



IRISH MEDICINES BOARD

# Overview of IMB and Integration of Cosmetics

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Cosmetics Information Day , September 15<sup>th</sup> 2010

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Dr Lorraine Nolan  
Healthcare Products Distribution Manager  
Irish Medicines Board

# Irish Medicines Board (IMB)

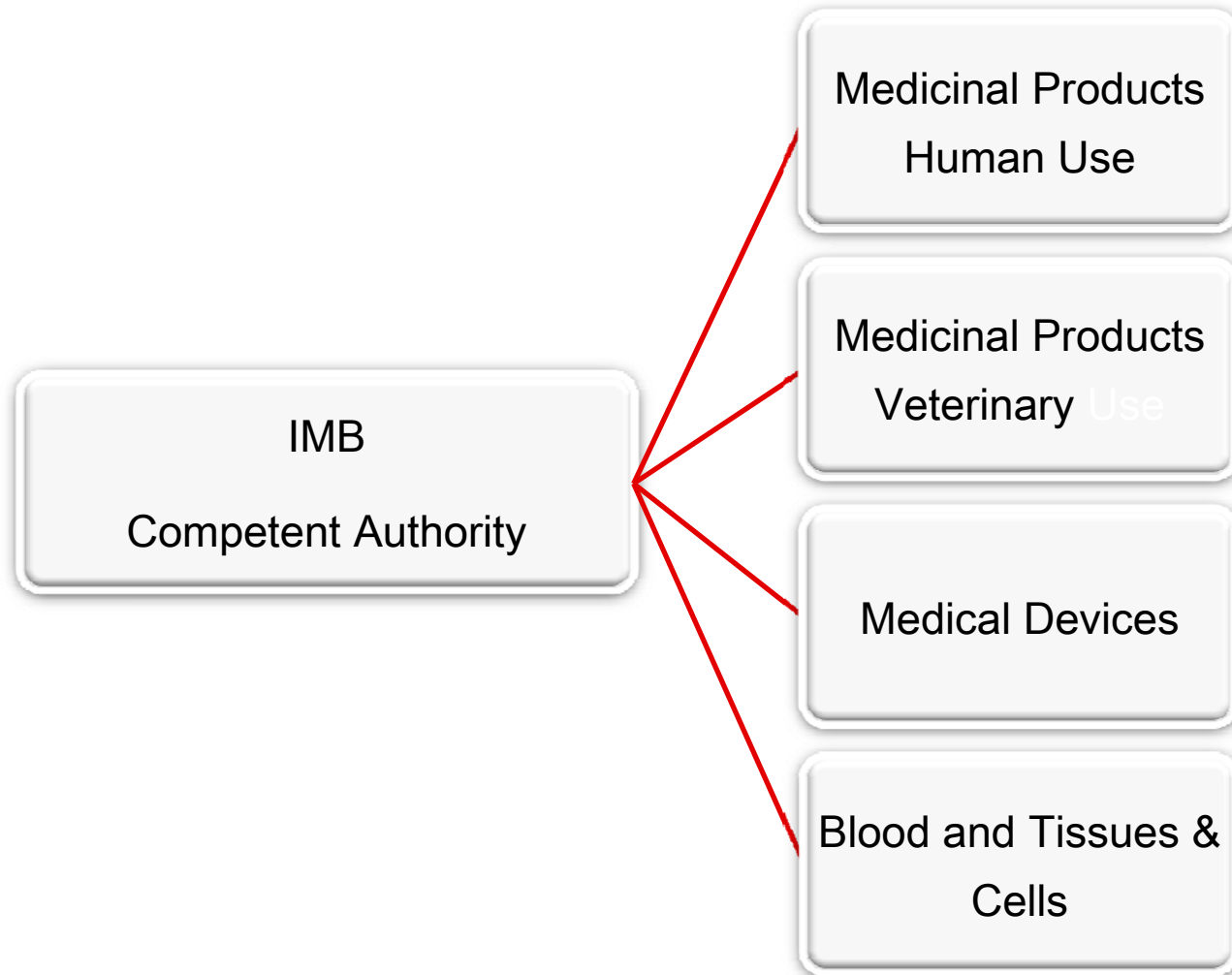
## Mission Statement

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



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# IMB's Roles



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# IMB Functions

1. Authorisation of medicinal products for Human (H) and Veterinary (V) use
2. Inspection and licensing of manufacturers (H & V) and wholesalers (H); GCP & Pharmacovigilance Inspection
3. Competent Authority for Medical Devices (MD), including designation of Notified Body
4. Competent Authority for Blood Directive and Tissues and Cells Directive, including inspection & vigilance
5. Approval of Clinical Trials (H) and clinical investigations (MD)
6. Pharmacovigilance/Vigilance (H, V& MD)



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# IMB Functions (cont.)

