Illustrative Regulations prepared by the Department of Health and Social Care to accompany passage of the Medicines and Medical Devices Bill through each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

MEDICINES

The Human Medicines (Amendment) (Electronic Package Leaflets) Regulations 2020

Made - - - -	***
Laid before Parliament	***
Laid before the Northern Ireland Assembly	***
Coming into force - -	***

The Secretary of State and the Department of Health in Northern Ireland make the following Regulations in exercise of the powers conferred by sections 1(1), 2(1)(j) and 5(1)(b) of the Medicines and Medical Devices Act 2020(**a**).

[In accordance with section 40(1) of that Act, the Secretary of State and the Department of Health in Northern Ireland have consulted such persons as they consider appropriate.]

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) (Electronic Package Leaflets) Regulations 2020 and come into force on [ ].

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**b**) are amended in accordance with the following provisions of these Regulations.

Insertion of regulation 260A (electronic package leaflets)

3. After regulation 260 (package leaflets) insert—

"**Electronic package leaflets**

260A.—(1) The information which must be included in—

(a) a package leaflet for a medicinal product in accordance with regulation 260(1) or (1A)(**c**); and

(b) an instruction leaflet in accordance with regulation 263(3),

(**a**) 2020 c. [ ]. The powers in section 1(1) are conferred on the "appropriate authority". *See* section 1(4) for the definition of appropriate authority.
(**b**) S.I. 2012/1916.
(**c**) Regulation 260(1A) was inserted by S.I. 2019/775.

must be made available to the public at all times in an electronic format.

(2) In this Regulation, "electronic format" means [*this is currently subject to consultation at EU level and would be subject to consultation in the UK before being finalised*].

(3) Regulations 261 and 266 apply to the information made available under paragraph (1) as they apply to the information in a package or instruction leaflet.".

Amendment of regulation 268 (offence relating to packaging and package leaflets: holder of authorisation etc)

4. In regulation 268(**a**)—

(a) omit the "or" at the end of paragraph (2)(a); and

(b) at the end insert—

"; or

(c) the person fails to make available to the public at all times in an electronic format the information required by regulation 260A(1) to be so available.".

Amendment of Part 1 of Schedule 27 (package leaflet: general requirements)

5. At the end of Part 1 of Schedule 27(**b**) insert—

"**15A.** An indication of where the information which must be made available in electronic format in accordance with regulation 260A(1) may be found.".

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

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Date

Name
A senior officer of the Department of Health in Northern Ireland

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend Part 13 of the Human Medicines Regulations 2012 in order to impose on the holders of marketing authorisations for medicinal products an obligation to make available at all times in electronic format the information which must be included in the package leaflet associated with such products.

(**a**) Regulation 268 was amended by S.I. 2019/62 and 2019/775.
(**b**) Schedule 27 was amended by S.I. 2014/1878 and 2019/775.

Illustrative Regulations prepared by the Department of Health and Social Care to accompany passage of the Medicines and Medical Devices Bill through each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2020 No.

MEDICINES

The Human Medicines (Amendment) (Sale at a Distance) Regulations 2020

Made - - - - ***

Coming into force - - ***

The Secretary of State and the Department of Health in Northern Ireland make the following Regulations in exercise of the powers conferred by sections 1(1), 2(1)(l) and 5(1)(b) of the Medicines and Medical Devices Act 2020(**1**).

[In accordance with section 40(1) of that Act, the Secretary of State and the Department of Health in Northern Ireland have consulted such persons as they consider appropriate.

In accordance with section 41(5) of that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.]

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment)(Sale at a Distance) Regulations 2020 and come into force on [ ].

Amendment of the Human Medicines Regulations 2012

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

Insertion of Part 12B (sale of Medicines to the public at a distance)

3. After Part 12 (dealings with medicinal products)(**3**) insert—

(**1**) 2020 c. [ ]. The powers in section 1(1) are conferred on the "appropriate authority". See section 1(4) for the definition of appropriate authority.
(**2**) S.I. 2012/1916.
(**3**) Part 12A was revoked by S.I. 2019/775.

"PART 12B

Sale of Medicines to the Public at a Distance

Interpretation

256O.—(1) In this Part—

"distance selling logo" means a logo that meets the requirements laid down in Schedule 23A;

"information society services" has the same meaning as in the Electronic Commerce (EC Directive) Regulations 2002(**4**);

"the list" means the list of persons who are entitled to supply medicinal products by information society services that is maintained on the website of the licensing authority;

"website of the licensing authority" means the website of the licensing authority providing information on the list of persons offering medicinal products for sale at a distance by means of information society services as well as their website addresses.

