



IRISH MEDICINES BOARD

Update to the Exempt Products Notification System

Wholesale Distribution Day, 25th February 2010

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Update to EMP Notification System

- Feb 2008 to Jan 2010: 31,797 product lines notified to IMB
- Product line counted on each occasion that an individual exempt product is notified to IMB
- Approx 1,000 exempt products
- All data notified uploaded to the Exempt Products (EMP) database



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Exempt Products Database

Problems encountered:

- Duplicate data uploaded
- Active incorrectly entered
- Batch numbers incorrectly entered
- Incorrect manufacturer details
- Incorrect supplier details



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Exempt Products Database

- Uploading of duplicate files:

be careful not to load the file twice!

- If in doubt, please check the number of files uploaded by your company by clicking on the 'reporting' button
- If you wish to correct a file, please email IMB first to request deletion of original file



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Active ingredients sheet

- Enter the active ingredient only
- Example of file uploaded:

Notifier Product Code	Active Ingredient(s) (Exactly as Labelled)
50IN00J006	1 g Magnesium Sulphate Hepahydrate in 2 ml
50IN00J007	5 g Magnesium Sulphate Hepahydrate in 10 ml



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Active ingredients sheet

- Amended file:

Notifier product code	Active ingredient (s) exactly as labelled
50IN00J006	Magnesium Sulphate Heptahydrate
50IN00J007	Magnesium Sulphate Heptahydrate



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Active ingredient sheet

- Multiple actives: enter each active ingredient on a separate line
- Example of file uploaded:

Notifier product code	Active ingredients (exactly as labelled)
N00059	Lidocaine 50mg/Hydrocortisone 2.75mg
N00059	0.1% Dexamethasone, 325units/ml Neomycin Sulphate, 2% Glacial Acetic Acid

Active ingredients sheet

Amended data:

Notifier product code	Active ingredients (exactly as labelled)
TC010	Lidocaine
TC010	Hydrocortisone
TC011	Dexamethasone
TC011	Neomycin Sulphate
TC011	Glacial Acetic Acid



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Batch number sheet

- Enter the Batch number only
- Example of file uploaded:

Notifier Product Code	Batch Number (Exactly as Labelled)
DRN5303	LOT79336



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Batch number sheet

- Do not include the words 'Batch', 'Lot', or letters 'BN'
- Amended data

Notifier Code Product	Batch Number (Exactly as Labelled)
DRN5303	79336



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Manufacturer/Supplier sheet

- Legislation requires notification of manufacturer name and address
- Essential that manufacturer name and address is known to wholesaler.
- If unknown or incorrect, product must not be sourced; stocks to be quarantined



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Example of issue resulting from manufacturer data

- March 2009:
Caution In Use Notice for Aurum pre-filled syringes issued to all wholesalers which had notified Aurum products
- May 2009:
complaint from one wholesaler - no IMB communication received

Reason: wholesaler had notified incorrect manufacturer name & address

Manufacturer/Supplier sheet

- Legislation requires that supplier name and address is notified
- IMB requires that the name of licensed site which holds the exempt product prior to arrival in Ireland be notified
- Do not notify name of company which invoices product, if different to the above (e.g. principal)
- 'Physical journey' of the product



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Product Sheet: Trading style

- Please enter the name of the Manufacturing Authorisation Holder in the Trading Style field
- If there is no MAH, enter N/A



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Help is available!

- If in any doubt about the data to be entered, email sample spreadsheet to ep@imb.ie



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