



IRISH MEDICINES BOARD

The Role of the Irish Medicines Board

Strategic Goals for 2011 – 2015

IPPOSI, 23 May 2011

Pat O'Mahony

Chief Executive

Our Mission

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



IRISH MEDICINES BOARD

Our Functions

- **High Level:**

- Authorisations
- Inspections and Audits
- Surveillance
- Advisory



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Our Functions

1. Authorisation of medicinal products for Human (H) and Veterinary (V) use
2. Inspection and licensing of manufacturers (H & V) and wholesalers (H)
3. Competent Authority for Medical Devices
4. Competent Authority for Blood Directive and for Tissues and Cells Directives
5. Competent Authority for Advanced Therapies
6. Competent Authority for Cosmetics
7. Approval of Clinical Trials (H) and Clinical Investigations (MD)



Our Functions

8. Pharmacovigilance/Vigilance
9. Sampling and Analysis
10. Enforcement (H)
11. Overseeing Recalls
12. Issue of Export Certificates
13. Issue of GMP Certificates
14. International representative function
15. Advice to Government



International Activities

- EMA Scientific Committees, Working Parties and Management Board
- European Commission
- International
 - ICH
 - Summit
 - Cooperation Agreements
 - HTA dialogue
- EU Benchmarking



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Strategic Objectives 2011 – 2015

- **Enhance** healthcare product safety and **patient outcomes** by effective risk management and market surveillance.
- **Deliver** clear, relevant and timely **communications to patients**, consumers and healthcare professionals.
- **Improve service delivery** within a high quality, risk-based regulatory framework.
- **Influence** legislation and **policy development** at European and international levels for the benefit of public and animal health.
- **Build** future **capabilities** to meet evolving regulatory requirements, and scientific and technological advances.



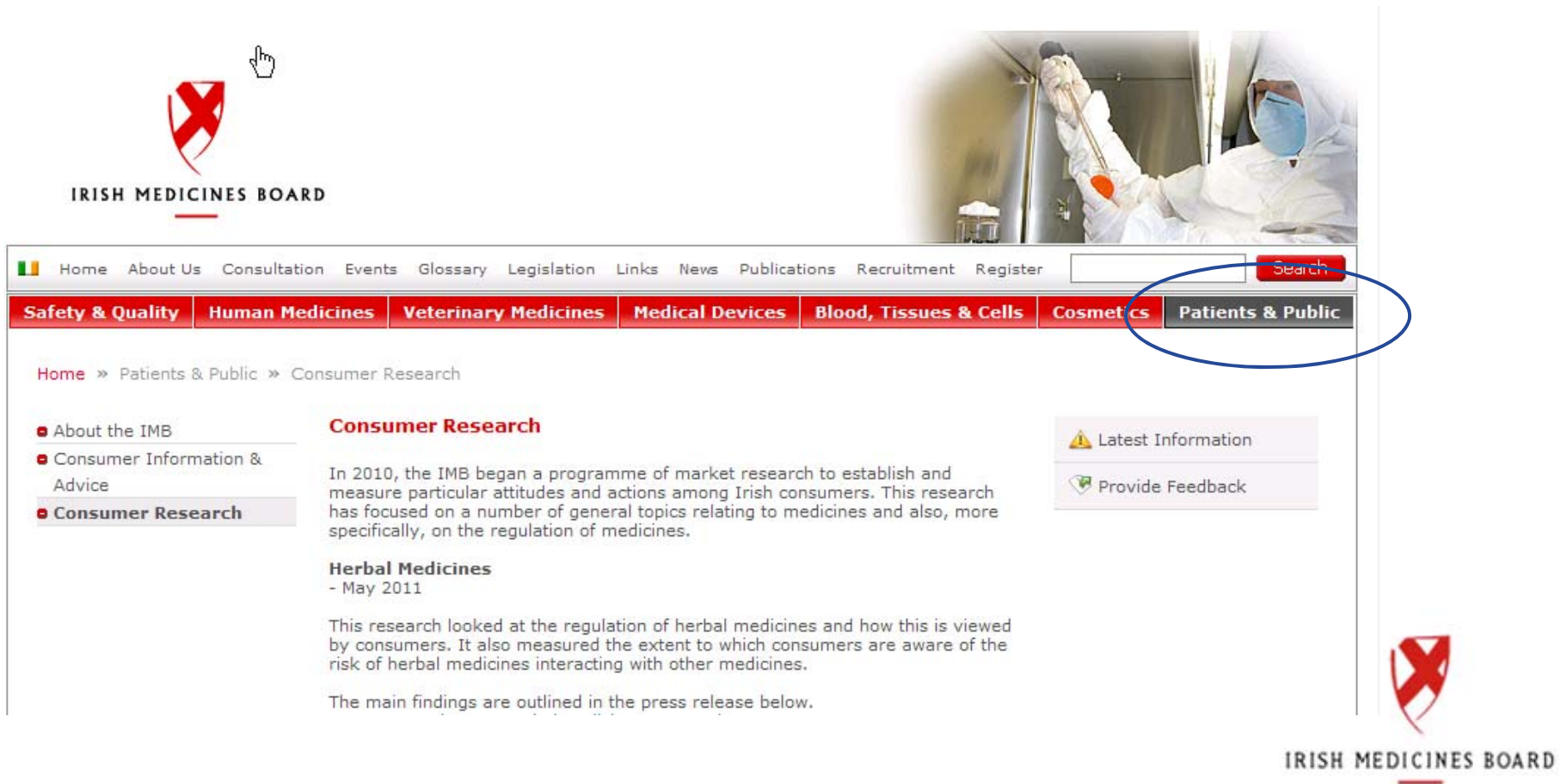
Patient and Public Engagement

- Mission = Protect and enhance public health
 - » Then we must involve patients and the public in the activities of the IMB.
- Goal: Develop a strategy for the greater involvement of patients and users in the regulatory activities of the organisation.
 - » Public and patient representatives are involved in the activities of the IMB and their knowledge, experience and views are taken into account in decisions and communications.
 - » IMB delivers clear, relevant and timely communications to patients.
 - » Improve information resources and transparency for the public.



IMB Website – New Patient Area

- Will be published this week on www.imb.ie.



The screenshot displays the Irish Medicines Board (IMB) website interface. At the top left is the IMB logo, a red shield with a white cross, and the text "IRISH MEDICINES BOARD". To the right is a photograph of a person in a white protective suit and blue mask, holding a test tube. Below the logo and photo is a navigation bar with the following links: Home, About Us, Consultation, Events, Glossary, Legislation, Links, News, Publications, Recruitment, Register, and a search box with a "Search" button. A blue circle highlights the "Patients & Public" link in the navigation bar. Below the navigation bar is a breadcrumb trail: Home » Patients & Public » Consumer Research. On the left side, there is a sidebar menu with the following items: About the IMB, Consumer Information & Advice, and Consumer Research (highlighted). The main content area features a section titled "Consumer Research" with a sub-section "Herbal Medicines - May 2011". The text under "Herbal Medicines" states: "This research looked at the regulation of herbal medicines and how this is viewed by consumers. It also measured the extent to which consumers are aware of the risk of herbal medicines interacting with other medicines. The main findings are outlined in the press release below." On the right side, there are two buttons: "Latest Information" and "Provide Feedback". At the bottom right is the IMB logo and the text "IRISH MEDICINES BOARD".

Consumer Information Leaflets



For download on www.imb.ie
or by calling (01) 6764971



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Thank You



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