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Distribution of Parallel Imported Medicinal Products

Wholesale Distribution Information Day, 25/2/2010

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IMB

Distribution of Parallel Imported Medicinal Products

Scope of Presentation

Inspection Programme

Statistical overview

Inspection triggers

Overview of Common Deficiencies

Contributing factors

Discussion of best practice

Suggestions for better compliance

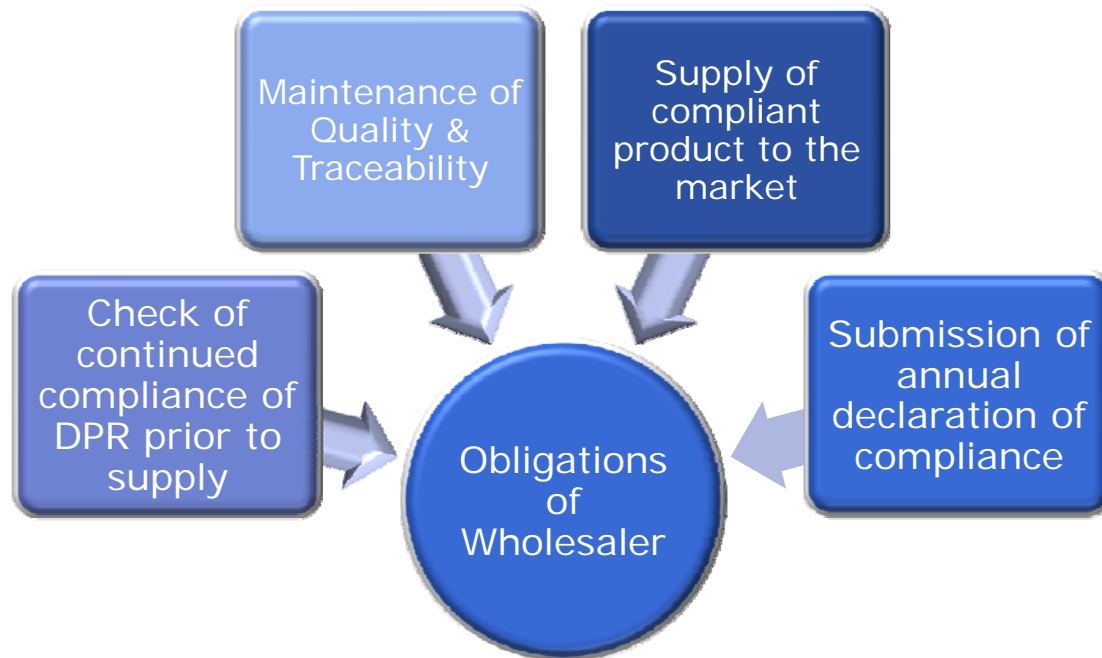


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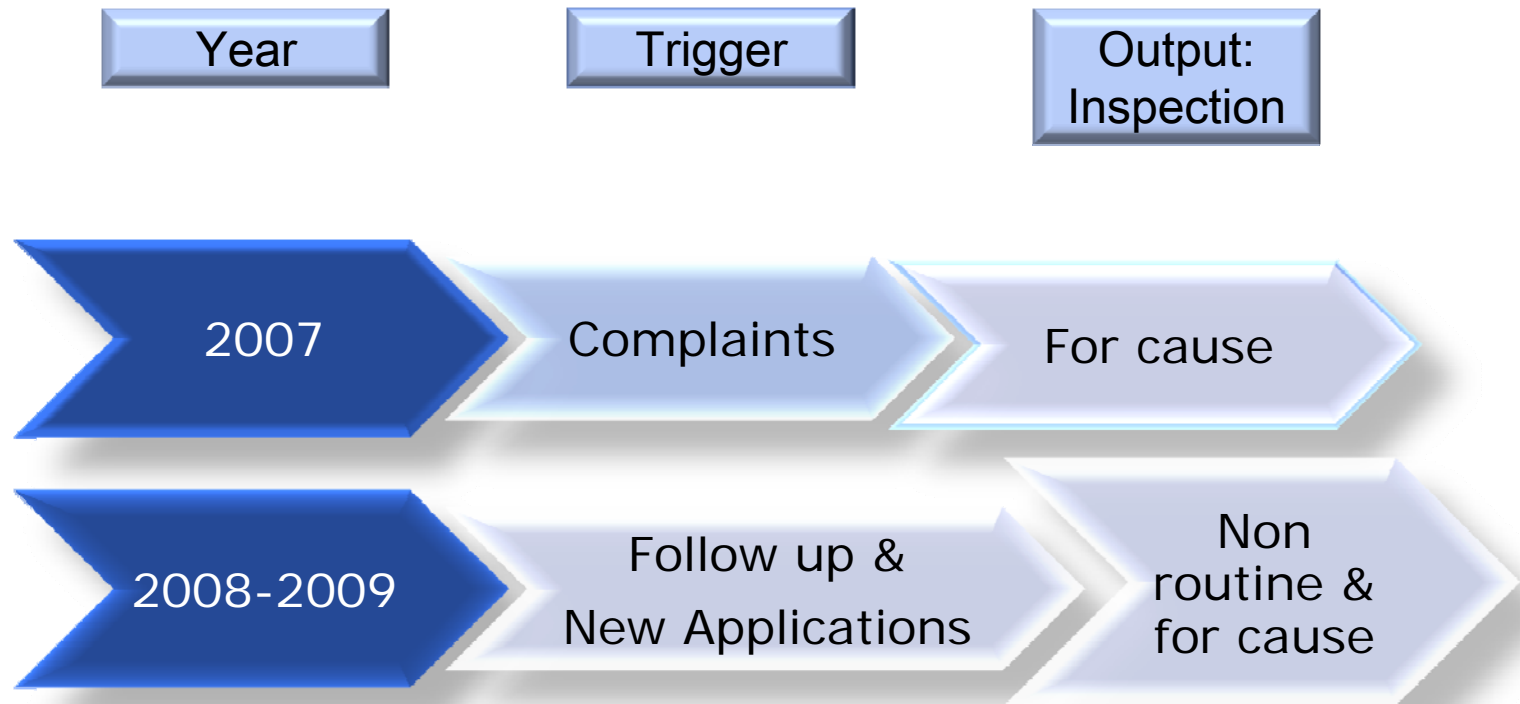
Main Focus: Wholesale distribution of Dual Pack Registered (DPR) Product

