EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Implementation of IRIS Marketing Status

7th Meeting of the EMA/Industry platform on the operation of the centralised procedure for human medicines

1st December 2021

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Introduction

The Agency has developed an IRIS system for reporting of Marketing Status that:

- replaces the reporting via e-mail of changes to marketing status of Centrally Authorised Products (CAPs) to the Agency by Industry
- allows a systematic approach to gather structured marketing status data for a CAP
- allows the creation of a database available to EC/NCAs that increases transparency on the actual marketing of authorised CAPs
- provides an overview of the marketing status of CAPs at a specific timepoint (past, present, future) at presentation level and at Member State level

The project was initially presented to Industry in the EMA/Industry platform meeting on Centralised Procedure in December 2020.

During the development phase, technical questions/issues were discussed in the IRIS Industry meeting on 21st May 2021 and there have been 3 demo/feedback sessions to the Marketing Status Industry volunteers group in July, Sept and Nov 2021.

Implementation plan

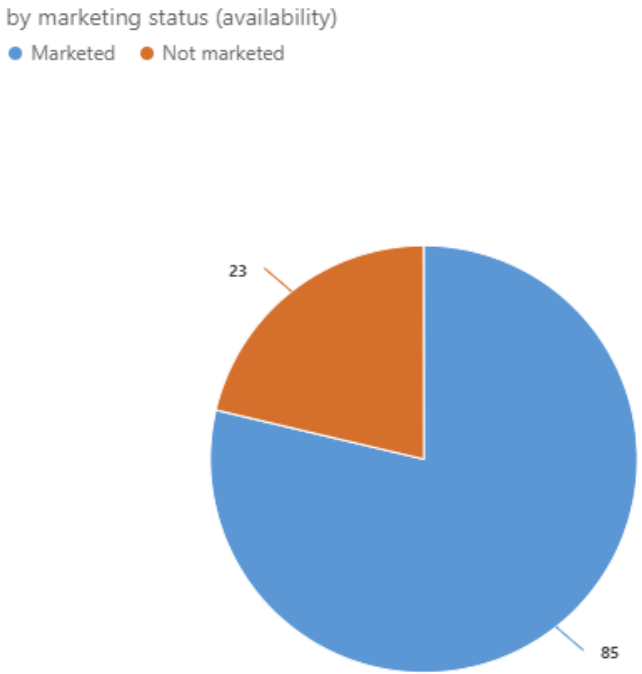
IRIS MS was launched on 26 July 2021

- **For CAPs not yet launched** in any EU/EEA MS, MAHs should report the initial placing in the market and any subsequent updates via IRIS from the launch of the system. Newly authorised CAPs are added to IRIS with a status "Not marketed" by default.
- **For Marketed CAPs** in at least one EU/EEA MS, MAHs can report changes to marketing status/withdrawals by email or via IRIS in the first **6 months after launch** of the new system.
  - CAPs that were authorised prior to the launch of IRIS Marketing Status, have their marketing status in IRIS as 'No data provided'. A baseline submission of the current marketing status in all EU/EEA MS for all presentations is required before starting to report any changes of marketing status in IRIS.
  - The baseline should be submitted within 6 months after launch of the IRIS system.

Marketing Status reporting

As per 29th Nov 2021:

- 127 separate IRIS cases have been received for 108 CAPs
- Less than 10% of CAPs have had at least one reporting for one presentation in at least one Member state.



Marketing Status reporting

- The reporting rate has been slow so far
- Some IT issues have been identified and have been solved or are being worked on.
- No issues detected with the single reporting
- Bulk upload was designed to facilitate the entry of data from Industry, but is the source of most issues. Some common problems have been identified. We are compiling the most common validation errors and updating the guidance for clarity.
- Guidance is being updated on a regular basis
- The IRIS Forum is also being updated with useful tips: Questions and answers on Marketing Status reporting submissions · IRIS (europa.eu)
- Suggestions from the Industry volunteers group have been implemented or are in the process of being implemented. A new meeting will be held in January 2022 to update the Questions and Answers document and gather new feedback.

Marketing Status reporting

All points raised by the Industry will be reviewed and the guidances will be updated to provide more clarity. The Questions and answers post will also be updated in the Forum.

Please encourage all reporters to read the IRIS guidance, the regulatory guidance and also check the Forum for tips and help.

Useful links

Home - access · IRIS (europa.eu)

Quick interactive guide to IRIS registration process (europa.eu)

IRIS guide to registration

IRIS guide to applicants (scientific applications) (step by step instructions)

Notifying a change of marketing status | European Medicines Agency (europa.eu)

Questions and answers on Marketing Status reporting submissions · IRIS (europa.eu)

EMA ServiceDesk Portal

Thank you for your attention

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