

US FDA sets up task force for antibacterial drugs

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New US FDA task force to support antibacterial drug development



Singapore: The US Food and Drug Administration has formed an internal task force that will support the development of new antibacterial drugs, a critical public health care goal and a priority for the agency.

As part of its work, the Antibacterial Drug Development Task Force will assist in developing and revising guidance related to antibacterial drug development, as required by the Generating Antibiotic Incentives Now (GAIN) Title of the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012.

Research and development for new antibacterial drugs has been in decline in recent decades, and the number of new FDA-approved antibacterial drugs has been falling steadily since the 1980s. During this time, the persistent and sometimes indiscriminate use of existing antibacterial drugs worldwide has resulted in a decrease in the effectiveness of these drugs. This phenomenon, known as antibacterial drug resistance or antibiotic resistance, has become a serious issue of global concern.

More than 70 percent of the bacteria that cause hospital-associated infections (HAIs) are resistant to at least one type of antibacterial drug most commonly used to treat these infections. In the US, nearly two million Americans developed HAIs in 2002, resulting in about 99,000 deaths.

"The creation of this new task force comes at a critical time," said Dr Edward Cox, director of the Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research and co-chair of the task force. "Establishing new ways of developing safe and effective new antibacterial drugs is an enormous challenge and not an effort that can be accomplished alone."

The task force is a multi-disciplinary group of 19 CDER scientists and clinicians who will use existing partnerships and collaborations to work with other experts in the field, including from academia, industry, professional societies, patient

advocacy groups, and government agencies, to identify priority areas and develop and implement possible solutions to the challenges of antibacterial drug development.

The task force plans to:

- Explore novel scientific approaches to facilitate antibacterial drug development, like the broader use of clinical pharmacology data, statistical methods, innovative clinical trial designs, use of additional available data sources, and the advancement of alternative measures to evaluate clinical effectiveness of potential new therapies;
- Identify issues related to unmet medical needs for antibacterial drugs, reasons for the lack of a robust pipeline for antibacterial drug development, and new approaches for weighing the risks, benefits, and uncertainties of potential new antibacterial drugs;
- Evaluate existing FDA guidances related to antibacterial drug development, determine if revision or elaboration is needed, and identify areas where future guidance would be helpful, as set forth in the GAIN Title of FDASIA; and
- Use existing collaborative agreements to work with think tanks and other thought leaders to explore various approaches that could enable antibacterial drug development, including innovative study designs and statistical analytical methods.

"By establishing this task force, FDA can help make real progress and change the paradigm," said Dr Rachel Sherman, associate director for Medical Policy in CDER, director of CDER's Office of Medical Policy and co-chair of the task force. "Our hope is that this effort will result in important new breakthroughs in the field of antibacterial drug development and help in the fight against antibiotic resistance."

The task force is part of FDA's efforts to promote antibacterial drug development and combat antibiotic resistance. Over several years, the agency has provided guidance to industry and hosted public workshops and meetings to address and discuss scientific challenges in the field of antibacterial drug development. The FDA also plays a key role in working with other federal agencies to implement a national plan to address antibiotic resistance.