8. Controlled Drugs Licensing and Inspection
9. Quality Defects, Recalls, Exempt Products & Market Compliance
10. Issue of Export Certificates (H & V)
11. Issue of GMP Certificates (H & V)
12. Enforcement (H & MD)
13. International representative function
14. Advice to Government



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# Functions Transferred From DoHC



2001 Medical Devices

2005 Controlled Drugs

2010 Cosmetics



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# IMB: Some Facts & Figures



- Established under IMB Act 1995 (No. 29 of 1995)
- Formerly National Drugs Advisory Board (NDAB)
- Located in Kevin O'Malley, House, Earlsfort Centre, Earlsfort Terrace, Dublin 2
- Region of 260 staff members
- Assess & monitor over
  - 6,700 Human Medicines*
  - 1,200 Veterinary Medicines*
  - 500,000 Medical Devices*on the Irish market



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# IMB Website (www.imb.ie)

The screenshot shows a Windows Internet Explorer browser window displaying the Irish Medicines Board website. The browser's address bar shows the URL <http://www.imb.ie/>. The website features a header with the IMB logo and a navigation menu with links for Consultation, Contact Us, Events, Legislation, Links, News, Publications, Recruitment, and Register. A search bar is also present. Below the navigation menu is a red navigation bar with tabs for Home, About Us, Safety & Quality, Medicines, Medical Devices, Blood, Tissues & Cells, and Cosmetics. The main content area is divided into several sections: a welcome message, a 'Current Topics' section with a red border containing links for HPV School Immunisation and Consumer Information Leaflets, an 'Online Reporting' section with a laptop icon and text about reporting issues, and a 'View & Search Product Listings' button. On the right side, there is a 'Latest Information' section with sub-sections for Notices, News, Publications, and Events, each with a list of recent updates and a 'view all >' link. The browser's taskbar at the bottom shows the Start button, several open applications, and the system tray with the date and time (17:06).

The Irish Medicines Board

IRISH MEDICINES BOARD

Consultation Contact Us Events Legislation Links News Publications Recruitment Register

Home About Us Safety & Quality Medicines Medical Devices Blood, Tissues & Cells Cosmetics

**Welcome to the Irish Medicines Board**  
Our role is to protect and enhance public and animal health through the regulation of human and veterinary medical products.

**Current Topics**

- HPV School Immunisation
- Consumer Information Leaflets

**Online Reporting**  
Report suspected issues via **on-line forms** to the Irish Medicines Board.

View & Search Product Listings

**Latest Information**

**Notices**

- 27 August 2010 - ASR™ Articular Surface Replacement and ASR™ XL Acetabular System
- 13 August 2010 - Effective Traceability of Medical Devices

**News** [view all >](#)

- 01 September 2010 - Invitation for Requests for Ireland to act as Reference Member State in the Decentralised Procedure
- 27 August 2010 - Recall of DePuy ASR Hip Systems

**Publications** [view all >](#)

- 19 August 2010 - Xyrem (sodium oxybate) - Important Safety Information from UCB (Pharma Ireland Ltd) as approved by the Irish Medicines Board
- 16 August 2010 - Drug Safety Newsletter 38th Edition

**Events** [view all >](#)

# IMB (Quarterly) Newsletter

http://www.imb.ie/images/uploaded/documents/IMB\_Newsletter\_issue\_no\_35\_180610.pdf - Windows Internet Explorer

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**news** **LETTER** MEDICINAL PRODUCTS

JANUARY - APRIL 2010 Issue No. 35

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2 TEL: 01 676 4971 FAX: 01 6767836 EMAIL: FOI@IMB.IE

**GENERAL**

**NEW VARIATIONS REGULATION**

The new 'Variations Regulation' (Commission Regulation EC No 1234/2008) came into force on 1 January 2010 and applies immediately to human and veterinary medicinal products authorised through the centralised and MRP/DCP routes. The regulation will become legally applicable to 'purely national' marketing

tion for both MA holders and the IMB. The IMB would like to highlight that the timelines set out in the Regulation and the 'automatic' approval of Type IB notifications after 30 days do not currently apply to variations for purely nationally authorised products; when further experience of the operation of the new regulation has been gained, this aspect of the regulation

