Question for written answer E-002280/2024 to the Commission Rule 144

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Subject: Involvement of patients and healthcare professionals in the evaluation, authorisation and monitoring of medicines in the EU

Patient experience plays a key role in the evaluation, authorisation and monitoring of medicines. For this reason, the European Medicines Agency (EMA) enables patients and their carers, including clinical health professionals, to directly participate in these regulatory stages, as well as in the early stages of development of new treatments.

However, in some cases the authorisation of medicines is denied or withdrawn, against the wishes of patients and the healthcare professionals who care for them on a daily basis and who notice significant improvements thanks to their use.

- 1. To what extent are patients and the healthcare professionals prescribing these medicines really and effectively involved the decision-making of the EMA and the European Commission?
- 2. In which situations do other criteria take precedence over the reported improvement of the patients undergoing these treatments?

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