STATUTORY INSTRUMENTS

S.I. No. 512 of 2008

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2008

(Prn. A8/1929)

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The Minister for Health and Children, in exercise of the powers conferred on her by section 32 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) (as adapted by the Health (Alteration of Name of Department and Title of Minister) Order 1997 (S.I. No. 308 of 1997)), hereby makes the following regulations:-

1. These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008.

2. (1) Subject to paragraphs (2) and (3), these Regulations come into operation on the 1st day of December, 2008.

(2) The provisions of Regulation 13 of the Principal Regulations as amended by Regulation 9 of these Regulations shall not apply to stocks of medicinal products that were on the market in the State on the date of coming into operation of these Regulations.

(3) Paragraph (2) of this Regulation ceases to have effect on 1 April 2009.

3. The Principal Regulations, the Regulations of 2005, the Regulations of 2007 and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2008 and shall be construed together as one.

4. In these Regulations-

"Principal Regulations" mean the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003);

"Regulations of 2005" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005); and

"Regulations of 2007" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007) and Part 4 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 5*th December*, 2008.

5. Regulation 4(1) of the Principal Regulations is amended by—

(*a*) substituting for the definition of "authorised person" the following definition:

"'authorised person' means a registered pharmacist;";

(*b*) inserting after the definition of "Board" the following definition:

"'certificate of registration' has the meaning assigned to it in Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);";

(*c*) inserting after the definition of "external use" the following definition:

"'general sale' has the meaning assigned to it in Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007;";

(*d*) substituting for the definition of "marketing authorisation" the following definition:

"'marketing authorisation' means an authorisation granted by the Board in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a medicinal product and includes a certificate of registration, a certificate of traditional-use registration and a parallel import licence;";

(*e*) inserting after the definition of "registered optometrist" the following definition:

"'registered pharmacist' means a person registered in the register of pharmacists established under section 13 of the Pharmacy Act 2007 (No. 20 of 2007);";

(*f*) inserting after the definition of "repeatable prescription" the following definition:

"'retail pharmacy business' has the meaning assigned to it by section 2(1) of the Pharmacy Act 2007;".

6. The Principal Regulations are amended by substituting for Regulation 5 the following:

"5. (1) Subject to the provisions of these Regulations, a person shall not supply a medicinal product of any of the following classes except in accordance with a prescription, namely—

(*a*) any medicinal product in respect of which a Community marketing authorisation or marketing authorisation has been

granted, and such authorisation contains a statement that the product is to be available only on medical prescription;

(*b*) any medicinal product, in respect of which no Community marketing authorisation or marketing authorisation has been granted, which consists of or contains a substance specified in column 1 of the First Schedule or a substance which is a new chemical molecule;

(*c*) any medicinal product which is intended for parenteral administration;

(*d*) any medicinal product that on administration emits radiation, or contains or generates any substance which emits radiation, in order that radiation may be used;

and the supply shall be made by a person lawfully conducting a retail pharmacy business and by or under the personal supervision of a registered pharmacist.

(2) The restrictions imposed by paragraphs (1)(*a*) and (*b*) shall not apply as respects a medicinal product where there is an entry in relation to a substance in the medicinal product in one or more of columns 3, 4 and 5 of the First Schedule; and

(*a*) where the maximum strength of the substance does not exceed that, if any, specified in column 3 of the said Schedule opposite the mention of that substance in column 1 thereof; and

(*b*) where the maximum pack size of the medicinal product does not exceed that, if any, specified in column 3 of the said Schedule opposite the mention in column 1 thereof of a substance contained in the said product; and

(*c*) where a pharmaceutical form is specified in column 4 of the said Schedule opposite the mention of the substance, contained in a medicinal product, in column 1 thereof, the medicinal product is supplied in such form; and

(*d*) where a manner of administration is specified in column 4 of the said Schedule opposite the mention of the substance, contained in a medicinal product, in column 1 thereof, the medicinal product is supplied only for such manner of administration; and

(*e*) where the container or package of a medicinal product is labelled to show a use specified in column 4 of the said