**CONTENTS**

*General*

- New Variations Regulation 1

*Human Medicines*

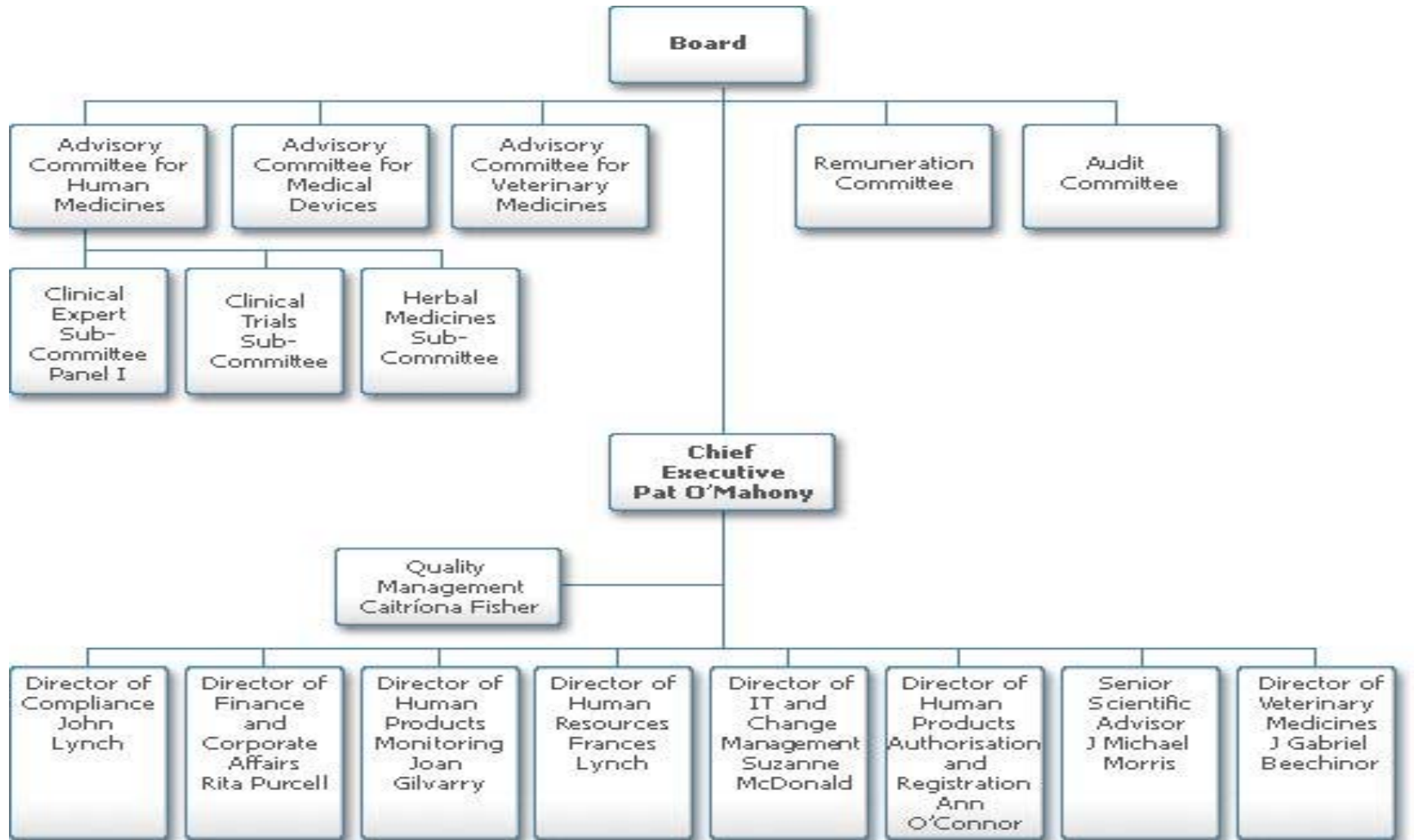
- Guidance for Marketing Authorisation Holders on Direct Healthcare Professional Communications – Publication of National Guidance 1
- Transfers of Product Authorisations and Parallel Product Authorisations

