Executive summary

Health Council of The Netherlands: Committee on adverse reactions to vaccinations in the national immunization programme. Adverse reactions to vaccinations in the national immunization programme 1996. Rijswijk: Health Council of the Netherlands, 1999; publication no. 1999/05

At the request of the Minister of Health, Welfare and Sport, a Committee of the Health Council of the Netherlands analyses cases involving suspected adverse reactions to vaccinations carried out under the Dutch national immunization programme and reports on the matter annually. From 1996 onwards, the Committee has adapted its working method to a new assignment. The Committee now only assesses reports of severe or unusual phenomena or phenomena with lasting consequences. This selection is carried out by the National Institute of Public Health and the Environment (RIVM) in accordance with criteria formulated by the Committee. In addition, the RIVM publishes a report dealing with *all* suspected adverse reactions. This report is evaluated by the Committee.

In the year under review, a total of 42 suspected adverse reactions were presented for the Committee's consideration, including 14 cases from previous years which could not be incorporated in the Committee's previous reports. The Committee classified seven of these as severe reactions which could, to some extent, be related to a vaccination carried out within the framework of the national immunization programme: two involved local reactions, two general skin reactions (one of which with fever), one febrile convulsion, one breath-holding spell and one instance of thrombocytopenia. To the best of the Committee's knowledge, none of these reactions had a lasting effect other than a scar as the result of an abscess. Six deaths were presented to the Committee for consideration. In five of these cases, the Committee concluded that a causal relationship with the preceding vaccination was unlikely. The Committee was unable to make a judgement regarding the sixth death, as no postmortem examination

results were available. However, had the Committee been able to confirm the clinical suspicion of cot death, this case would also have been classified as having no causal link with the preceding vaccination.

The Commmittee states that it has not encountered any previously unknown adverse reactions in the year under review.

At the time of the completion of this report, the first in the series of annual RIVM reports on all cases of adverse events following national immunization programme vaccinations, the report for 1994, had been made available to the Committee for evaluation. In the Committee's view, the report offers a sound basis for evaluating adverse reactions to vaccinations carried out under the national programme.

Out of a total of approximately two million vaccinations, the RIVM reported 590 cases of possible or probable adverse reactions. As far as can be determined on the basis of present knowledge and experience, all of these reactions were temporary in nature and not harmful in the long term. In view of the role played by the immunization programme in preventing a large number of cases of serious illness, the Committee regards the scale of the adverse reactions as fully acceptable. The Committee considers the adverse reactions reported by the RIVM and by the Committee itself as no reason for making changes to the national immunization programme.

The Committee recommends that:

- the guidelines with regard to the national immunization programme should be carefully observed
- in cases of sudden and unexpected death, a multidisciplinary examination should be carried out in accordance with the current protocol (Gen92)
- all serious and unusual adverse events following vaccinations, regardless of whether a causal link is thought to be present, should be reported to the National Institute of Public Health and the Environment*, together with as complete a description of both symptoms and medical history as possible. This also applies to adverse events which are not or are no longer regarded as contraindications or are considered to be 'known'.

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