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SCIENCE MEDICINES HEALTH

Launch of IRIS for Scientific Advice

Update and feedback exchange after go-live

5th Industry Stakeholder Platform on R&D support

Presented by Paolo Tomasi and Tarita Toufexi on 16 November 2020

Operational processes

1. **Research Product Identifier** creation and management
2. **Orphan designation** and related procedures
   - First pilot of IRIS CRM at EMA
   - First automated procedure management (annual reports)
3. **Parallel distribution** procedures and public register
   - Huge backlog cleared
   - First automated public register in IRIS
   - First integration with SAP-finance
4. **Innovation Task Force** briefing meeting requests
5. **Scientific Advice** procedures
   - First veterinary medicines processes onboarded
   - IRIS 2.0 now operational

Feedback on scientific advice go-live

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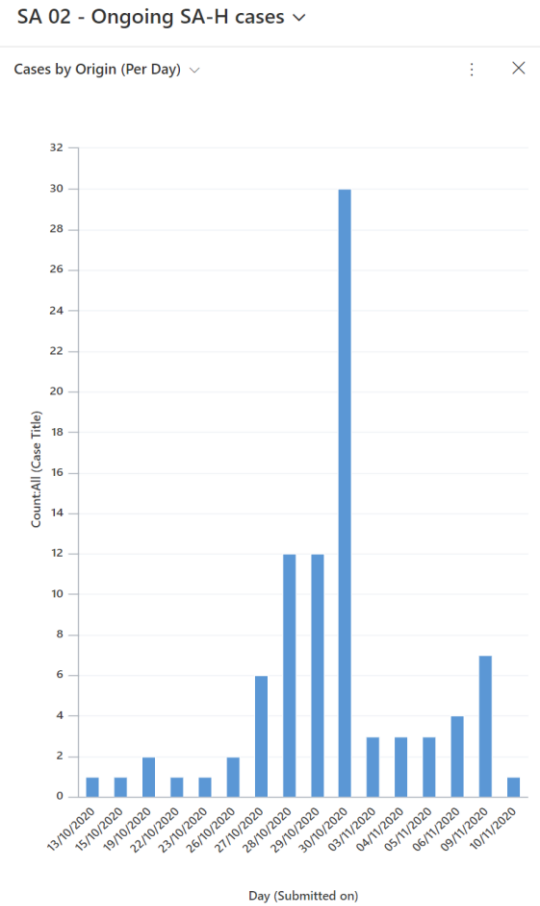
1. 80 submissions received, of which 30 on a single day (30/10)
2. No major problems – better start than orphan designation
3. Main feedback to Industry:
    1. Substances and RPI are two different things. Registration is independent and managed by different services and different tools at EMA.
    2. RPIs identify a product across life-cycle and different sponsors
    3. Regulatory entitlements and RPIs should be assigned to a single location of the parent organisation (the legal address in the business register) → Industry to reconcile data wherever possible.



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Marketing status

from IRIS public forums (https://iris.ema.europa.eu/forums/)

✔Answer

Posted 2 days ago by Poonam Sabharwal

Please find our responses to your questions:

Is it still planned to launch of marking status reporting in IRIS in the first week of December (this date is mentioned here in the forum)?
No. we do not have yet a fixed launch yet but we intend to launch I QTR 2021

Will there be a staggered roll-out? Meaning the newly granted MA first, followed by older authorised CP products?
Yes. We plan a staggered approach to be presented and discussed with Industry associations on EMA industry Platform meeting on centralised procedure on 3rd Dec 2020.

Will the launch data be available for the public?
The data will not be publicly available.

Will the use become immediately mandatory or optional?
There is a legal obligation to report marketing status to EMA. This constitutes a new way of reporting the marketing status to EMA.

Will marking status data of CP products be migrated or do users have the enter all dates?
Users will require to enter a baseline data for authorized products. These details are intended to be discussed and agreed with Industry associations on 3rd December

Will the same granularity be used as for the current EMA template/notification?
The level of granularity is similar.

Will training to be offered?
The system for data entry is very intuitive, similar to all other IRIS submissions. The IRIS guidance is being updated to include information on the new procedures. If needed, training could be considered.

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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