BEST PRACTICE: SUBMITTING PRODUCTS PENDING APPROVAL TO XEVMPD

1 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/ Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.3	03 February	First released

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3 Document Purpose

The purpose of this document is to provide a Best Practice defining the process of submitting products which are pending approval to XEVMPD. From mid-January 2025, a new authorisation status value of 'Valid – pending national phase' has been introduced. This status can be used when a medicinal product has been authorised by the reference member state but is still under evaluation by the concerned member states during an MRP or DCP. This has been introduced so that the product can be made available in the eAF, in case a variation needs to be submitted before the national phase is complete. There is no need to submit products which are pending approval unless you wish to use the eAF before the national phase is complete.

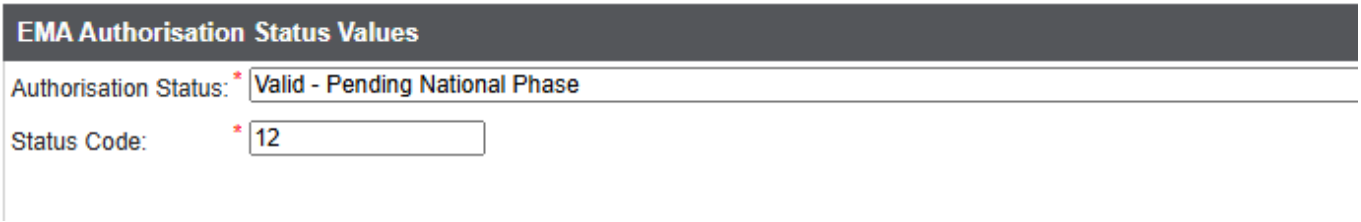
4 Scope

XEVMPD submissions for products authorised via MRP/DCPs in Ennov InSight.

5 Data Administration Activities

From Data Administration, navigate to the section 'Registration Maintenance' and open the list 'EMA Authorisation Status Values.

1. Click 'Create'
2. Enter the following attributes:
    a. Authorisation Status: Valid - Pending National Phase
    b. Status Code: 12



3. Click 'Save'.

This authorisation status can now be associated with the appropriate Full Product Presentation, and will allow the FPP to be submitted to XEVMPD.