(2) In this Part, references to selling a medicinal product at a distance to the public by means of information society services, however expressed, include supplying and offering to sell or supply a medicinal product at a distance to the public by means of information society services (and related expressions are to be interpreted accordingly).

Person who may sell medicinal products by information society services

256P.—(1) A person may not sell a medicinal product at a distance to the public by means of information society services unless that person satisfies the following conditions.

(2) Condition A is that the person is included on the list.

(3) Condition B is that where the sale is to a member of the public in the United Kingdom, the product to be sold by information society services is covered by a UK marketing authorisation, a certificate of registration or a traditional herbal registration.

(4) Condition C is that the person selling the medicinal product is authorised or entitled to sell to the public, including by information society services, medicinal products of that type or classification.

(5) Condition D is that where the sale is to a member of the public in the United Kingdom, it is in accordance with regulations 214 (sale or supply of prescription only medicines), 220 (sale or supply of medicinal products not subject to general sale) and 221 (sale or supply of medicinal products subject to general sale).

(6) Condition E is that the person selling the medicinal product has given a valid notification to the licensing authority in accordance with regulation 256Q.

(7) Condition F is that the person selling medicinal products at a distance complies with the relevant provisions of the Electronic Commerce (EC Directive) Regulations 2002.

(8) A person has not given a valid notification for the purposes of paragraph (6) if—

(a) that person is not included on the list;

(b) that person's entry on the list is suspended by the licensing authority; or

(c) the licensing authority has been notified under regulation 256S(b) to remove that person from the list.

(**4**) S.I. 2002/2013.

Notification requirements for sellers of medicinal products at a distance

256Q.—(1) The licensing authority may not enter a person's details on the list unless it has been notified in accordance with paragraphs (2) to (5).

(2) The notification must include—

(a) the name or corporate name of the person to be listed;

(b) information about—

(i) that person's permanent address from which the activity of selling medicinal products by information society services is to be carried out,

(ii) the commencement date of the activity of selling medicinal products by information society services,

(iii) the address of the website used for the purposes of selling medicinal products by information society services,

(iv) all relevant information necessary to identify the website, and

(v) information about the classification of all the medicinal products offered for sale at a distance.

(3) The notification must—

(a) be in English; and

(b) unless paragraph (4) applies, in relation to the person whose details are to be entered on the list—

(i) be signed by that person, and

(ii) contain that person's telephone number and e-mail address if this is available.

(4) Where the notification is made by another person ("A") on behalf of the person whose details are to be entered on the list, the notification must—

(a) contain the name and address of A;

(b) be signed by A; and

(c) contain the telephone number and e-mail address for A if this is available.

(5) The notification must contain contact details for the site from which the activity of selling medicinal products by information society services is to be carried out including the--

(a) site address;

(b) name of person who may be contacted; and

(c) telephone number and e-mail address of the person who may be contacted.

Procedure for listing persons who may supply medicinal products at a distance

256R.—(1) On receipt of a notification from a person to be included in the list—

(a) the licensing authority must include that person on the list; or

(b) if it considers it necessary or appropriate to do so, the licensing authority must refuse to include that person on the list having had regard to the provisions of these Regulations.

(2) The licensing authority must accept or refuse to include the person on the list within the period of 90 days beginning immediately after the day on which the notification is received by the authority.

(3) Paragraph (2) applies only if the requirements of regulation 256Q(2) to (5) have been met.

(4) Before determining if a person can be included on the list, the licensing authority may require the person giving the notification to provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(5) If a notice under paragraph (4) requires the person giving the notification to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (2).

(6) In paragraph (5), the "information period" means the period—

(a) beginning with the day on which the notice is given, and

(b) ending with the day on which—

(i) the licensing authority receives the information; or

(ii) the person from whom the information is requested shows to the satisfaction of the licensing authority that the information cannot be provided.

(7) The licensing authority must give the person giving the notification a notice stating reasons for its decision in any case where—

(a) the licensing authority refuses to include the person giving the notification on the list; or

(b) if the licensing authority lists the person giving the notification otherwise than in accordance with the information supplied in the notification.

(8) Where the licensing authority decides to include a person on the list the licensing authority must ensure that the website of the licensing authority includes—

(a) the name or corporate name of the person that is listed; and

(b) the person's website address in the United Kingdom.

Removal of a person's entry from the list

256S. The licensing authority may remove a person's entry from the list if—

(a) regulation 256V(1)(c) applies; or

(b) a notification to remove the entry is received from the person on the list.

