



Indian Ministry of Environment, Forest and Climate Change notification,  
Environment (Protection) Amendment Rules, 2020.

## **Wellcome Trust Consultation Response**

The Wellcome Trust wishes to communicate support for the draft notification *Environment Protection Amendment Rules 2020*, released by the Indian Ministry of Environment, Forest and Climate Change on the 23rd of January 2020. This proposal marks the first instance of national standards on antimicrobial levels released in pharmaceutical manufacturing effluent, and we wish to applaud India's leadership and public commitment to address drivers of antimicrobial resistance (AMR) across the one health spectrum.

To successfully implement this proposal, we hope that the Indian Government continues to engage with stakeholders across this sector in a number of ways:

- Seek input from independent experts to ensure that standards and regulatory approaches are rooted in science and guide the best possible practices known to us at this time. As knowledge grows, the Government response must be prepared to adapt to remain both ambitious and appropriate.
- Engage pharmaceutical companies to understand their concerns and needs in responding to new standards. With scope to significantly change the footing of Indian industry on the global stage, the Government can provide much needed support as they implement necessary changes.
- Provide a strong mandate for regulators, at both national and state level, to effectively enforce standards. Development of a robust implementation framework will be necessary to ensure the can be done in an effective and sustainable way.
- Develop a dialogue with communities to support collective understanding of benefits and risks for populations local to manufacturing, allowing a fuller appreciation of the impact new regulations will have on their health and livelihoods.

Antimicrobial resistance (AMR) presents a major challenge to global health. The global community has committed to addressing AMR through a "One health" approach, including human, animal and environmental dimensions. However, review of country-level AMR National Action Plans (NAPs) show that the environmental dimensions of AMR remain poorly recognised [1]. This is a major short coming that could undermine progress being made through initiatives on other sectors.

Human-generated activities contaminating the environment with antimicrobials have been shown to accelerate the development of antimicrobial resistance genes and pathogens beyond natural levels [2]. Each year, antimicrobial production exceeds 100,000 tons worldwide, with a significant proportion of this undertaken in India [3]. Current manufacturing practices have been seen to result in discharge of active pharmaceutical ingredients (APIs) into local environments, with a number of case studies in India measuring both APIs and high levels of resistance genes in areas local to manufacturing. While the clinical risk this poses to humans has not been fully elucidated, these activities heighten the risk of drug-resistant infections in a way that can no longer be ignored [4].

While voluntary measures from industry to reduce levels of antimicrobials being discharged from manufacturing should be commended, country-level leadership in this space has been lacking. It is therefore significant that the Indian Government has taken the step of developing proposed effluent standards, and we very much hope that others will follow this lead.

The achievement of a sustainable solution to AMR requires the inclusion of the environment as a key driver of resistance. The proposed standards not only showcase India's leadership on this issue but are also a crucial step forward in the global effort to tackle AMR. We look forward to seeing this proposal enacted by the Indian Government and stand ready to work with them and other global partners to make plans to mitigate AMR in every sector a reality.

- 1 World Health Organization. Monitoring global progress on addressing antimicrobial resistance: Analysis report of the second round of results of AMR country self-assessment survey 2018. Available from:  
<https://apps.who.int/iris/bitstream/handle/10665/273128/9789241514422-eng.pdf?ua=1>
- 2 Centers for Disease Control and Prevention, UK Science and Innovation Network, Wellcome Trust. Initiatives for Addressing Antimicrobial Resistance in the Environment: Current Situation and Challenges. 2018. Available from:  
<https://wellcome.ac.uk/sites/default/files/antimicrobial-resistance-environment-report.pdf>
- 3 Changing Markets. Superbugs in the Supply Chain: How pollution from antibiotics factories in India and China is fuelling the global rise of drug-resistant infections. 2016. Available from:  
[https://epha.org/wp-content/uploads/2016/10/Superbugsinthesupplychain\\_CMreport.pdf](https://epha.org/wp-content/uploads/2016/10/Superbugsinthesupplychain_CMreport.pdf)
- 4 Larsson, D.G.J. et al. Environmental factors influencing the development and spread of antibiotic resistance. FEMS Microbiology Reviews 42 (2018).  
<https://doi.org/10.1093/femsre/fux053>