Important to highlight that DPR is a self-certification scheme



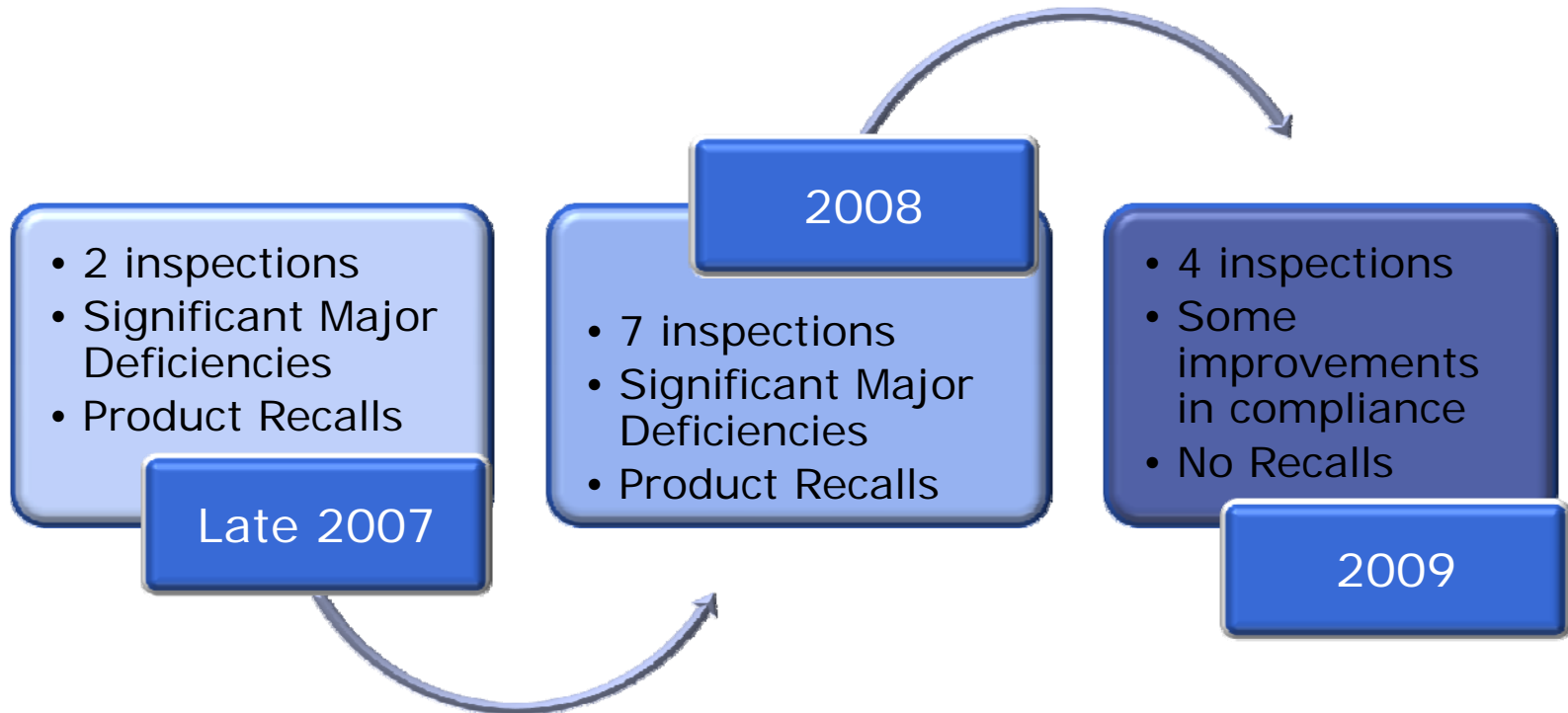
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2007-2008
Main factor contributing to high number of major deficiencies

