



Painful predicament. Clinicians have struggled to purchase childhood vaccines that prevent eight different diseases.

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Situation in the Netherlands for medicines and medical devices.

- Medicines quality; the responsibility of the medical evaluation board (MEB) which is a governmental organisation.
- Before vaccine batches can be sold on the Dutch market, the final lot formulation has to be tested and released by an OMCL (a national control laboratory in the EU). In the past, there has been several examples where the product was effected by the packaging or packaging process.
- Another system is for medical devices (MD); the products are controlled by the Notified Bodies (NB); if medicines are incorporated in a medical device advice is required from the MEB. The final responsibly is at the NB are private organisations, controlled by the inspectorate.
- Administration of a vaccine is part of the dossier; using different administration routes may require extensive clinical studies.
- Vaccines are often administered to health young people; this effects the risk-benefit evaluation. This may have an impact on acceptance of new vaccine formulations when the current products have an extensive safety and efficacy record. Furthermore, stability of vaccines is in some Ph. Eur. Monographs (e.g. Measles)
- The systems of medicines and MD are getting more and more integrated due to issues like personalised medicines (IVD), more frequent use of medicines in MD and risks of use of MD. An integrated guidance for MD and medicines is feasible to anticipate on this development.