Provision of information to the licensing authority

256T.—(1) A person on the list must immediately inform the licensing authority and, where applicable, the marketing authorisation holder, of medicinal products which that person—

(a) identifies as;

(b) knows or suspects to be; or

(c) has reasonable grounds for knowing or suspecting to be,

falsified.

(2) The person entered on the list must notify the licensing authority of any change of circumstances which is material as regards that person's entry on the list.

(3) The licensing authority may give a notice to a person on the list, requiring that person to provide information of a kind specified in the notice within the period specified in the notice.

(4) A notice under paragraph (3) may not be given to a person on the list unless it appears to the licensing authority that it is necessary for the licensing authority to consider whether that person's entry on the list should be varied, suspended or removed.

(5) A notice under paragraph (3) may specify information which the licensing authority thinks necessary for considering whether the person's entry on the list should be varied, suspended or removed.

Conditions to be met by a person entered on the list

256U.—(1) A person entered on the list must not sell a medicinal product at a distance by information society services unless the following conditions are satisfied.

(2) Condition A is that the person entered on the list must comply with regulation 256P.

(3) Condition B is that the website used to sell medicinal products at a distance must contain—

(a) the contact details of the licensing authority; and

(b) a hyperlink to the website of the licensing authority.

(4) Condition C is that the website used to sell medicinal products at a distance must contain the distance selling logo which—

(a) is clearly displayed on every page of the listed person's website that relates to medicinal products offered for sale at a distance; and

(b) contains a hyperlink to the entry of that person in the list.

Power to suspend, vary or remove a person's entry on the list

256V.—(1) The licensing authority may in accordance with regulation 256W—

(a) suspend a person's entry on the list for such period as the licensing authority thinks fit;

(b) vary a person's entry on the list; or

(c) remove a person's entry from the list.

(2) The suspension of a person from the list may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products sold at a distance from specified premises or a specified part of any premises.

(3) The power conferred by this regulation may only be exercised on one or more of the following grounds—

(a) in relation to any information notified to the licensing authority under regulation 256Q as a result of which the person was included in the list—

(i) the information so supplied was false or incomplete in a material respect, or

(ii) a material change of circumstances has occurred in relation to any of the matters stated in the notification;

(b) the person on the list has materially contravened a condition required to be met by a person entered on the list under regulation 256U; or

(c) the person on the list has without reasonable excuse failed to supply information to the licensing authority with respect to their notification when required to do so under regulation 256T(3).

Procedure where the licensing authority proposes to suspend, vary or remove a person's entry on the list

256W.—(1) This regulation applies where—

(a) the provisions of regulation 256X do not apply; and

(b) the licensing authority proposes to exercise the power in regulation 256V.

(2) The licencing authority must notify the person on the list in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) a specified date on which it is proposed that the suspension, variation or revocation should take effect.

(3) The specified date in paragraph (2)(c) must be no earlier than 28 days following the date of the notice given by the licensing authority.

(4) The person to whom notice is given under paragraph (2) may before the date specified in the notice—

(a) make written representations to the licencing authority with respect to the proposal; or

(b) notify the licensing authority that the person wishes the licensing authority to submit the proposal to review upon oral representations.

(5) If a person on the list makes written representations in accordance with sub-paragraph (4)(a) the licensing authority must take those representations into account before making a decision in the matter.

(6) If the person on the list gives notice of the proposal to review upon oral representation in accordance with paragraph (4)(b)—

(a) Schedule 5 has effect; and

(b) the person on the list must pay a fee for a review upon oral representations in accordance with the Fees Regulations.

(7) If the licensing authority proceeds to suspend, vary or remove a person's entry on the list in accordance with the provisions of regulation 256V it must give a notice to that person.

(8) The notice must—

(a) give particulars of the suspension, variation or removal; and

(b) give reasons for the decision to suspend, vary or remove the person's entry on the list.

(9) Paragraphs (7) and (8) are without prejudice to any requirement of Schedule 5 as to notification.

Suspension of a person's entry on the list in cases of urgency

256X.—(1) The licensing authority may immediately suspend a person's entry on the list for a period not exceeding three months where it appears to the licensing authority that in the interests of safety it is appropriate to do so.

(2) This paragraph applies where—

(a) a person's entry on the list has been suspended under paragraph (1); and

(b) it appears to the licensing authority that it is necessary to consider whether the person's entry on the list should be—

(i) further suspended or varied, or

(ii) removed from the list.

