The National regulatory authority

Key point

The safety of vaccines is under the mandate of the National regulatory authority (NRA).

Note: The NIP is also involved in securing the safety of vaccines and their use. Both the role of the NRA and the NIP should therefore be clearly defined.

All countries should have a National regulatory authority to ensure that all medicines, including vaccines, used within the country are safe, effective and of good quality. NRAs function within the framework of national medicines policy and overall health policy, and as with any public entity, must abide by principles of transparency, fairness and accountability.

After **licensure**

- **License**: The granting of a license to conduct a regulated procedure, for example, to conduct a trial of a new vaccine or to approve a vaccine for routine delivery to the public in a vaccination programme.

- **Adverse event following immunization (AEFI)**: Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease, surveillance. It is important to ensure exchange of information between the NRA and the system of vaccination delivery or the national immunization programme.

Because the NRA may have limited knowledge of the structure and management of the NIP, it is essential that the immunization programme manager is involved in AEFI surveillance and that everyone's role in monitoring and responding to vaccine safety issues is clear.