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Wholesale Distribution and Continuity of Supply

Wholesale Distribution Information Day, 28th September 2012

Catherine Neary
Inspector

Overview

- Legislative requirements
- Considerations for Best Practice
- Emerging Trends
- Feedback from the Inspection Programme
- Conclusions

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Legislative Requirements (1)

DIRECTIVE 2001/83/EC

Wholesale Distribution of Medicinal Products

Article 81

*The **holder of a marketing authorisation** for a medicinal product and the **distributors** of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure **appropriate** and **continued** supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered*

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Legislative Requirements (2)

Marketing Authorisation Holders (MAHs)

Obligations of Persons placing Medicinal Products on the Market (Part 3) of the **Medicinal Products (Control of Placing on the Market) Regulations, 2007 – 2012**:-

Obligation to ensure that supplies continue to be available to meet the needs of patients

19. *A person who is the **holder** of a Community marketing authorisation, marketing authorisation, certificate of registration or certificate of traditional-use registration, and **any person acting on behalf of such a person**, in respect of a medicinal product actually placed on the market in the State, and **within the limits of his responsibility**, shall ensure **appropriate** and **continued** supplies of that product to pharmacies and other persons authorised to supply such products, so that the needs of patients in the State in respect of any such medicinal product are catered for*

General Obligations

15. *(1) The holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration shall be responsible for placing the relevant medicinal product on the market **and the designation of a representative shall not relieve the said holder of his responsibilities***

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Legislative Requirements (3)

Wholesalers

Requirements to be met by the Authorisation Holder (Schedule 2) of the **Medicinal Products (Control of Wholesale Distribution) Regulations, 2007 – 2012**:-

*11. The **authorisation holder** shall, in respect of a medicinal product that has actually been placed on the market in the State and **within the limits of his or her responsibility**, ensure **appropriate** and **continued** supplies of that product to the persons referred to in paragraph 4(d)* and (e)**, so that the needs of patients in the State in respect of such medicinal product are covered.*

4. The authorisation holder shall only sell medicinal products by wholesale to persons -

**(d) who are authorised or entitled to supply the said medicinal products to the public, or*

***(e) who are lawfully entitled to administer those products to patients in the course of a professional practice or business as a hospital.*

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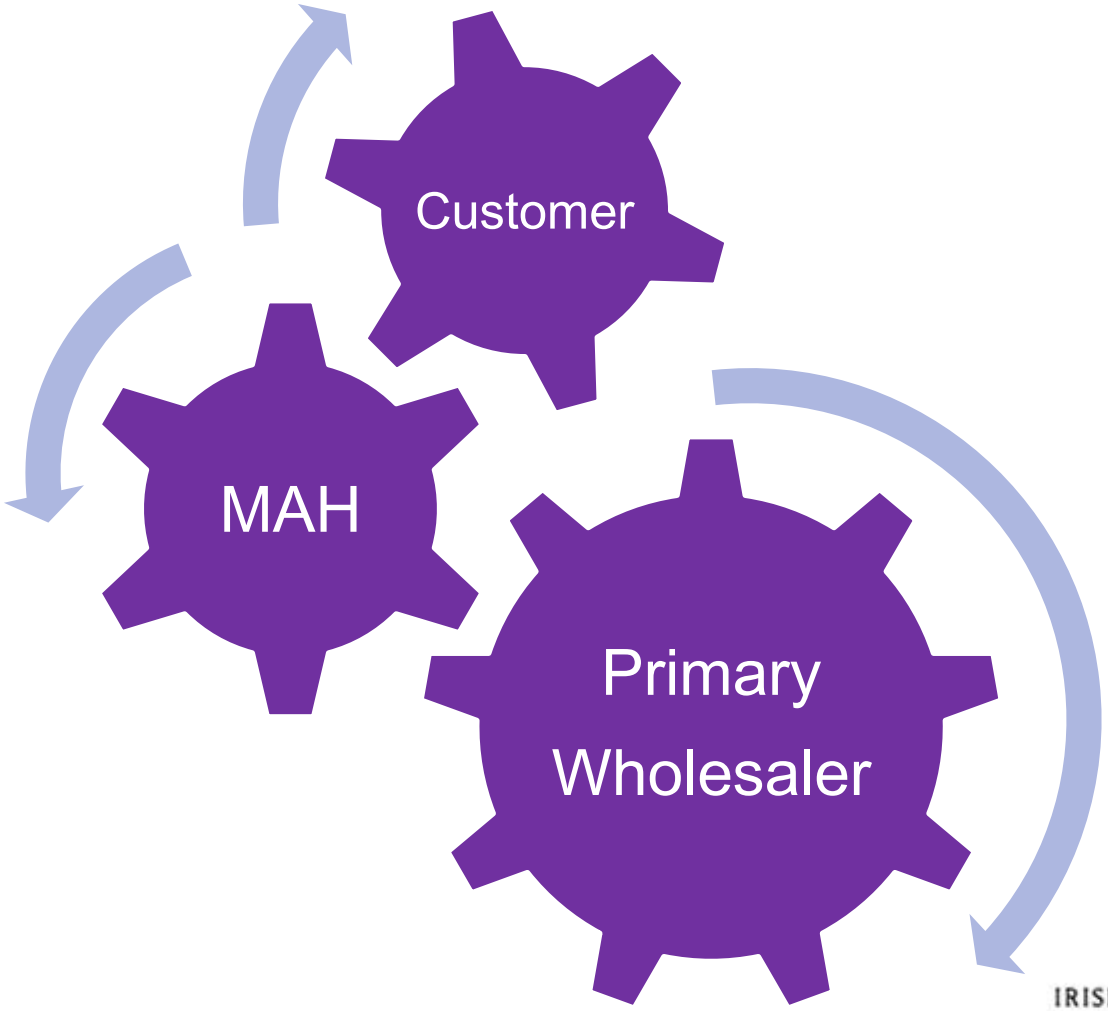
Considerations for Best Practice Primary Wholesaler (1)



