Insight

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Preparing for an EU MAA—Centralised Procedure

The journey from Phase 3 clinical trials to Marketing Authorisation Application (MAA) is exciting as the final steps in development work are concluded and preparations to launch the product are made. The workload, procedural complexities and importance of careful planning however, should not be underestimated. This Insight summarises the key procedural milestones and considerations for the Centralised Procedure, to ensure each step taken is one closer to success.

Key procedural milestones and pre-submission timelines

- Eligibility request: 7-18 months
- Notification of Intent to submit MAA: 7-9 months
- Pre-submission meeting request: 7-9 months
- Allocation of Rapporteurs: 7-9 months
- Pre-submission meeting: 6-8 months
- Application submission and validation: Time 0

Eligibility request

In terms of procedural steps, the first is to confirm eligibility to the Centralised procedure. This is mandatory for all products regardless of whether they fall under the mandatory scope. Products for which the Centralised procedure is mandatory should submit a simple statement of the legal basis and the reason why the procedure is mandatory should suffice. For products for which the centralised procedure is optional, a little more detail should be added to justify the choice of procedure. It is noteworthy that both National (followed by Mutual Recognition Procedure) and Decentralised procedures are also open to new drug substances.

Notification of Intent to submit MAA

Once eligibility is confirmed, the Letter of Intent (LoI) and request for pre-submission meeting can be submitted, either separately or together. It is possible to submit the eligibility request, LoI and PSM request simultaneously, however it should be borne in mind that whilst this clearly optimises efficiency, sufficient time should be planned between the submission of these documents, the PSM and the intended submission date. Consequently, it is recommended to submit each document in a step-wise fashion where possible. In practice, the Pre-Submission Meeting (PSM) often takes much longer than 1 month to arrange and as such, it is advisable to submit this request a few months prior to the minimum 7 months pre-submission milestone. Similarly, a little more time between the PSM and submission date can provide additional space to incorporate recommendation made by EMA during that meeting.

Pre-submission meeting request

Unlike the Scientific Advice and Orphan Drug Designation procedures, the PSM is mandatory for the Centralised procedure. This is an important opportunity to introduce the product to EMA and to ask any procedural questions and can be particularly beneficial if the product is unusual.

Allocation of Rapporteurs

No action is needed from the Company at this stage, and notifications of the Rapporteurs appointed will be communicated by the European Medicines Agency (EMA).

Application submission and validation

Finally, the MAA is submitted and the validation stage starts. Following notification of a valid application, the assessment is started and the MAA fees will become due within 45 days. Companies which hold Small and Medium Enterprise status in the EU can defer fees for up to 1 year.

Insights

- The timelines for each step are indicative only and in reality depend on the workload at EMA.
- Whilst some time savings can be made at the Letter of Intent step, the earlier each milestone is reached, the smoother the process will be.
- The applicant cannot select the Rapporteurs as this internal process is managed by EMA. Some correlation between Agencies providing advice during development and Rapporteurship is possible.
- Early and thorough preparation and planning is the key to a smooth process and valid, right first time submission.