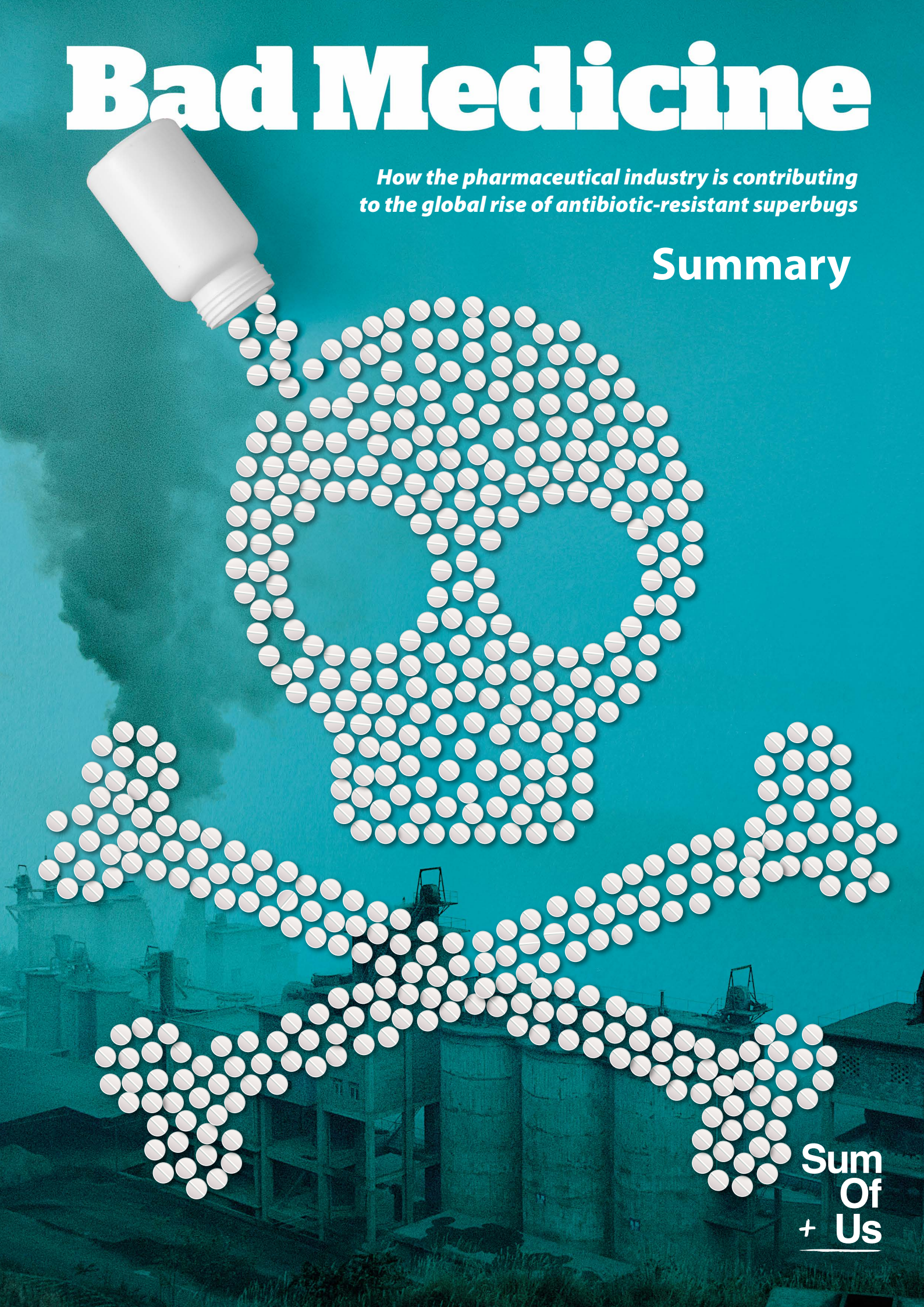
Bad Medicine

How the pharmaceutical industry is contributing to the global rise of antibiotic-resistant superbugs

Summary



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EXECUTIVE SUMMARY

The effective treatment of infections and diseases, which has been taken for granted for decades, is under threat. The emergence of virulent strains of drug-resistant bacteria, commonly known as superbugs, is prompting scientists and medical practitioners around the world to warn of a return to the pre-antibiotic era and a looming public health disaster.

Antimicrobial resistance (AMR) has been singled out as one of the main risks to mankind by the World Health Organization (WHO) and governments everywhere. The Chairman of a major UK Government-backed review into AMR estimates that by 2050, drug-resistant infections could kill 10 million people per year globally, and the UK's Chief Medical Officer has spoken of a "catastrophic threat." AMR is also extremely costly, with studies showing that the world could lose up to US$100 trillion worth of economic output between now and mid-century if it is not addressed, lowering projected GDP by 2 to 3.5 percent.