(3) Where paragraph (2) applies, the licencing authority must proceed as set out in regulation 256W (but this is subject to paragraph (4) and (5)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 256W and any proceedings under that regulation have not been finally disposed of before the end of the period for which the person's entry was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the licensing authority may further suspend the person's entry on the list for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 256W to suspend, vary or remove a person's entry on the list is made on an application under regulation 322(4) (validity of decisions and proceedings), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (interim order of the High Court).

Variation of a person's entry on the list on the application of that person

256Y.—(1) This regulation applies if a person entered on the list applies to the licensing authority for a variation of the person's entry on the list.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant; and

(d) be accompanied by such information as may be required to enable the licensing authority to consider the application.

(3) The licensing authority must vary a person's entry on the list or refuse to vary it within 30 days beginning with the day after the date when that competent authority receives the application.

(4) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period--

(a) beginning with the day on which notice under paragraph (4) is given; and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 256V and 256X.

Offences: breach of regulations and false information

256Z.—(1) A person is guilty of an offence if the person—

(a) contravenes regulation 256P(1); or

(b) offers medicinal products for sale at a distance otherwise than in accordance with the conditions in regulation 256U.

(2) A person is guilty of an offence if the person knowingly gives false information in—

(a) an application to be entered on the list in accordance with regulation 256Q(2);

(b) response to a notice under regulation 256R(4);

(c) an application for a variation in accordance with regulation 256Y(2); or

(d) response to a notice under regulation 256Y(4).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 256T(3).

(4) A person is guilty of an offence if that person fails to inform the licencing authority—

(a) of a falsified medicinal product in accordance with regulation 256T(1); or

(b) about a material change of circumstances in accordance with regulation 256T(2).

(5) It is a defence for a person charged with an offence under paragraph (4) to show that the person exercised all due diligence to avoid committing the offence.

Penalties

256Z1.—(1) A person guilty of an offence under regulation 256Z(1), (2) or (4) is liable—

(a) on summary conviction to a fine; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 256Z(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.".

Amendment of regulation 327 (powers of inspection, sampling and seizure)

4. In regulation 327(1)(d)(**a**), for "Part 12A" substitute "Part 12B".

Amendment of Schedule 5 (review upon oral representations)

5.—(1) Paragraph 1 of Schedule 5(**b**) is amended as follows.

(2) In sub-paragraph (1)(d), for "regulation 256J(4)(b)" substitute "regulation 256X(4)(b)".

(3) In sub-paragraph (2)(d)—

(a) for "regulation 256J(4)(b)" substitute "regulation 256X(4)(b)"; and

(b) for "Part 12A" substitute "Part 12B".

Insertion of Schedule 23A (requirements for the distance selling logo)

6. After Schedule 23 (particulars in pharmacy records) insert—

(**a**) Regulation 327 was amended by S.I. S.I. 2013/1855 and 2019/62 and 775.
(**b**) Schedule 5 was amended by S.I. 2013/1855 and 2019/775.

"SCHEDULE 23A Regulation 256O(1)

Requirements for the Distance Selling Logo

1. The distance selling logo referred to in regulation 256O(1) must conform with the following design:

[*design to be inserted*]

2. The distance selling logo must have a minimum width size of 90 pixels.

3. The distance selling logo must be static.

4. If the distance selling logo is used on a coloured background, which makes it difficult to see, a delimiting outer line around the logo must be used to improve contrast with the background colour.".

Signed by the authority of the Secretary of State

Name
Date Department of Health and Social Care

Name
Date A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations").

Regulations 3 to 6 insert requirements relating to the sale at a distance of medicinal products.

Illustrative Regulations prepared by the Department of Health and Social Care to accompany passage of the Medicines and Medical Devices Bill through each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

MEDICINES

The Human Medicines (Amendment) (Exemption for Supply by Dental Hygienists and Dental Therapists) Regulations 2020

Made - - - -	***
Laid before Parliament	***
Laid before the Northern Ireland Assembly	***
Coming into force - -	***

The Secretary of State and the Department of Health in Northern Ireland make the following Regulations in exercise of the powers conferred by sections 1(1) and 2(1)(n) of the Medicines and Medical Devices Act 2020(**a**).

[In accordance with section 40(1) of that Act, the Secretary of State and the Department of Health in Northern Ireland have consulted such persons as they consider appropriate.]

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) (Exemption for Supply by Dental Hygienists and Dental Therapists) Regulations 2020 and shall come into force on [ ].

Amendment of the Human Medicines Regulations 2012

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

Amendment of Schedule 17 (exemption for sale, supply or administration by certain persons)

3.—(1) Schedule 17 is amended as follows.

