



IRISH MEDICINES BOARD

Welcome

# GMP & Market Compliance Information Day 2008

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October 23<sup>rd</sup> 2008

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Chief Executive  
Irish Medicines Board

# Aims of the Information Day

Improve adherence to GMP and Market Compliance requirements in key areas to ensure that the patient receives medicinal products of the appropriate quality, safety and efficacy.

- Provide information from the GMP inspection programme and market compliance activities over the past two years. The afternoon parallel sessions will facilitate more in-depth discussion of the selected topics
- Discussion of new requirements and challenges for the industry and regulators
- Discussion of new regulatory initiatives and IMB's developing role

# New Developments & Challenges

New Developments and Challenges Facing the Pharma Industry include:-

- Ensuring a robust and trust-worthy supply chain for starting materials.
- Integration of development, regulatory, manufacturing & supply chain activities.
- Growing sophistication and prevalence of counterfeit medicinal products.
- Emergence of new therapies and combinations and new regulatory requirements.
- Maintaining cost-effectiveness



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# New Developments & Challenges

IMB's role in meeting those challenges:-

- Provision of update information and guidance to industry through initiatives such as Information Days etc.
- Enhancement and development of own knowledge through participation in various EU Committees and Working Groups.
- Embracing change to ensure that activities are performed to the highest standards of efficiency and effectiveness.
  - Increased number of inspections national & third countries.
  - Decreased turn-around time for issue of inspection reports
  - Introduction of new Deficiency Summary Report (DSR) within 15 days of completing inspection



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# New Developments & Challenges

IMB's role in meeting those challenges continued:-

- Engaging in EU (EMEA and HMA Europe) and global (International Summit of Regulatory Agencies) initiatives to expand the range of regulatory co-operation has resulted in IMB's :-
  - Imminent participation with EU and global partners (FDA; TGA) in pilot programme of inspections of API manufacturers in third-country locations.
  - Proposed participation in joint-inspections with FDA.
  - Continued & increased participation in third-country inspections on behalf of EMEA & EDQM.
- Commitment to working with all stakeholders, and operation of a clear policy of open dialogue.

# New Developments & Challenges

IMB's role in meeting those challenges continued:-

- Minimising possibility of counterfeit medicinal products entering the supply chain.
  - Active monitoring of trade in medicinal products through inspection, licensing, market surveillance and enforcement activities.
  - Proactive working with State Agencies e.g. Revenue Customs, Gardaí Síochána.
  - Communication with international regulatory authorities to ensure swift information exchange e.g. Rapid Alert Notification
  - Monitoring of internet sales for illegal promotion and sales
  - Participation in measures to ensure the integrity of the supply chain for starting materials and finished products



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# New Developments & Challenges

IMB's role in meeting those challenges continued:-

- Participation in international anti-counterfeit initiatives:-
  - EU Commission's anti-counterfeit proposal.
  - Council of Europe's Convention on Measures to Prevent Counterfeiting of Pharmaceutical Products.
  - WHO "International Medical Products Anti-Counterfeiting Taskforce" (IMPACT).
  - Chair of HMA's Working Group of Enforcement Officers.



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# IMB Developments

## IMB Developments over next years

- Growth and expansion in remit.
  - Drug component of drug-device combinations
  - Advanced therapies.
  - Cosmetics.
- Restructuring Human Medicines and Medical Devices to ensure that we have integrated structures around all human products as convergence of these various technologies will occur over the coming years & ensuring particular focus on safety and authorisation / registration



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# IMB Developments

## IMB Developments over next years:-

- Budget 2008 announcement.
  - Merging of IMB with Food Safety Authority of Ireland (FSAI) and Office of Tobacco Control (OTC).
  - Planned two year roll-out.
  - Initial discussions between the Agencies have begun.
  - In the mean-time, business as usual for IMB.



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# Concluding Remarks

- Thank-you for your interest in today's event:-  
Increased level of interest with over 250 participants including representation from a wide range of sectors including manufacturers, and various supporting services.
- Please do participate and ask questions, it is your day!
- Please do complete the evaluation questionnaires in the information packs. Your feed back is vital in improving and developing future events.



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