The global spread of AMR means that serious and highly contagious illnesses such as gonorrhoea and pneumonia, may soon become incurable. As the number of untreatable cases rises worldwide, doctors and medical staff are increasingly falling back on antibiotics of last resort.

There are several factors fuelling the AMR crisis. An inexpensive and seemingly endless supply of antibiotics, coupled with perverse financial incentives encouraging their prescription, are leading to inappropriate use and overconsumption in humans and animals reared for food. The lack of investment by industry in new drug discovery is further exacerbating the situation.

One frequently overlooked cause of AMR, and the focus of this report, is environmental pollution from the production of the raw materials used to make antibiotics at the very beginning of the supply chain.

Most of the world's antibiotic drugs are manufactured in China and India. China is now the top manufacturer of penicillin industrial salts, a vital building block in the production of many antibiotics, and produces 80-90 percent of antibiotic active pharmaceutical ingredients (APIs). India, which has the world's third largest pharmaceutical industry, represents a smaller yet still sizeable share of global antibiotic API manufacturing. Indian companies have also positioned themselves as leaders in the production of 'finished dose' antibiotic products using APIs mainly imported from China. The trade in antibiotic drugs between China and India is now worth billions of dollars, with large pharmaceutical companies in the United States and Europe among their biggest clients.

In 2014, China was rocked by a series of investigations exposing pollution from antibiotics factories. The pharmaceutical industry has long maintained that antibiotic manufacturing does not play a significant role in fuelling drug resistance, arguing that the final product is so valuable that it would not be economically rational to discharge vast quantities of it as waste. However, the Chinese revelations as well as several scientific studies have clearly demonstrated that this is not the case.

Hot on the heels of the recent pollution scandals, this report documents links between some of the global pharmaceutical industry's biggest household names and dirty antibiotics factories in China. On-the-ground investigations and desk research have uncovered a complex and murky web of commercial relationships between Chinese suppliers, Indian middlemen, and trusted global brands. While information on where pharmaceutical companies source their antibiotics may be provided confidentially to national authorities, it is classified as commercially sensitive, making it impossible to fill the supply chain gaps highlighted in our research.

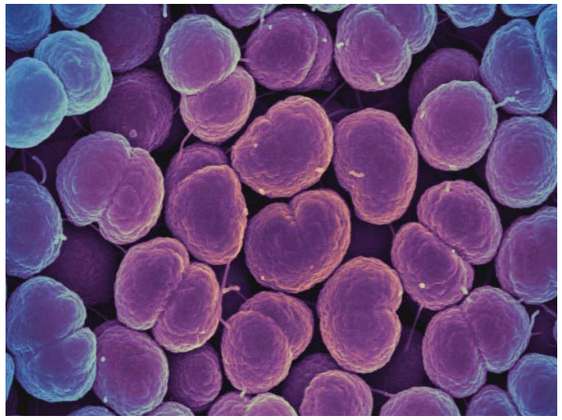
Despite the shocking lack of transparency in the global pharmaceutical supply chain, our investigation has revealed that Pfizer is among the well-known brand names which have sourced antibiotics for human and animal use from NCPC, a company that stands accused of discharging pharmaceutical effluent into the environment and numerous other serious manufacturing deficiencies. There also appear to be direct links between one of the world's largest generic drug manufacturers, McKesson, which owns several European brands, and Indian company Aurobindo, which sources from at least four polluting Chinese factories. The world's largest generics manufacturer, Israeli company Teva, likewise has links with at least three of the Chinese companies identified in this report, all of which have been in the Chinese media spotlight for various offences including improper waste management and the release of noxious chemicals.

The report reveals that the largest pharmaceutical corporations are complicit in fuelling one of the most serious public health crises facing society today. It is essential for pharmaceutical companies to lift the veil on their supply chains and stop buying antibiotic APIs from polluting Chinese factories. In an age when AMR is threatening to destroy the health system as we know it, there is simply no excuse for turning a blind eye.

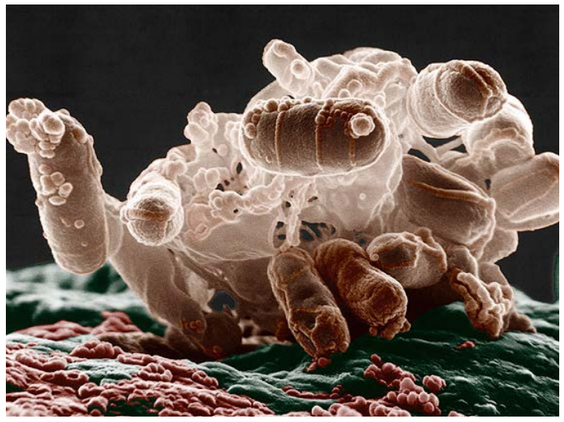
Policy-makers should demand more transparency and expand existing production standards and the Good Manufacturing Practices (GMP) framework to incorporate and enforce environmental protection criteria. This is a critical, yet still missing, part of the puzzle in the global strategy to combat AMR.

