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Parallel Imports – Authorisation Procedures

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Introduction

- Background discussion
- Brief overview of schemes

- Parallel Distribution
- Parallel Imports
- Dual Pack Registration



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Background - 1

- Legal basis: Article 28 & 30 of EC Treaty
- Key Documents:
 - EC Communication COM(2003) 839
 - IMB Guide to Parallel Imports
 - EMA 'Post-Authorisation Guidance on Parallel Distribution'



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Background - 2

- EC Communication
 - “Proportionally simplified procedure”
 - Heavy focus on trademark issues; not within IMB remit!
- Currently 1100+ PPAs authorised
- Approx. 500 DPRs registered



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Parallel Distribution - 1

- Centrally-authorized products
- IMB has no role in licensing
- Notification to EMA



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Parallel Distribution - 2

- Overlabelling requirements:
 - Manufacturer (as per original leaflet)
 - Parallel Distributor
 - Repackager
- Detailed list of requirements in EMA Guidance



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Parallel Importation - 1

- Product sourced from within EEA
- 45-day procedure
- 15-day procedure for initial assessment
 - a) Eligibility as parallel import
 - b) Product information
- 'PPA' issued at end of procedure



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Parallel Importation - 2

- Product Information:
 - Parallel-imported product must be overlabelled/repackaged with all relevant info:
 - without damaging product
 - primary pack must be left intact
 - any contradictory/confusing info obscured
 - Manufacturing licence required
- ‘PPA’ issued at end of procedure



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Parallel Importation - 3

- Post-Authorisation
 - Trade-mark owner must be given reasonable time to examine product prior to marketing (after approval by IMB)
 - PPA holder is obliged to keep product info up to date, i.e. in line with imported and reference products
 - Additional source countries possible
 - Renewed after 5 years → Indefinite validity



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Dual Pack Registration - 1

- Eligibility

Identical in all respects to Irish-market product

i.e. product appearance, labelling, PIL, shelf-life

- MAH of Irish reference product must be informed one month in advance of submission
- No formal assessment – Self-certification, in keeping with “proportional” simplified system
- Ongoing monitoring of compliance with scheme is essential; SOPs required



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Recent Changes

Public consultation; Oct – Nov 2009

Main outcomes:

- a) Requirement for overlabelling of DPRs from 1/3/2010:
 - Name of DPR holder
 - DPR number
 - “Parallel imported by...”
- b) DPR applicant to submit product information to IMB



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Recent Changes Continued

- DPRs issued under the previous system will continue to be valid
- The requirement for overlabelling/overprinting will apply to all stock placed on the market, i.e. dispatched from wholesalers' premises from 1/3/2010
- A single copy of the revised DPR application form should be submitted stating details of the manufacturing site(s) proposed for the overlabelling/overprinting operation(s) by 1/3/2010 to the Receipts and Validation Section of the IMB.



Recent Changes Continued

- A full list of DPRs held by the applicant should be attached to the DPR application form along with a *representative* sample of an overlabelled/overprinted product.
- A copy of the Manufacturing Authorisation(s) for the overlabelling/overprinting site(s) should also be appended.



DPR- Annual Compliance Form

2. Declaration

On behalf of the holder of the Dual Pack import Registration for the above named product, the undersigned confirms the following:

- A dual pack continues to exist for Ireland and (insert here Member State from which imported)
- Outer and inner Packaging remain identical
- Package leaflets remain identical
- Summaries of Product Characteristics remain identical (delete if not included in pack)
- Shelf lives remain identical

(Note: If any of the above cannot be confirmed the DPR is no longer valid and must be withdrawn)

- Each carton placed on the Irish market was overlabeled with the name and address of the DPR holder and the DPR number
- Each batch placed on the market in Ireland during the period covered by this declaration was checked against the originator's pack was found to be identical in all respects.

Wholesaler

Thank you for your attention



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