



United Nations Office in Geneva (UNOG)
Ms. Melinda Ching Simon
Human Rights Officer
Sustainable Human Development Section
CH-1211 Geneva 10
Switzerland

OHCHR REGISTRY

30 MAY 2016

Recipients : **SPB**
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**Communication by the UN Special Rapporteur on
Toxics on the German NAP on Business and Human Rights**

Dear Baskut Tuncak,
dear Melinda Ching Simon,

Thanks very much for sending a copy of the official communication and report letter to the German Government to Bayer. We very much appreciate this courtesy and confirm that we have received the report.

In the communication you make reference to two alleged cases that concern Bayer.

One of the cases relates to clinical trials in India. Our commitment to consistent standards for clinical trials can be found at

<http://pharma.bayer.com/en/commitment-responsibility/ethics-and-transparency/ethics-in-r-and-d/worldwide-standards/>

All clinical studies at Bayer are carried out in accordance with uniform global standards. There are no attempts made of any kind to locate studies in any specific countries.

It is our aim to make new drugs available to patients as widely as possible throughout the world, and clinical studies are thus carried out globally and also in India. In addition, it is often a necessary requirement on the part of regulatory authorities that studies are carried out locally in the country in which approval is being sought.

The patients included in clinical trials are – depending on the illness to be treated – in some cases elderly and seriously ill. Due to their underlying

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disease and advanced age, these patients are considered high-risk patients, for whom the mortality rate is generally high.

In clinical studies, the principal investigator records and reports all adverse events, irrespective of whether these might be associated with the drug or not. Every reported case of an adverse event is carefully reviewed and assessed by our company. If there is any entitlement to compensation according to local, in this case Indian law, such compensation is of course made by us.

Our company was requested by the Drug Controller General of India in mid-2011 to report on the status of compensation payments to the surviving relatives of a total of five patients. These cases had previously been reported to the authority by our company in accordance with local reporting obligations.

In these five cases, our company made compensation payments in accordance with local regulations and in agreement with the ethics committee. These compensation payments were made taking account all the relevant circumstances of each individual case.

As part of the approval procedure, the Drug Controller General of India usually consults external experts. Our company has no influence on the selection of these experts or on their opinions.

In your communication to the German ministries there are also remarks concerning our crop science business activities in India.

Bayer adheres to national and international best practices in the area of crop protection product management in India and worldwide. This includes nationally approved label and leaflet requirements and conditions mentioned on the registration certificates of pesticides issued by the Central Insecticides Board & Registration Committee constituted under Insecticides Act (1968) & Rules 1971 of India.

In addition, our company also complies with the International Code of Conduct on Pesticide Management set forth by the Food and Agriculture Organization of the United Nations (FAO). Bayer is committed to stringent standards and the responsible use of its crop protection products and continuously promotes the highest stewardship standards in agriculture across the country. Regular farmer trainings and awareness programs are put in place to help farmers identify and purchase authentic crop protection products, safe transportation, responsible use as well as secure storage of



crop protection products, proper use of personal protection equipment, and first aid practices.

During 2014 alone, Bayer Crop Science India has trained more than four million farmers in these critically important areas. In Punjab, the company has trained more than eighty thousand farmers.

In response to the Ad Hoc Monitoring Report by the European Center for Constitutional and Human Rights, Bayer's management has expressed to FAO that we support all efforts to also establish a multi stakeholder dialogue on the issues raised in the above mentioned report. Bayer looks forward to discuss the topics in-depth with other stakeholders including the Indian government to also access the situation in detail on-site in India and to implement improvements together, where agreement has been reached.

I hope this background helps to better understand the alleged cases mentioned. If you have further questions please don't hesitate to contact us.

Yours sincerely,

Bayer AG

A handwritten signature in black ink, appearing to read "Denise Rennmann".

Denise Rennmann
Head Public and Governmental Affairs