

Guide to the HPRA Emergency Medicines Portal



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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1	WHAT IS THE EMERGENCY MEDICINES PORTAL?	3
2	CREATING AN ACCOUNT ON THE EMERGENCY MEDICINES PORTAL	3
3	LOGGING IN TO THE EMERGENCY MEDICINES PORTAL	4
4	REGISTERING YOUR ORGANISATION USING THE PORTAL	4
5	ADDING ORGANISATION DETAILS	5
6	ADDING ADDITIONAL PREMISES DETAILS	6
7	ADDING EMERGENCY MEDICINE DETAILS	6
8	ADDING ACCOUNTABLE PERSON DETAILS	7
9	MAKING A PAYMENT	8
10	GENERATING AN ORDER FORM FOR EMERGENCY MEDICINES	8
11	FURTHER INFORMATION	8

1 WHAT IS THE EMERGENCY MEDICINES PORTAL?

The Health Products Regulatory Authority (HPRA) Emergency Medicines Portal is an online system that allows organisations to register their intention to procure, store and use an emergency medicine. The portal is an easy-to-use, secure, electronic system that an organisation can use to submit a valid notification as defined in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI 540/2003), as amended. It is the responsibility of any organisation that wants to procure an emergency medicine to be familiar with the relevant legislation. Further information is available on the 'Emergency medicines' section of the HPRA website.

An organisation must:

- Register using the portal **before** procuring an emergency medicine.
- Appoint at least one person who will make sure the emergency medicine is stored and used correctly. This person is known as the 'accountable person'. The accountable person is legally responsible for ensuring compliance with the relevant legislation.
- Ensure there is at least one person trained to use the emergency medicine. That person must hold a valid certificate to show they have completed training on how to use the medicine. Training must be completed before registering on the portal.

If an organisation wishes to store and use an emergency medicine at more than one premises, this information can be registered using the portal.

The portal allows information to be updated to make sure details are up to date. Updates should be made **within four weeks** of any changes taking place.

2 CREATING AN ACCOUNT ON THE EMERGENCY MEDICINES PORTAL

Each organisation must create a user account during the registration process, as follows:

- 1 ~~Select 'Register' on the Emergency Medicines Portal homepage.~~
- 1 Select 'Register' on the Emergency Medicines Portal homepage.
- 2 Enter your email address, first name, and last name.
- 3 Select 'Register'.
- 4 An email will be sent to your email address to verify your registration. Please click on the link provided in the email and follow the instructions to set your password.
- 5 Keep a record of your login details somewhere safe and secure for future use.

3 LOGGING IN TO THE EMERGENCY MEDICINES PORTAL

Once you have created an account on the Emergency Medicines Portal, log in by following these steps:

- 1 Select 'Login' on the Emergency Medicines Portal homepage.
- 2 Enter your email address and password.
- 3 Select 'Log in'.

Resetting your password: If you forget your login details, you can set a new password. To do so, select 'Forgot password?' on the login screen and follow the instructions.

4 REGISTERING YOUR ORGANISATION USING THE PORTAL

Once logged in to the system, you will see the navigation menu on the left-hand side of the screen. It is suggested that you work through each section in turn.

The 'Home' section of the portal shows a checklist of the information that must be entered to complete registration. 'Section status' is shown on the right-hand side of the screen using a traffic light system.

Welcome to the HPRA Emergency Medicines Notification Portal

Below is a checklist of the overall status of your Emergency Medicines Notification.

NOTIFICATION CHECKLIST		
▶	Account	User registration complete. ✔
▶	Organisation	The listed organisation that wishes to procure a medicinal product for use in emergencies. ✔
▶	Products	Medicinal product(s) which may be supplied and administered by a trained person in an emergency situation. ✔
▶	Accountable Person	An individual or individuals employed or engaged by the organisation to oversee and manage storage, conditions of storage, procurement of a medicinal product and its supply to trained individuals. The accountable person must also maintain confidential records, ensure appropriate training of trained person(s) and assist in any investigations as per SI 449 of 2015. □
▶	Payment	Payment of notification fee □
▶	Status	Notification incomplete 60%

If the section status is red, it indicates that information is missing and must be filled in before registration can be completed.

If the section status is amber, it signals a warning. Click into the relevant section to see what information is missing or needs to be updated.

When a section has been completed successfully, a green tick box will appear for that section. Once all sections are green the organisation becomes a 'listed organisation' and the status will read 'Notification completed'. The progress bar will show as 100%.

If you later edit or delete information from the portal, the status may change and some or all information may be removed from the HPRA website. You can also add more information at any time.

Once registration is complete, please review the 'Emergency Medicines Register' on the HPRA website to make sure your organisation's information is appearing correctly.

5 ADDING ORGANISATION DETAILS

In the 'Organisation' section, please enter the details of the organisation that intends to procure the emergency medicine. Further information on some of the requested details are included below.

Type of organisation: Select an option from the dropdown menu. If your organisation does not fall into any of the categories listed, select 'Other Organisation'. You can provide further details in the 'Additional Information' section at the bottom of the section.

Business name or trading as: If the business name or trading style is different to the organisation name, please complete this field.

Address, town/city, postcode, country, phone number, fax: Enter the contact details of the organisation that intends to procure the emergency medicine. If no postcode is entered, this field will auto-populate to 0000.