(2) In the table in Part 1(**c**) (exemption from restrictions on sale and supply of prescription only medicines), after item 13 in the table insert—

"14 Registered dental	14 The following	14 The sale or supply shall

(**a**) 2020 c. [ ]. The powers in section 1(1) are conferred on the "appropriate authority". See section 1(4) for the definition of appropriate authority.
(**b**) S.I. 2012/1916.
(**c**) Part 1 was amended by S.I. 2014/1878, 2016/186, 2017/715 and 2019/775.

hygienists or registered dental therapists against whose names are recorded in the dental care professionals register annotations signifying that they are qualified to use the medicines specified in column 2.	prescription only medicines— (a) Sodium fluoride dental paste, (b) Nystatin oral suspension.	only be in the course of their professional practice.”

(3) In the table in Part 3(**a**) (exemptions from the restriction on administration of prescription only medicines), after item 11 in the table insert—

“12 Registered dental hygienists or registered dental therapists against whose names are recorded in the dental care professionals register annotations signifying that they are qualified to use the medicines specified in column 2.	12 The following prescription only medicines— (a) Lidocaine with adrenaline, (b) Articaine hydrochloride with adrenaline, (c) Mepivacaine hydrochloride, (d) Prilocaine with felypressin, (e) Sodium fluoride varnish, (f) Lidocaine and prilocaine periodontal gel, (g) Minocycline periodontal gel.	12 The administration shall only be in the course of their professional practice and where the medicine includes a combination of substances in column 2, those substances shall not have been combined by the dental hygienist or dental therapist. ”

(4) In the table in Part 4(**b**) (exemptions from the restrictions in regulations 220 and 221 for certain persons who sell, supply, or offer for sale or supply certain medicinal products), after item 13 in the table insert—

“14 Registered dental hygienists or registered dental therapists against whose names are recorded in the dental care professionals register annotations signifying that they are qualified to use the medicines specified in column 2.	14 All medicinal products subject to general sale, all pharmacy medicines and the following prescription only medicines— (a) Sodium fluoride dental paste, (b) Nystatin oral suspension.	14 The sale or supply shall only be in the course of their professional practice.”

Signed by the authority of the Secretary of State

Name
Date Department of Health and Social Care

(**a**) Part 3 was amended by S.I. 2014/490 and 2017/715.
(**b**) Part 4 was amended by S.I. 2013/2593, 2016/186, 2017/715 and 2019/775.

Name

Date A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations").

Regulation 3 amends Schedule 17 of the 2012 Regulations so that dental hygienists and dental therapists can sell, supply and administer certain medicinal products in the course of their professional practice.

Illustrative Regulations prepared by the Department of Health and Social Care to accompany passage of the Medicines and Medical Devices Bill through each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

MEDICINES

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2020

Made - - - - ***

Coming into force - - ***

The Secretary of State and the Department of Health in Northern Ireland make the following Regulations in exercise of the powers conferred by sections 1(1) and 4(1)(c) of the Medicines and Medical Devices Act 2020(**a**).

[In accordance with section 40(1) of that Act, the Secretary of State and the Department of Health in Northern Ireland have consulted such persons as they consider appropriate.

In accordance with section 41(5) of that Act, a draft of these Regulations has been laid before and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.]

Citation and commencement

1. These Regulations may be cited as the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2020 and come into force on [ ].

Amendment of the Human Medicines Regulations 2012

2. The Medicines for Human Use (Clinical Trials) Regulations 2004(**b**) are amended as follows.

Amendment of regulation 2 (interpretation)

3. In regulation 2(**c**), at the appropriate place insert—

> ""type A trial" means a clinical trial involving only medicinal products which have a marketing authorization and which, for the purposes of the trial, are not—
>
> (a) used, assembled, formulated or packaged in a way different from the form of the product authorised under that authorization, or

(**a**) 2020 c. [ ]. The powers in section 1(1) are conferred on the "appropriate authority". See section 1(4) for the definition of appropriate authority.
(**b**) S.I. 2004/1031.
(**c**) Regulation 2 was amended by S.I. 2004/3224, 2005/2759, 2006/562 and 1928, 2007/3101, 2008/941, 2010/231, 2011/2581, 2012/1479, 1641 and 1916, 2013/235, 2016/696 2019/593 and 744

(b) used for an indication not included in the summary of product characteristics under the authorization for that product;".

Amendment of regulation 32 (notification of adverse events)

4. In regulation 32, after paragraph (10) insert—

"(11) This regulation does not apply to type A trials.".