Presence of dual MAs on packaging incorrectly interpreted as basis for DPR

For both markets

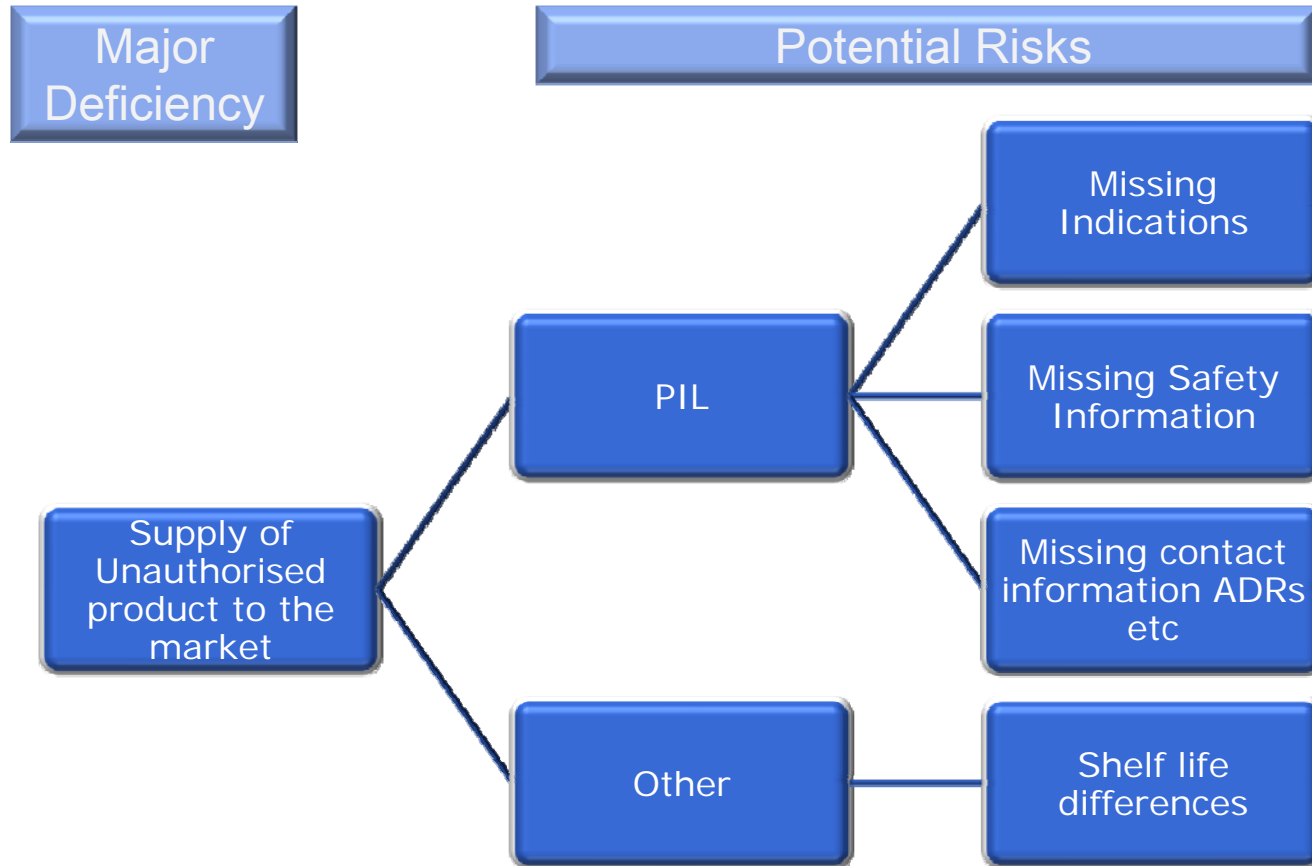
- No review of inner & outer packaging details
- No review of package leaflet
- No review of product shelf-life as stated in SPC
- No review of SPC where provided in pack

