



Pharmaceutical company view - Janssen Finland Primary pack identification details

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Starting up the project

- Email from Pharmaceutical Information Center on 28May2020
- Project evaluation in Regulatory Affairs
 - Evaluation of the content of recommendation
 - Amount of pharmaceutical products
 - Exclusion of products
 - Analyses of the added information
 - Small size of primary packs
 - Management of GTIN numbers
 - Change control
 - Need of informing Health Authorities
 - Email notification in SE, NO, IS vs. 90-day application to Health Authorities

Internal communication

- Internal meetings in Jun/Aug 2020
 - Pricing and hospital tenders, Governmental Affairs
 - Regulatory Affairs (product contacts, packaging material team, variation team)
- Description of the project and internal instructions
- Project started in the beginning of September 2020

Products and their selection

- 25 % of the Nordic packs have already the GTIN on the primary packs (Danish requirement for hospital tender products)
- 75 % of the Nordic packs don't have GTIN on the primary packs -> Half of them included into the project
 - Both hospital and open care products
 - Blisters are excluded from the project at the moment
- The change of packaging materials (artworks) has now been initiated for 42 % of the products in scope of the project

What is added to the primary packs and how?

- GTIN is added by printing a 2D datamatrix code on the primary pack packaging material
 - Lot and EXP details not possible to print online at the moment
- The 2D code will be added with other changes to the packaging material
 - New products contain it already from the launch
- Completing of the project will take several years
 - Compare with serialization: artworks of whole portfolio updated in 1 years 8 months



Remarks

- Small size of primary pack is challenging
 - Multicountry packs have even less space
 - Human readable form may not fit
 - Challenging to implement on blisters
 - 90-day applications to Health Authorities when needed (font, size, lay-out) – 90 days evaluation time
- Definition of primary pack
- Hospital products / hospital tender products may be updated first

Remarks

- Online-printing is challenging and an expensive investment if the production line doesn't currently support it
 - A wish that it won't be a requirement
 - Different companies will add different things
- Database challenges in the Nordics
 - In Norway and Iceland, the primary pack code can be added to the database by a company
 - In Finland, it can be added to the database, but the code is informed via email
 - In Denmark and Sweden, there is no database where the codes could currently be added by a company
 - DK: information sent via email to DLI and Amgros
 - SE: information not sent as it can't be utilized yet
 - Possible mistakes due to manual email process?
 - how to discover and fix?

Remarks

- Implementation will take several years
- A wish for several years implementation time, if primary pack codes would become a hospital tender requirement
- Important to have common guidance in the Nordics

THANK YOU!



janssen 

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