Reporting marketing status to EMA via IRIS

EMA/Industry Platform meeting on Centralised Procedure. 3 December 2020

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Legal provisions requiring reporting of placing on the market

Marketing and cessation notification

- Article 13(4) of Regulation (EC) No 726/2004

Sunset-clause monitoring

- Article 14(4) & (5) & (6) of Regulation (EC) No 726/2004

Withdrawn-product notification

- Article 14b of Regulation (EC) No 726/2004

Paediatric indication authorised in accordance with a PIP

- Art 33 and 35 of Regulation (EC) 1901/2006

Introduction

As part the EMA's strategy to digitalise our operations, the Agency is developing a **new system for reporting of Marketing Status data** electronically by Industry for centrally authorized human medicinal products.

The tool aims to:

- provide a single reporting system to replace the current reporting to the Agency via 2 different emails (marketingstatus@ema.europa.eu and withdrawals@ema.europa.eu),
- allow MAHs to have a better overview of the current status for their CAPs reported to EMA,
- provide a structured way of data reporting data that facilitates better data management by all stakeholders.

Introduction

The tool allows the creation of a database with marketing status data for human CAPs available to EC/NCAs that will increase transparency on the actual marketing of authorised CAPs in the EU/EEA MS. Sharing marketing information with the general public will be considered as a second step.*

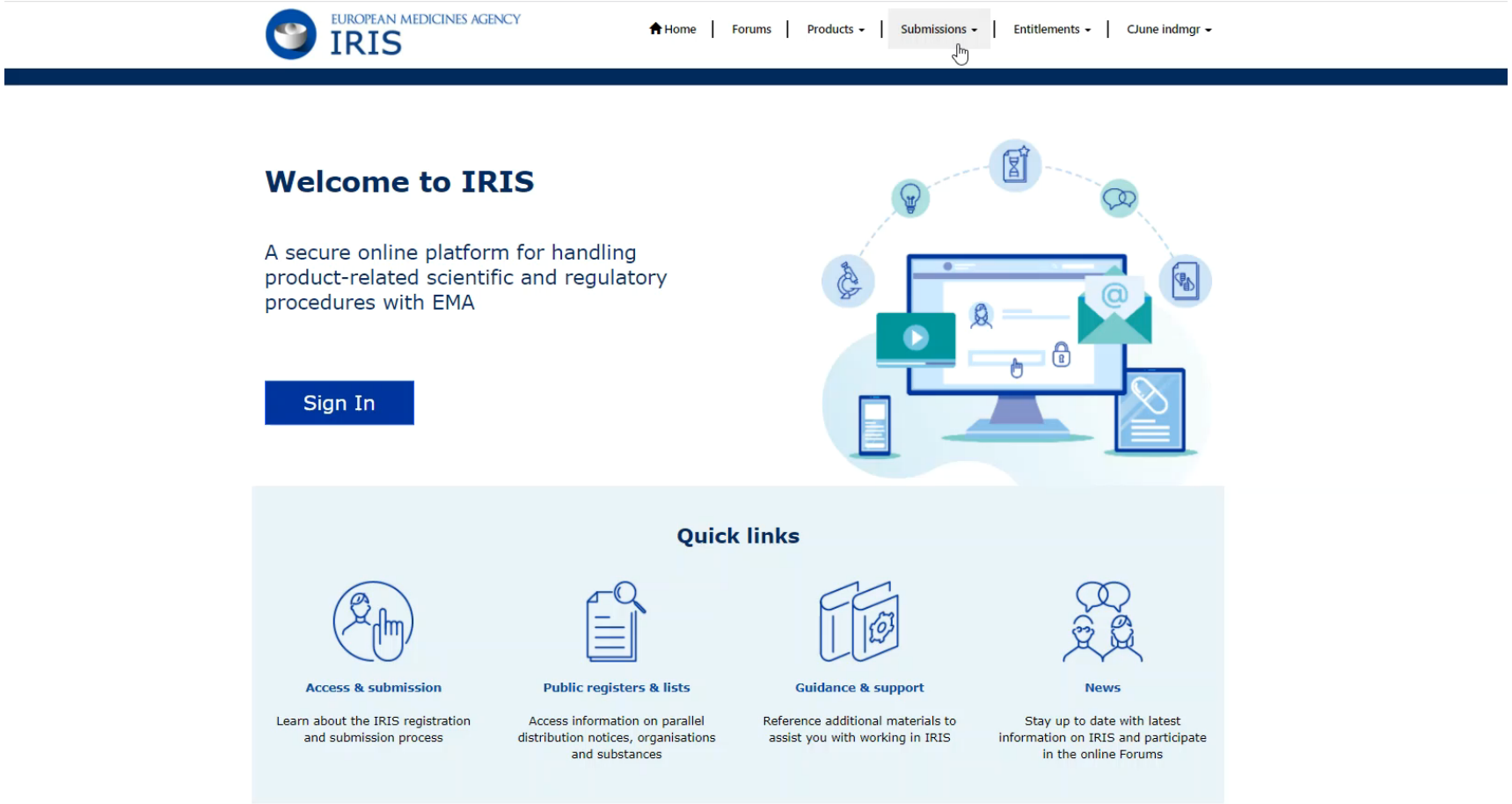
This functionality of the system was presented to Industry representatives at the IRIS Scientific Advice User group volunteers meeting on 28/08/20 and feedback received considered in the development.