Organisation is a corporate body: If the organisation is a corporate body registered under the Companies Act 2014, please tick the checkbox and complete the additional fields.

Additional information: Enter any other information that you think might be relevant.

Once all details have been entered, click 'Save'.

Note: 'This field is required' will appear in red under a section if required information has not been entered.

6 ADDING ADDITIONAL PREMISES DETAILS

If an emergency medicine will be stored at an address that is different to the address of the listed organisation, you must register these details on the portal. Add details for each premises where the emergency medicine will be stored. The premises must not be a dwelling.

Details of additional premises can be added by completing the following steps:

- 1 Click on the 'Additional Premises' tab within the 'Organisation' section.
- 2 Click on the 'Add' button on the top right of the screen.
- 3 Enter the name, address, town/city, postcode, and country of the premises where the emergency medicine will be stored.
- 4 Enter any other information that you think might be relevant in the 'Additional information' field.
- 5 Select 'Save changes'.
- 6 Use the 'Add' tab to add as many additional premises as needed, repeating the steps above.

Once an additional premises has been added, 'Edit' and 'Delete' buttons will appear to the right of that premises. Use these buttons to update or remove information for each additional premises.

7 ADDING EMERGENCY MEDICINE DETAILS

In the 'Products' section, you can enter details of the emergency medicine that will be procured by the organisation. To do so, complete the following steps:

- 1 Click the 'Add' button on the top right of the screen. A pop-up window will appear.
- 2 Use the dropdown menu or scroll down the full list of emergency medicines to find the medicine of interest.
- 3 Once you find the correct emergency medicine, click the '+' button next to the name of that medicine. The chosen medicine will disappear from the list and will appear on the 'Products' main page. Repeat this to select all emergency medicines your organisation intends to procure.
- 4 Once all relevant emergency medicines have been added, click the 'Close' button at the bottom of the pop-up window.
- 5 For each medicine, add the 'Starting date of the activity of holding medicinal products for use in emergencies.' This is the date that the organisation is ready to procure the product. For example, this could be the date of registration or the date that suitable storage

conditions are available. The medicine will not appear on the Emergency Medicines Register until this date.

- 6 For each medicine, click on the 'Trained Personnel' tick box to confirm that at least one person working with or engaged by your organisation has been trained on how to use the medicine. This training must be completed as part of an approved training course. Enter the 'Certification Expiry Date' of the person's training.

Note: Refresher training must be completed as needed. When retraining is completed, please update the 'Certification Expiry Date' within four weeks. If the 'Certification Expiry Date' is not current, details of the emergency medicine will not appear on the Emergency Medicines Register. This may result in the organisation no longer appearing on the register.

- 7 For each medicine, select 'Save'.

Once an emergency medicine has been added, 'Save' and 'Delete' buttons will appear to the bottom right of that medicine. Use these buttons to update or remove information for each emergency medicine.

8 ADDING ACCOUNTABLE PERSON DETAILS

The accountable person is legally responsible for ensuring compliance with the relevant legislation. There is a legal declaration that must be completed by each accountable person as part of registration. The names of each accountable person will be published on the Emergency Medicines Register as required under legislation.

In the 'Personnel' section, enter details of the accountable person by completing the following steps:

- 1 Click the 'Add' button on the top right of the screen. A pop-up window will appear.
- 2 From the dropdown menu, select the accountable person's title.
- 3 Enter the accountable person's first name, last name, and email address.
- 4 Select 'Save & Send Email'.
- 5 An email will be sent to the accountable person's email address. Please check junk mail if the email is not received to the inbox. The accountable person should read and fully understand the email.
- 6 The accountable person must click on the link within the email to confirm they accept the terms. The link will only work once. If you click the same link again you will see an error message.
- 7 If the accountable person needs to receive the email again, click the 'Send Email' button in the 'Personnel' section.
- 8 To add another accountable person, repeat the steps above.

Once an accountable person has been added, a 'Delete' button will appear to the right of the accountable person's name. This button can be used to remove the accountable person from the Emergency Medicines Register.

Note: This section will only be considered complete if the accountable person clicks the link in the email. If this step has been successful, the declaration confirmation in the 'Personnel' section will change from 'No' to 'Yes'.

9 MAKING A PAYMENT

A once-off administrative fee must be paid to complete registration. In the 'Payment' section of the portal:

- 1 Enter the payment details and click 'Pay now' at the bottom right of the screen.
- 2 You will see confirmation that the payment is successful and will be provided with a reference number.
- 3 An email will be sent to the email address provided, confirming the payment has been successful. Please retain this for your records.

Note: Payment information supplied to the HPRA is not held on the HPRA's website. This information is securely transferred to a third-party payment provider.

10 GENERATING AN ORDER FORM FOR EMERGENCY MEDICINES

Once registration is completed, an order form can be generated by clicking on the 'Order Form' tab on the left side of the portal homepage. The form will be populated using the details entered during the registration process.

To procure an emergency medicine, present the order form to a pharmacist or wholesaler.

11 FURTHER INFORMATION

If you have any questions about the HPRA Emergency Medicines Portal, please contact info@hpra.ie.

For information on how the HPRA processes your personal data, please see the privacy notice for the ~~HPRA Emergency Medicines Register~~ [HPRA Emergency Medicines Register](#).