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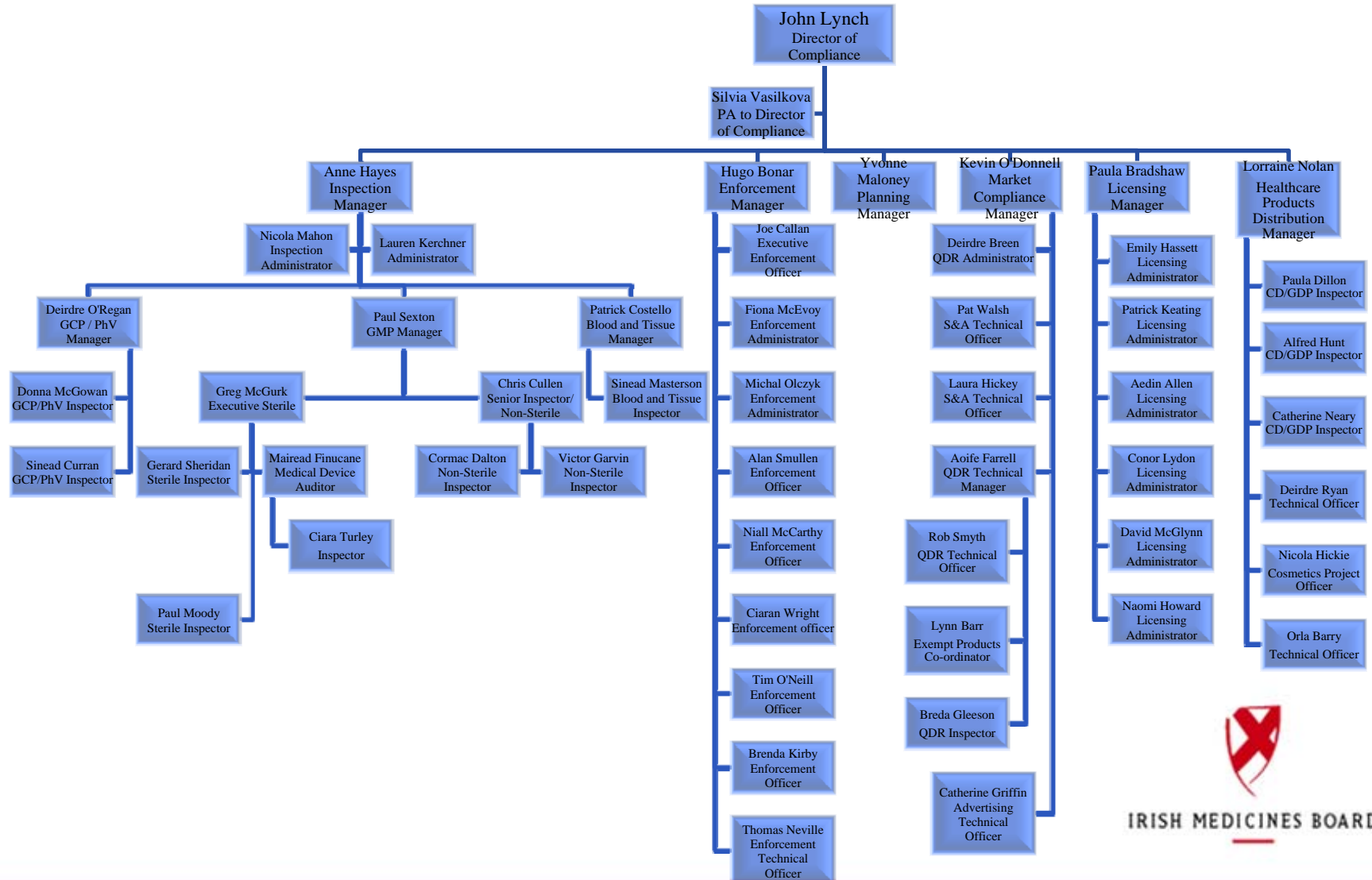
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# IMB Structure

