

# **CMDh Meeting with Interested Parties**

**21 June 2010**

**Issues encountered with  
Type IA implementation**

# IA<sub>IN</sub> Immediate Notification

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- IA<sub>IN</sub> are mainly administrative changes (notified immediately after implementation) the following agencies: BE, LU, DK, IE, PT and UK have defined immediately as 14 days after implementation.

Example of IA<sub>IN</sub>

Change in name of Release Site

- **Meaning of “implementation” for Type IA variations:**

**EMA: For CMC only changes:**

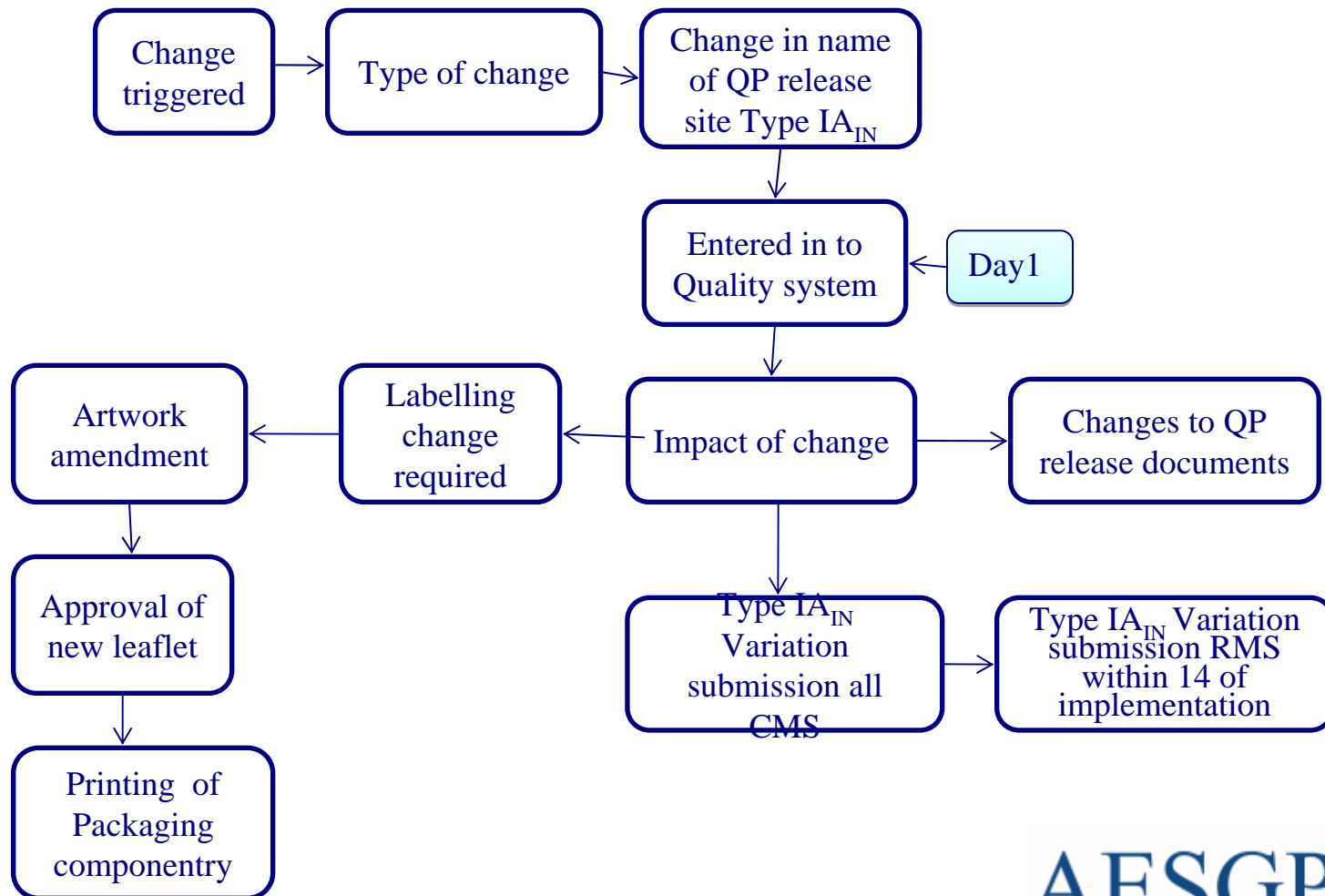
Implementation is when the Company makes the change in its own Quality System

- **Pharmacovigilance system (DDPS)**

Implementation is when the Company makes the change in its DDPS (i.e. when it internally approves the DDPS incorporating the changes).

# IA<sub>IN</sub> Immediate Notification

## Logistics of IA<sub>IN</sub> change of Name of QP Release Site



# IA<sub>IN</sub> Immediate Notification

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- **Logistics of IA<sub>IN</sub> Change of Name of QP Release Site**
- **Impact of change**
- QP documentation changes to new site name in conformance with the Quality system, but product leaflet reflects old site name.
- **Alignment of QP documentation and labelling**

The labelling change procedure requires a longer lead time, than the proposed 14 day implementation time.
- **Financial Impact of immediate implementation**
- Typically labelling changes can take up to 6 months to implement, to expedite the change will result in decommissioning of existing labels which will create additional financial burden for the industry.

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- **Proposal**
- Tell and do procedure is a welcomed addition to the variation procedure, however a 14 day notification for an administration change seems restrictive.
- Proposal of a longer submission time frame of 6 months is a more practical time frame.