



IRISH MEDICINES BOARD

Primary Distribution Activities

Wholesale Distribution Information Day, 25th February 2010

Paul Sexton
GMP
Manager

Topics

- What is a Primary Distributor / Wholesaler
- Special Responsibilities of the Primary Distributor
- Typical Deficiencies



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What is a Primary Distributor ? (1)

- Not specifically defined in legislation
- Wholesaler who first places the batch of product on the Irish market on behalf of the MAH
 - Not mandatory for MAH to appoint a primary wholesaler
 - Where a Primary Distributor is appointed by the MAH it may be named on product packaging (not mandatory)



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What is a Primary Distributor ? (2)

- Primary Distributor may distribute to the retailers or other wholesalers
- Special cases
 - sourcing PA/PL product from UK other than as Primary Distributor appointed by MAH – Dual Product Registration scheme applies.
 - Parallel importation – (PPA required & Manufacturer's Authorisation (MIA))
 - MIA required for importation from outside EEA



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What is a Primary Distributor? (3)

IMB's identification of Primary Distributor

Wholesaler's Authorisation

- Application should state intention to act as Primary Distributor
- List on Annex to the Authorisation
 - Name of MAH and first 4 nos. of PA (PA0001) or EU numbers (EU/1/00/000) for Centrally Authorised Product



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Responsibilities of Primary Distributor (1)

Ensuring that batches are certified by the QP before distribution?

- (a) Primary Distributor storing product under quarantine not yet released by the QP. (contract storage for manufacturer)

Documented and agreed mechanism (TA) between the manufacturer and Primary Wholesaler.



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Responsibilities of Primary Distributor (2)

Ensuring that batches are certified by the QP before distribution

- (b) Product QP released but entering Ireland from another EEA country.

“Control Report” (ref Manufacturing Regulations, SI 539)

- document provided by manufacturer or distributor supplying the product to the Primary Distributor in Ireland.



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Responsibilities of Primary Distributor (3)

Should document:

Product manufactured in accordance with:-

- product authorisation
- GMP

Signed by QP



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Responsibilities of Primary Distributor (4)

Official Control Authority Batch Release

Additional testing performed at Official Medicines Control Laboratory (OMCL)

Applies to certain biological medicines (e.g. Vaccines, blood products)

IMB notifies MAH's of products where OCABR is required for Irish market.



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Responsibilities of Primary Distributor (5)

Official Control Authority Batch Release

Primary Distributor to verify that OCABR certificate has been issued by OMCL successful testing prior to distribution of product.

Technical Agreement with MAH to cover products requiring OCABR.



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Responsibilities of Primary Distributor (6)

Product Recall

MAH often assigns particular responsibilities to Primary Distributor for recall of medicines. E.g co-ordination of recall and reconciliation of recalled product

Responsibilities assigned to be covered in a Technical Agreement with MAH.

Recall procedure should reflect responsibilities



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Responsibilities of Primary Distributor (7)

Medical Samples

Primary Distributor may be responsible for distribution of Free Samples to Medical Representatives

Traceability of samples to be maintained.



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Responsibilities of Primary Distributor (8)

Complaints

Primary Distributor may receive complaints relating to product quality.

Technical Agreement should cover communication of complaints to MAH.



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Typical Deficiencies (1)

- Responsibilities of Primary Distributor not adequately defined in Technical Agreements or Procedures (SOPs for Recall / Complaints)
- Actual supply chain not verified for goods received
- Complexity of operation not reflected in QMS (e.g. different requirements for different MAHs with regard to cold chain supply)
- Inadequate training with regard to primary distribution responsibilities



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Typical Deficiencies (2)

- Products released to saleable stock without verification of OCABR certification
- Products released to saleable stock without verifying batch certification for Irish market



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Thank you



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