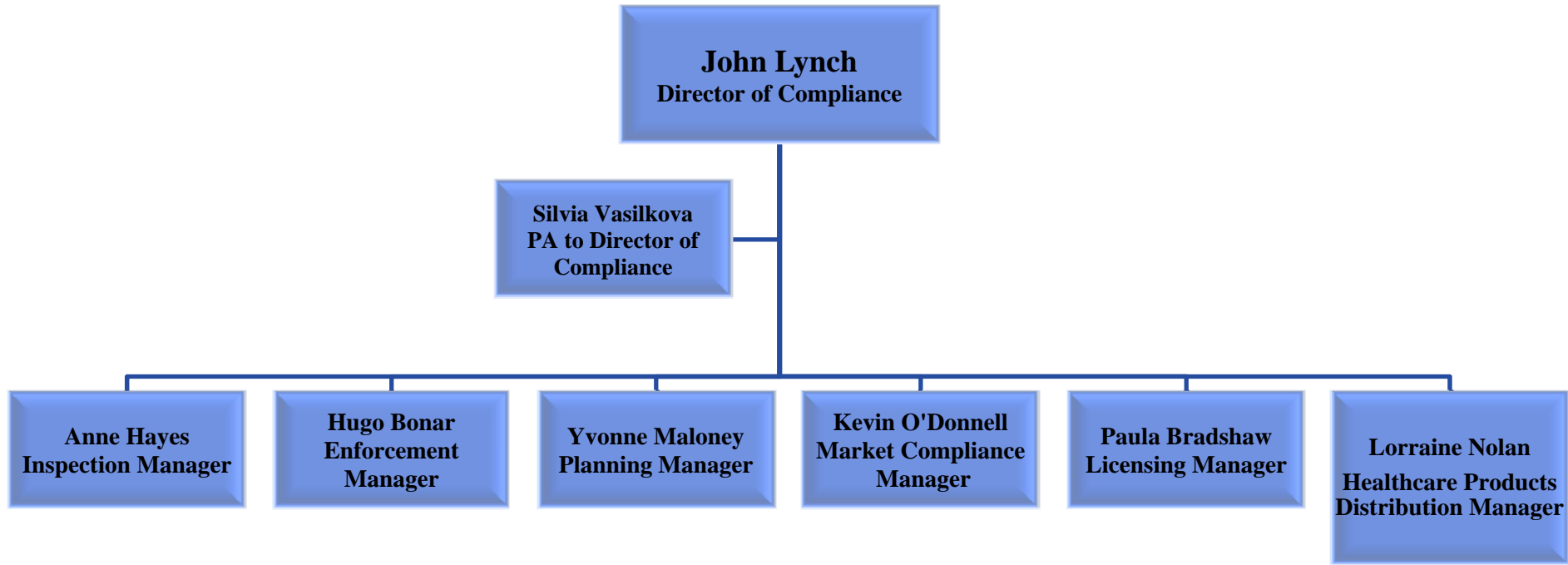


# Compliance Department Structure



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# Compliance Department Structure



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# Compliance Department Structure

- 6 person management team
- 5 sections – Licensing, Market Compliance, Enforcement, Inspection (including Audit) and Healthcare Products Distribution
- Department headcount 54
- Location – 5<sup>th</sup> Floor – Alexandra House



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# Healthcare Products Distribution Section

