EuropaBio Statement from Secretary General John Brennan

Regarding the European Ombudsman’s Strategic inquiry into pre-submission activities organised by the European Medicines Agency (OI/7/2017/KR).

24 July 2017

EuropaBio takes note of the European Ombudsman’s own initiative inquiry into pre-submission activities organised by the European Medicines Agency.

Pre-submission activities, including scientific advice, are extremely important to facilitate the development and availability of high quality, effective and safe medicines, for the benefit of patients. Developers must follow formal and rigorous procedures of the European Medicines Agency throughout these interactions.

It is important to note that scientific advice does not provide for an assessment of the data. Rather, it is an essential part of the process to ensure that the development plan is relevant to the decision makers. In rare diseases, for example, patient numbers are small and special consideration must be given to the conduct of clinical trials so that regulators, prescribing physicians and ultimately patients can rely on a high quality of evidence. Equally valuable, pre-submission meetings provide an opportunity to discuss and foresee the procedural and administrative requirements associated with the submission of a marketing authorisation. This facilitates the filing of complete and compliant dossiers to the European Medicines Agency.

As such, early interactions with authorities, who are responsible for public health protection, play a critical role. The feedback received helps those seeking to innovate, develop and advance needed medicinal treatments to provide high quality submissions for approval.

Better designed clinical trials, higher quality data and fully compliant submissions mean more efficient use of authority review time. It avoids calling for points for clarification or additional specific data sets that could have been anticipated and generated much earlier in the development process. This allows patients faster access to biomedical innovations and breakthrough medicines.

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and...
feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents 79 corporate and associate members and bio-regions, and 17 national biotechnology associations in turn representing over 1800 biotech SMEs.

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