

Guidelines on non-clinical evaluation of vaccines

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On 6 October 2020, the Turkish Medicines and Medical Devices Agency published [*Guidelines on Non-Clinical Evaluation of Human Vaccines*](#) (Turkish language) to provide guidance on vaccine development procedures.

The guidelines regulate non-clinical evaluations and obtaining appropriate results from them, which are prerequisites for initiating clinical trials on a vaccine candidate. Non-clinical evaluation refers to all in vivo and in vitro tests performed before and during the clinical development of vaccines.

The guidelines advise on the following aspects of vaccine development:

- Production, characterisation and quality of vaccine candidate.
- Toxicology studies.
- Primary and secondary pharmacodynamic studies.
- Adjuvants, additives (excipients and preservatives).
- Vaccine formulation and delivery device.
- Alternative routes of administration.

The guidelines took effect from 6 October 2020.