*more details in Pharmaceutical Committe 12.03.20 / ad-hoc WG on Market launch of CAPs.

Data to be provided in IRIS Marketing Status tool

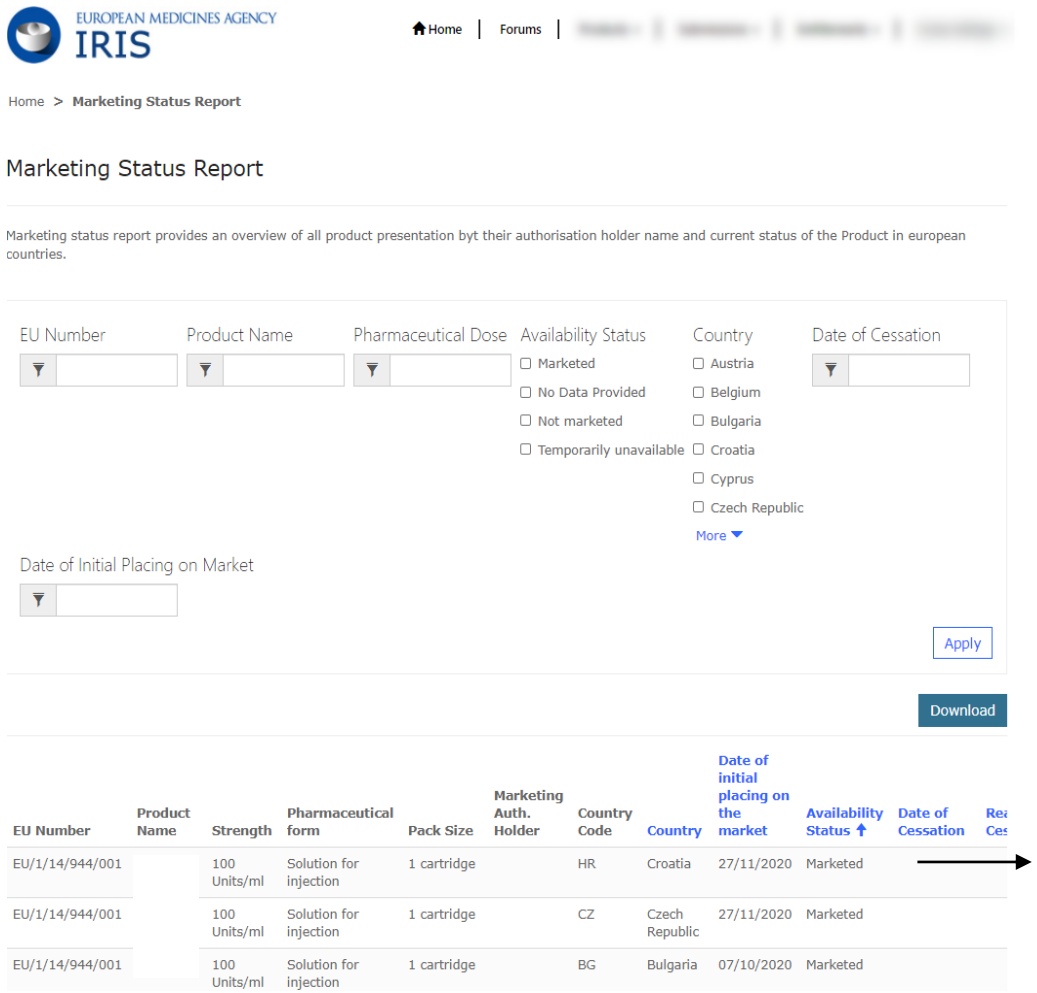
The following information for all CAPs at presentation level (EU number) for each EU/EEA MS.