RECOMMENDATIONS FOR ACTION

Our research reveals that the pharmaceutical industry, with its complex web of interconnections and opaque supply chains is also playing a role in fuelling the international AMR crisis. China supplies the vast majority of antibiotic raw materials to the global market; it seems from extensive research that several multinational drug companies are sourcing antibiotics from Chinese factories which have been exposed in the media as dumping waste water and antibiotic APIs in the environment. Some of these factories have been fined or have promised to relocate, but there is little evidence that more serious measures are being taken to effectively address the problem.



Microscope image of neisseria gonorrhoeae, bacteria responsible for the common sexually transmitted infection gonorrhoea. © National Institute of Allergy and Infectious Diseases (NIAID)



A cluster of E.coli bacteria under the microscope. Some strains of this bacteria can cause diarrhoea, urinary tract infections, respiratory illness and pneumonia. © Microbe World

AMR is a global emergency which requires a comprehensive approach, obliging companies to take responsibility for their supply chains. The unmonitored dumping of API-rich effluent into rivers and waterways in China and India is demonstrably leading to the proliferation of resistant bacteria, which is not only damaging for local populations, but can also lead to the spread of these bacteria around the world through travel and trade. The message is clear: bad production practices in one location impact public health all over the world and therefore need to be addressed globally.

For pharmaceutical companies:

1. Stop buying APIs from factories which manufacture in an environmentally irresponsible way until effective measures to clean up production processes are implemented and enforced. This should include measures to address any environmental damage and any compensation for the affected communities.

2. Embrace full transparency and promote the transfer and adoption of cleaner production technologies and pollution prevention policies across their supply chains. The pharmaceutical industry already has a set of voluntary principles on supply chain management, which include guidelines on environmental protection. Among other things, these guidelines say that "[s]uppliers shall have systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges." These principles should become an industry standard and be duly enforced for all actors in the supply chain.

For EU legislators and governments:

1. The EU and U.S. should amend the rules under the GMP (Good Manufacturing Practice) framework for the production of pharmaceutical products by including environmental criteria. GMP rules are largely harmonised and cover all companies importing APIs and/or products into the EU or U.S. Amending these principles would therefore have a tangible impact on production. This process should define pollution prevention policies, in particular best available techniques and best environmental practices (BAT/BEP), and ensure the enforcement of good waste management.

2. The EU and U.S. should enforce greater transparency across the supply chain by asking pharmaceutical companies to disclose the origin of their drugs right back to the factory that produced the ingredients. This would not only be useful for encouraging good production practices, but would also contribute to greater patient safety.

For International stakeholders:

1. Include pharmaceutical pollution, in particular antibiotic pollution and its contribution to AMR, as a global emerging issue under Strategic Approach to International Chemicals Management (SAICM), so as to foster international exchange on the best ways to tackle this growing problem. SAICM has as its overall objective the achievement of the sound management of chemicals throughout their life cycle so that, by 2020, chemicals are produced and used in ways that minimise significant adverse impacts on human health and the environment.

