

## Adverse reactions to vaccines are now being monitored more extensively, thanks to co-operation between Fimea and THL

At the annual development days for its administrative sector, the Ministry of Social Affairs and Health drew attention to co-operation between the agencies operating under it. In her speech, Fimea's Director General mentioned the remodelled monitoring of adverse reaction to vaccines as an example of good cooperation between Fimea and the National Institute for Health and Welfare (THL).

Reliable adverse effect monitoring is vital for several reasons. It can be used to find vaccine batches in whose case adverse reactions exceed the expected and approved level. Use of harmful vaccines can then be discontinued, the needed treatment can be targeted appropriately and compensation can be calculated for those entitled to it. Detection of adverse signals is one of the critical factors required in the investigation of the connection between suspected adverse reactions and vaccines. In turn, such detection helps to preserve the general population's trust in the vaccination program.

Previously, the adverse effects of vaccines were primarily monitored by THL. Fimea's task was to forward the records to the marketing authorisation holder and internationally to the European Medicines Agency and the World Health Organisation. To improve monitoring and clarify the division of responsibilities, the agencies remodelled this arrangement at the turn of the year.

Due to the change in pharmaceutical legislation, a record can be created not only by the person who administered the vaccine or the health care professional who discovered the adverse effect, but also by the person being vaccinated or, for example, his or her guardian. This change is certain to broaden the range of recorders as well as records, making their analysis more difficult.

THL concentrates on providing instructions on the national vaccination programme, as well as executing the programme and monitoring its efficiency in co-operation with municipal health care professionals. The task of THL is to conduct a detailed epidemiological investigation of the signals detected by the record system, or received by some other route. THL is also responsible for analysing the occurrence of an adverse reaction and determining whether there is a causal relationship between the reaction and the administered vaccine, or whether the relationship is merely a random, temporal one. Based on this information and the supplementary results describing the mechanism of action, the vaccine's role in the adverse reaction can be determined.

This remodelling is a good example of how agencies can increase the efficiency of their operations as resources become more scarce. At the same time, it demonstrates the willingness of the two sister agencies to create new forms of co-operation for the benefit of Finns' health.

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[Go back](#)

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### NICE TO KNOW

The commenting period on the Government's proposal for the Act on Communicable Diseases ended at the beginning of August, and the proposal will be issued to Parliament in September. The proposed Act would transfer the processing of adverse reaction records from THL to Fimea.

For the time being, health care professionals will send adverse reaction records on vaccines and vaccinations to THL. Any changes in record submission procedures will be notified separately.

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