draft of this instrument was laid before Parliament and the Northern Ireland Assembly and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.

(**1**) 2021 c. 3. The powers in section 2(1) of the Act and the provisions that relate to it are exercisable by the "appropriate authority". As defined in section 2(6)(a) of the Act, the appropriate authority for England and Wales and Scotland is the Secretary of State. In relation to Northern Ireland, as defined in section 2(6)(b)(ii), the appropriate authority can mean the Secretary of State and the Department of Health in Northern Ireland acting jointly.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024.

(2) These Regulations come into force on the 28th day after the day on which they are made.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**2**) are amended as follows.

Amendment of regulation 213

3. In regulation 213(1) (interpretation)(**3**) after the definition of "registered orthotist and prosthetist" insert—

> ""registered pharmacy technician" means a person registered in Part 2 of the Register of pharmacists and pharmacy technicians established and maintained under article 19(1) and (2) of the Pharmacy Order 2010(**4**);".

Amendment of Schedule 16

4. In Schedule 16 (patient group directions), in Part 4 (classes of individuals by whom supplies may be made), after "Registered paramedics." insert "Registered pharmacy technicians.".

Amendment of Schedule 17

5.—(1) Schedule 17 (exemption for sale, supply or administration by certain persons) is amended as follows—

(2) In Part 2 (exemption from the restriction on supply of prescription only medicines)(**5**), in paragraph 1, after item 12 insert—

"**13.** Registered dental therapists or registered dental hygienists who are qualified to use the medicines specified in column 2.	**13.** The following prescription only medicines— (a) Lidocaine 2% with 1:80,000 adrenaline, (b) Articaine hydrochloride 4% with 1:100,000 adrenaline, (c) Articaine hydrochloride 4% with 1:200,000 adrenaline, (d) 3% Mepivacaine hydrochloride, (e) 3% Prilocaine with 0.54 microgram/ml felypressin, (f) 2.5%/2.5% Lidocaine and prilocaine peridontal gel,	**13.** The supply shall be only in the course of their professional practice.".

(**2**) S.I. 2012/1916.
(**3**) There are amendments but none is relevant.
(**4**) S.I. 2010/231, amended by S.I. 2019/593.
(**5**) Item 12 was added to the table in paragraph 1 by S.I. 2016/186. There are other amending instruments but none is relevant.

	(g) Sodium fluoride varnish, 50mg/ml (2.26%) dental suspension (containing 22600ppm fluoride), (h) Minocyline 2% periodontal gel, (i) Sodium fluoride 0.619% (2800ppm fluoride) dental paste, (j) Sodium fluoride 1.1% (5000ppm fluoride) dental paste, (k) 15% Lidocaine, 0.15% cetrimide oromucosal spray, (l) Nystatin oral suspension.	

(3) In Part 3 (exemptions from the restriction on administration of prescription only medicine)(**6**), in paragraph 1, after item 11 insert—

"**12.** Registered dental therapists or registered dental hygienists who are qualified to use the medicines specified in column 2.	**12.** The following prescription only medicines for parenteral administration— (a) 2% Lidocaine with 1:80,000 adrenaline, (b) Articaine hydrochloride 4% with 1:100,000 adrenaline, (c) Articaine hydrochloride 4% with 1:200,000 adrenaline, (d) 3% Mepivacaine hydrochloride, (e) 3% Prilocaine with 0.54 microgram/ml felypressin.	**12.** The administration shall be only in the course of their professional practice.".

(4) In Part 4 (exemption from the restriction in regulations 220 and 221 for certain persons who sell, supply, or offer for sale or supply certain medicinal products)(**7**), in paragraph 1, after item 13 insert—

"**14.** Registered dental therapists or registered dental hygienists who are qualified to use the medicines specified in column 2.	**14.** All medicinal products on a general sale list, all pharmacy medicines and the following prescription only medicines which are not for parenteral administration— (a) 2.5%/2.5% Lidocaine and prilocaine periodontal gel, (b) Sodium fluoride varnish, 50mg/ml (2.26%) dental suspension	**14.** The sale, supply or offer for sale or supply shall be only in the course of their professional practice.".

(**6**) Item 11 was added to the table in paragraph 1 by S.I. 2017/715. There are other amending instruments but none is relevant.
(**7**) Item 13 was added to the table in paragraph 1 by S.I. 2016/186 and amended by 2017/715. There are other amendments not relevant to these Regulations.

(containing 22600ppm fluoride),

(c) Minocycline 2% periodontal gel,

(d) Sodium fluoride 0.619% (2800ppm fluoride) dental paste,

(e) Sodium fluoride 1.1% (5000ppm) dental paste,

(f) 15% Lidocaine, 0.15% cetrimide oromucosal spray,

(g) Nystatin oral suspension.

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

[NAME]
Parliamentary Under Secretary of State,
DATE Department of Health and Social Care

Sealed with the Official Seal of the Department of Health in Northern Ireland

[NAME]
A senior officer of the Department of Health in
DATE Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 (S.I. 2012/1916) ("HMRs") which govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use. The amendments extend to the whole of the United Kingdom.

Regulations 214(1) and (2), 220 and 221 in Part 12 (Dealings with medicinal products) of the HMRs impose prohibitions on the sale, supply and administration of prescription only medicines, general sale and pharmacy only medicines. Chapter 3 (Exemptions) of Part 12 of the HMRs contains exemptions to those prohibitions for certain individuals to sell, supply and administer certain medicines. These Regulations introduce amendments that enable suitably qualified registered dental therapists and hygienists and registered pharmacy technicians to sell, supply and administer certain medicines relevant to their professional practice in reliance on the applicable exemptions in chapter 3 to the prohibitions.

Regulation 3 inserts a new defined term of registered pharmacy technician into regulation 213(1) of the HMRs.

Regulation 4 adds registered pharmacy technicians to the list of registered healthcare professionals in Schedule 16 to the HMRs. The effect of this amendment is to add registered pharmacy technicians to the list of health care professionals who may supply and administer medicines under a Patient Group Direction (commonly referred to as a 'PGD') in the course of their professional practice.

Regulation 5 amends Parts 2, 3 and 4 of Schedule 17 to the HMRs in relation to registered dental therapists and registered dental hygienists. These amendments enable registered dental therapists and hygienists who are qualified to supply and administer the medicines listed in column 2 of the amendments to sell, supply and administer them to individuals whom they are treating in the course of their professional practice in accordance with the exemptions contained in regulation 235 (Exemption for sale, supply or administration by certain persons).

Impact assessments relating to this instrument have been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU and are available on the www.legislation.gov.uk website.