Insertion of regulation 32A (notification of serious adverse reactions: type A trials)

5. After regulation 32 (notification of adverse events), insert—

"Notification of serious adverse reactions: type A trials

32A.—(1) This regulation applies to type A trials only.

(2) An investigator must report any serious adverse reaction which occurs in a subject at a trial site at which the investigator is responsible for the conduct of a clinical trial immediately to the sponsor.

(3) An immediate report under paragraph (2) may be made orally or in writing.

(4) Following the immediate report of a serious adverse reaction, the investigator must make a detailed written report on the event.

(5) Paragraphs (2) to (4) do not apply to serious adverse reactions specified in the protocol or the investigator's brochure as not requiring immediate reporting.

(6) Adverse reactions, other than those to which paragraphs (2) to (4) apply, that are identified in the protocol as critical to evaluations of the safety of the trial must be reported to the sponsor in accordance with the reporting requirements, including the time periods for such reporting, specified in that protocol.

(7) The reports made under paragraphs (2) and (4) must identify each subject referred to in the report by a number assigned to that subject in accordance with the protocol for the trial.

(8) The number assigned to a subject in accordance with the protocol must be different from the number of any other subject in that trial, including any subject at a trial site outside the United Kingdom.

(9) Where the reaction reported under paragraph (2) or (4) consists of, or results in, the death of a subject, the investigator must supply—

(a) the sponsor; and

(b) in any case where the death has been reported to the relevant ethics committee, that committee,

with any additional information requested by the sponsor or, as the case may be, the committee.

(10) The sponsor must keep detailed records of all serious adverse reactions relating to a clinical trial which are reported to the sponsor by the investigators for that trial.

(11) The licensing authority may, by sending a notice in writing to the sponsor, require that sponsor to send the records referred to in paragraph (10), or copies of such records, to the authority.".

Amendment of regulation 33 (notification of suspected unexpected serious adverse reactions)

6.—(1) Regulation 33(**a**) is amended as follows.

(**a**) Regulation 33 was amended by S.I. 2019/744

(2) Omit paragraph (1)(b)(iii).

(3) Omit sub-paragraph (3)(c).

Amendment of regulation 35 (annual list of suspected serious adverse reactions and safety report)

7.—(1) Regulation 35(**a**) is amended as follows.

(2) In paragraph (1), after "clinical trials" insert ", other than type A trials,".

(3) After paragraph (1) insert—

"(1A) As soon as practicable after the end of the reporting year, a sponsor must, in relation to each investigational medicinal product tested in type A trials in the United Kingdom for which they are the sponsor furnish the licensing authority and the relevant ethics committees with—

(a) a list of all the suspected unexpected serious adverse reactions which have occurred during that year in relation to—

(i) those type A trials, whether at trial sites in the United Kingdom or elsewhere, or

(ii) any other type A trials relating to that product which are conducted outside the United Kingdom and for which they are the sponsor,

including those reactions relating to any investigational medicinal product used as a placebo or as a reference in those type A trials; and

(b) a report on the safety of the subjects of those type A trials.".

Signed by the authority of the Secretary of State

Name
Date Department of Health and Social Care

Name
Date A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the 2004 Regulations").

Regulation 3 updates the general interpretation provisions in the 2004 Regulations to insert a new definition of a "type A trial".

Regulations 4 removes the requirement for investigators to report serious adverse events to the sponsor for type A trials.

Regulation 5 imposes a new requirement on investigators in type A trials to report serious adverse reactions to the sponsor.

Regulation 6 amends regulation 33 of the 2004 Regulations to remove the requirement for Sponsors to report suspected unexpected serious adverse reactions which occur during the course of a clinical trial to the relevant ethics committee.

Regulation 7 amends regulation 35 of the 2004 Regulations to remove the requirement for sponsors of type A trials to provide the licensing authority and the relevant ethics committees with

(**a**) Regulation 35 was amended by S.I. 2019/744

a list of all the suspected serious adverse reactions which have occurred during a reporting year and replaces this with a requirement to just provide a list of the suspected unexpected serious adverse reactions which have occurred during that year.

Illustrative Regulations prepared by the Department of Health and Social Care to accompany passage of the Medicines and Medical Devices Bill through each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

MEDICINES

The Human Medicines (Amendment) (Exemption for Supply in Response to Spread of Pathogenic Agents etc) Regulations 2020

Made - - - - ***

Coming into force - - ***

The Secretary of State and the Department of Health in Northern Ireland make the following Regulations in exercise of the powers conferred by sections 1(1) and 6 of the Medicines and Medical Devices Act 2020(**a**).