Result
Product fundamentally not eligible for DPR was registered



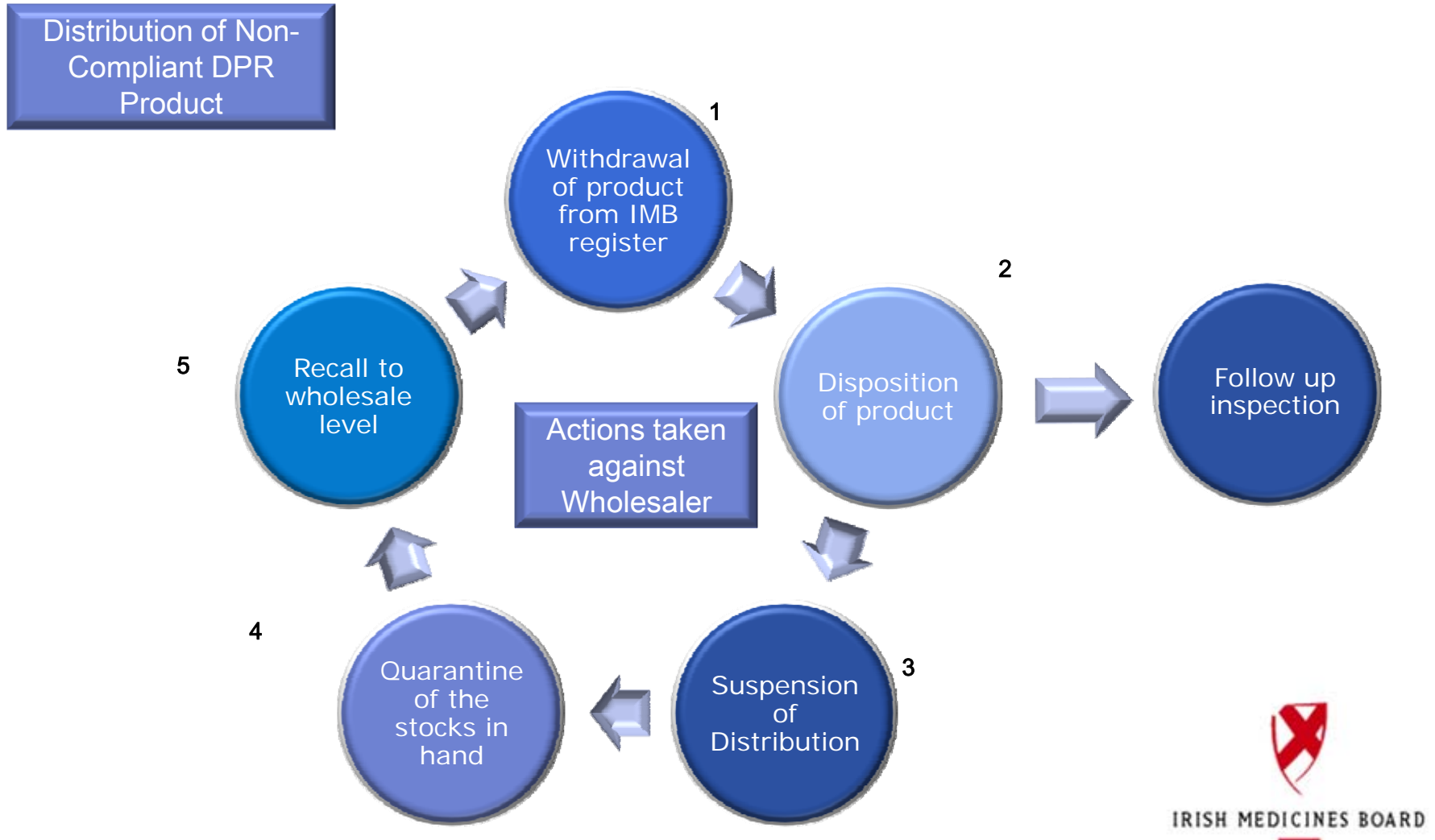