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Considerations for Best Practice Primary Wholesaler (2)

Maintain sufficient stock, including a minimum stock holding (ideally at least 3 - 6 months), or ready access to this, to fulfil the market share of the MAH

Proactive approach where MAH aims for increased market share - liaise with MAH to ensure required stock holding is available in the market place in advance of undertaking marketing campaign aimed at increasing market share for the product

Ensure effective oversight of customer purchasing patterns and investigate any significant increase in purchase of a particular medicinal product

Do not knowingly sell a product for the purpose of parallel trading

Ensure ordering, storage and distribution capabilities are sufficient, in context of normal business operations, to ensure continued availability of product to patients in the State; the business practices conducted by wholesalers should not unduly impact on patient access to medicinal products

Document obligations/responsibilities in technical agreement/contract with MAH

Considerations for Best Practice Primary Wholesaler (3)

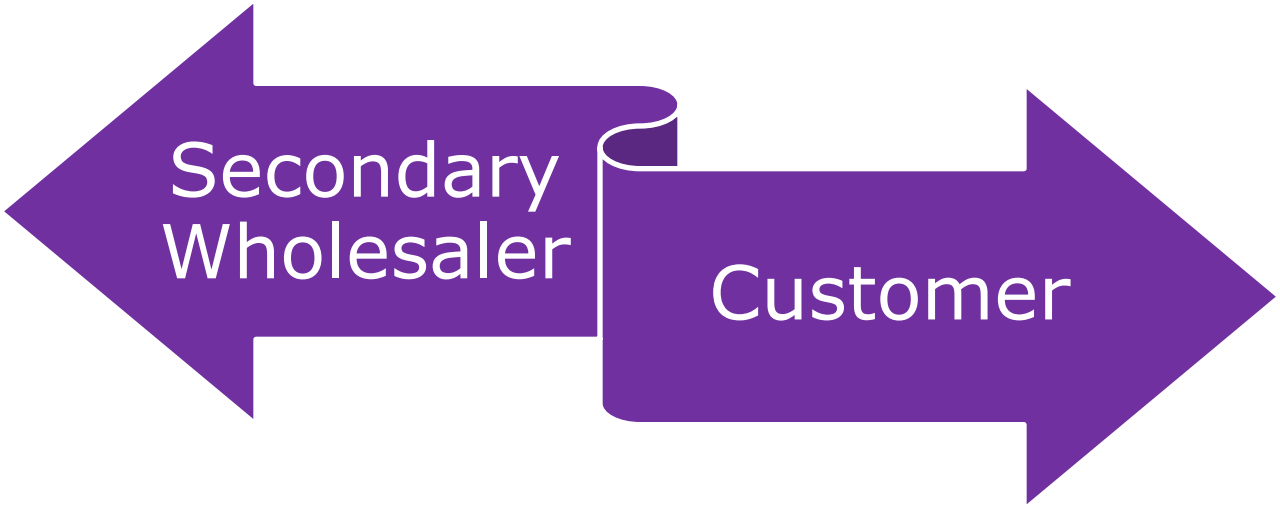
Relationship with Customers - secondary wholesalers, hospitals, pharmacies and other retailers

