IDMP
STARTER PACK

IDMP is no longer a future consideration: it's here, and there are major changes to the implementation plan at the EMA.

The EMA have shifted to a progressive implementation. Instead of a single milestone, as we've been used to for regulations, there will be a series of deadlines and MAHs will be expected to enrich data iteratively in the Product Management Service. More and more data will be required with each iteration of PMS. This is more challenging, and preparing data in advance will be essential to ensure continued compliance.

Without the right preparation MAHs could find themselves with inefficient manual processes becoming more burdensome with every new demand for data from the EMA, leaving them at risk of falling behind and not being able to meet EMA requirements. Putting in place efficient solutions, effective processes and the right tools is vital.

MAHs need to be ready: timelines vary depending on portfolio, but all MAHs face new deadlines. Don't delay: get your data, tools and people ready today.

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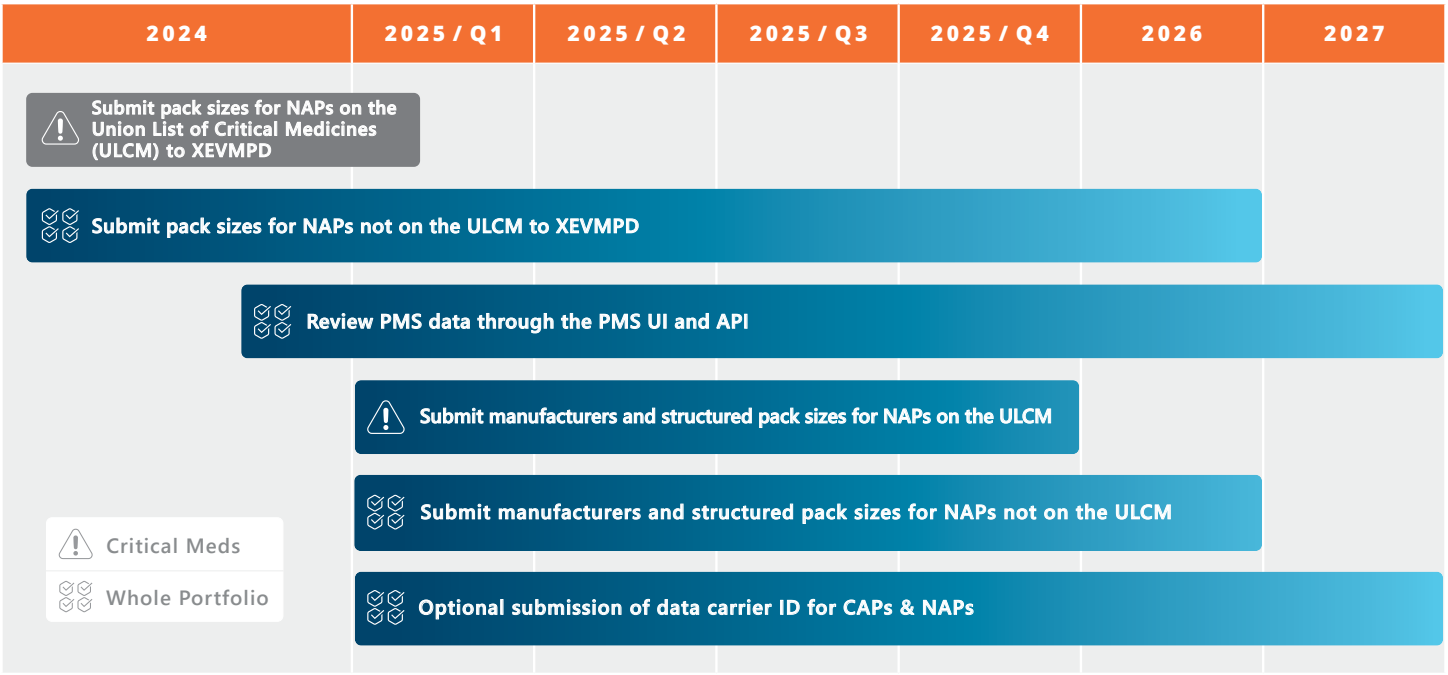
Know your timelines

Do you have products on the EU Union List of Critical Medicines? If so, you need to get ready fast – the EMA has set a deadline of 31 December 2025 to submit structured pack size, manufacturers and manufacturing business operations.

Don't forget the rest of your portfolio. While the deadlines are more pressing for products on the ULCM, you'll need to submit the same information for the full portfolio by 31 December 2026.



Prepare your first data package

Depending on your company's preparations, IDMP data may be stored in a wide range of sources. Before you can begin to submit your data enrichment packages, you'll need to get your data ready to go.

- **Prepare XEVMPD:** XEVMPD submissions must be made at package level before data enrichment can begin. This will then be synced to PMS, ready to start enriching the PMS products.
- **Consider your sources:** If pack size and manufacturer information is still in unstructured sources, such as Module 3 documents, it will need to be moved into a structured database, preferably your RIM system.

Check your systems

While all leading RIM systems will allow your company to capture IDMP data in some way, being truly IDMP ready is quite a different story. A truly IDMP ready tool will also boast the following:

- **Full alignment with SPOR.** Your IDMP tool must be mapped with SPOR, ensuring that controlled vocabularies and organisations are aligned with RMS and OMS data.
- **Seamless connections with PMS.** Your IDMP tool must be able to seamlessly link PMS and your internal data. It's not enough to simply be able to import a FHIR message, or connect via the PMS API: the system must be able to present this data in a user-friendly format.
- **User-friendly data comparison.** Data enrichment and maintenance requires repeated comparison with PMS. The EMA have asked MAHs to check data for Centralised Procedure products, and once data enrichment is complete for non-CAP products, comparisons will be necessary to identify changes that need to be made to the PMS information. Doing this manually would be both time consuming and error prone. An IDMP tool that allows you to directly compare PMS and your RIM system in a user-friendly format is essential.
- **Flexible, scalable comparison tools.** Restrictive comparison tools will limit your ability to complete PMS enrichment. Your IDMP tool should allow you to compare either on a product-by-product basis or compare a large number of products at once. You must also be able to compare either the whole IDMP data set or just a subset of data points. This will ensure you can prioritise product sets such as critical medicines, and drill down to the EMA's data requirements.
- **One-click submissions to PMS.** The EMA is beginning to release information on the write API, which will allow machine-to-machine submission to PMS, rather than having to go through the PMS user interface. Will your IDMP tool allow you to directly submit through the API?
- **Agile and adaptable.** Your IDMP tool must be quickly configurable, allowing your vendor to quickly respond to changing EMA requirements – not leaving you waiting for the next scheduled release.

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Prepare Your People

Managing even a subset of IDMP data requires rigorous processes with clearly defined responsibilities.

1 PREPARING DATA

Start with processes for managing this data internally – extracting it from Module 3 documents, adding it to your RIM system and maintaining this data throughout the product lifecycle.

2 ENRICHMENT

Of course, you'll also need processes for submitting the initial data enrichment. Consider whether it would be better to submit information product-by-product, or update products in batches.

3 MAINTENANCE

Don't forget that once you've submitted this data to PMS, you'll need to maintain it. The EMA are asking that data be updated monthly at minimum for now, but they've said they will eventually expect MAHs to adhere to the same timelines as apply for XEVMPD.

Your processes must allow you to submit updates within 30 calendar days and information on new products within 15 calendar days.

Go!

Now that you've prepared your data, got the right tools and built your processes, it's time to start submitting to PMS. As EMA requirements evolve, you may need to revisit your preparations, but with the right tools in place, you'll be ready for whatever the future brings.

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