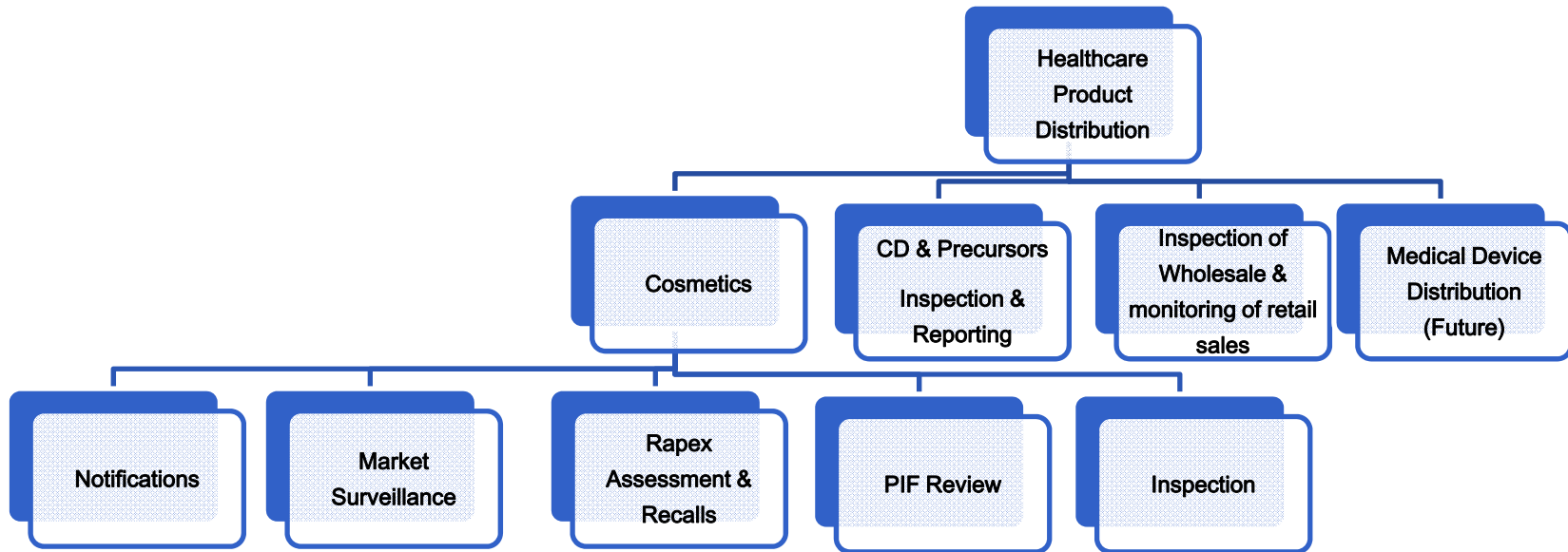
Established in Jan 2010

- Restructuring of Compliance Department to include Healthcare Products Distribution Section
- Allow for integration of new areas of remit including cosmetics, distribution of medical devices.
- Incorporation of existing current remit relating to the distribution of medicinal products, regulation of controlled drugs, monitoring of general retail sales
- Focus of expertise on the regulation of the Healthcare Products supply chain



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# Healthcare Products Distribution Section



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# Healthcare Products Distribution Section

- 7 member team
- Work in various technical roles
- Inspection resource (3) span a number of areas: medicinal product wholesale; CD & precursors; monitoring of retail sales
- Currently 2 members of staff specifically working on cosmetics with additional assistance from other team & IMB staff members



