Launch of IRIS for reporting changes on Marketing Status

6th Meeting of the EMA/Industry platform on the operation of the centralised procedure for human medicines

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Presented by: Alberto Gañán Jiménez
Head of Procedures Office. Committees and Quality assurance Department. Human Division

Introduction

The Agency has developed a new IRIS system for reporting of Marketing Status that will:

- replace the current reporting system to EMA via email.
- allow a systematic approach to gather structured marketing status data for a Centrally Authorised Product (CAP).
- allow the creation of a database available to EC/NCAs that will increase transparency on the actual marketing of authorised CAPs.

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

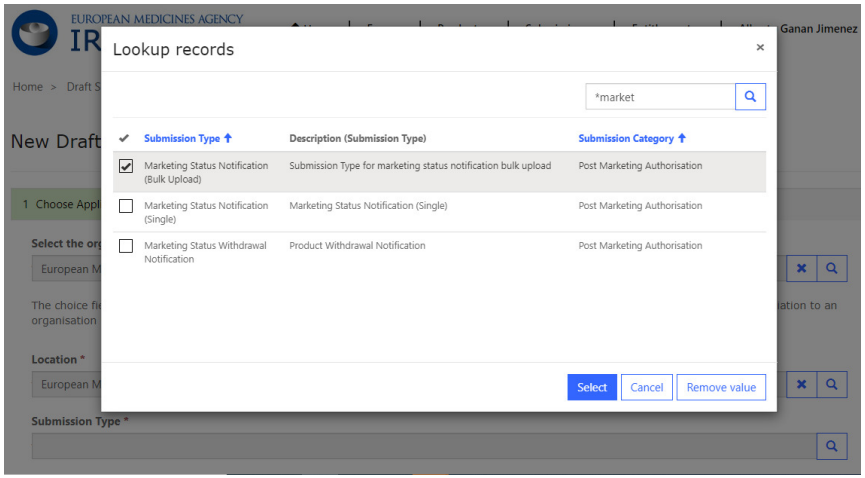
During the development phase, technical questions/issues were discussed in the IRIS Industry meeting on 21st May and a demo/feedback session to Marketing Status Industry volunteers group took place on 24th June.

Launch of IRIS Marketing Status

EMA targets to launch the new IRIS system to report the changes to marketing status/product withdrawals via IRIS in **July 2021**.

From launch, the system will allow 3 types of submissions:

- Marketing status Notification (single)
- Marketing status Notification (bulk upload)
- Withdrawal/permanent cessation of a medicinal product



Change of Marketing status: Submission types and data

A **single** submission is to report the same change in marketing status affecting one or more presentations of a medicinal product in one or more MS.

Bulk submission is to report multiple different changes in marketing status affecting one or multiple presentations of a medicinal product in one or multiple MS.

Data at CAP presentation level (EU number) for each EU/EEA MS:

- New marketing status (marketed/not marketed/temporary cessation)
- Date of placing into the market / cessation to market
- Reasons for cessation (according to Art 116, 117, commercial)
- In case of temporary cessation: Expected date of reintroduction in the market
- Does the cessation led to shortage? (y/n)

Withdrawal of a CAP: data reported

Withdrawal is to report the withdrawal/permanent cessation of all presentations of a medicinal product in all EU MS.

Data to be provided:

- MAH intentions (i.e. withdraw the MA, not renew MA, permanent cessation of marketing)
- Intended date
- Reasons for withdrawal/permanent cessation (Art 116, 117, commercial)
- Specific details of the reason (free text)
- Details of any actions taken at MS level or in third countries (free text)
- Information related to paediatric incentives benefits

Content of the Marketing Status database at launch:

MAHs will have access to the reported information on Marketing Status for the CAPs belonging to the MAH.

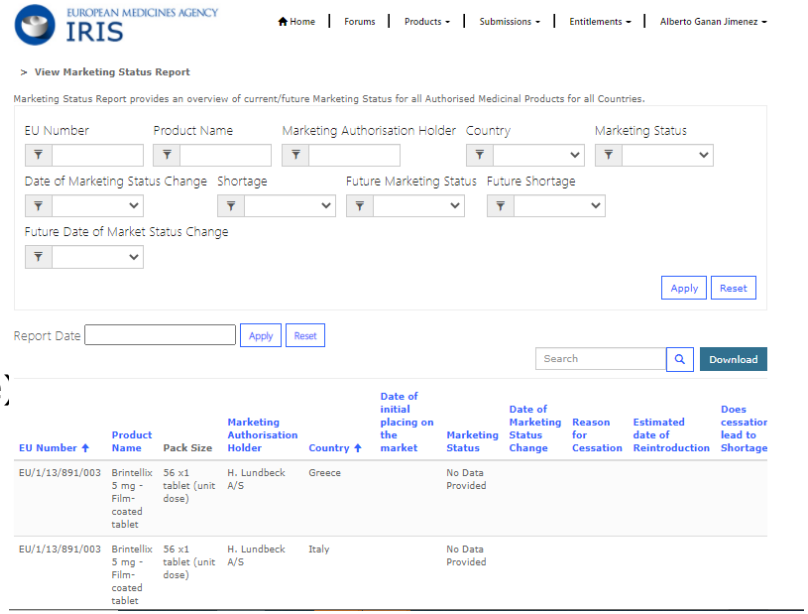
At launch, **the database will reflect** for each CAP with a valid marketing authorisation:

- the details of all valid presentations

(i.e. EU number, product name/strength/pharm. form/pack size)

- the marketing status will show as ´No data provided´

for all presentations in all MS.