- Date of placing into the market
- Date of cessation to market
  - Type of cessation (permanent/ temporary)
  - In case of temporary cessation: Expected date of reintroduction in the market
  - Reasons for cessation (according to Art 116, 117, commercial, industrial)



Please see video in Youtube:
https://youtu.be/k-sRKlSZvZs

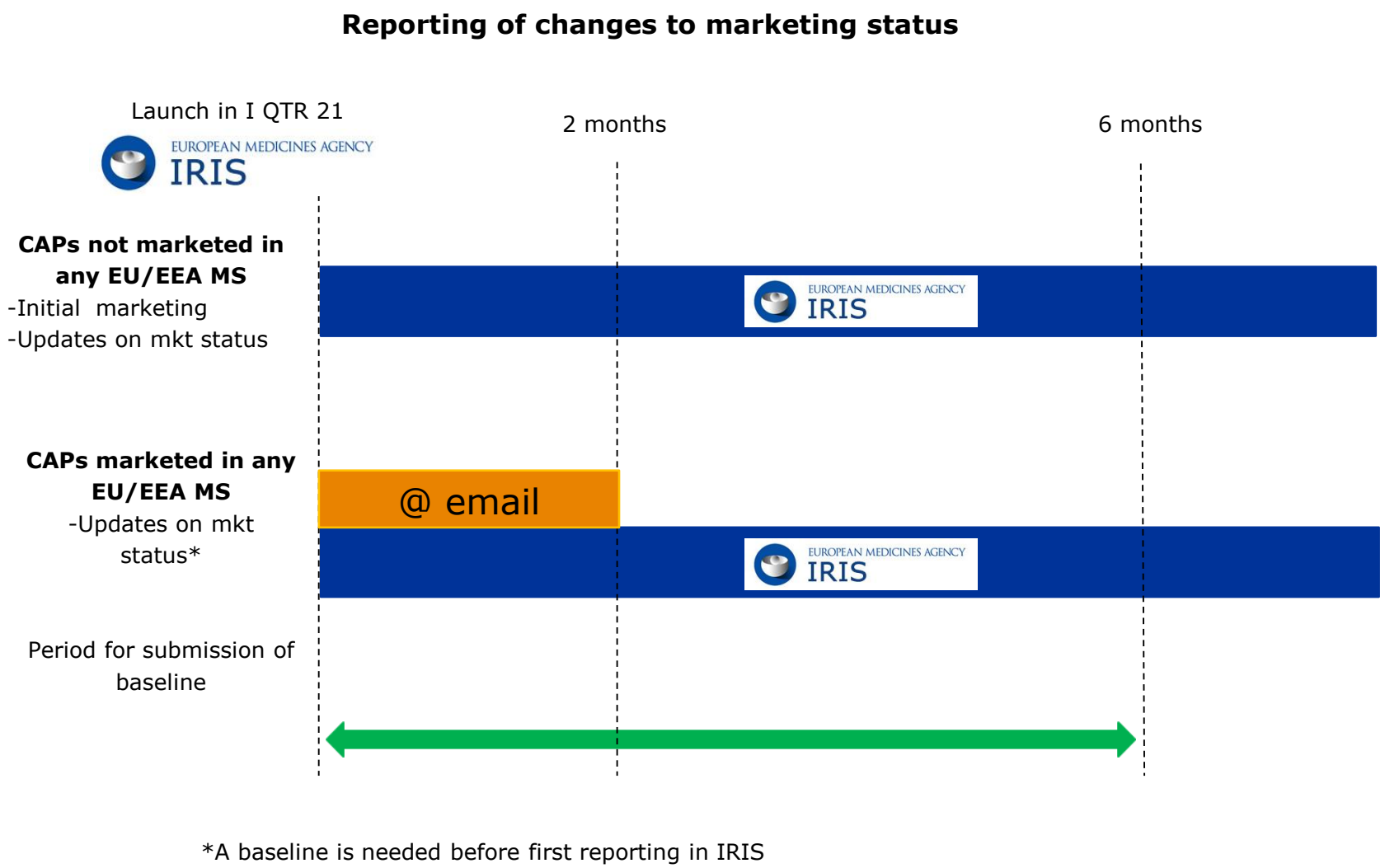
EMA Dashboard of Marketing status data



- The reported data will support the Agency for sunset clause monitoring and withdrawals reporting.

Member State(s) incl. NO, LI, IS	EU number	Name of medicinal product	Strength	Pharmaceutical form	Package size	Date of initial placing on the market	Marketing status	Date of cessation (filter by period)	Reasons for cessation (Art 14b)	Estimated date of reintroduction	Does cessation lead to shortage?
							Marketed/Not marketed				

Proposed launch and implementation plan of the tool



*A baseline is needed before first reporting in IRIS

Proposed launch and implementation plan

- The new reporting system is intended to be launched in I QTR 2021.
- Phased approach for data submissions through the new system:

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

- <u>CAPs already marketed in at least one EU/EEA MS</u> require a baseline submission of the current maketing status in all EU/EEA MS for all presentations before starting to report any changes of marketing status in IRIS.

Information required for the baseline submission for all EU presentations of the medicinal product and EU/EEA MS.

Member State(s) incl. NO, LI, IS	EU number	Name of medicinal product	Strength	Pharmaceutical form	Package size	Date of initial placing on the market	Marketing status	Date of cessation (filter by period)	Reasons for cessation (Art 14b)	Estimated date of reintroduction	Does cessation lead to shortage?
							Marketed/Not marketed				

Baseline submissions

For already marketed medicinal products, the baseline data required for every presentation (EU number) in every EU/EEA MS is:

