Fighting 'Superbugs' With Next Generation Antibiotics

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Alarmed by the real health, economic and security risks associated with “superbugs” that are resistant to antibiotics — the lynchpins of modern medicine — President Obama has included anti-microbial resistance as a focus of his 26-nation partnership Global Health Security Agenda. He recently announced a Sept. 26, 2014, White House international conference that will highlight the countries’ commitment to prevent, detect and respond to infectious disease threats, including efforts to combat antibiotic resistant bacteria. In June, President Obama and G7 leaders committed to drive forward the development of a Global Action Plan on Antimicrobial Resistance with the World Health Organization. Health ministers from 194 countries have directed the WHO to consult widely with governments, industry and others and to complete a global action plan with concrete targets by May 2015. They specifically asked the WHO to collaborate with the U.N. Food and Agriculture Organization and the World Organization for Animal Health on an approach that brings together human health, animal health and agriculture.

WHO Director General Dr. Margaret Chan has indicated that the impacts and costs of the AMR crisis are already here. At a 20-nation meeting of health ministers in June, she stated that, “Drugs that were once lifesavers are now worthless. Hospitals have become hotbeds for the transmission of highly resistant superbugs, increasing the risk that hospitals kill rather than heal. For a growing number of serious infections, doctors are empty-handed. The rise of resistance has vastly outpaced the development of replacement drugs.”

In recent years, the global availability, use and overuse of antibiotics in both humans and animals has become widespread. Hundreds of millions of lives have been saved by antibiotics, but there has been inadequate attention given to the inevitable counter-threat of superbugs that become resistant to these life-saving drugs. Global leaders now see that despite this crisis, the pipeline of new antibiotics is nearly empty and investment in new antibiotics has been slashed — the antibiotics market is broken. Many large companies in the research-based pharmaceutical industry no longer view an antibiotic market dependent on short-term therapies to fight infections as the place where blockbuster drugs can be discovered.

Clearly, these antibiotic “wonder drugs” do not provide the commercial returns associated with drugs
that provide long-term treatments for chronic diseases and medical conditions, such as high blood cholesterol levels. The failure to develop a robust, sustainable pipeline of effective new antibiotics, treatments and diagnostics for infections means that diseases that had become survivable, and medical procedures that are now considered safe, routine and low cost, are becoming life-threatening once again, and treatment costs are rising.

It is very expensive to develop new antibiotics, and as they eliminate diseases and provoke resistance, they lose their market value. Leaders also fear that terrorists will try to take advantage of these vulnerabilities and the prevalence of superbugs to inflict great harm. U.K. Chief Medical Officer Dame Sally Davies warns of the possibility of a postantibiotic “apocalyptic scenario” and stresses that “this is an issue of markets and economics.” The current and potential costs of a failure to address AMR are obviously very high.

Academic and industry experts are now urging a new business model that rewards the development of new antibiotics, even if their use is carefully controlled and limited. Such experts argue that governments may need to commit in advance to purchase new antibiotics for a period of years and to help to defray research and development costs; fiscal incentives and longer patent periods may be part of the mix as well as higher payments (including reimbursements) and “orphan drug” approaches to facilitate getting new antibiotics to market more quickly and at lower cost. Experts believe that governments will also have to implement new regulations aimed at preventing infection and controlling the use of antibiotics in humans and animals.

Later this year, after extensive consultations, the WHO secretariat in Geneva will unveil an initial draft AMR global action plan which will be considered in January 2015 by 35 countries that are members of the organization's executive board. Assuming it is approved to go forward by consensus by the body, the AMR global action plan will be refined for consideration by the 194 health ministers of the member states at the WHO World Health Assembly in May.

The standards and policy guidance that will be recommended by the WHO in this action plan process can be considered as nonbinding “soft law.” Each nation must ultimately decide whether and how to adopt them and there is usually wide discrepancy as to uptake based on public health need, resource availability, regulatory sophistication and capacity and health infrastructure. The intense interest in this subject in the advanced economies means that WHO standards on such issues as mechanisms to promote drug innovation, development of key pathogen lists, surveillance protocols, intellectual property considerations and “stewardship” standards relating to curbing antibiotic overuse in both humans and animals could become critical regulatory and legal templates. In middle-income, developing countries and in large, emerging markets, adoption of standards and practices may also move forward fairly rapidly with the major challenges arising from inadequate implementation due to funding shortfalls and regulatory weakness. The ability of the poorest developing countries to join in a worldwide effort will depend largely on support and funding from the donor community.

At the WHO, the enormous complexity of designing standards to fight anti-microbial resistance on a global scale and defining policies to remedy the antibiotic market failure could easily fall prey to ideological battles, especially given the organization's ambivalence to cooperating with the private sector. Failure-causing ingredients abound in such a policy dialogue environment. These include poor nations with urgent needs and minimal resources, activists who are openly hostile to market-based solutions and commercial imperatives, a WHO secretariat looking for quick wins and deeply affected and concerned advanced economies, which know they need to get this policy right globally to begin to turn the tide on the AMR issue.
The WHO has already launched the policy development process with an online public consultation being held in June and July that is designed to solicit ideas from a broad range of stakeholders. Given the impact of this standard setting exercise on medical practices, pharmaceutical companies, animal husbandry and fisheries industries, agriculture, the global food chain — not to mention security considerations — the task ahead is daunting and the stakes high.

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