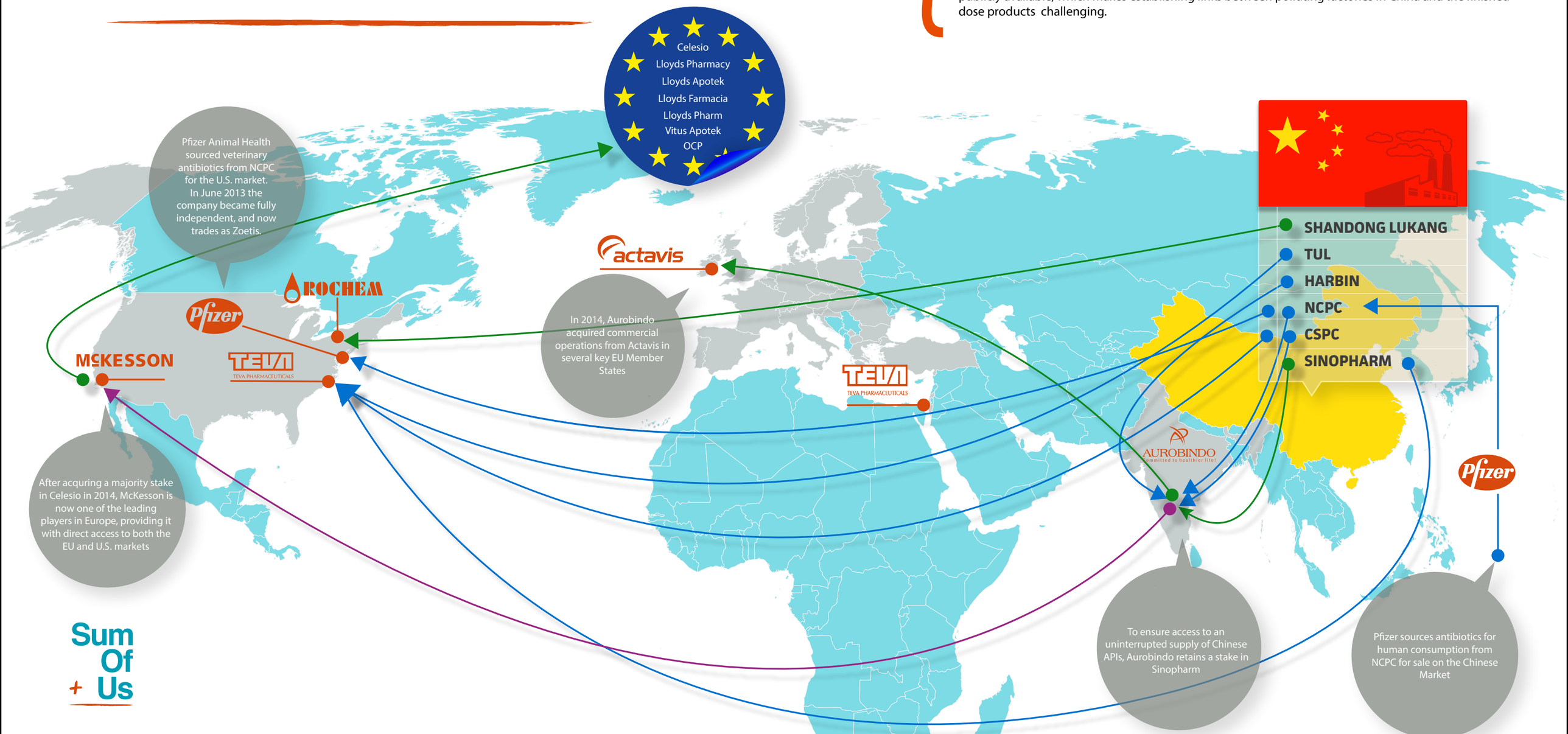
2. Include environmental criteria in the implementation of good manufacturing practices and make this part of the WHO global policy package to combat antimicrobial resistance. WHO has developed a draft global action plan for combatting AMR which was discussed by world governments in May. The WHO should include the impacts of pharmaceutical production on the development of resistant bacteria in its plan. In addition to this, WHO GMP guidelines should also be updated to include principles on environmental protection.

It is only by adopting a global and truly comprehensive approach to antibiotics manufacturing, with companies at every step of the way accepting responsibility for their actions, that the world will be able to prevent the dawning of a post-antibiotic era, where the contraction of a currently harmless infection once again becomes a potential death sentence. At present, this is neither part of the WHO's international strategy nor of action plans being developed at national level. It is time for the pharmaceutical industry to embrace transparency from the very beginning to the very end of the supply chain, and take on an active role in heading off a public health disaster of global proportions, a move that would once more make it part of the solution, rather than the problem.

+ Bad Factories & their Customers

The lack of transparency

Pharmaceutical supply chains lack transparency. In the EU, for example, importers must report the origin of APIs at their point of entry into the EU and prove that they have been manufactured in compliance with GMP. When importing finished dose products, they must also inform the authorities about where the product was manufactured when applying for its authorisation. However, none of this information is publicly available, which makes establishing links between polluting factories in China and the finished dose products challenging.



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LEGEND

- Imports antibiotics APIs from bad Chinese factories
- Imports from Aurobindo, which sources antibiotic APIs from several bad factories in China
- Other commercial ties (e.g. acquisitions, strategic supply arrangements, cooperation agreements)

Good manufacturing practices ?

To be able to import to the EU or to the U.S. market, companies need to prove that the products they are importing were produced in line with Good Manufacturing Practices (GMP). GMP criteria are not prescriptive and provide pharmaceutical manufacturers with flexibility on how to meet the minimum requirements to ensure that their product does not pose a risk to consumers. National authorities also have a right to inspect factories to verify whether GMP are being properly implemented. There are currently no GMP criteria on safety in the workplace or environmental protection - these depend exclusively on national legislation and enforcement.

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ACKNOWLEDGMENTS
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