- date of initial placing in the market,
- current marketing status: MARKETED / NON MARKETED / TEMPORARILY CEASED

  in the case of temporary ceased: Reason for cessation, estimated date of reintroduction, shortage (Y/N)

Information required for the baseline submission for all EU presentations of the medicinal product and EU/EEA MS.

Member State(s) incl. NO, LI, IS	EU number	Name of medicinal product	Strength	Pharmaceutical form	Package size	Date of initial placing on the market	Marketing status	Date of cessation (filter by period)	Reasons for cessation (Art 14b)	Estimated date of reintroduction	Does cessation lead to shortage?
							Marketed/Not marketed				

Proposed launch and implementation plan

- CAPs already marketed in at least one EU/EEA MS
  - During the first 2 months, changes to marketing status can be reported via email or IRIS.
  - After the second month, changes/updates to marketing status can only reported via IRIS.
  - Within sixth month, all CAPs should have submitted a baseline sequence.

- At the time of IRIS MS launch, all funtionalities may not be fully available (e.g. intent to withdraw a medicinal product may continue being reported via email for some time). An update of the EMA regulatory guidance* will provide all details on what/how to report.

*Human Regulatory/'Notifying a change of marketing status'

Final remarks

- The IRIS MS platform is intended to be launched in I QTR 2021 following a phase approach.
- EMA aims that all data of marketing status in EU/EEA MS for all CAPs is submitted via the new system within 6 months.
- The Agency is developing technical and update of regulatory guidance to support a smooth transition to the new way of reporting:
  - an IRIS user guide to cover technical aspects,
  - regulatory guidance detailing what and how to report Marketing status.

Any questions?

Further information

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