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# Cosmetics Team



**Nicola Hickie**  
Cosmetics Project Officer



**Orla Barry**  
Market Surveillance Project  
Officer

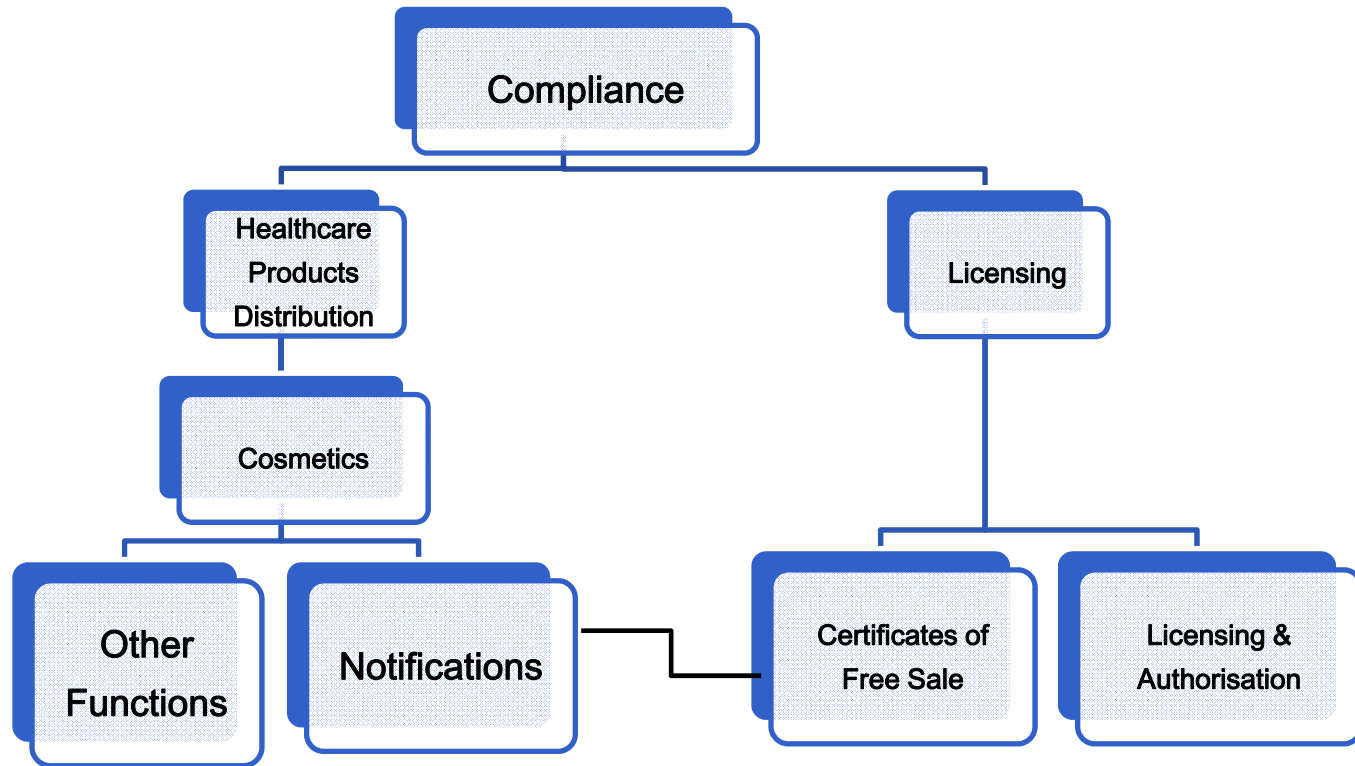


**Catherine Neary**  
Inspector



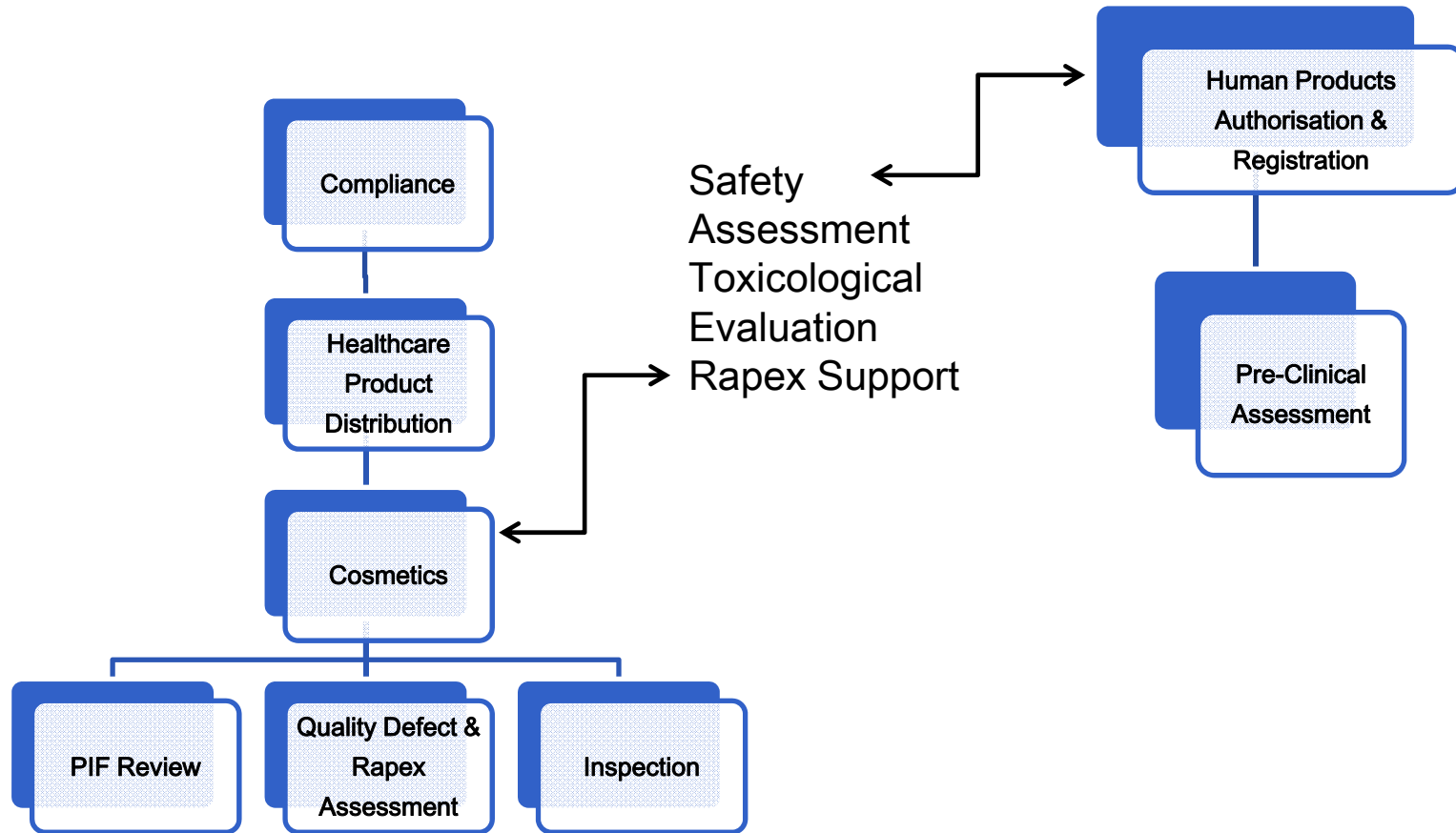
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# Cosmetics Interfaces in Compliance