Be familiar with normal purchasing patterns of customers. Where these increase significantly, investigate and if necessary, discuss with the MAH & customers

Reactive approach where the increase is due to an apparent increase in market share, a plan to address the increase should be developed accordingly

Where it is established that a product is being parallel traded by the customer the primary wholesaler should, if necessary to ensure continued supplies to patients in the State, refuse or curtail supply while explaining its obligations/responsibilities to the customer

Considerations for Best Practice
Secondary Wholesaler (1)



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Considerations for Best Practice Secondary Wholesaler (2)

Document the obligations/responsibilities in a written policy/procedure and ensure that this is known to all who sell on its behalf

Ensure ordering, storage and distribution capabilities are sufficient, in context of normal business operations, to ensure continued availability of product to patients in the State; the business practices conducted by wholesalers should not unduly impact on patient access to medicinal products

Ensure effective oversight of customer purchasing patterns and investigate any significant increase in purchase of a particular medicinal product

Where it is apparent that this is due to an increasing market share for the product, this should be communicated by the secondary wholesaler to the primary wholesaler, as appropriate

Ensure that supply needs of patients in the State are prioritised over and above supply for any other purposes

Considerations for Best Practice Secondary Wholesaler (3)

Before knowingly selling a product for the purpose of parallel trade, ensure that sufficient stocks are available to meet established patient requirements

The needs of patients in the State should continue to be reviewed in the context of on-going activities which knowingly result in consigning product to parallel traders within the State or in other Member States

Where it is established that a product is being parallel traded by the customer the wholesaler should, if necessary to ensure continued supplies to patients in the State, refuse or curtail supply while explaining its obligations/responsibilities to the customer

Carefully manage pharmacy retail customers who hold a wholesalers' authorisation; the retail and wholesale customer accounts should be separated and the basis on which the customer is ordering stock (i.e. through the retail or wholesale account) established

Maintain batch traceability to pharmacy wholesale level

Emerging Trends (1)

Emerging Trends

- Parallel Export
- Direct to Pharmacy (DTP) Supply Model

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Emerging Trends (2)

Increased participation by Irish Wholesalers in 'Parallel Export' activities

'Parallel Export' is the exporting of medicines intended for use in Ireland to other countries in the EEA

- IMB Letter, September 2011
  - reminded Wholesalers of obligations
  - requested appropriate systems be implemented to manage and monitor demand and stock flow to ensure the needs of Irish patients are covered

- Series of targeted inspections to review this aspect of the wholesale market place and to assess compliance with Article 81 of Directive 2001/83/EC, as amended

- Increasing number of applications for Wholesalers' Authorisations received from pharmacies

- Follow up inspection of new applicants 12-18 months after authorisation granted