[In accordance with section 40(1) of that Act, the Secretary of State and the Department of Health in Northern Ireland have consulted such persons as they consider appropriate.

In accordance with section 41(5) of that Act, a draft of these Regulations has been laid before and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.]

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) (Exemption for Supply in Response to Spread of Pathogenic Agents etc) Regulations 2020 and come into force on [ ].

Amendment of the Human Medicines Regulations 2012

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

(2) After regulation 247 (exemption for supply in the event or anticipation of pandemic disease)(**c**) insert—

"Exemption for supply in response to spread of pathogenic agents etc

247A.—(1) Regulations 214, 220 and 221 do not apply to the supply of a medicinal product that meets the following conditions.

(2) Condition A is that the supply is made in response to, or in anticipation of, the suspected or confirmed spread of —

(**a**) 2020 c. [ ]. The powers in section 1(1) are conferred on the "appropriate authority". See section 1(4) for the definition of appropriate authority.
(**b**) S.I. 2012/1916.
(**c**) Regulation 247 has been amended by S.I. 2013/235.

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which gives rise to a need to protect the public or a section of the public from serious harm to health.

(3) Condition B is that the supply is in accordance with a protocol that—

(a) is published by the appropriate authority;

(b) specifies—

(i) the description or class of medicinal products to which the protocol relates,

(ii) the clinical situations which medicinal products of that description or class may be used to treat or manage, and

(iii) the clinical criteria under which a person is to be eligible for treatment;

(c) contains requirements as to the recording of—

(i) the name of the person who supplies the product to the person to be treated ("the patient") or to a person acting on the patient's behalf, and

(ii) evidence that the product was supplied to the patient or to a person acting on the patient's behalf; and

(d) only has effect for a period of time specified in the protocol.

(4) The appropriate authority is able to withdraw or amend a protocol that is published under paragraph (3)(a).".

Signed by the authority of the Secretary of State

Name
Date Department of Health and Social Care

Name
Date A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations").

Regulation 2 inserts regulation 247A into the 2012 Regulations in order to provide an exemption from the restrictions in regulations 214, 220 and 221 of those Regulations for the supply of medicines in response to, or in anticipation of, an event that gives rise to a need to protect the public or a section of the public from serious harm to health. Exempt supplies will need to be in accordance with protocols published by the Secretary of State and the Department of Health in Northern Ireland.

Illustrative Regulations prepared by the Department for Environment, Food and Rural Affairs to accompany passage of the Medicines and Medical Devices Bill through each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2020 No. 0000

MEDICINES

The Veterinary Medicines (Amendment) Regulations 2020

Made - - - - ***

Coming into force - - ***

The Secretary of State and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland make the following Regulations in exercise of the powers conferred by sections 8(1), 9(1)(l), 9(2) and 10(1)(a) of the Medicines and Medical Devices Act 2020(**a**).

[In accordance with section 40(1) of that Act, the Secretary of State and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland have consulted such persons as they consider appropriate.]

[In accordance with section 41(5) of that Act, a draft of this instrument has been laid before and approved by a resolution of, each House of Parliament and the Northern Ireland Assembly.]

Citation and commencement

1. These Regulations may be cited as the Veterinary Medicines (Amendment) Regulations 2020 and come into force on […].

Amendment of the Veterinary Medicines Regulations 2013

2.—(1) The Veterinary Medicines Regulations 2013(**b**) are amended as follows.

(2) In regulation 2(2), after the definition of "adverse reaction" insert—

> ""advertising" includes anything designed to promote the prescription, supply, sale or use of a veterinary medicinal product, including in particular the following activities—
>
> (a) door-to-door canvassing;
>
> (b) visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;
>
> (c) the supply of samples;

(**a**) 2020 c. X.
(**b**) S.I. 2013/2033. [Amendments to be footnoted for final version].

(d) the provision of inducements to prescribe or supply veterinary medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except where the intrinsic value of such inducements is minimal;

(e) the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;

(f) the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including the payment of their travelling and accommodation expenses in that connection;".

