What did we find in the MMRV (Priorix Tetra) vaccine?

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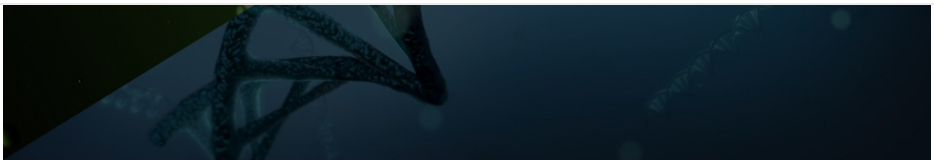

We want to take stock of the situation together with you. Eight months have passed since July 2018 and in these length of time we have achieved extremely satisfying results. We have presented a research program and regarding the vaccines analysis we are able to make a point of reference, with the objectives achieved, those being finalised and those only planned for now.

To begin with, the analyses of 2 compounds for each vaccine have been verifyed by means of standards, using certified control standards with a concentration in the order of micrograms / mL. The compounds we have chosen are among those known for their critical hazard profile. We are talking about a cumulative quantity, a total amount of those recognized as identities and those to be identified, which can be estimated within the order of 50 micrograms / mL, in contrast to the EMA / FDA guidelines.

These tests have given positive results, therefore they fully confirm the analysis method! The contaminations observed are probably due to different and variable manufacturing process' phenomena and topics. What has been observed in the course of the studies is an "inter-batches" variation of the composition, which makes us assume that there are some steps along the whole product manufacturing process that are difficult to control.

Summary table showing the results of analyses (Priorix tetra)

1. **Antigens** - 3 out of 4 attenuated viruses were identified and sequenced. Rubella was detected in a very low number of copies. Varicella, mumps and measles viruses have higher mutations, probably derived from the attenuation of a large number of minor variants (quasipecies).

2. **Chemical Contaminants (signals) -** 115-173 (29-43% known)

3. **Chemical toxins -** NO

4. **Protein Contaminants -** Sarcoplasmin calcium-binding protein, Actina e Vimentina

5. **Free peptide contaminants -** NO

6. **Residual DNA/RNA deriving from cultured cells -** Total amount of DNA: 1.7-3.7 µg/dose, the 80% of which was human (Human fetal DNA / RNA from the MRC-5 cell line). Other amount of DNA: chicken

7. **Adventitious viruses -** Human endogenous retrovirus K, Equine infectious anemia virus, Avian leukosis virus, HERV-H/env62

8. **Other microbial contaminants -** Proteobacteria, nematode-helminth

9. **Processing residues of genetic material -** NO

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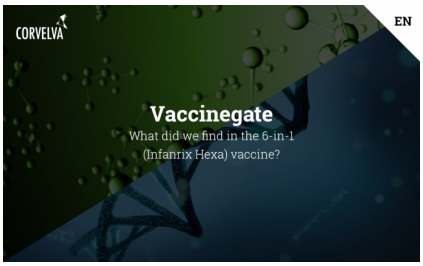

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Priorix Tetra (GlaxoSmithKline) [1] Chemical composition profile study [2]

a. Lot #1 and Lot #2 are different in many respects, 115 signals vs. 173 signals detected. A very different amount of known [3] signals [4] (compounds).

b. What should concern us is yes what we found, that is the known signals, but also and above all those not identifiable because we are in the field of hypotheses and can be anything. (between 29 and 43% is known)

c. Both lots contain traces that can be quantified between nanograms and micrograms as an indicative order of magnitude, i.e. above the threshold normally defined as residual (below nanograms). This data is important because some compounds are highly toxic, others are known allergens and others are most likely pharmaceutical molecules which, if present in vaccines, must be reported in the data sheet and quantified.

d. In both batches of product, proteins potentially coming from the purification process, of human and animal origin, have been detected, which can give hypersensitivity and allergy phenomena, especially with boosters, but also autoimmunity due to similarity with human proteins.

e. Both lots contain traces that can be associated with different antibiotics (some of which are not allowed, e.g. penicillin and cephalosporin derivatives because they are highly allergenic), herbicides, acaricides and morphine metabolites.