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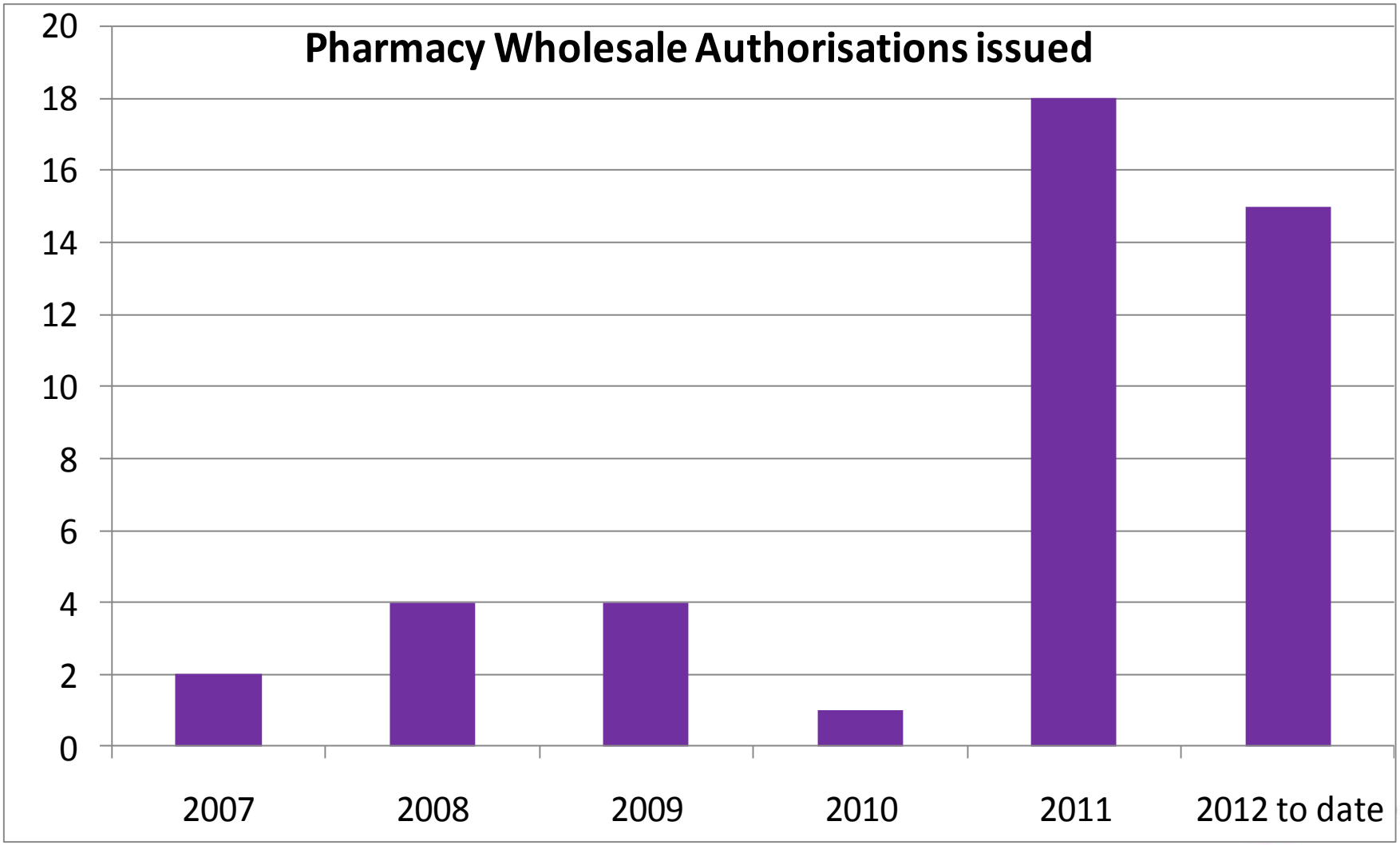