Schedule opposite the mention of a substance, contained in such medicinal product, in column 1 thereof, the medicinal product is supplied in such a container or package so labelled and which does not show any use not so specified; and

(*f*) where the product is one for which a maximum dose is specified in column 5 of the said Schedule opposite the mention of a substance, contained in a medicinal product, in column 1 thereof, it is in a container or package labelled to show a maximum dose not exceeding that so specified; and

(*g*) where the product is one for which a maximum daily dose is specified in column 5 of the said Schedule opposite the mention of a substance, contained in a medicinal product, in column 1 thereof, it is in a container or package labelled to show a maximum daily dose not exceeding that so specified; and

(*h*) where the product is one for which a maximum period of treatment is specified in column 3 of the said Schedule opposite the mention of a substance, contained in a medicinal product, in column 1 thereof, it is in a container or package labelled to show a maximum period of treatment not exceeding that so specified.

(3) Paragraph (1) shall not apply as respects a medicinal product which is intended exclusively for veterinary use and is supplied in a container or package which is labelled with the words "For Animal Treatment Only".

(4) Paragraph (2) shall not apply in the case of a medicinal product containing a substance specified in Part 1 of the Second Schedule unless the product—

(*a*) is the subject of a product authorisation or a marketing authorisation,

(*b*) is supplied in the original container and outer package (if any) supplied by the manufacturer or person responsible for placing the product on the market, and

(*c*) is in a presentation, labelled by the manufacturer or person responsible for placing the product on the market, showing that the said product is of a classification which may be supplied without a prescription.

(5) The container and outer package of a medicinal product, which by reason of sub-paragraphs (*f*) or (*g*) of paragraph (2) is supplied without a prescription, shall be labelled to show the words “Warning. Do not exceed the stated dose.”.”.

7. The Principal Regulations are amended by substituting for Regulation 6 the following:

> "6. (1) Subject to paragraphs (2) and (3), a person shall not supply a medicinal product which by virtue of Regulation 5 may be supplied without a prescription unless he or she is a person lawfully conducting a retail pharmacy business and the supply is carried out by or under the personal supervision of a registered pharmacist.
>
> (2) Paragraph (1) shall not apply to a medicinal product which has been assigned a general sale sub-category under Regulation 12(1)(*b*) of the Medicinal Products (Control of Placing on the Market) Regulations 2007.
>
> (3) In this Regulation the term 'medicinal product' shall have the same meaning as in section 2(1) of the Pharmacy Act 2007.".

8. Regulation 7(3) of the Principal Regulations is amended by inserting after subparagraph (*b*) the following subparagraph:

> "(*c*) In respect of any medicinal product to which this paragraph applies, the provisions of sub-paragraph (*a*) shall cease to apply when a marketing authorisation is granted which assigns a different sub-category of classification (under Regulation 12 of the Medicinal Products (Control of Placing on the Market) Regulations 2007) from that which corresponds to the said Part B of the First Schedule.".

9. Regulation 13(2) of the Principal Regulations is amended by substituting for sub-paragraphs (*d*) and (*e*) the following:

> "(*d*) in the case of a medicinal product intended for use in children under 6 years of age and each dosage unit of which contains not more than 120mg of paracetamol, the pack size does not exceed 24 such units, or in the case of a liquid form of the said product in which the said quantity of paracetamol is contained in 5 millilitres, the pack size does not exceed 140 millilitres;
>
> (*e*) in the case of a medicinal product in liquid form, intended for use in children over 6 years of age and under 12 years of age, in which each 5 millilitre dosage unit contains not more than 250mg of paracetamol other than a product to which sub-paragraph (*d*) applies, the pack size does not exceed 140 millilitres; or
>
> (*f*) in the case of a medicinal product in liquid form in which each 5 millilitre dosage unit contains not more than 250mg of paracetamol, other than a product to which sub-paragraph (*d*) or (*e*) applies, the pack size does not exceed 240 millilitres;".