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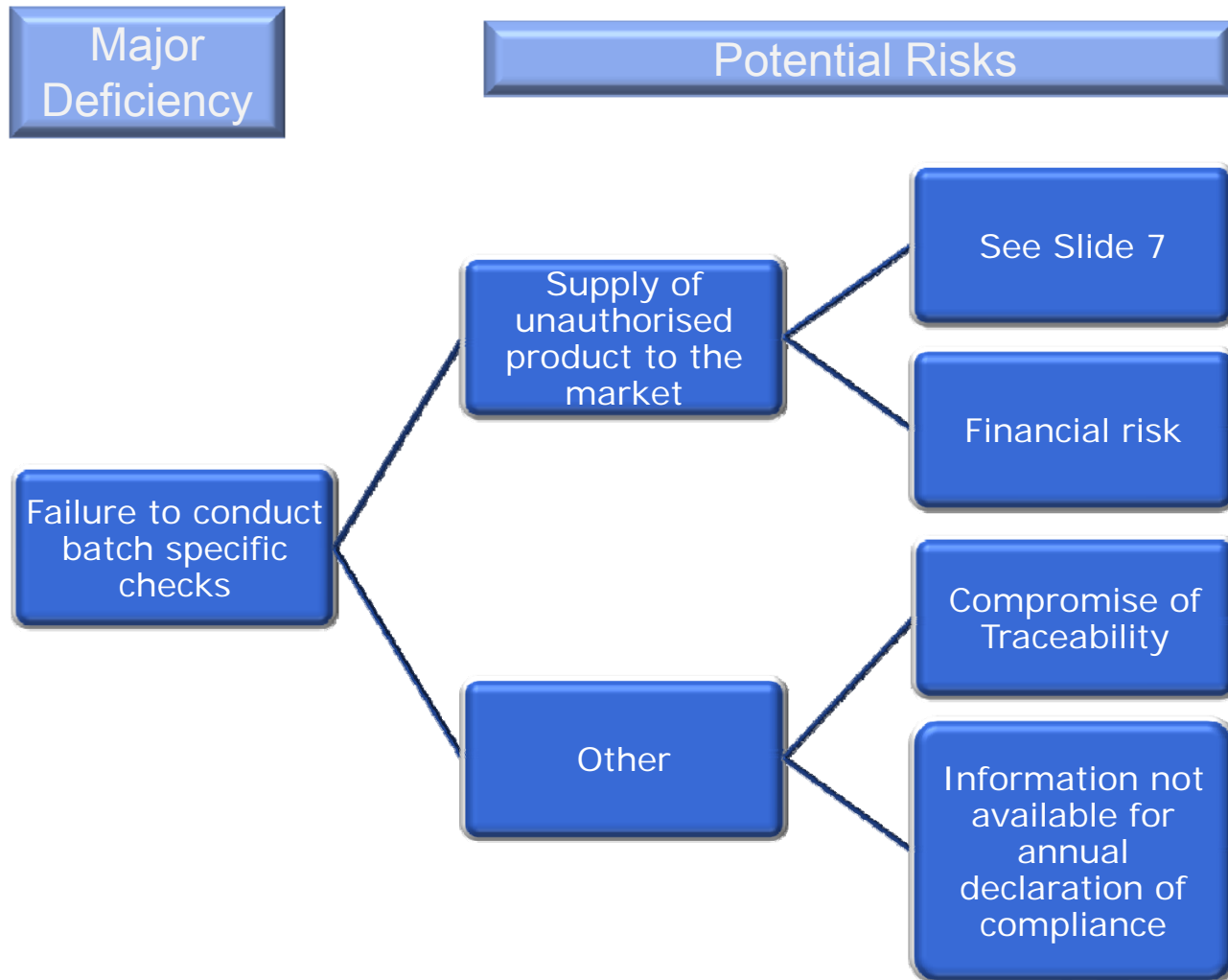


