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To: Michael Gove
Secretary of State for Environment, Food and Rural Affairs

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Dear Mr Gove,

We are writing to you from the Changing Markets Foundation, Health Action International (HAI), the European Public Health Alliance (EPHA), Health Care Without Harm Europe and the Alliance to Save Our Antibiotics, to call for urgent action to tackle environmental pollution at pharmaceutical factories supplying the UK's National Health Service (NHS). Of particular concern to us is pollution at antibiotics manufacturing sites, which is fuelling the rise of antimicrobial resistance (AMR) worldwide.

In September 2016, the *Government response to the Review on Antimicrobial Resistance*[1] acknowledged the need to reduce the dissemination of pharmaceutical manufacturing discharges to the environment, and tasked Defra with developing an evidence base to help inform any future regulatory action on this issue.

In correspondence with Changing Markets in December 2016, the Secretary of State for Health, Jeremy Hunt, confirmed that: "the UK Government views the discharge of antimicrobial residue into the environment as a significant area for further action" and noted that action on a global scale is required in light of the global nature of the pharmaceutical industry.[2]

However, one year on from this, we are concerned that the impacts of pharmaceutical pollution on the health of British citizens are not being addressed with sufficient speed or priority by the UK Government and that production facilities supplying global markets are continuing to pollute in impunity.

[1] https://www.gov.uk/government/publications/government-response-the-review-on-antimicrobial-resistance
[2] Correspondence received by Changing Markets on 22.12.2016

There is a substantial and growing body of scientific evidence demonstrating the link between the presence of antibiotics in the environment and the proliferation of drug-resistant bacteria.

A study published in March 2017 by scientists investigating companies supplying the German market showed that insufficient wastewater management by drug manufacturing facilities in India is leading to "unprecedented" contamination of water resources with antimicrobial pharmaceuticals.[3] The researchers found concentrations of antibiotics and antifungal substances that were several hundred times, or even several thousand times, higher than the levels predicted to select for resistance. In addition, 95 per cent of all samples tested positively for multi drug-resistant bacteria.

This is just the most recent in a series of alarming studies pointing to a relationship between emissions from pharmaceutical manufacturing and the spread of AMR. The Changing Markets Foundation has carried out research and on-the-ground investigations which have revealed uncontrolled pollution at factories in India and found antibiotic-resistant bacteria around pharmaceutical manufacturing sites in four Indian cities.[4] It has also investigated factories in China, where a substantial share of the world's antibiotic Active Pharmaceutical Ingredients (APIs) are produced and where pollution is rife.

This is not a problem that only affects India and China: expanding global trade and tourism mean that AMR is able to travel easily around the world, affecting people everywhere. Supply chain research has shown that a large share of the drugs produced in polluting and substandard conditions are bought by major pharmaceutical companies and large government purchasers in Europe and North America, including NHS Trusts.[5]

This past year has seen the global threat of AMR continue to rise in all parts of the world; from the spread of 'super malaria' in Southeast Asia[6] and drug-resistant pneumonia in China,[7] to news that four in ten E.coli bloodstream infections are now resistant to the most commonly used antibiotic in the UK.[8] In September, the World Health Organization (WHO) warned that the world is running out of antibiotics as a result of rising AMR and a lack of new antibiotics in the pipeline.[9] The UK's Chief Medical Officer, Professor Dame Sally Davies, warned in October of an impending "post-antibiotic apocalypse".[10]

These news stories further underline the urgent need for the UK Government to take swift action, both nationally and internationally, to curb AMR and protect the effectiveness of our existing antibiotics.

The voluntary approach currently undertaken by the pharmaceutical sector will not solve this problem. Of the top 10 producers of generics worldwide, only one (Cipla Inc) has committed to the Davos Declaration and industry roadmap. This demonstrates that the 'main offenders' identified in the investigations undertaken by Changing Markets and the German media are

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[3] Study: http://link.springer.com/article/10.1007%2Fs15010-017-1007-2
[4] https://changingmarkets.org/portfolio/bad-medicine/
[5] https://www.thebureauinvestigates.com/stories/2017-05-06/big-pharmas-pollution-is-creating-deadly-superbugs-while-the-world-looks-the-other-way
[6] http://www.bbc.co.uk/news/health-41351160
[7] http://www.cidrap.umn.edu/news-perspective/2017/08/hypervirulent-highly-resistant-klebsiella-identified-china
[8] https://www.thetimes.co.uk/article/four-in-ten-e-coli-cases-now-resistant-to-drugs-0srk2h2ld
[9] http://www.who.int/mediacentre/news/releases/2017/running-out-antibiotics/en/
[10] http://www.telegraph.co.uk/news/2017/10/13/britain-could-face-post-antibiotic-apocalypse-warns-top-doctor/

not in any way committed to changing practices. A binding approach is urgently needed to ensure all pharmaceutical companies and suppliers worldwide are obliged to stop contaminating the local environment with pharmaceutical including antimicrobial waste.

We therefore call on you to take urgent action to address the threat posed by pollution at manufacturing sites supplying the NHS by:

- Bringing forward proposals to regulate pharmaceutical manufacturing including the incorporation of environmental criteria into Good Manufacturing Practices (GMP). This can be done either in cooperation with other EU Member States in the framework of the upcoming strategic approach on pharmaceuticals in the environment[11] or independently by the UK government, following Brexit;

- Demanding that the pharmaceutical industry clean up its supply chain and introduce full transparency on the origin of antibiotic drugs right back to the factory that produced the APIs;

- Introducing an obligation for NHS trusts to purchase drugs only from responsible providers that, amongst other things, implement proper pharmaceutical discharge management in line with the approach adopted by the Swedish regions.[12]

We would welcome an opportunity to meet with you to discuss these calls to action, and hear how you and your team at Defra intend to tackle this important issue. Please do not hesitate to get in touch should you have any questions or comments.

We look forward to hearing from you in due course.

Yours sincerely,

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[11] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630_en
[12] https://noharm-europe.org/documents/procurement-presentation-pauline-gothberg-swedish-county-councils-and-regions

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