10. Regulation 14(1) of the Principal Regulations is amended by substituting for sub-paragraphs (*c*) and (*d*) the following:

"(*c*) in the case of dosage units each of which contains more than 600mg of paracetamol but not more than 1000mg of paracetamol, the pack size does not exceed 6 such units;

(*d*) in the case of a medicinal product intended for use in children under 6 years of age and each dosage unit of which contains not more than 120mg of paracetamol, the pack size does not exceed 12 such units, or in the case of a liquid form of the said product in which the said quantity of paracetamol is contained in 5 millilitres, the pack size does not exceed 60 millilitres; or

(*e*) in the case of a medicinal product in liquid form, in which each 5 millilitre dosage unit contains not more than 250mg of paracetamol, other than a product to which sub-paragraph (*d*) applies, the pack size does not exceed 60 millilitres.".

11. Regulation 20 of the Principal Regulations is amended by—

(*a*) substituting for paragraph (4) the following:

"(4) Until the 30th April 2011, the provisions of Regulation 5 shall not apply to a homeopathic medicinal product which contains a substance specified in Part 3 of the Second Schedule at a level not exceeding one part per million, and which is the subject of a marketing authorisation granted in accordance with Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 or a certificate of registration.",

(*b*) substituting for paragraph (6) the following:

"(6) The provisions of Regulations 5 and 6 shall not apply to the supply of a medicinal product in the form of a free medical sample of such product, to a person who is qualified to prescribe such product, in compliance with the conditions specified in Regulation 22 of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007).".

12. The Principal Regulations are amended by—

(*a*) deleting Part 2 of the Second Schedule;

(*b*) substituting for the Seventh Schedule the following Schedule:

"Seventh Schedule

PART 1

MEDICINAL PRODUCTS THAT MAY BE SUPPLIED TO PRE-HOSPITAL EMERGENCY CARE PROVIDERS FOR USE BY ADVANCED PARAMEDICS

(Regulation 20(8)(a))

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Column 1	Column 2	Column 3	Column 4
Adenosine Solution for Injection	Intravenous	Adults: Supraventricular tachycardias (SVT).	According to CPG or on registered medical practitioner's instructions.
Amiodarone Injection	Intravenous	Adults and children: Cardiac arrest.	According to CPG or on registered medical practitioner's instructions.
Aspirin (various oral dosage forms)	Oral	Adults: Cardiac chest pain.	According to CPG or on registered medical practitioner's instructions.
Atropine Injection	Intravenous Endotracheal	Adults and children: Cardiac arrest, Bradycardia, Poisoning.	According to CPG or on registered medical practitioner's instructions.
Benzylpenicillin Injection	Intravenous Intramuscular	Adults and children: Suspected or confirmed meningococcal sepsis.	According to CPG or on registered medical practitioner's instructions.
Cefotaxime Powder for Injection	Intravenous Intramuscular	Adults and children: Suspected or confirmed meningococcal sepsis.	According to CPG or on registered medical practitioner's instructions.
Ceftriaxone Powder for Injection	Intravenous Intramuscular	Adults and children: Suspected or confirmed meningococcal sepsis.	According to CPG or on registered medical practitioner's instructions.
Clopidogrel Tablets	Oral	Adults: Myocardial Infarction.	According to CPG or on registered medical practitioner's instructions.
Cyclizine Injection	Intravenous	Adults and children: To prevent or treat opiate induced nausea and vomiting, Anti emetic.	According to CPG or on registered medical practitioner's instructions.
Dextrose 5% Solution for Infusion	Intravenous	Adults and children: Dilutant for medications	According to CPG or on registered medical practitioner's instructions.

