

Outcome of the FMD - IDMP Integration Workshop

EMA - London

27th June 2016

- Introduction
 - This is the output from a multiple stakeholder workshop held at EMA on June 27th.
- Market Authorisation Phase.
 - MAH submits data to SPOR system in IDMP format in accordance to the Art57 legal requirements.
 - During the submission, the MAH should also complete the IDMP optional element 'data carrier identifier' and should use the value of the 'product code' as used in EMVS (often the GTIN).
 - A successful upload in the SPOR system completing with the MAH being provided with the MPID/PCID for each product submitted.

- EMVS Master Data Submission Phase.
 - Assuming that the MAH has completed the SPOR submission and has populated the 'data carrier identifier' the master data submission to the EMVS (European Hub) can be made using a lightweight data payload including the product code value.
 - The EMVS will use the product code to obtain the full data set from.
 - If the SPOR system is unable to return the data set (e.g. the product code has not been uploaded to IDMP), the submission to EMVS will fail and the error returned.
 - The MAH must amend the IDMP product record to include the 'data carrier identifier' element.
 - Once updated, the submission process to EMVS can be retried.
 - This process will quickly force compliance at the authorisation submission phase (to include the product code value) as it will be impossible to ship product (because the EMVS submission will be blocked) until the product code/'data carrier identifier' element is part of the product registration.

- EMVS Master Data Submission Phase (2).
 - If the IDMP system is unavailable(e.g. off-line for maintenance purposes), the MAH will be able to submit a full EMVS data set.
 - Where known, the full data set should include the evCode or PCID.
 - If subsequently the IDMP system becomes 'online', the MAH can must re-submit the data using the lightweight data set, and all the previously uploaded data will be overwritten by the SPOR authoritative set.
 - Parallel traded products remain an issue to be fully addressed within SPOR and the current Art57 systems and therefore, until a full SPOR or current Art57 capability is in place for parallel distributed products, a full data set submission to EMVS will be expected. (i.e. no SPOR/Art57 data exchange).

Market Authorisation Process

Full diagrams included
as PDF here:



Adobe Acrobat
Document

EMVS Product Master Data Submission Process

