operating within the NAMMD and improvement of the adverse reactions/events reporting system, so that gathering of information is allowed from the most comprehensive sources, reporting is undertaken in the simplest manner and feedback is quickly delivered to encourage participation.

e performance of actions for ensuring rm and e cient surveillance of medicinal products for human use throughout Romania; Insurance of full NAMMD undertaking of its role in enforcing EU legislation on increasing the number of authorised medicinal products, particularly for the treatment of children;

Provision of certain adequate information/instructions to the public on the safe use of medicinal products, as well as warnings concerning their safe use, when needed, for both on-prescription and over-the-counter (OTC) medicinal products.

Communication, Information and Cooperation

Address healthcare professionals with targeted information, for improved adverse reactions/events reporting and promotion of safe use of human medicinal products (e.g. by adequate description, search and request of adequate information from the NAMMD);

Make targeted information available to the public, in view of better adverse reaction reporting by the patient, promotion of better informed patient decision concerning the use of medicinal products for human use:

Contribute to better understanding by the public and/or healthcare professionals of the bene t/risk balance of medicinal products for human use;

Cooperate with professional bodies, academic sta and others, in order to ensure an adequate content of training programmes for healthcare professionals, in such issues as safety and risk in prescription and use of medicinal products for human use;

Particularly following accession, within the European pharmaceutical regulatory system, the NAMMD cooperates with all national competent authorities in the European Union (EU) and in the European Economic Area (EEA), as well as with the European Medicines Agency (EMA).

Via the EMA, the NAMMD hopes to be able to also further develop international connections with the US Food and Drug Administration (FDA), within the cooperation framework established between the EMA/EU and the FDA/USA.