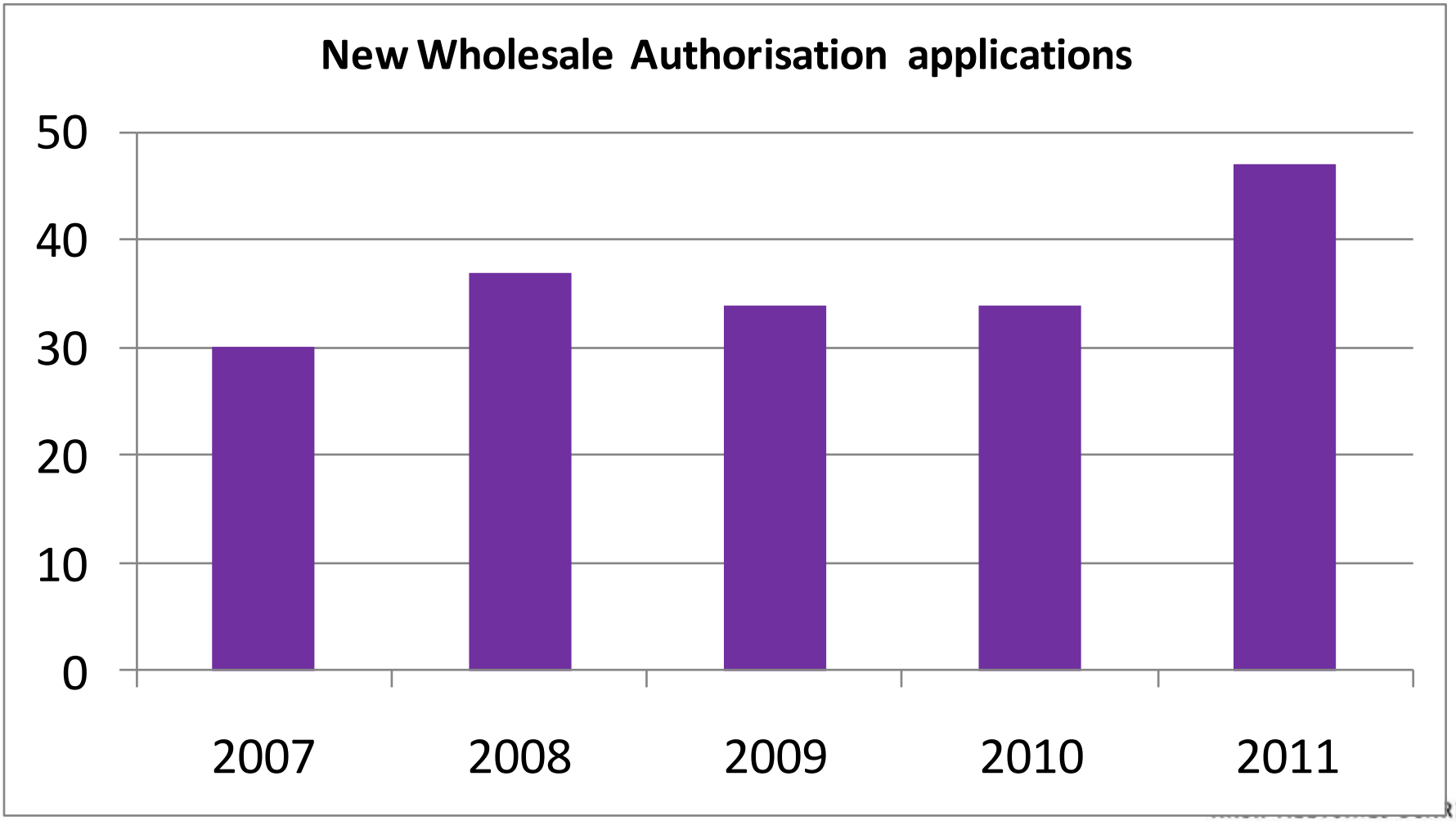
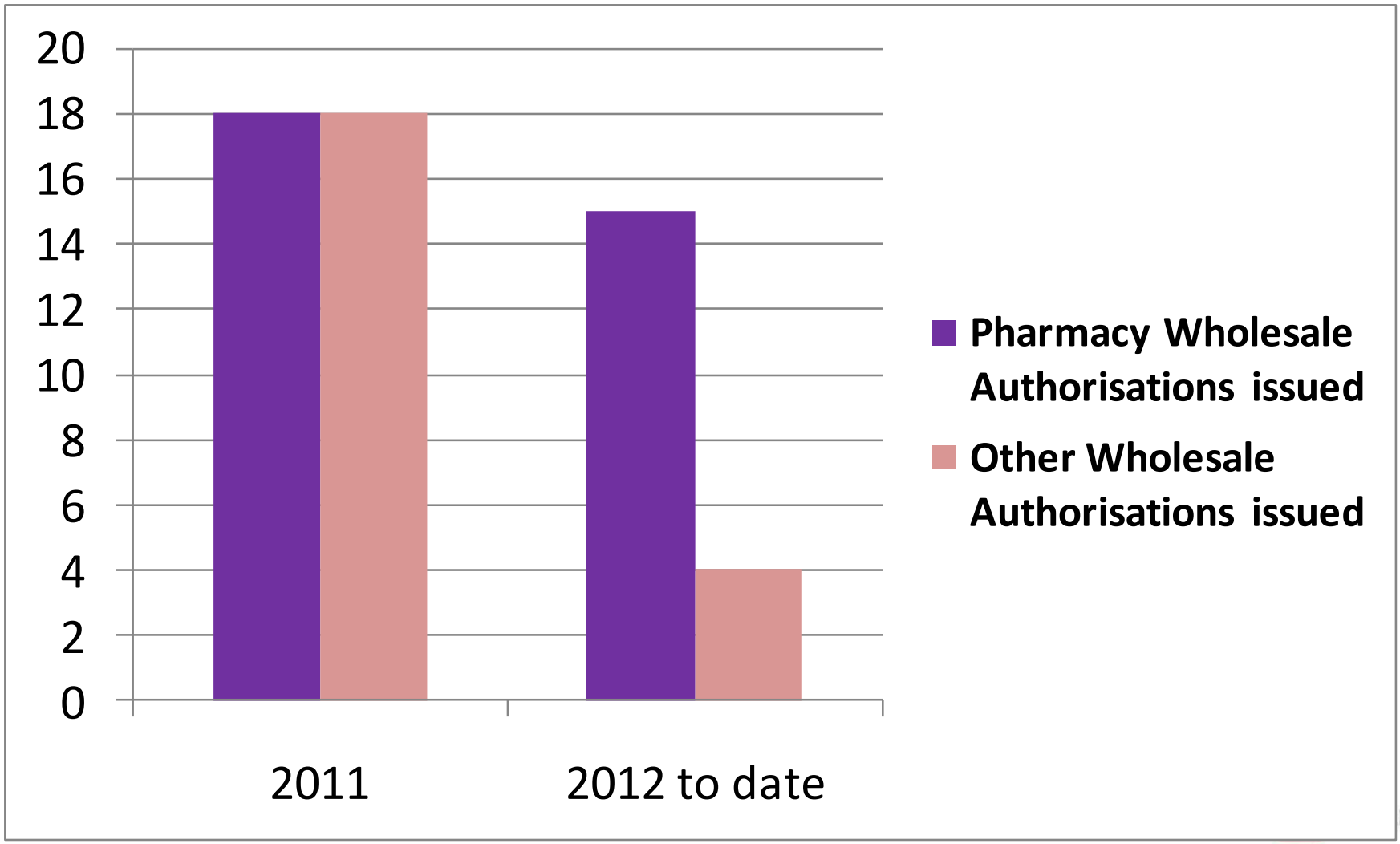
Emerging Trends (3)