Timelines for launch and implementation plan

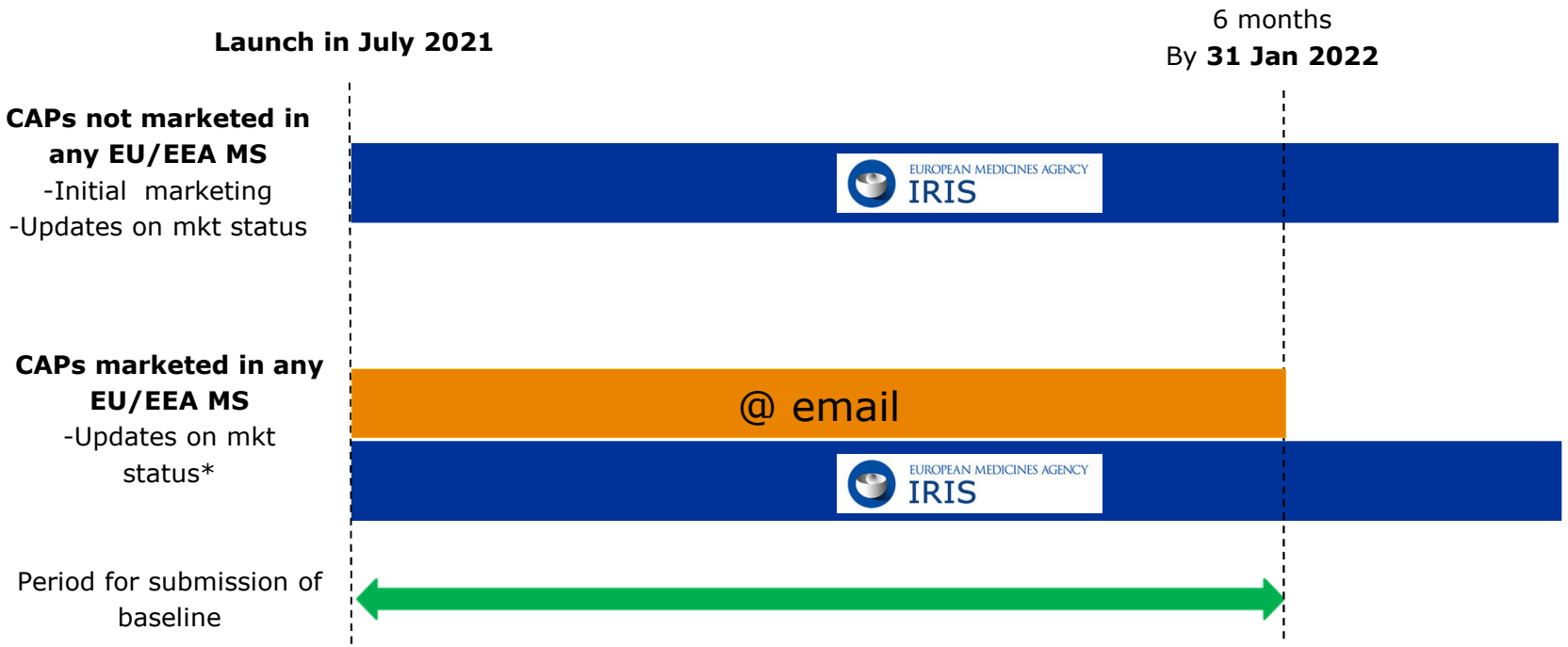
The launch of the IRIS MS reporting system is intended in July 2021

CAPs not yet launched in any EU/EEA MS should report the initial placing in the market and any subsequent updates via IRIS from the launch of the system.

Marketed CAPs in at least one EU/EEA MS can report changes to marketing status/withdrawals by email or via IRIS in the first **6 months after launch** of new system.

- A baseline submission of the current makerting 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 IRIS system.

Timelines for launch and report of current marketing status



*A baseline is needed before first reporting in IRIS

Communication and MAHs support

The exact date of the launch will be communicated to Industry Associations via EMA Stakeholders liaison in advance.

EMA news item, IRIS User guide and Regulatory guidance will be published on EMA website by the date of launch.

MAHs can report via Service desk any issue with the new IRIS system after launch

A meeting with the Industry volunteers group will be organised in Aug/early Sep to discuss the use of system.

Final remarks

EMA notes Industry concerns on duplicate data reporting and preference of a single channel through SPOR/PMS for product information submission.

The Agency recognizes that duplicate / potentially inconsistent provision of data is undesirable and is working to ensure harmonisation in data content as well as the interoperability among systems with regards to Marketing status.

- IRIS marketing status reporting has already been implemented in compliance to ISO IDMP data model.
- PMS is being extended to cover the same data elements as those reflected in IRIS.
- IRIS replaces the current reporting system to EMA via email of marketing status for **Centrally Authorised Products only.**
- IRIS and PMS will be interoperable and able to exchange marketing status data on Centrally authorised products.

The Agency values efficient data flows and is giving due consideration to the preference for single channels across CAPs/NAPs.

- EMA recognizes that a solution may be required to support the reporting of marketing status also for **Non-Centrally authorised products** and is looking into options for the best way to collect this information in the future.

EUROPEAN MEDICINES AGENCY

Thank you for your attention

alberto.ganan@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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