

Shri J. P. Nadda
Hon'ble Minister of Health and Family Welfare
Room No. 348, 'A' Wing
Nirman Bhavan, New Delhi-110011

29th April, 2019

Dear Nadda ji,

**Ad-hoc donations of bedaquiline threaten sustainable, affordable access for patients;
Create conflict of interest for MOHFW in regulating Johnson & Johnson**

As treatment activists, public health organizations, patients affected by TB and patients affected by Johnson & Johnson's (J&J) faulty hip implants, we are writing in response to the recent announcement about a second round of donations of 10,000 courses of bedaquiline (BDQ) by J&J to the Indian Government¹.

J&J had previously donated 10,000 courses of BDQ to India's TB programme in 2016, as part of a global donation programme operated in partnership with the U.S. Agency for International Development (USAID). The announcement of the new donation comes a full three years later in the backdrop of multiple regulatory actions and investigations by the MOHFW into harmful medical devices and cosmetic products marketed by J&J in India. Not only do these ad-hoc and piece-meal drug donations threaten the sustainability and predictability of the government's MDR-TB treatment programme, the timing of the announcement certainly raises serious concerns that the donations are aimed at undermining strict regulatory action by the Ministry of Health and Family Welfare (MOHFW) and extracting concessions or leniency from the government.

Pitfalls of drug donations and threat to treatment access

BDQ is an important new drug in the treatment of MDR-TB. The "WHO consolidated guidelines on drug-resistant tuberculosis treatment", 2019² has recommended that BDQ be incorporated as a core drug in the MDR-TB regimen and that the drug replace and minimise the use of injectable aminoglycosides in the standard MDR-TB treatment regimen. Injectable

¹ <https://www.jnj.in/statement-on-doubling-of-bedaquiline-donation-program-in-india>

² <https://www.who.int/tb/publications/2019/consolidated-guidelines-drug-resistant-TB-treatment/en/>

aminoglycosides are associated with a number of serious side effects, including irreversible hearing loss³.

As a result countries with a high burden of MDR-TB will be looking to buy BDQ at affordable prices. India plays an important role in supporting global health as a producer of affordable medicines not only for domestic purposes but also to serve the needs of other countries, especially in respect of epidemics such as HIV/AIDS and TB.

The donations of BDQ to India not only create dependence on donations from a single supplier but also stifle the Government's willingness to promote local production of BDQ by generic manufacturers to ensure affordable, sustainable and predictable supply to the Government programme.

Donations are known to delay the entry of generic producers in the market which would increase affordability through competition. The 2010 edition of the World Health Organization (WHO)'s comprehensive guidelines on drug donation⁴ sound the following note of caution:

“The negative impact that donations may have on sustainable access to medicines is often not well appreciated, especially where it concerns expensive medicines with few alternatives. **Donations of these products may influence the market and suppress competition.** The donation may eliminate or greatly delay the import of cheaper alternatives, which will be necessary once the donation programme has ended and regular provision from public health budgets is necessary.”

J&J's attempts to extend its monopoly on BDQ in India are being challenged by people living with HIV and people with TB through patent oppositions of secondary patent claims; health groups have also called on the government to issue a government use license under Section 100 of the Patents Act to enable generic producers to make BDQ for India and for the rest of the developing world. It is therefore extremely disappointing to see the government's continued reliance on donations from J&J for MDR-TB treatment.

This is an unsustainable approach to running India's TB programme that is meant to serve and treat the world's highest burden of TB and MDR-TB cases. This is also antithetical to the Government's goal to eliminate TB in India by 2025.

The use of donations by India represents a larger threat to the global supply of affordable BDQ, particularly important for low- and middle-income countries which are grappling with high burdens of TB, and will contribute to keeping the price of BDQ high worldwide.

³ Reuter A et al. “The devil we know: is the use of injectable agents for the treatment of MDR-TB justified?”, Int J Tuberc Lung Dis. 2017 doi:10.5588/ijtld.17.0468

⁴ “Guidelines for Medicine Donations”, WHO 2010, http://apps.who.int/iris/bitstream/10665/44647/1/9789241501989_eng.pdf

Conflict of Interest in respect of regulating J&J

On the one hand, J&J continues to control the supply of BDQ to the detriment of patients in India and the rest of the developing world. On the other, it is employing every tactic possible to avoid civil and criminal responsibility for harmful medical devices that it has sold to patients in India.

