STATUTORY INSTRUMENTS.

S.I. No. 32 of 2022

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2022
S.I. No. 32 of 2022

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2022

I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995), hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2022.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007), Part 4 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (S.I. No. 512 of 2008), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009 (S.I. No. 442 of 2009), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 449 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. No. 530 of 2018), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2020 (S.I. No. 117 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2020 (S.I. No. 204 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020 (S.I. No. 241 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020 (S.I. No. 401 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020 (S.I. No. 614 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2021 (S.I. No. 2 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021 (S.I. No. 8 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2021 (S.I. No. 43 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 (S.I. No. 81 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2021 (S.I. No. 130 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6)

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 28th January, 2022.
Regulations 2021 (S.I. No. 155 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021 (S.I. No. 245 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 8) Regulations 2021 (S.I. No. 411 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021 (S.I. No. 492 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021 (S.I. No. 511 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 11) Regulations 2021 (S.I. No. 558 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 12) Regulations 2021 (S.I. No. 578 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 13) Regulations 2021 (S.I. No. 605 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 14) Regulations 2021 (S.I. No. 692 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021 (S.I. No. 718 of 2021) and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2022.

2. In these Regulations “Principal Regulations” means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

3. The Eighth Schedule (as amended by the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021 (S.I. No. 411 of 2021) to the Principal Regulations is amended—

   (a) by substituting for the text in column 1 of the entry for the medicinal product “Herpes zoster vaccine for injection” the following:

   “Zostavax powder and solvent for suspension for injection herpes zoster vaccine (live, attenuated)”, and
(b) by inserting the following entry:

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<table>
<thead>
<tr>
<th>Medicinal Product</th>
<th>Form and presentation of product administered</th>
<th>Route of administration</th>
<th>Indication for which the medicinal product may be administered</th>
<th>Dosage and conditions of administration</th>
<th>Place of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
<td>Column 4</td>
<td>Column 5</td>
<td>Column 6</td>
</tr>
<tr>
<td>Shingrix powder and suspension for injection</td>
<td>Adjuvanted recombinant Varicella Zoster Virus glycoprotein E antigen</td>
<td>Intramuscular (IM) injection only</td>
<td>Prevention of zoster and zoster-related post-herpetic neuralgia</td>
<td>Two doses of 0.5 mL each in accordance with the summary of product characteristics of the product administered and Immunisation Guidelines for Ireland, as published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland</td>
<td>The premises of the retail pharmacy business in which the authorised person carries on professional practice.</td>
</tr>
<tr>
<td>Herpes zoster vaccine (recombinant, adjuvanted)</td>
<td>Powder and suspension for suspension for injection.</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
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STEPHEN DONNELLY, Minister for Health.
EXPLANATORY NOTE

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

These Regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

The purpose of these Regulations is to add an additional herpes zoster vaccine to the Eighth Schedule to the Regulations of 2003.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulation 2022.