

## **Open letter to Prime Minister Rishi Sunak on the UK-India Free Trade Agreement and its impact on access to affordable, lifesaving generic medicines from India**

31<sup>st</sup> October 2023

Dear Prime Minister Rishi Sunak,

Amidst reports that the negotiations are in the final stages, we are writing to you to express our deep concern regarding the UK-India Free Trade Agreement (FTA) and its potential impact on access to affordable, lifesaving generic medicines from India. **We call on you to urgently and publicly commit that there will be no clauses proposed by the UK that will require India to amend its intellectual property (IP) laws as a result of the FTA.**

There are critical safeguards included in Indian Patent laws which protect public health whilst complying with international IP rules. Earlier this month, we saw a breakthrough in global access to a key drug for drug-resistant tuberculosis (DR-TB), bedaquiline, as pharmaceutical corporation Johnson and Johnson (J&J) was pressured into agreeing not to enforce its secondary patents on the drug in 134 low- and middle-income countries (LMICs).<sup>1</sup> The foundation for this victory was laid by two public health safeguards in India's IP law that we are concerned the UK could dismantle through the terms of this FTA.

First, when a secondary patent application for bedaquiline was filed in India by J&J, which if granted, would have resulted in four more years of a monopoly for J&J, a patient group and two TB survivors filed a legal challenge called a 'pre-grant patent opposition.'<sup>2</sup> This mechanism enables any third party, including individuals and patient groups, to oppose a patent before it is granted. As a result of the filing, the Indian patent office scrutinised and eventually rejected J&J's secondary patent application.

Second, the patent application was rejected because of India's more rigorous laws on the level of innovation required to patent a drug. Since J&J's secondary patent application on bedaquiline merely changed the compound into a different formulation, with no therapeutic benefit, India's IP office rightfully rejected the application.

The decision by India to reject the secondary patent on bedaquiline led to these patents being questioned more widely,<sup>3,4,5,6</sup> and international pressure culminated in J&J's announcement in early October that it will not enforce its secondary patents on bedaquiline in LMICs. TB is the biggest infectious disease killer globally, causing over 1.6 million deaths annually.<sup>7</sup> These vital public health safeguards in Indian IP law are designed to save lives, and now they will; this groundbreaking development will now pave the way for unfettered access to affordable generic versions of bedaquiline for all people living with DR-TB in LMICs.

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<sup>1</sup> <https://msfaccess.org/msf-responds-groundbreaking-news-johnson-johnson-will-not-enforce-patents-key-tb-drug-bedaquiline>

<sup>2</sup> <https://time.com/collection/time100-next-2023/6312042/nandita-venkatesan-phumeza-tisile/>

<sup>3</sup> <https://msfaccess.org/ukraine-open-letter-urgent-action-johnson-johnson-needed-improve-equitable-access-bedaquiline-based>

<sup>4</sup> <https://msfaccess.org/belarus-open-letter-urgent-action-johnson-johnson-needed-improve-equitable-access-bedaquiline-based>

<sup>5</sup> <https://www.theguardian.com/global-development/2023/sep/22/south-africa-launches-unprecedented-investigation-of-johnson-johnson-over-tb-drug-prices>

<sup>6</sup> <https://unitaid.org/news-blog/johnson-johnson-pricing-agreement-for-critical-tb-drug-still-unfairly-restricts-access-in-countries-where-the-need-is-greatest/#en>

<sup>7</sup> <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>

Yet, we are deeply concerned that the UK could dismantle these safeguards through the FTA with India. A leaked text of the UK-India FTA revealed that the UK was proposing provisions in the IP chapter which would impede these crucial mechanisms through requiring amendments to India's IP laws.<sup>89</sup> As negotiations continue, it has emerged that the Indian Government is indeed considering amending its patent rules.<sup>10</sup> Civil society organisations and patient groups in India have repeatedly expressed their concerns about these proposed amendments because of their potential negative impact on access to affordable medicines.<sup>111213</sup>

Despite FTAs being long-standing and largely irreversible commitments, there are unprecedented levels of secrecy from both the UK Parliament and the public on what is being negotiated. As such, it is not clear how the UK's specific proposals to gut India's public health safeguards have appeared in the broad-ranging agreement. However, it is clear that the IP chapter is a contentious section of the agreement<sup>14</sup> and appears to be one of the last remaining issues still under negotiation.<sup>15</sup>

Several of the undersigned civil society organisations met with the Minister of State for International Trade back in May this year to raise our concerns; they were repeatedly told no information could be shared about the UK position as negotiations were ongoing, and subsequent requests for meetings have gone ignored. And yet, a recent Freedom of Information (FOI) request submitted by Médecins Sans Frontières (MSF) to the Department of Business and Trade showed that the UK is regularly and consistently meeting with members of the multinational pharmaceutical industry to consult them on the FTA negotiations.<sup>16</sup> There are additional reports that the UK's life sciences and biotech industry demanded "37 changes" to the IP chapter, suggesting they are heavily influencing the text itself.<sup>17</sup> Full transparency and public and parliamentary scrutiny on negotiations are urgently needed to ensure that public health concerns are not circumvented in favour of private profits.

