The history and development of the HPRA

Our organisation was established in 1996 and was previously known as the Irish Medicines Board (IMB). We became the HPRA in July 2014. Our new name better reflects our broader remit and regulatory functions which have expanded significantly.

Regulatory Timeline

	2014	
	2013	IMB becomes the Health Products Regulatory Authority
	2012	
Protection of animals used for scientific purposes	2011	Human organs for transplantation
	2010	
	2009	Cosmetics
	2008	
	2007	
	2006	
	2005	Tissues and cells
Blood and blood components	2004	
	2003	
	2002	
Controlled drugs (licensing remains with the Department of Health)	2001	
	2000	Medical devices
Enforcement	1999	
	1998	
	1997	
	1996	Export certification for medicines
IMB established	1995	
		IMB Act incorporating human and veterinary medicines, and clinical trials

For more detailed information on the role and work of the HPRA across each of the health product areas we regulate, please visit **www.hpra.ie**.

HPRA
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Health Products Regulatory Authority

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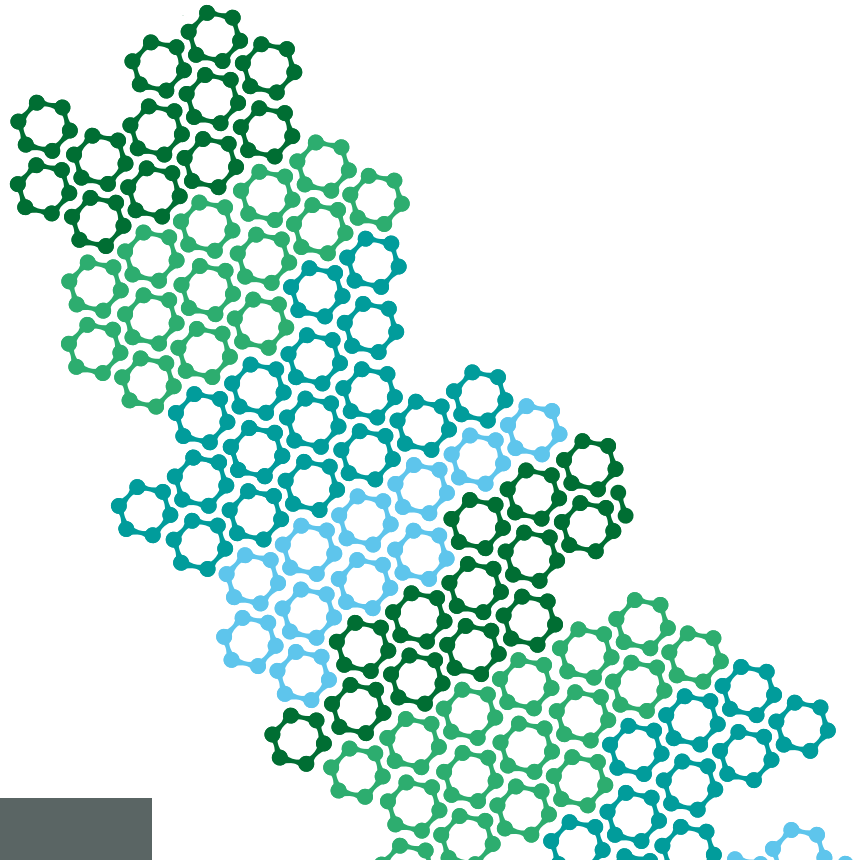
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

ABOUT THE HPRA

Our role in protecting public and animal health



ABOUT THE HPRA

Our role in protecting public and animal health

The Health Products Regulatory Authority (HPRA) is an independent public sector organisation responsible for the regulation of health products.

The health products area is vast and includes medicines for both people and animals as well as all medical devices and equipment used for medical purposes.

Health products can be life-saving. They can also improve the health and the quality of our lives. At the HPRA, we work to make sure that the health products you use are as safe as possible and do what they are intended to do.

Our mission:

To protect and enhance public and animal health through the regulation of medicines, medical devices and other health products.

Our regulatory remit includes the following health products and related areas:

- Human medicines
- Veterinary medicines
- Clinical trials
- Medical devices
- Blood and blood components
- Tissues and cells
- Controlled drugs
- Cosmetic products
- The protection of animals used for scientific purposes
- Human organs intended for transplantation

How we work and what we do

The regulation of each product and area under the remit of the HPRA is dependent upon relevant national and European legislation. Our functions in respect of each product are set out in legislation and each has its own unique regulatory system.

While the legislation may differ across each product, our goal and approach is consistent. Our goal is to protect the health of those who use and benefit from health products. Our approach is to use our scientific and clinical expertise to review and monitor health products available in Ireland or exported abroad.

Our primary functions:

- We grant licences to companies to make, distribute and market medicines after a review of their safety, quality and effectiveness.
- We continuously monitor medicines, medical devices and other health products once they are available on the market and respond quickly to any safety or quality concerns. This includes operating national reporting systems which allow people to report safety and quality issues directly to us.
- We produce safety and quality information on health products for patients and healthcare professionals to support their safe use.
- We inspect companies and facilities which test, make or distribute health products to ensure that they comply with relevant standards and legislation.
- We contribute to regulatory committees and working parties at a national, European and global level for all products under our remit.

Our goal is to protect the health of those who use and benefit from health products.