

12 December 2018
EMA/MB/781386/2018 Noted
Management Board meeting of 12-13 December 2018

Financial compensation and workload estimation of the EMA organisation of translations of product related information

Issues for consideration

On 29 September 2005 the Agency's Management Board agreed on the introduction of a revised handling of translations of product related information for human and veterinary medicines. Further to such agreement, cooperation agreements were signed with the National Competent Authorities (NCAs) of the Member States to provide financial compensation for their participation in the linguistic checking of product related information in their respective national languages.

Additional background

The financial compensation/remuneration scheme for the NCAs' involvement in the linguistic checking process is based on workload estimations multiplied by a fixed flat hourly cost. Workload estimations are based on the information provided in the official Agency's Work Programme.

At the beginning of each year the financial compensation/remuneration is calculated taking into account the workload as forecasted for that particular year on the basis of the official workload figures as stated in the Agency's Work Programme of that year. The fixed flat hourly rate is revised annually by EMA's Finance Department taking into account the official inflation rate and applied to the existing rate. Based on this calculation, the updated fixed flat hourly rate for 2019 is increased.

The Management Board is invited to endorse the fixed flat hourly cost for 2019 to be set as €45 (for information, this cost was €44 in 2018).