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EMA Hopes New Requirement Will Make Companies Stick To Their Filing Plans

by Vibha Sharma

An additional form that marketing authorization applicants must now complete during the pre-submission stage emphasizes the importance of companies providing accurate information on their intended submission date.

The European Medicines Agency has introduced a new mechanism to help address the concerns it has over not being able to predict accurately how many initial drug marketing authorization applications (MAAs) it can expect to receive and is a problem that is draining its resources.

The mechanism, introduced on 1 February, requires companies to complete an additional form during the pre-submission stage and provide more context around their MAA submission plan.

At the moment, a large number of planned submissions are either postponed or withdrawn by companies, sapping the resources of the EU medicines network as it involves the appointment and co-ordination of rapporteurs and reviewers who will assess the filing.

The new form applies to MAAs submitted to the agency through the centralized procedure for products seeking EU-wide approval, or via the "EU-Medicines for all" (EU-M4all) procedure, which is for products to be used outside the EU.

The *form* is an annex to the company's "letter of intent" to submit an MAA, which the EMA needs to be able to appoint the rapporteurs who would lead the dossier's evaluation. For a full MAA, two rapporteurs (ie, a rapporteur and a co-rapporteur) are appointed, who are usually members/alternate members of the agency's human medicines committee, the CHMP.

In the case of MAAs for cell and gene therapies, the rapporteur and co-rapporteur are appointed from the agency's Committee for Advanced Therapies along with two co-ordinators from the CHMP. Additionally, for all MAAs, a rapporteur and a co-rapporteur from the agency's

pharmacovigilance committee, the PRAC, are also appointed.

The agency told the *Pink Sheet* that the new annex has been introduced to serve three key purposes:

- It clearly expresses that the “letter of intent” and the rapporteurs’ appointment amounts to “booking an appointment” with the EMA and the national agencies and therefore it is important that companies submit accurate information.

- It provides more context around the declared submission date.

- It gives EU member states more details on the planned MAA submission, so they can make better informed bids with regard to participating in the filing’s assessment.

The annex also clarifies that changes to the MAA submission date may trigger a change of rapporteurs if these have already been assigned. If the applicant wishes to retain the rapporteurs, the new submission date might need to be agreed with them. "The applicant will be asked to justify any changes to the intended submission date," it adds.

The annex was developed to “better help with submission predictability” and ensure the sustainability of the EU medicines network, an agency spokesperson explained. It was among several new measures that were being considered by the EMA last year, after an earlier initiative to address the issue yielded disappointing results.

The earlier initiative was launched in December 2022 and involved the EMA checking the planned MAA submissions against actual ones it received every quarter and becoming more systematic in pursuing companies to provide a rationale when they changed their submission dates, withdrew submissions, or where there were “no-shows” (ie, MAAs not being submitted in time with no heads-up of any delay). (Also see "*EMA Takes Steps To Improve Predictability Of Drug Submissions*" - Pink Sheet, 25 Jan, 2023.)

However, data from the first half of 2023 showed that this initiative failed to have any meaningful impact on improving the predictability of submissions. (Also see "*EMA To Get Tough On Companies That Repeatedly Delay New Marketing Applications*" - Pink Sheet, 17 Jul, 2023.)