

## ALUMINIUM AND HEALTH

### Fact sheet 7

#### ALUMINIUM IN VACCINES.

Aluminium is present in some vaccines as an adjuvant in the form of aluminium hydroxide, aluminium phosphate or aluminium hydroxyphosphate. An adjuvant is present in a vaccine to enhance the immune response, and certain vaccines need this in order to be effective.

The vaccines containing an adjuvant are primarily those against diphtheria, tetanus, pertussis and hepatitis A and B. It was observed that these vaccines were not sufficiently effective without the addition of an adjuvant.

The only known reactions that can eventually be attributed to aluminium contained in vaccines are local inflammatory reactions.

In France, biopsies of deltoid muscle, a common site for vaccinations, have revealed a few cases of minute inflammation which contain aluminium salts (macrophagic myofasciitis, MMF). The biopsies were not localised to the injection site, and the MMF has only been found in a small number of the biopsies. Hence there is no established link between muscle pain and the small local lesion of MMF. The quantity of aluminium present in the vaccine varies between 0.3 and 1.5 mg per dose. Considering the different vaccinations and number of repeats necessary, the maximum dose a person would receive from this over a lifetime is 15 mg. This is about the same as the normal oral intake over two days.

Aluminium injected by subcutaneous and intramuscular routes is gradually dissolved and enters the bloodstream. It is then eliminated through the urine, in the same way as aluminium absorbed from the gastro-intestinal system.

For the World Health Organisation (WHO), the assessment of the safety of vaccines is important, because replacement of currently used adjuvant would necessitate the thorough investigation of alternatives before these could be licensed and threaten vaccination programmes worldwide.

The WHO therefore initiated a broad consultation on the issue in 1999, assisted by their advisory committee on vaccines, Global Vaccine Safety Advisory Committee (GACVS). On the recommendation of WHO a study was started to establish whether or not there is an association between local MMF lesions and any generalised illness. This group has regularly evaluated new publications and information on the safety of vaccines with aluminium adjuvants. The latest report is published in the Weekly Epidemiological Record No 30, 27 July 2012. GACVS concludes that the recent comprehensive US FDA risk assessment further supports the safety of aluminium in vaccines.

In France ANAES and INSERM jointly regularly evaluated the potential secondary effects from using vaccines containing aluminium compounds for both children and adults. The French High Council on Public Health (HCSP), upon request from the General Directorate of the French Health Ministry, has recently (2013) published a report on the use of aluminium in vaccines. *“The HCSP believes that the currently available scientific evidence does not allow to question the safety of vaccines containing aluminum, in terms of their benefit/risk balance. The HCSP recommends continuing vaccinations in accordance with the schedule currently in force and warns against the consequences, in terms of recurrence of infectious diseases that a decreased coverage of vaccinations may have, resulting from questioning the aluminum-containing vaccines in the absence of scientific justification”.*

Reference list:

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