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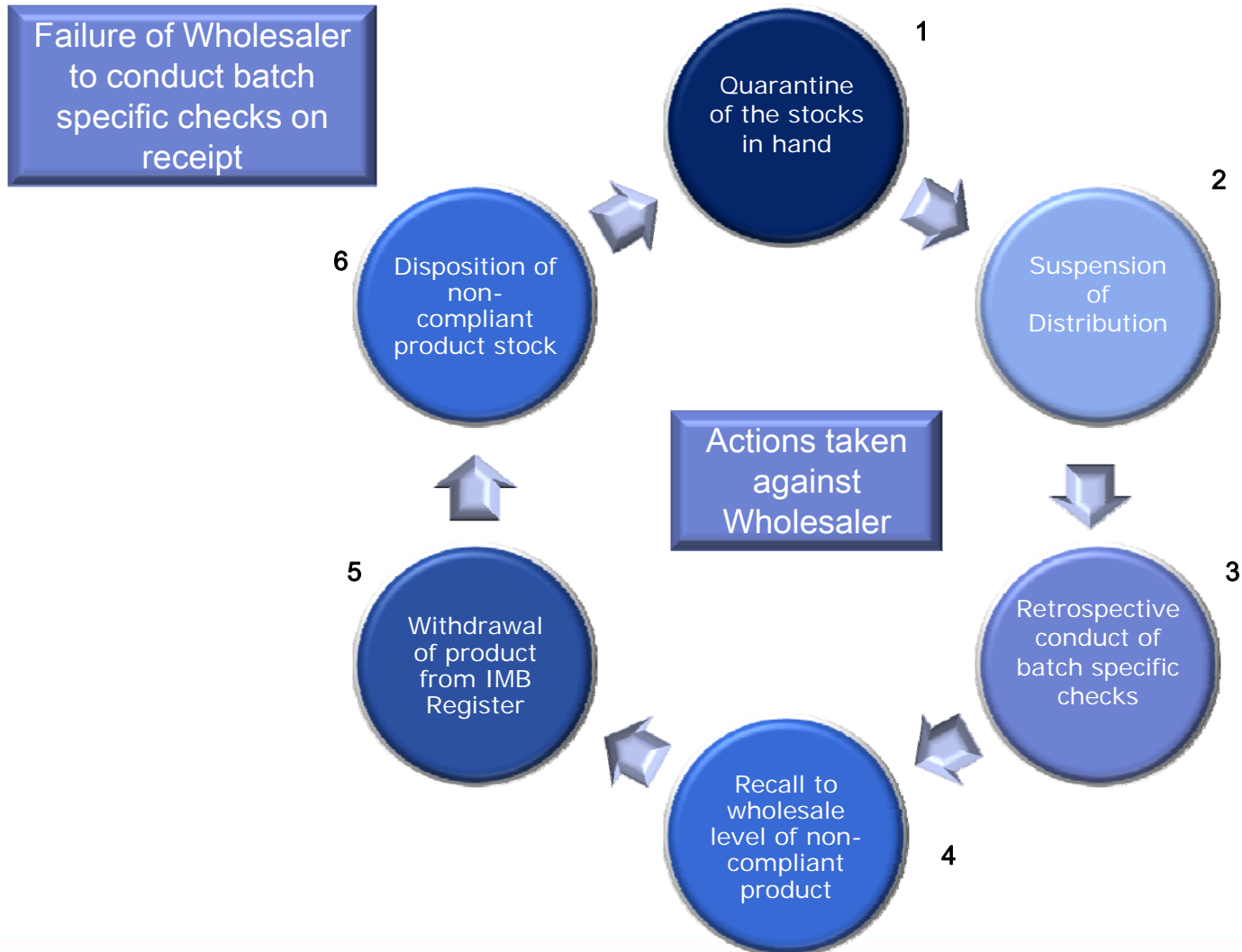


