De forskande läkemedelsföretagen

Lif comments on the EU Commission's Proposal on fees and charges payable to the European Medicines Agency

Lif Sweden is the trade association for the research-based pharmaceutical industry in Sweden. Lif welcomes the opportunity to comment on the EU Commission's EMA fees proposal.

The up-coming revision of the EU regulatory system is an opportunity to make the system faster, more efficient and flexible and thereby strengthen EU global competitiveness. It is crucial to have a financing system for the European Agency that is sustainable, balanced and ensure that the Agency can adequately perform its current tasks but also quickly adapt to the fast evolution of science to meet medical needs. Improving the EMA fees system at the same time as the review of the general pharmaceutical legislation offers a once in a generation opportunity.

Lif Sweden would like to highlight the following:

Adequate and appropriate funding of the EMA and NCAs is essential to support the effective and efficient operation of the European Medicines Regulatory Network (EMRN). The European regulatory system relies on the EMRN's capacity. The scientific expertise provided by the NCAs is the cornerstone of this system. The Fees regulation needs to ensure that the funding of activities is adequate to support NCAs and ensure that NCA that are funded by fees can continue to contribute to those centralised initiatives beyond MAA assessment activities. Lif Sweden would appreciate confirmation that the new proposal support a sustainable development to ensure adequate availability of resources to support high quality scientific assessment by highly qualified experts within competitive timeframes. Lif Sweden positively notes in article 5(2) that for fees reductions, the NCA will still receive the full amount. However, Lif Sweden notes that the Performance information (6) listed in Annex VI is limited to the number of hours spent by the rapporteurs and co-rapporteurs. It should be clarified that these hours account for the experts and colleagues employed by their NCAs to support the assessment, which is pertinent for Multi-National Assessment Teams (MNATs).

Lif Sweden notices that the remuneration for some activities will decrease in comparison to the amount in the current system. As an example, the scientific advice (SA) procedure can be mentioned. Our members are concerned that remuneration for the SA procedure will significantly decrease in real terms. This decrease is being implemented at a time when the resources and capacity of the EU Network are under significant strain, and at a time when companies are experiencing delays in SA procedures. The distribution to an NCA for its participation in an SA procedure will also decrease proportionally compared to some other NCA supported activities (e.g., serving as MAA Rapporteur). This could function as an unintentional deterrent for NCAs' contributions to SA, and thus could lessen opportunities for continued development of cutting-edge scientific expertise within NCAs. As such, we strongly urge the EC to confirm that the fee and remuneration genuinely reflect the actual costs for NCA participation. The cost-based approach for SA should include indicators of timelines achieved and should be closely monitored and transparently shared. The fees should be drafted in a way

that allows EMA to charge for the full range of scientific advice (e.g. follow-up scientific advice, SA on drug-device/drug-companion diagnostic combination, parallel joint scientific advice consultations with HTA bodies).

Given EMAs essential role in patient health, public funding should contribute significantly to achieve a well-resourced, robust EU regulatory system. Many non-fee-generating activities and infrastructure investments necessitate increased public funding to ensure their future viability.