(3) In Schedule 1—

(a) for paragraph 11(3) substitute—

"(3) The product must not be placed on the market until the following period of time has elapsed from the initial authorisation of the reference product—

(a) for a veterinary medicinal product for cattle, sheep for meat production, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application, 14 years;

(b) for any other veterinary medicinal product for cattle, sheep for meat production, pigs, chickens, dogs and cats, 10 years;

(c) for a veterinary medicinal product for bees, 18 years;

(d) for a veterinary medicinal product for an animal species other than a species referred to in points (a) to (c), 14 years.";

(b) after paragraph 24(2)(f) insert—

"(g) the veterinary medicinal product is intended to be used in food-producing animals and the Secretary of State is satisfied that the active substance within the veterinary medicinal product is—

(i) persistent, bioaccumulative and toxic, or

(ii) very persistent and very bioaccumulative,

unless it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health.";

(c) after paragraph 48(2) insert—

"(3) The Secretary of State may publish a list of abbreviations and pictograms which the Secretary of State considers satisfy the requirements in sub-paragraph (1) if used on the immediate packaging.";

(d) after paragraph 49(4) insert—

"(5) The requirements set out in this paragraph must either appear in legible and comprehensible characters, or in abbreviations or pictograms which appear in a list published in accordance with sub-paragraph (6).

(6) The Secretary of State may publish a list of abbreviations and pictograms which the Secretary of State considers satisfy the requirements in this paragraph if used on immediate or outer packaging.".

(4) In Schedule 2, after paragraph 13 insert—

"**Importers, manufacturers and distributors of active substances**

13A.—(1) A person must not import, manufacture or distribute active substances with the intention to use such substances as starting materials in veterinary medicinal products, except under a registration issued by the Secretary of State in accordance with this paragraph.

(2) An application for registration must specify:

(a) the applicant's name or company name and permanent address or registered place of business;

(b) the active substances which are to be imported, manufactured or distributed;

(c) particulars regarding the premises and the technical equipment.

(3) The Secretary of State may inspect premises registered under this paragraph under this paragraph, based on the risk associated with the activities carried, the history and the nature of the products handled at the premises.

(4) Registration holders must notify the Secretary of State of any changes in the information required under sub-paragraph (2).

(5) Registration holders must notify the Secretary of State immediately of any changes that may have a material impact on the quality or safety of the active substances that are imported, manufactured or distributed.".

(5) In Schedule 3, after paragraph 3 insert—

"**Online sale of veterinary medicinal products**

3A. A person may only sell veterinary medicinal products online from a website registered with the Secretary of State in accordance with paragraph 3B.

Registration of a website for online retail supply

3B.—(1) A person may apply to the Secretary of State to register a website for the online sale of veterinary medicines.

(2) The Secretary of State must approve an application for registration under sub-paragraph (1) if the Secretary of State is satisfied that the applicant's website complies with these Regulations.

(3) The Secretary of State may suspend or withdraw a registration if the Secretary of State is satisfied that the registration-holder has breached a provision of these Regulations.

(4) If the Secretary of State refuses an application for, or suspends, or withdraws, the registration of a website, the applicant or registration-holder may appeal to the Veterinary Products Committee.

(5) The Secretary of State must maintain an online list of registered websites.".

(6) In Schedule 7, after paragraph 59 insert—

"**Fee for the registration of a website**

59A. The fee to register a website for the retail sale of veterinary medicines under paragraph 3B of Schedule 3 is £X.

Fee for an active substances registration

59B. The fee for a registration to import, manufacture or distribute active substances used as starting materials in veterinary medicinal products under paragraph 13A of Schedule 2 is £X.".

Name
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

Date
Signatory text

Name

A senior officer of the Department of Agriculture, Environment and Rural Affairs in Northern Ireland
Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations amend the Veterinary Medicines Regulations 2013 (S.I. 2013/2033). The majority of these amendments correspond to a number of changes made in Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products (OJ No L 4, 7.1.2019, p. 43) ("the EU Regulation"). The EU Regulation is to come into force on 28 January 2022, so will not become retained EU law under the European Union (Withdrawal) Act 2018 (c. 16) (see section 3).

Regulation 2(2) inserts a new definition of "advertising". This is based on the definition contained at regulation 7 of the Human Medicines Regulations 2012 (S.I. 2012/1916).

Regulation 2(3)(a) amends the time limits relating to granting a marketing authorisation under the procedure for a pharmacologically equivalent product.

Regulation 2(3)(b) inserts a new ground on which the Secretary of State must refuse to grant a marketing authorisation.

Regulation 2(3)(c) and (d) provide for the use of abbreviations and pictograms in the labelling and packaging of veterinary medicinal products, subject to Secretary of State approval.

Regulation 2(4) provides for the registration of persons importing, manufacturing or distributing active substances used as starting materials in veterinary medicinal products.

Regulation 2(5) provides for a new online accreditation scheme, corresponding to that which is set out at Article 104 of the EU Regulation.

Regulation 2(6) sets fees payable for registering an internet site under the accreditation scheme and for a registration to import, manufacture or distribute active substances for veterinary medical products.