

Jim O'Neill: Global action needed to ensure a safer and better-regulated supply chain for antibiotics

The growth of unregulated internet sales of antibiotics, and manufacturers producing poor quality medicines, are two factors that risk fuelling the rise of drug-resistant superbugs, according to a new report published today. The short paper, *Safe Secure and Controlled: Managing the Supply Chain of Antimicrobials*, is being released to coincide with World Antibiotics Awareness Week and is the latest in a series of reports produced by Lord Jim O'Neill's independent Review on Antimicrobial Resistance (AMR). It calls for global action by governments, regulators and internet companies around the world to clamp down on unlicensed internet sales of antibiotics, and to implement better monitoring of global drug quality, particularly in low and middle-income countries.

The excessive and unnecessary use of antibiotics is already widely recognised as a significant driver of the emergence of drug-resistant strains of common infections – as the increased exposure of bacteria to the drugs encourages the development of drug resistance, through a process of evolutionary natural selection. Although this is a problem even when antibiotics are prescribed by a doctor, it is exacerbated by patients self-medicating, without proper clinical direction – often using antibiotics purchased over-the-counter or, increasingly, via online pharmacies. Over-the-counter sales of antibiotics are illegal in most countries, with good enforcement of these rules in some parts of the world. However in practice the use of antibiotics without a prescription – usually bought over-the-counter – remains relatively commonplace in Southern and Eastern Europe and many low- and middle-income countries.

But online pharmacies represent a new challenge for regulators. They are often based in countries where regulation is lax but they offer to ship prescription drugs anywhere in the world – so represent a problem for all countries. Even powerful, last-line antibiotics such as colistin can be found from online retailers willing to dispatch it to Europe without evidence of a doctor's prescription. This is the drug at the centre of fresh concern from public health authorities worldwide this week, after a novel form of resistance to colistin was found in bacterial infections in animals and humans by a team of Chinese scientists.

The report highlights the need for a concerted international effort to address the emerging risk of online sales, involving collaboration between medicines regulators, customs authorities, governments and internet companies to close the gaps in domestic and global regulatory

mechanisms that allow illegal and unscrupulous online pharmacies to sell antibiotics without a prescription, and so to support dangerous and irresponsible self-medication.

The report also draws attention to the threat posed by poor quality antimicrobial medicines entering the global supply chain. These substandard drugs drive the development of resistance by delivering a dose of the active ingredient that is less than that expected by the doctor or patient, exposing bacteria and other microbes to a sub-therapeutic dose that drives the development of drug resistance but without treating the infection properly. This leaves patients sick for longer, and creates perfect conditions for drug-resistant superbugs to develop and then spread.

The report calls for better monitoring of this problem within the supply chain for all antimicrobials. Monitoring mechanisms for substandard and counterfeit versions of some other types of antimicrobial drugs (particularly those for malaria) is relatively well established, but needs to be improved, and significant gaps remain in respect of antibiotics. This includes the identification of so-called ‘tiered production’ – whereby unscrupulous manufacturers produce drugs of lower quality for markets where regulatory oversight is known to be limited. Action is also required from industry to ensure that antibiotics are properly handled and stored along the full length of the supply chain so that they reach patients with no degradation in quality.

Speaking about the report, Lord Jim O’Neill, Chairman of the Review on AMR, said:

“Even in those countries where it’s next to impossible to buy antibiotics over-the-counter in a shop, it’s still often the case that an unscrupulous online pharmacy is just a few clicks away. I find it frankly alarming that even antibiotics as powerful and as important to us as colistin can be found for sale on websites that don’t ask for any evidence of a prescription. These internet drug stores could be based anywhere in the world, so it’s vital that regulators – along with the industry, customs organisations and internet companies – work together, across national boundaries, to crack down on unregulated online sales of antibiotics, which fuel dangerous self-medication practices and rising drug resistance.

“And wherever the antibiotics that we consume come from, doctors and patients alike need to be sure that the drugs they’re taking are of good quality. So we need real vigilance from governments and regulators to ensure that substandard products that can cause resistance don’t enter the supply chain in the first place, and can be rapidly identified and weeded out if they do.”

Notes for Editors

1. AMR or ‘antimicrobial resistance’ is the term used to describe drug-resistant infections, sometimes referred to as ‘superbugs’. Antimicrobials include antibiotics (which act only on bacteria), antivirals, antiparasitics and antifungals.
2. The short report, *Safe Secure and Controlled: Managing the Supply Chain of Antimicrobials*, will be published on the Review’s website at www.amr-review.org on Friday 20th November.

3. The UK Prime Minister, David Cameron, commissioned the Review on Antimicrobial Resistance in July of last year to address the growing global problem of drug-resistant infections. It is Chaired by Lord Jim O’Neill and backed by the Wellcome Trust and the UK Government.
4. Lord Jim O’Neill is the current Commercial Secretary to HM Treasury, as well as the Chairman of the Review on AMR. He is an internationally published economist and until 2013 was Chairman of Goldman Sachs Asset Management, having previously been the organisation’s Head of Economic Research. Before chairing the Review on Antimicrobial Resistance he led the Cities Growth Commission which played a central role in the Government’s decision to devolve significant new powers to large urban centres in the UK starting with Manchester and the Northern Powerhouse project. He is particularly well known for his work in relation to developing and middle-income economies, having coined the BRIC (Brazil, Russia, India, China) acronym – meaning that he is especially well-placed to understand the broad range of international interests raised by antimicrobial resistance.
5. Action to better-regulate the global supply of antibiotics represents one part of the solution to the diverse challenges of increasing drug resistance, as outlined in our previous four papers and those still to be published in 2015 and early 2016. The areas the Review will be covering in the coming months include: antibiotic use in agriculture and the environment, infection control and alternatives to antibiotics.
6. World Antibiotics Awareness Week, running from 16th – 22nd November, is a global initiative coordinated by the World Health Organization increase awareness of global antibiotic resistance and to encourage best practices among the general public, health workers and policy makers to avoid the further emergence and spread of antibiotic resistance. More information can be found at <http://www.who.int/mediacentre/events/2015/world-antibiotic-awareness-week/event/en/>
7. The Wellcome Trust is a global charitable foundation that spends more than £700 million a year on advancing human and animal health. It is the second highest-spending charitable foundation in the world, after the Bill & Melinda Gates Foundation, investing principally in biomedical science, the medical humanities and public engagement. The Trust is providing part-funding for the work of the Review, and hosting the team at its London headquarters.

This Press Release and the accompanying report will also be available on Friday 20th November 2015 on www.amr-review.org.

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