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Dextrose 10% Solution for Infusion	Intravenous	Adults and children: Hypoglycaemia, Dilutant for medications	According to CPG or on registered medical practitioner's instructions.
Diazepam Injection	Intravenous Intramuscular	Adults and children: Seizures, Sedation.	According to CPG or on registered medical practitioner's instructions.
Diazepam Rectal Solution	Per rectum	Adults and children: Seizures.	According to CPG or on registered medical practitioner's instructions.
Enoxaparin Sodium Solution for Injection	Intravenous Subcutaneous	Adults: ST - elevation myocardial infarction (STEMI).	According to CPG or on registered medical practitioner's instructions
Epinephrine (Adrenaline) 1 mg/1ml (1:1000) Injection	Intramuscular	Adults and children: Anaphylaxis, Bronchospasm.	According to CPG or on registered medical practitioner's instructions.
Epinephrine (Adrenaline) 1 mg/10ml (1:10 000)	Intravenous Endotracheal	Adults and children: Cardiac arrest, Bradycardia, Anaphylaxis.	According to CPG or on registered medical practitioner's instructions.
Ergometrine Injection 500 mcg/ml	Intravenous Intramuscular	Adults: Post partum haemorrhage.	According to CPG or on registered medical practitioner's instructions.
Furosemide Injection	Intravenous Intramuscular	Adults: Pulmonary oedema.	According to CPG or on registered medical practitioner's instructions.
Glucagon for Injection	Intramuscular Subcutaneous	Adults and children: Hypoglycaemia.	According to CPG or on registered medical practitioner's instructions.
Glyceryl Trinitrate Aerosol	Sublingual	Adults: Cardiac chest pain, Congestive heart failure.	According to CPG or on registered medical practitioner's instructions.
Haloperidol Injection 5 mg/ml	Intravenous Intramuscular	Adults: Sedation.	According to CPG or on registered medical practitioner's instructions.
Hartmann's Solution for Infusion	Intravenous	Adults and children: Hypovolaemic shock, Anaphylaxis, Decompression illness, Burns, Cardiac arrest, Bradycardia Dilutant for medications	According to CPG or on registered medical practitioner's instructions.
Hydrocortisone Powder for Solution for Injection	Intravenous Intramuscular	Adults and children: Bronchospasm.	According to CPG or on registered medical practitioner's instructions
Ipratropium bromide Nebuliser Solution	Inhalation	Adults and children: Bronchospasm in acute asthma.	According to CPG or on registered medical practitioner's instructions.

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Ibuprofen (various oral dosage forms)	Oral	Adults and children: Pain.	According to CPG or on registered medical practitioner's instructions.
Lidocaine Hydrochloride Injection	Intravenous Endotracheal	Adults: Cardiac arrest.	According to CPG or on registered medical practitioner's instructions.
Lorazepam Injection	Intravenous Intramuscular	Adults and children: Seizures.	According to CPG or on registered medical practitioner's instructions.
Lorazepam Tablets	Oral	Adults and children: Sedation.	According to CPG or on registered medical practitioner's instructions.
Magnesium Sulphate Injection BP	Intravenous	Adults and children: Cardiac arrest, Bronchospasm.	According to CPG or on registered medical practitioner's instructions.
Meropenem Powder for Injection	Intravenous	Adults and children: Suspected or confirmed meningococcal sepsis.	According to CPG or on registered medical practitioner's instructions.
Midazolam Solution for Injection	Intravenous Intramuscular Intranasal	Adults and children: Seizures, Sedation.	According to CPG or on registered medical practitioner's instructions.
Midazolam Solution (Buccal)	Buccal	Adults and children: Seizures.	According to CPG or on registered medical practitioner's instructions.
Morphine Injection	Intravenous Intramuscular	Adults and Children: Moderate to severe pain.	According to CPG or on registered medical practitioner's instructions.
Morphine Oral Solution	Oral	children: Pain.	According to CPG or on registered medical practitioner's instructions.
Naloxone for Injection	Intravenous Intramuscular Subcutaneous Intranasal	Adults and children: Respiratory depression secondary to known or suspected narcotic overdose.	According to CPG or on registered medical practitioner's instructions.
Nifedipine Capsules	Oral	Adults: Inhibition of labour.	According to CPG or on registered medical practitioner's instructions.
Nitrous oxide — Oxygen mixture – medical gas	By inhalation	Adults and children: Pain relief.	According to CPG or on registered medical practitioner's instructions
Ondansetron Hydrochloride Injection	Intravenous	Adults and children: To prevent or treat opiate induced nausea and vomiting, Anti emetic.	According to CPG or on registered medical practitioner's instructions.
Oxytocin Solution for Injection	Intravenous Intramuscular	Adults: Post partum haemorrhage.	According to CPG or on registered medical practitioner's instructions.

