



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

31 January 2022  
EMA/61851/2022  
Information Management Division

## IRIS Veterinary Signal Management/PhV Inspection Outcomes – Production Release notes

Release 1.0.0

Release date: 28 January 2022



# 1. Overview of functionality

This release to production environment will bring the Veterinary Signal Management Process and Pharmacovigilance (PhV) Inspection Outcomes process to go-live on 28 January 2022 via the IRIS Platform. The system, that is compliant with new Veterinary Regulation (EU) 2019/6 requirements (Art 77. (10), Art. 79 (1), Art. 81 (2), Art. 81 (3), Art. 126.6 of NVR.), will be enhanced in future releases.

## 1.1. Deployed features

Deployed features	
<b>Signal management submission</b>	Industry Veterinary Signal Submission
<b>Annual Statement Submission</b>	Industry Annual Statement Submission
<b>Targeted Signal management Submission</b>	Network Veterinary Signal Submission
<b>PhV Inspection Outcomes</b>	Network Pharmacovigilance Inspection Outcomes submission

## 1.2. Pending features to be deployed in future releases

Features to be deployed	
<b>Period of Analysis – Signal Submission</b>	Period of Analysis field will be removed from the Signal Submission form (not relevant for this type of submission) in a future release.
<b>Product View – Invented Name</b>	Currently in the product selection view the Invented Name of the product is available for search. The Full Presentation name will be added in a future release.
<b>PhV Inspection Outcomes – PSMF Code, PSMF Location</b>	PSMF Code and PSMF Location are retrieved from UPD, this is information that is only mandatory from the 28 of January 2022, therefore for products authorized before the 28 of January 2022 this information is not up-to-date and will become available gradually.
<b>PhV Inspection Outcomes</b>	In the current submission form, the product from which the PSMF code, PSMF Location was selected is displayed. This will be removed in a future release.