Reactie Aurobindo:

Verzonden: dinsdag 7 juli 2020 18:13

Dear ….,

We are not going to comment on this.

Do let us know the batch numbers if at all possible.

Thank you.

Best wishes

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Sent: 06 July 2020 16:01

Dear ….,

Hope you are doing well. We've been in contact in late March when you provided us with a statement on behalf of your client Aurobindo. The statement concerned Aurobindo's facility Apotex based in the Netherlands. Are you still representing Aurobindo for media inquiries? If this is not the case, please let me know immediately due to the urgency of our following request for Aurobindo.

We are working on a new investigation involving Aurobindo/Apotex (hereafter: Apotex). In collaboration with the Dutch newspaper NRC we are working on a story about impurities in active pharmaceutical ingredients (API's) used in the manufacturing of paracetamol. For our investigation, a certified lab analysed samples of paracetamol API produced by two Chinees API manufacturers. The lab results show impurities of 4-chloroaniline (PCA) in samples of three different batches coming from the Chinees company Anqiu Lu'an Pharmaceutical. The analysis detected PCA levels of 6mg/kg in two samples and 5mg/kg in one samples of Anqiu Lu'an. The sample from the other Chinees company contained concentrations of PCA less than 1mg/kg.
According to our sources Apotex is (or has been) sourcing API from Anqiu Lu'an.

According to experts, the levels of impurities found in the batches of Anqiu Lu'an are just below the approved daily intake limits of PCA for paracetamol API intended for the European market when looking at the risk assessment and safety standards laid down in the ICH Guideline M7.

Considering the conclusions of the European Food Safety Authority (EFSA) and their used methodology of risk assessment of PCA, experts say that within EFSA's position and risk assessment, the concentration of PCA impurities present in the three samples from Anqiu Lu'an exceed the acceptable levels with a factor of 20. (Please find more information on the conclusions the following report: EFSA, 2015 Peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA)

We are looking into the different positions of the European bodies and what the lab findings mean when it comes to the risk PCA poses for the health of patients due to the genotoxic and carcinogenic effects.

Leading toxicologists qualify the results as being of concern for the health of patients. Due to the large population of patients using paracetamol, the lack of sufficient mandatory control mechanisms for the detection of PCA impurties and requirements of European standards and the fact that the lab findings are just below the approved levels, experts say that further testing should be done to find out structural deficits causing the impurities. They state that the three batches of paracetamol API should not have been used in the manufacturing of paracetamol.

To obtain your statement, we would like to ask you to respond to the following questions:

1. Has Apotex been sourcing paracetamol API from Anqiu Lu'an for the production of paracetamol at the Apotex facility?
2. Is it correct that Anqiu Lu'an is the major supplier of paracetamol API for the Apotex facility?
3. Since when is Apotex sourcing paracetamol API from Anqiu Lu'an?
4. Has Apotex sourced any API for the manufacturing of paracetamol from Anqiu Lu'an in the periode January 2019 up to now?
5. In case of the manufacturing of paracetamol in the Apotex facility, does Apotex (or a qualified person or othere quality manager appointed by Apotex) analyse the sourced APIs on impurities of PCA? Is this testing carried out for each batch of API used in the production process?
6. Is it correct that the Apotex facility manufactures paracetamol for the Dutch retailers Albert Heijn, Etos, Jumbo, Trekpleister, DA and Kruidvat?
7. Is Aurobindo willing to check and inform us if any API comming from the three batches we analysed has been used in the manufacturing process of paracetamol at the Apotex facility?
8. Is Aurobindo willing to check and inform us if any API comming form the three batches we analysed has been used in the manufacturing process of paracetamol of any Aurobindo facility?

Our report on the matter is planned at the end of this week. The article will be published in the newspaper NRC and our online platforms.

In order to process your statement accurately and diligently, please send us Aurobindo's statement tomorrow, Tuesday July 7th, before 6 p.m. (CET).

Please let me know if you have any questions. Please also send me a brief receipt of my inquiry.

Kind regards,

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