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Paracetamol suppositories	Per rectum	children: Pyrexia.	According to CPG or on registered medical practitioner's instructions.
Paracetamol (various oral dosage forms)	Oral	Adults and children: Pain, Pyrexia.	According to CPG or on registered medical practitioner's instructions.
Salbutamol for Nebulisation	Inhalation	Adults and children: Bronchospasm in anaphylaxis, and acute asthma.	According to CPG or on registered medical practitioner's instructions.
Salbutamol Inhaled Aerosol	Inhalation	Adults and children: Bronchospasm in anaphylaxis, and acute asthma.	According to CPG or on registered medical practitioner's instructions.
Sodium Bicarbonate Injection BP	Intravenous	Adults and children: Crush injury, Poisoning.	According to CPG or on registered medical practitioner's instructions.
Sodium Chloride 0.9% for Infusion	Intravenous	Adults and children: Hyperglycaemia, Dehydration, Cardiac Arrest, Crush injury, Hypothermia, To keep vein open, Cannula flush, Dilutant for medications.	According to CPG or on registered medical practitioner's instructions.
Tenecteplase Powder for Injection	Intravenous	Adults: ST - elevation myocardial infarction (STEMI).	According to CPG or on registered medical practitioner's instructions.
Tetracaine Gel 4%	Topical	Adults and children: Anaesthesia prior to venepuncture.	According to CPG or on registered medical practitioner's instructions.

PART 2

MEDICINAL PRODUCTS THAT MAY BE SUPPLIED TO PRE-HOSPITAL EMERGENCY CARE PROVIDERS FOR USE BY PARAMEDICS

(*Regulation* 20(8)(*b*))

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Column 1	Column 2	Column 3	Column 4
Aspirin (various oral dosage forms)	Oral	Adults: Cardiac chest pain.	According to CPG or on registered medical practitioner's instructions.
Cyclizine Injection	Intramuscular	Adults and children: To prevent or treat opiate induced nausea and vomiting.	On registered medical practitioner's instructions.
Dextrose 10% Solution for Infusion	Intravenous	Adults and children: Hypoglycaemia.	According to CPG or on registered medical practitioner's instructions.
Diazepam Rectal Solution	Per rectum	Adults and children: Seizure.	On registered medical practitioner's instructions.
Epinephrine (Adrenaline) 1mg/1ml (1:1 000) — Injection	Intramuscular	Adults and children: Anaphylaxis.	According to CPG or on registered medical practitioner's instructions.
Glucagon for Injection	Intramuscular Subcutaneous	Adults and children: Hypoglycaemia.	According to CPG or on registered medical practitioner's instructions.
Glyceryl Trinitrate Aerosol	Sublingual	Adults: Cardiac chest pain, Congestive heart failure.	According to CPG or on registered medical practitioner's instructions.
Hartmann's Solution for Infusion	Intravenous	Adults and children: Hypovolaemic shock, Anaphylaxis, Decompression illness, Burns, Cardiac arrest, Bradycardia Dilutant for medications	According to CPG or on registered medical practitioner's instruction
Ibuprofen (various oral dosage forms)	Oral	Adults and children: Pain.	According to CPG or on registered medical practitioner's instructions.
Midazolam Solution for Injection	Intranasal	Adults and children: Seizures.	According to CPG or on registered medical practitioner's instructions.
Midazolam Solution (Buccal)	Buccal	Adults and children: Seizures.	According to CPG or on registered medical practitioner's instructions.
Morphine Injection	Intravenous Intramuscular	Adults and children: Moderate to severe pain.	On registered medical practitioner's instructions.