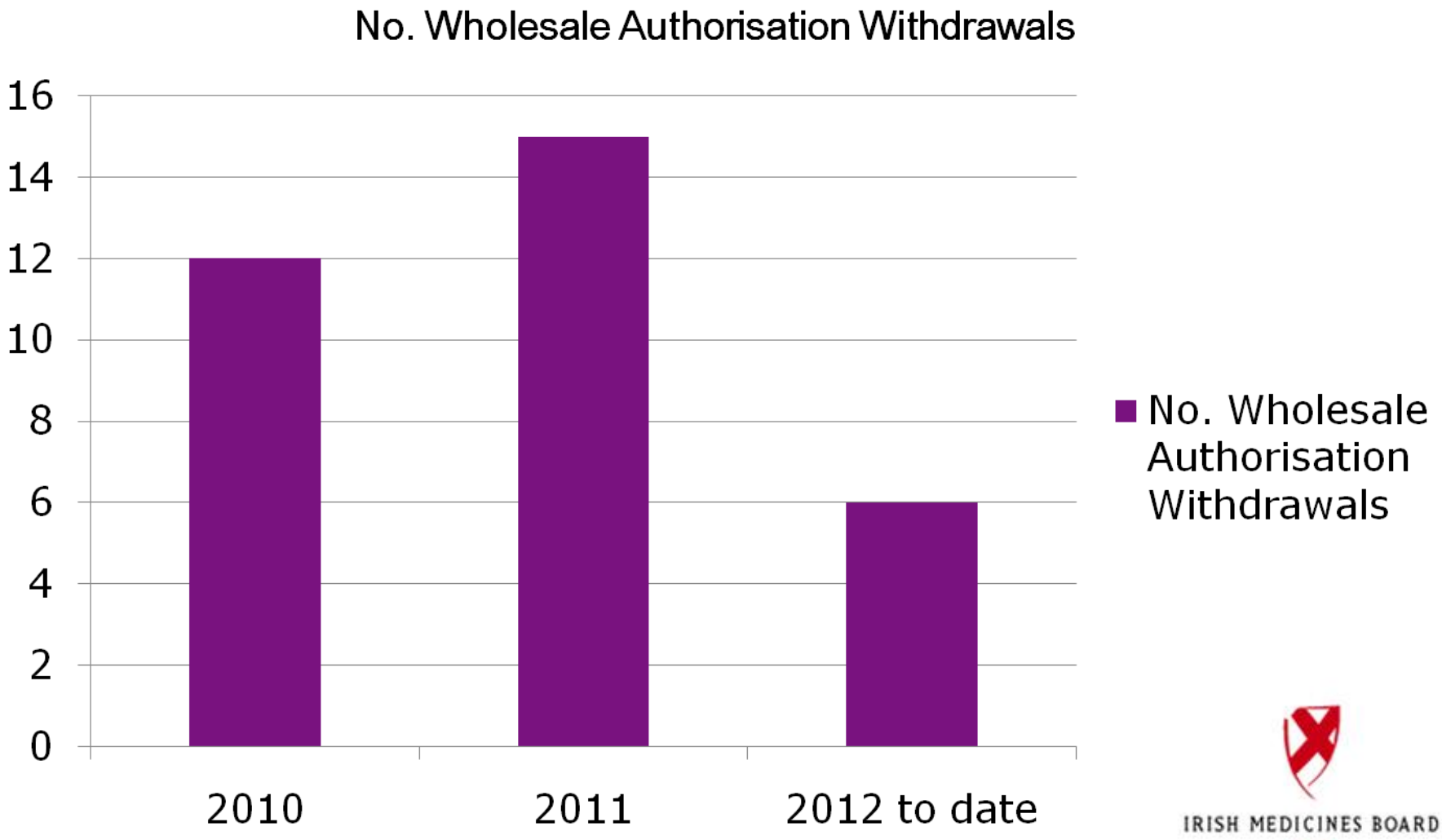
Emerging Trends (4)