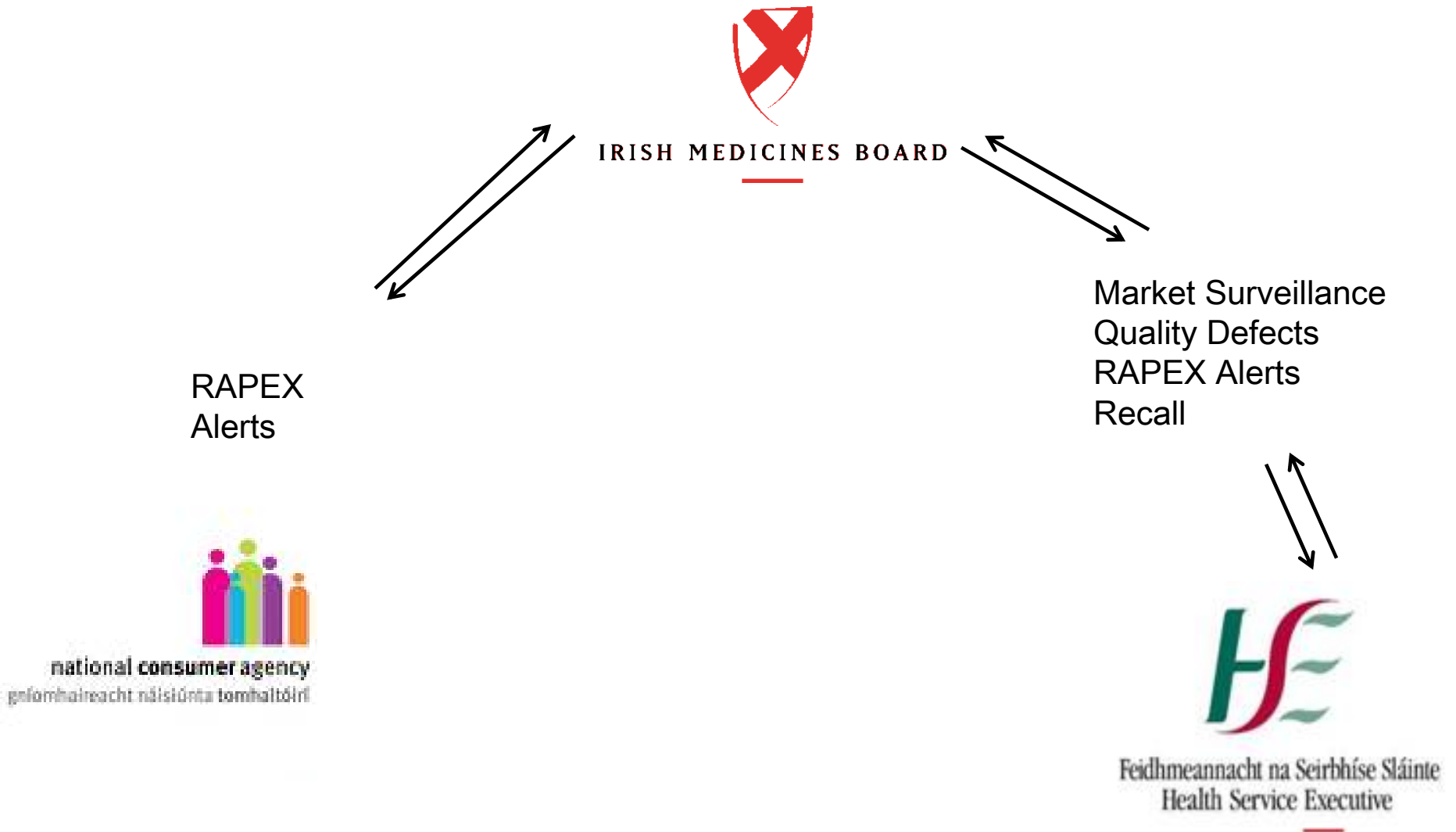
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# Cosmetics Interfaces in IMB



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# Cosmetics Interfaces Externally



# Cosmetics Information Day

- Thank you for your attention
- Happy to take questions within Q&A Session



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