As you are aware, some time back a Committee appointed by the MOHFW had looked into the issue of J&J's ASR hip implants. During the course of the enquiry into this matter, the company was found to have violated regulatory rules, concealed information that had bearing on patient safety and to have demonstrated negligence in informing patients about the recall of the ASR hip implant. As a result grievous harm was caused to patients.

To redress the injury and delay in justice to patients, a process was initiated under the MOHFW to compensate patients for the faulty hip implants. However, J&J launched a legal challenge against the compensation mechanism in the Delhi High Court and while flouting the Ministry's instructions has refused to pay compensation to any patients, in spite of there being no stay on the relevant orders.

Recently concerns have emerged regarding the safety of other products marketed by J&J⁵ and about unethical business practices⁶.

Given the string of regulatory actions and investigations into J&J's products recently, the announcement of the BDQ drug donations has led to apprehensions that the donations are an attempt to whitewash its image and induce leniency by the Government for the company's transgressions, particularly in relation to refusal to compensate Indian patients of ASR hip implants, which the Government is pursuing actively both in and outside the Courts.

Therefore, we urge that there is a need for the MOHFW to put in place clear guidelines in accepting donations from pharmaceutical companies, to safeguard against potential conflicts of interest that can undermine the role of the MOHFW and any of its agencies/committees, to regulate companies and take actions necessary for protecting patient safety. The Government and in particular the MOHFW should maintain an "arm's length approach" from any such seemingly benevolent acts of welfare by J&J, as it continues to defend a position that smacks of corporate greed and apathy towards Indian patients in faulty hip implants and multiple such cases.

⁵ <https://indianexpress.com/article/business/rajasthan-drug-regulator-flags-jj-baby-shampoo-for-harmful-ingredients-5651968/> ; <https://theprint.in/india/governance/modi-govt-writes-to-jj-for-details-on-surgical-pelvic-mesh-after-us-ban/225494/>

⁶ <https://prime.economictimes.indiatimes.com/news/68983321/pharma-and-healthcare/investigation-did-jjs-pharma-arm-illegally-push-the-opioid-ultracet-in-india>

We therefore request the MoHFW to:

- discontinue and phase out the drug donations of BDQ offered by J&J to RNTCP and immediately establish a proper forecast mechanism to determine the number of people with MDR-TB who would require BDQ based regimes and ensure that RNTCP initiates the process of independently procuring the drug through a procurement mechanism based on tendering supported by its own domestic budget or by The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).
- ensure long term sustainability and encourage alternative suppliers after taking law and policy measures to overcome patent barriers for the generic production of BDQ, especially through the issuance of government use authorisation under Section 100 of the Patents Act.
- based on WHO guidance on drug donations and in consultation with public health groups and patients, formulate a clear policy on regulation, acceptance and monitoring of drug donations to central and state health programmes in India
- ensure that the MOHFW, the Central Drugs Standard Control Organisation (CDSCO) and the committees operating as part of the compensation mechanism for ASR hip implant patients are able to perform their mandate in respect of ensuring justice for hip implant patients independently and without any conflicts, real or perceived.

Sincerely,

All India Drug Action Network (AIDAN)
ARK Foundation, Nagaland
Charanjit Sharma, TB/HIV Activist
Delhi Harm Reduction and Advocacy Forum
Delhi Network of Positive People (DNP+)
Drug Action Forum-Karnataka
Drug User's Union of Meghalaya (DUUM)
Empower India
Francis Joseph, Social Activist and PWID
Fundación GEP, Argentina
Ganesh Acharya, TB survivor and TB/HIV Activist
Global Coalition of TB Activists
Hari Shanker Singh, TB/HIC Activist
Hip Implant Patients Support Group (HIPS)
Henry Zohmingthanga, PLHIV, Aizawl, Mizoram
HOPE(CBO) Churachandpur, Manipur
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Nandita Venkatesan, DR-TB Advocate
Network of Nagaland Drugs and AIDS Organization (NNagaDAO)
Prayas, Rajasthan
Sankalp Rehabilitation Trust
Sikkim Drug Users Forum
South Indian Drug Users' Forum
Third World Network
Touched by TB
Treatment Action Group

Copy to:

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Ms. Preeti Sudan, Secretary, Ministry of Health & Family Welfare
Shri Sanjeeva Kumar, Additional Secretary, Ministry of Health & Family Welfare
Shri Arun Singhal, Additional Secretary, Ministry of Health & Family Welfare
Dr. S. Eswara Reddy, Drugs Controller General of India, CDSCO, Ministry of Health & Family Welfare

For further information, contact:

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