Emerging Trends (5)



Emerging Trends (6)



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Emerging Trends (7)

Development of Direct To Pharmacy (DTP) Supply Model for distribution of medicinal products

- Significant increase in implementation of DTP supply model during 2011 by MAH/Primary Wholesalers
- Communication with pharmacies well in advance of implementation important
- Service levels should provide for essential medicines to be made available in timely manner (typically within 24 hours)
- Emergency out of hours service should be communicated to pharmacies
- Appropriate arrangements should be in place to cover Saturdays & bank holiday weekends

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Feedback from the Inspection Programme (1)

Findings – Pharmacy Wholesalers
The company had sourced medicinal products through the group owned retail pharmacies who were not authorised to supply medicinal products for wholesale distribution. There were no records available to verify the source of medicinal products wholesaled by the company.
The company had no defined method for ensuring that the supply of medicinal products to wholesale customers located outside of the Republic of Ireland did not result in a shortage of these products on the Irish market.
There were no records to confirm that suppliers had been informed that the pharmacy had placed orders for medicinal products in its capacity as a wholesaler.
There were no technical agreements in place with wholesale customers to whom the company exported medicinal products outlining the responsibilities of both parties with respect to the supply of medicinal products.
Technical agreements in place with UK based wholesalers to whom the company exported medicinal products did not include the responsibilities of each party in relation to complaints, recalls or suspected counterfeit medicinal products

Feedback from the Inspection Programme (2)

Findings – Other wholesalers

There was no system in place for the company to identify pharmacy customers who were ordering products for the purposes of wholesaling

The company were not recording the batch number of products supplied to customers who were identified on the company's system as receiving on the basis of a wholesaler

The company had no defined method for ensuring that the supply of medicinal products to wholesale customers located outside of the Republic of Ireland did not result in a shortage of these products on the Irish market.

The method for determining whether the exporting of a medicinal product would have an impact on the availability of said product to patients within the State was not adequately described in the 'Export' procedure

Conclusions

- Wholesaling operations should be conducted in a responsible manner to ensure appropriate and continued supplies of medicinal products to meet the needs of patients in Ireland

- Appropriate systems should be in place:-
  - to manage and monitor demand and stock flow
  - to maintain oversight of customer purchasing patterns
  - to maintain product traceability
  - to distinguish between pharmacy retail and wholesale accounts

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