Reporting suspected safety issues with medicines and medical devices

A guide for members of the public, produced by the HPRA Patient Forum

September 2023

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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Reporting suspected safety issues with medicines and medical devices to the Health Products Regulatory Authority (HPRA)

We all use health products like medicines and medical devices at some point in our lives. While they have many benefits, there can be risks or safety issues when they are used. Sometimes, safety issues that are new or rare may only be discovered after the product has been used by a large number of people, or by a particular group of people.

What is a suspected safety issue?

A suspected safety issue is something that you think may have been caused by a health product, including a medicine or medical device.

This can include known side effects listed in the leaflet that comes with the health product, as well as a safety issue that isn't listed or is not expected. It may occur soon after you have used the health product, or sometimes only long after use.

Typical side effects to medicines
These can include an allergic reaction, rash, nausea, headache, for example.

Typical safety issues with medical devices
These can include an incorrect test result, a problem with a pacemaker or an insulin pump not working.

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What can I do?

You can report a suspected safety issue to the HPRA using its online reporting system, by post, or by telephone. Full details on how to submit a report are available on the HPRA website. You can submit a report for yourself or someone in your care.

When you submit a report, you give the HPRA information that can help to make medicines and medical devices safer for others.

Reporting a safety issue
Submit a report to the HPRA using its online reporting system, by post or by telephone.

Every report counts and helps to make health products as safe as possible.

What happens when I report to the HPRA?

When you submit a report, the HPRA:

- Will review your report
- Will reply to let you know it has been received
- May contact you for more information about your experience.

Reports can help to find new safety issues or trends and are used together with all new information about the health product.

Making a report to the HPRA does not mean that the health product caused the safety issue. However, it is important to share the information with the HPRA so it can be looked at.

If you are worried about your health or the health of someone you care for, it is really important to speak to your doctor, pharmacist, or nurse.

The HPRA cannot give medical advice.

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What is the HPRA?

The HPRA protects and promotes public health by making sure that health products meet safety and quality standards. Its role is to watch over the safety of medicines and medical devices, and to check new information that becomes available.

That way, any action needed to improve safety can be quickly taken. This might include, for example, updated advice for patients and healthcare professionals on how a health product should be used. You can find out more about the **role of the HPRA here**.

What does the HPRA regulate?

The HPRA regulates health products including:

- Medicines, such as those prescribed by doctors or bought in a pharmacy or on general sale
- Vaccines
- Medical devices, such as COVID-19 antigen tests, pacemakers, and orthopaedic implants

You can find information about a health product you are using, including advice on how to use the product and any known side effects, in the leaflet that comes with the product. It is important to take time to read this information. If you have any questions, talk to your doctor, pharmacist, or nurse.