From:

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USA

To:

Ms. Preeti Sudan,
Secretary, Ministry of Health & Family Welfare.
Room No. 156-A, Nirman Bhavan,
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April 25, 2019

Dear Ms. Sudan,

By way of introduction, I am a public health activist, who has formerly worked in the Indian pharmaceutical industry. I was responsible for exposing the blatant regulatory violations at Ranbaxy after which the company was prosecuted and fined $500 million under the American legal system. Since the end of my whistleblower lawsuit against Ranbaxy in 2013, I have been engaged in advocacy to rehaul the Drugs & Cosmetics Act, 1940. This includes a report that I submitted to the Ministry (https://dineshthakur.com/wp-content/uploads/2016/06/CDSCO-Reform.pdf) on measures to improve drug regulation in India as well as an ongoing petition LPA No. 687 of 2018 before the Delhi High Court on the controversial approval of 4 drugs without sufficient clinical evidence.

In this letter, I would like to draw your attention specifically to the issue of stability testing. From a regulatory perspective, stability testing involves putting the manufactured formulations through various heat and pressure testing to test the stability of the formulation at various temperatures and conditions. This is to ensure that formulations meant to survive without refrigeration meet the prescribed standards for storage. While stability testing has been mandatory in most countries for the longest time, the Indian government made such testing mandatory only in 2018, after I made representations on this point.

At a meeting of the 53rd meeting of the Drug Consultative Committee (DCC) held on April 9th, 2018 it was decided that Smt. Rubina Bose, Deputy Drugs Controller (India) was to produce a "guidance document" to help state authorities implement the new mandatory requirement for stability testing. The relevant minutes are available at this URL: http://www.cdsco.nic.in/writereaddata/Minutes_of_53rd_DCC_Meeting_held_on_09_04_2018.pdf

As far as I am aware, this document has either not yet been prepared nor has not been made publicly available. In either event, I request your urgent intervention on this issue because of certain troubling reports from the state of Bihar.

In the attached news item, from the portal Pharmabiz (http://www.pharmabiz.com/NewsDetails.aspx?aid=115253&sid=1), it has been reported that local manufacturers in the state are attempting to bully the state drug controller against enforcing the requirement for stability testing. These elements in the state industry, appear to be unaware of the change in the law to make stability testing mandatory. This is most disconcerting and I would request that the DCGI be ordered to study the status of implementation of the new stability testing requirement across all states.

In addition, I would request that the "Guidance Document" be made available for public comment so that all stakeholders may contribute to the process.

I look forward to your co-operation on this issue.

Sincerely,

Dinesh Thakur