Health systems around the world, including in low-and middle-income countries, rely on the availability of quality-assured, affordable generic medicines from India, as do global organisations such as The Global Fund to Fight AIDS, TB and Malaria, GAVI, and UNITAID. The UK NHS purchases 25% of its medicines from Indian generic companies.<sup>18</sup> Yet the same secondary patent on bedaquiline that was rejected by the Indian Government has been granted in the UK, forcing the NHS to use expensive branded versions of this medicine rather than more affordable generics.<sup>19</sup> Recent figures show that TB cases in the UK are rising and progress against elimination of TB is stalling.<sup>20</sup> In lieu of undermining Indian legislation, the UK should learn from this case and amend our own laws to favour patients and the NHS.

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<sup>8</sup> <https://www.bilaterals.org/?uk-india-fta-draft-intellectual>

<sup>9</sup> <https://msfaccess.org/damaging-provisions-access-medicines-uk-india-fta-negotiation-text>

<sup>10</sup> 'Patients' rights and access to drugs could be hurt by proposed amendments in patent rules' - The Hindu

<sup>11</sup> 'Proposed changes in Indian Patent Rules 2023 raise concerns over access to affordable medicines' | Mumbai News - Times of India (indiatimes.com)

<sup>12</sup> Proposed changes to Patents Act will undermine public health, say patient advocacy groups - The Hindu BusinessLine

<sup>13</sup> Patient groups and public health experts raise concern over draft amendment on Patents Act (pharmabiz.com)

<sup>14</sup> <https://www.telegraph.co.uk/politics/2023/09/07/sunak-will-not-offer-more-visas-india-trade-deal/>

<sup>15</sup> <https://www.india-briefing.com/news/india-uk-fta-25699.html/>

<sup>16</sup> Freedom of Information reference number: FOI2023/01006

<sup>17</sup> <https://www.india-briefing.com/news/india-uk-fta-25699.html/>

<sup>18</sup> Four out of five drugs used in the NHS are generics, a third of these generics are produced in India - 25% of the total: <https://www.telegraph.co.uk/business/2021/05/29/indian-crisis-risks-severing-supply-vital-drugs-uk/>

<sup>19</sup> <https://register.epo.org/application?number=EP07847697>

<sup>20</sup> <https://www.gov.uk/government/news/tuberculosis-tb-cases-continue-to-rise-in-england-in-2023>

The UK has previously committed to ensuring that the FTA with India will not undermine access to affordable medicines for the NHS.<sup>21</sup> **We call on you to urgently and publicly commit that there will be no provisions proposed by the UK that will require India to change its IP laws as a result of this FTA, and that it will not undermine access to affordable medicines in India and for the rest of the world.**

Yours sincerely,

### **Academics**

Dr Andrew Hill - Senior Visiting Research Fellow, University of Liverpool  
Dr Graham Dufield – University of Leeds  
Dr Olga Gurgula - Brunel University London  
Dr Rose Parfitt - Kent Law School, University of Kent  
Professor Chloe Orkin - Queen Mary University of London  
Professor Gail Davey - Brighton & Sussex Medical School  
Professor Ian Wall – Fellowship of the Royal Society of Edinburgh (FRSE)  
Professor Laura Camfield - School of Global Development, UEA  
Professor Maryam Shahmanesh – UCL Institute for Global Health  
Professor Nick Grief - Emeritus Professor of Law, University of Kent  
Professor Susan Michie - Health Psychology, UCL  
Professor Tim Colbourn - UCL Institute for Global Health  
University of Strathclyde

### **Civil society organisations**

Alex Runswick - RESULTS UK  
Amnesty International  
Baby Milk Action (IBFAN)  
Ben Gilchrist – Chief Executive, Caritas Shrewsbury  
Dr Andrea Hotchkin – BMS World Mission  
Dr Mark Hotchkin - BMS World Mission  
Foundation for Integrative AIDS Research (FIAR)  
Global Justice Now  
Harm Reduction International  
HIV Justice Network / Edwin J Bernard - Executive Director  
Just Treatment  
Mohga Kamal-Yanni - Senior Policy Advisor to UNAIDS and The People Vaccine Alliance, Key advisor to the NGOs reps at UNITAID, Global Health and Access to Medicines Consultant  
Médecins Sans Frontières (MSF) UK  
Oxfam  
People's Vaccine Alliance  
STOPAIDS  
Trade Justice Movement  
Universities Allied for Essential Medicines (UAEM) UK  
War on Want UK

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<sup>21</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1046839/uk-india-free-trade-agreement-the-uks-strategic-approach.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1046839/uk-india-free-trade-agreement-the-uks-strategic-approach.pdf)

## **Healthcare workers and individuals**

British HIV Association (BHIVA) - Chair Prof Yvonne Gilleece  
Dr Gill Turner - Royal College of Paediatrics and Child Health  
Dr Fiona MacLeod - Clinical Psychologist  
Dr Ian Cropley - Médecins Sans Frontières (MSF)  
Dr Mike Downham - Zero Covid Scotland campaign  
Dr Rageshri Dhairyawan – HIV/Sexual Health NHS Consultant  
Dr Rhiannon Mihranian Osborne – NHS Doctor  
Leslie Cunningham - Unite Scotland member  
Martin Ayres – Senior Nurse Manager  
Mich Okada - The City of Edinburgh Council  
Michael Schwaabe – Association of Flight Attendants CWA Council 7 President  
Neil Barton  
Paul Wilson  
Roy Trevelion – HIV Treatment Activist  
Stephen Matlin - Development Consultant  
The Queen's Nursing Institute

## **Members of Parliament/House of Lords**

Claudia Webbe MP  
Dr Philippa Whitford MP  
Kenny MacAskill MP  
Kim Johnson MP  
Pauline Bryan, Baroness Bryan of Partick  
Richard Burgon MP