Metagenomic Profile Study [5]

The metagenomic tests of the vaccine "Priorix Tetra" presented a population of mutant viruses, for each attenuated virus, called quasispecies. Genetic variants of vaccine antigens could significantly alter both the safety of the vaccine and its effectiveness. In addition, there are serious dilemmas not only of a medical and scientific nature but also of an ethical nature; we list below the points that are most relevant to us:

1. The amount of DNA: The presence of fetal DNA was confirmed in large quantities: 1.7 µg on the first lot and 3.7 µg on the second lot, about 325 times higher than the maximum

limit of 10 nanograms and as many as 325,000 times higher than the minimum limit of 10 picograms, limits that EMA told us to refer only to cells that are known for carcinogenic activity. [6-7]

2. DNA size: We have more precisely determined the size of the DNA fragments detected and it has been established that the DNA contained has a molecular weight of 20,000/60,000 bp. This basically means that there are no "fragments" of DNA within this drug, i.e. degraded, but an intact genome, belonging to a male human being, confirmed by the comparison between the fetal DNA of the vaccine and that of the cell line MRC-5 used for the production of the vaccine.

3. Non-detection of rubella virus: with the level of sequencing used for screening, it was not possible to detect rubella virus. Since there was doubt that this was an error in the procedure used, the level of sequencing was increased significantly to a very high depth (260 million sequences produced). In this way the rubella virus was detected in 114 copies, equal to 0.00004% of the total of the sequences and through a manual reading of the sequences it was possible to eliminate any source of error of the software used and confirm definitively the (minimum) presence of rubella in the sample. However, this procedure has also made it possible to identify the a**dventitious viruses** present in low copy numbers, and what has been seen is that **the number of copies of the adventitious viruses exceeds that of rubella virus.**

4. So there were two other very important issues to be resolved:

   1. Is the rubella in the vaccine in sufficient quantity to produce an immunogenic effect or can it be considered subthreshold (i.e. an adventitious contamination)?

   2. Are the adventitious viruses really present? If so, can they be dangerous?

As far as point 1) is concerned, we can strongly question the ability of the attenuated rubella virus to act as an immunogenic antigen, for the negligible quantity and for the attenuation that further

weakens its effectiveness. **This aspect needs to be investigated because there is a real risk that there are lots of vaccines on the market that do not immunize and are therefore not effective, not containing what is stated in the technical data sheet.**

As regards point 2) is concerned, or the presence of adventitious viruses: to confirm it, it was necessary to check the sequences one by one manually using a different software (BLAST). It was thus possible to **confirm the presence of the following contaminating retroviruses:** [8]

- **Human endogenous retrovirus K - 32 sequences**
- **Equine infectious anemia virus - 2 sequences**
- **Avian leukosis virus - 2 sequences**
- **HERV-H/env62 - 4 sequences**

These viruses are known to be adventitious vaccine contaminants and are known to **be potentially dangerous, which is why manufacturers are required to verify that they are completely absent from the vaccine.**

It follows that this in-depth analysis in this vaccine **confirms two nonconformities on efficacy and safety**:

a. **The presence of rubella in a very low number of copies (subthreshold)**

b. **The presence of potentially dangerous adventitious viruses** which certifies that there is no adequate control on vaccines because if there were, these elements would have been detected.

Remember the EMA guidelines [9-10-11] which state that reads of "foreign" viruses must be ABSENT so not even 1 copy is allowed. In addition, the presence of a non-residual quantity of human fetal DNA is reconfirmed, so as to make this impurity a real constituent of the vaccine, which should be reported in the technical data sheet and quantified.

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2. https://drive.google.com/file/d/1cNtdBczAX1-

xowPEDep1kZOjy84IypAB/view
3. By "known" it is meant that the signals relating to a compound with a given molecular weight, present in the databases, generate one or more possible associations with known chemical structures.
4. the mass spectrum represents the relative abundance of ions as a function of their mass/charge ratio; a compound can generate more ions and therefore more signals, in particular the higher the molecular weight of the molecule the more signals it generates.
5. https://drive.google.com/file/d/1isH0XIWLCF0zEaossjrvmltEdNpXoBN-/view
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