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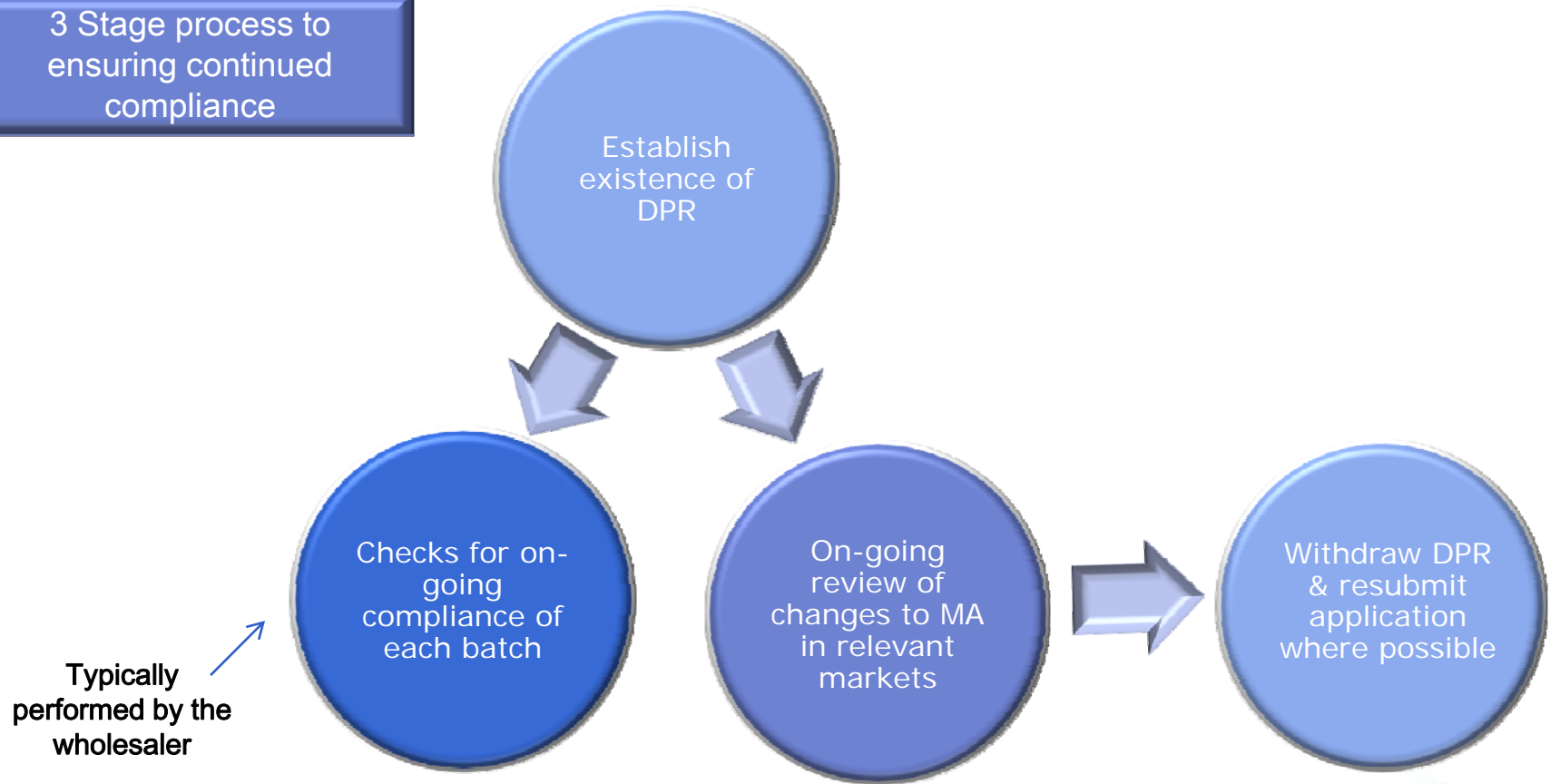
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3 Stage process to ensuring continued compliance



