The preclinical toxicological data available for aluminum, since 1996, prohibited its presence in drugs for human use

The toxicological reference values, for dietary aluminum, have been determined by the FDA, in order to measure the toxicity inherent in the quantities of aluminum, of food origin, which a man can ingest every day, in particular in drinking water.

A single experimental toxicological study (toxicokinetic study) of aluminum has been carried out to date, based on the results of experimental work, carried out in animals (rats), by 2 independent aluminum scientists, who work in 2 different fields. They used aluminum marked ^{26}Al.

The calculation of this minimum Toxic Dose (minimum Risk Level) was carried out by an expert of the FDA, according to the rules of the art, from the results of their work. This is how the FDA and the WHO were able to promulgate, in 1996, the following toxicological reference data:

Minimum toxic dose of aluminum, in animals, in the diet, i.e. by oral route: 1 mg aluminum / kg body weight / day

- **Christopher EXLEY** is an English chemist, an undisputed specialist in aluminum and its toxicity in biological environments of the organism, such as the brain. He clearly demonstrated the great toxicity of aluminum in the body, by calculating its **minimum Toxic Dose in animals**, which he set at **0.01 mg of aluminum / kg of weight**. (reference: Christopher Exley, Ellen Burgess, J. Philip Day, Elizabeth H. Jeffery, Srikumaran Melethil, Robert A. Yokel. ALUMINUM TOXICOKINETICS, in RESEARCH ISSUES IN ALUMINIUM TOXICITY, Edited by Robert A. Yokel and Mari S. Golub, Volume 48, number 6, August 30, 1996, p. 117-132). **This preclinical toxicological data was obviously sufficient to prohibit aluminum in all drugs for human use**, regardless of the amount of aluminum in these drugs. Especially since Christopher EXLEY has recently further reduced this minimum toxic dose in the body, in animals, to 0.001 mg of aluminum / kg of weight, so that aluminum is a zero tolerance compound , for humans.

- **Philippe JOUHANNEAU** is a French scientist, who works at CEA, at GIF sur Yvette. He measured the **bioavailability of aluminum in rats**, that is to say the amount of aluminum which enters the body, **when given orally**, in the form of marked aluminum chloride $^{26}AlCl_3$. **He showed that the absorption of aluminum by the oral route was very low, and between 0.1 and 1%** (reference: Jouhanneau, P., Raisbeck, GM, Yiou, F., Lacour, B., Banide , H., and Drüeke, TB 1995. Gastrointestinal absorption, tissue retention and urinary excretion of dietary levels of aluminum in rats as determined by 26Al. Clin. Chem., 1997).

This is how the FDA was able to calculate the minimum Toxic Dose of aluminum by the oral route in animals, by placing itself in the worst conditions of toxicity for the oral route, that is to say for a maximum absorption of 1 %. They multiplied the minimum Toxic Dose in the body, defined by EXLEY, or 0.01 mg of aluminum / kg in the body, by 100. And they added per day, because this study was intended to assess the inherent toxicity aluminum present in food (mostly drinking water) ingested daily.

What lessons should we draw from these toxicological data?

1- Regarding the dangerousness of aluminum in the diet, this minimum Toxic Dose equal to 1 mg of aluminum / kg of weight / day, is much greater than the amounts of aluminum of dietary origin that a man can ingest daily, mainly in drinking water. In fact, the public health code has set a threshold equal to 0.200 mg of aluminum / liter for distribution water (tap water). For mineral waters the amounts of aluminum are less than 0.032 mg / liter. Thus, a 60 kg man will ingest less than 0.400 mg of aluminum, if he drinks 2 liters of tap water per day; which is much lower than the minimum Toxic Dose equal to 60 mg of aluminum for its body weight.

2- But, when aluminum enters the composition of a medicine, it becomes, itself, a medicine.

Therefore, the minimum Toxic Dose of aluminum, orally:

Minimum Toxic Dose of Aluminum, in animals, orally:
1 mg aluminum / kg body weight / day

constitutes preclinical toxicological data, carried out according to "the rules of the art", which prohibits the administration of any toxic drug to humans.

2- Mais, lorsque l'aluminium entre dans la composition d'un médicament, il devient, lui-même, un médicament.

It's an intangible rule:

A toxic drug in animals
cannot be administered to humans

Preclinical toxicological studies, carried out in animals, are intended for the protection of humans: a drug deemed toxic in animals cannot be used as a drug in humans.

There is no precedent for which this rule has been broken.

Toxic drug leads to death, short or medium term