EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Publication of RMPs

Status update

10th Industry Stakeholder Platform on the Operation of the Centralised Procedure for Human Medicines

Presented by Emil Cochino on 27 June 2023
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What EMA publishes

- Full RMPs (body + Annex 4 + Annex 6) for:
  - ✓ New approved products (CAPs) containing a new active substance, receiving an Opinion after 1 June 2022;
    - ✓ Post-authorisation updated of RMPs for these products;
  - ✓ COVID-19 products;
  - ✓ RMPs released through access to documents requests;
- RMP summaries for all other RMP initial submissions / updates.

- So far, 65 full RMPs published on EMA website.

Other information about Comirnaty

Key developments since authorisation

Comirnaty : EPAR - Medicine overview (PDF/126.53 KB)

First published: 23/12/2020
Last updated: 15/06/2022
EMA/365655/2022

Comirnaty : EPAR - Risk-management-plan (PDF/3.73 MB)

First published: 23/12/2020
Last updated: 13/04/2022

This EPAR was last updated on 18/07/2022

Authorisation details

COMIRNATY (COVID-19 mRNA VACCINE) RISK MANAGEMENT PLAN

RMP Version number: 5.0

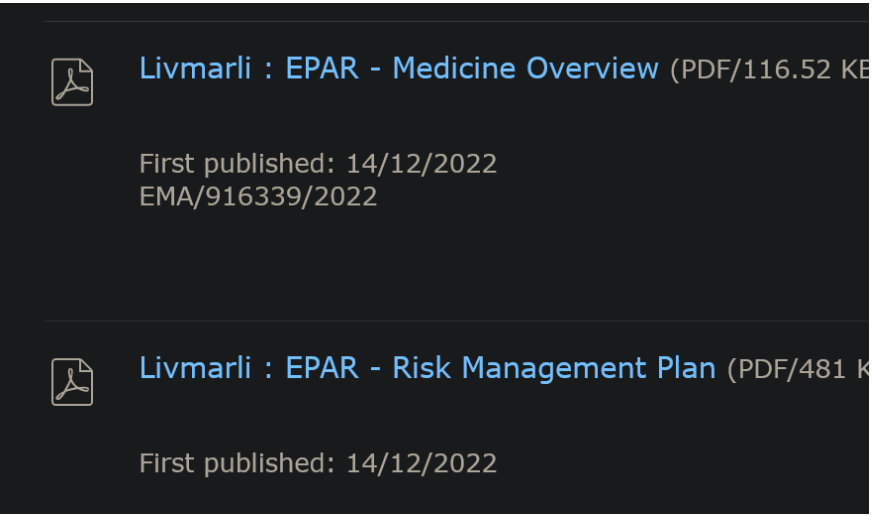
Data lock point for this RMP: See below

Age group	Module SIII. Clinical Trial Exposure	Module SVII.3. Details of Important Risks
5 to <12 years of age	06 September 2021	06 September 2021 (Pfizer Clinical Database) 18 June 2021 (Pfizer Safety Database)
12-15 years of age	13 March 2021 (Pfizer Clinical Database)	30 September 2021 (Pfizer Safety Database, for both CT and non-CT datasets)
Booster in severely immunocompromised aged 12 -15 years of age	N/A	30 September 2021 (Pfizer Safety Database, non-CT dataset)
16 years and older	13 March 2021 (Pfizer Clinical Database) 23 October 2020 (BioNTech Clinical Database)	30 September 2021 (Pfizer Safety Database, for both CT and non-CT datasets)
Booster in 16 years and older [a], including immunocompromised	17 June 2021 (Pfizer Clinical Database)	30 September 2021 (Pfizer Safety Database, for both CT and non-CT datasets)
Post-Authorisation Experience: 30 September 2021		

a. The safety and immunogenicity of a booster dose (third dose) of Comirnaty in individuals 65 years of age and older is based on safety and immunogenicity data in adults 18 to 55 years of age.

Date of final sign off: 02 February 2022

Rationale for submitting an updated RMP (v 5.0): EU-RMP v 2.6 was submitted in procedure EMEA/H/C/005735/II/0087 to update the RMP following the outcome of procedure



Mirum Pharmaceuticals, Inc.

EU Risk Management Plan for Livmarli (Maralixibat Chloride)

RMP Version number	0.9
Data lock point:	17 September 2020
Date of final signoff	12 October 2022
Rationale for submitting an updated RMP:	Not applicable
Summary of significant changes in this RMP:	Not applicable

Challenges noted during the pilot

- Anonymisation of personal protected data (PPD) and removal of commercial confidential information (CCI) difficult for Applicants in the framework of a rapid-changing requirements for the PI and RMP, especially if started just before Opinion;
- While starting the process early in the assessment reduces workload for later stages, repeating the check at each stage duplicates activity;
- Assessment teams in Member States lacking resources and training to check for PPD and CCI;
- Coordination within the EMA Product Team around Opinion stage adds to the already very busy period;
- Post-marketing updates' short timelines add to the challenges.

Next steps /actions

Short term:

- ✓ Redesign process to address current challenges;
- ✓ Until updated process is communicated to Applicants and MAH: **continue** the current arrangements for **RMP publication**!

Medium term (Autumn 2023):

- ❑ Communicate and train Industry on new process, when finalised;
- ❑ Draft similar to EPAR publication process: post Opinion, only on one finalised RMP step, more time, redaction, take activity forward for next RMP update;
- ❑ EMA check – risk based approach

Next steps /actions

Long term (2024 and onward):

- ❑ GVP V (rev 3) and RMP Template update to minimise the risk of PPD / CCI being included in first draft of the RMP submitted with the iMAA;
- ❑ Continue Industry training and communication (e.g. EMA info days, RMP trainings);
- ❑ Monitor the need for redaction and adjust risk-based check;
- ❑ Improve discoverability of RMPs on EMA Medicines page.

Any questions?

Further information

https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency

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