Typically performed by the wholesaler



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Challenge in Separation of the Regulatory Affairs & Wholesale Operation

Regulatory Affairs

Wholesale

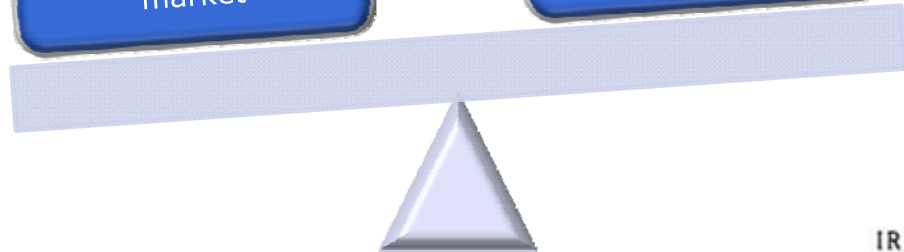
Establish existence of DPR

Completion of annual declaration of compliance

Manage changes to MA in relevant market

Conduct of checks on each batch of DPR

On-going review of compliance with product sourced from Irish market



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Wholesale Authorisation

- Ensure it provides authority to distribute DPR and PPA product
- Need to include these specific product categories

Distribution Records

To ensure traceability ensure detailed records are maintained

Standard GDP Requirements

- Date of receipt, supplier, quantities
- Customer, date of supply, batch number, quantity

Receipt Procedures

- Maintain an approved list of DPR Products
- Define the conduct of batch specific checks on receipt in an SOP
- Quarantine stocks on receipt
- Review sample of batch for compliance with DPR
- Notify the supplier in the case of non-conformance and await instruction
- Maintain detailed records (including sample pack) of the checks covering compliance of outer & inner packaging. PIL, SPC (if appropriate)
- Record batch numbers, expiry dates

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On-going Compliance Checks

- Source appropriately from the market place
- Ensure samples are representative of the most recent stock available on the market i.e. in general longest available shelf-life
- Check the compliance sample against the packaging, PIL & SPC version used in the DPR application
- Frequency at which the checks should be performed. IMB would recommend quarterly intervals.
- Maintain detailed records (including sample pack) of the checks covering compliance of outer & inner packaging. PIL, SPC (if appropriate)
- Record batch numbers, expiry dates

Stock Levels

- Need to be managed carefully
- To avoid financial loss do not stock pile
- Balance stock levels against the frequency at which the on-going compliance checks are performed
- Longer intervals between compliance checking presents more risk in terms of maintaining higher stock levels



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Where the Wholesaler is not the DPR Holder

- Managing the on-going compliance presents challenges
- Put in place supplier agreements
- Where the wholesaler is assigned responsibility ensure
 - Access to the information used in the DPR application
 - System for on-going compliance monitoring against current market is defined
 - Protocol in the event of non-compliance is defined



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Changes to the DPR Scheme

- Over-labelling/over-printing of packs required from 1/3/10
- Check of compliance of the pack with requirements will form part of the goods-in check
- Change will facilitate differentiation of DPR packs from Irish market product at wholesale
- Facilitate wholesalers in maintaining traceability
- Will facilitate identification of DPR product returns



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Conclusion

- Wholesale distribution of DPR products is more complex
- Requires extra resource from a wholesale perspective
- Requires additional management and monitoring to standard to wholesale distribution
- Will be more compliant where there is on-going engagement between product regulatory affairs & wholesale



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