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Naloxone for Injection	Intramuscular Subcutaneous Intranasal	Adults and children: Respiratory depression secondary to known or suspected narcotic overdose.	According to CPG or on registered medical practitioner's instructions.
Nitrous oxide — Oxygen mixture — medical gas	By inhalation	Adults and children: Pain relief.	According to CPG or on registered medical practitioner's instructions.
Paracetamol suppositories	Per rectum	children: Pyrexia.	On registered medical practitioner's instructions.
Paracetamol (various oral dosage forms)	Oral	Adults and children: Pain, Pyrexia.	According to CPG or on registered medical practitioner's instructions.
Salbutamol for Nebulisation	Inhalation	Adults and children: Bronchospasm in anaphylaxis and acute asthma.	According to CPG or on registered medical practitioner's instructions.
Salbutamol Inhaled Aerosol	Inhalation	Adults and children: Bronchospasm in anaphylaxis, and acute asthma.	According to CPG or on registered medical practitioner's instructions
Sodium Chloride 0.9% for Infusion	Intravenous	Adults and children: Hyperglycaemia, Dehydration, Cardiac Arrest, Crush injury, Hypothermia, To keep vein open, Cannula flush, Dilutant for medications.	According to CPG or on registered medical practitioner's instructions.
Tetracaine Gel 4%	Topical	Adults and children: Anaesthesia prior to venepuncture.	On registered medical practitioner's instructions.

PART 3

MEDICINAL PRODUCTS THAT MAY BE SUPPLIED TO PRE-HOSPITAL EMERGENCY CARE PROVIDERS FOR USE BY EMERGENCY MEDICAL TECHNICIANS

(Regulation 20 (8) (c))

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Column 1	Column 2	Column 3	Column 4
Aspirin (various oral dosage forms)	Oral	Adults: Cardiac chest pain.	According to CPG or on registered medical practitioner's instructions.
Cyclizine Injection	Intramuscular	Adults and children: To prevent or treat opiate induced nausea and vomiting.	On registered medical practitioner's instructions.
Epinephrine (Adrenaline) injection 1mg/1ml (1:1000) - prefilled disposable syringe (auto)	Intramuscular	Adults and children: Anaphylaxis.	According to CPG or on registered medical practitioner's instructions.
Glucagon for Injection	Intramuscular Subcutaneous	Adults and children: Hypoglycaemia.	According to CPG or on registered medical practitioner's instructions.
Glyceryl Trinitrate Aerosol	Sublingual	Adults: Cardiac chest pain.	According to CPG or on registered medical practitioner's instructions.
Morphine Injection	Intravenous Intramuscular	Adults and children: Moderate or severe pain.	On registered medical practitioner's instructions.
Naloxone for Injection	Intramuscular Subcutaneous Intranasal	Adults and children: Respiratory depression secondary to known or suspected narcotic overdose.	On registered medical practitioner's instructions.
Nitrous oxide — Oxygen mixture — medical gas	By inhalation	Adults and children: Pain relief.	According to CPG or on registered medical practitioner's instructions.
Paracetamol (various oral dosage forms)	Oral	Adults and children: Pain, Pyrexia.	According to CPG or on registered medical practitioner's instructions.
Salbutamol Inhaled Aerosol	Inhalation	Adults and children: Bronchospasm in anaphylaxis and acute asthma.	According to CPG or on registered medical practitioner's instructions."

L.S.

GIVEN under my Official Seal,
1 December 2008

MARY HARNEY.
Minister for Health and Children.

EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation).

The purposes of these Regulations are—

(*a*) to bring certain of the terminology used in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) into line with that in the Pharmacy Act 2007 (No. 20 of 2007);

(*b*) to facilitate the control of medicinal products as such products in their own right and not as scheduled poisons as has been the case to date. The passing of the Pharmacy Act 2007, including the amendments made by section 74 of that Act to the Poisons Act 1961 (No. 12 of 1961), has enabled the exclusion from the scope of the Poisons Act, of all of those substances the sole use of which is as a medicinal product;

(*c*) to make certain amendments to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) in order to make the provisions of those Regulations clearer as between the controls that have their origin in these Regulations and those that follow the assignment of the various sub-category classifications by the Irish Medicines Board in its granting of marketing authorisations;

(*d*) to make certain changes to the controls applicable to certain liquid preparations containing paracetamol with a view to making the controls clearer; and

(*e*) to update the list of medicinal products that may be supplied to the various grades of ambulance personnel (i.e. advanced paramedics, paramedics and emergency medical technicians) for use in the course of their work in pre-hospital emergency care.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
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