

National Action Plan to Contain Antimicrobial Resistance (2016-2020)

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It does not describe anywhere exactly what are the problems in China that need to be addressed

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Has major weaknesses to use as examples

To promote the management of antibacterial agents and containment of bacterial resistance, and to protect the public health and guarantee harmonious economic and social development, the National Action Plan to Contain Antimicrobial Resistance was prepared.

I. Introduction



China is one of the major countries for the production and use of antibacterial agents. Antibacterial agents are widely used in healthcare and animal husbandry. It plays a significant role in treating infections and saving patient lives, preventing and treating animal diseases, improving farming efficiency, and guaranteeing public health security. However, antimicrobial resistance has become increasingly prominent due to insufficient research and development capacity of new antimicrobials, sales of antimicrobials without prescriptions in pharmacies, irrational use of antibacterial agents in medical and food animal sectors, non-compliant waste emissions of pharmaceutical enterprises, as well as lack of public awareness toward rational use of antimicrobials. Bacterial resistance ultimately affects human health, but the cause of bacterial resistance and consequences are beyond the health sector. Antimicrobial resistance brings increasing biosecurity threats, worsens environmental pollution, constrains economic development and other adverse effects to human society, thus, there is an urgent need to strengthen multi-sectoral and multi-domain collaborative planning to jointly cope with this issue.

II. The Goals of the National Action Plan

In order to deal with the challenge of antimicrobial resistance, the National Action Plan aims to establish comprehensive management strategies and measures on the national level for the overall implementation of strengthening the supervision of antimicrobial research and development, production, circulation, use and environmental protection, promoting advocacy and education, and international exchanges and cooperation. The following goals will be achieved by 2020:

1.To launch 1-2 new initiative antibacterial agents and 5-10 new diagnostic instruments and reagents.

2.The proportion of sales with prescription of antibacterial agents in retail pharmacies will be basically realized in whole country with full-coverage. The proportion of sales with veterinary prescription of antibacterial agents in animal sector will be realized in 50% in Provinces (autonomous regions and municipalities).

3.To optimize the surveillance networks of antibacterial agents consumption and antimicrobial resistance in both healthcare and food animal sectors; to set up reference laboratories of antimicrobial resistance and bacterial strain banks; to establish evaluation system for antimicrobials use and antimicrobial resistance control in healthcare system and animal husbandry.

4.To establish the antimicrobial stewardship program in secondary- and tertiary-level hospitals. To effectively control the increasing trend of the main antimicrobial-resistant bacteria in healthcare system.

5.The antimicrobials shared by humans and animals or easily producing cross-resistance should be gradually withdrawn from the market of animal growth promoters. To effectively control the increasing trend of the main animal origin antimicrobial-resistant bacteria.

6.To develop and implement educational efforts to ensure that medical staff, veterinarians and animal producers receive information and training of rational use of antibacterial agents. To implement education and training about rational use of antibacterial agents in primary and secondary schools. To set up publicity week of the rational use of antimicrobials.

III. Major Strategies and Actions

1.To exploit advantages of joint prevention and control, and fulfill the department responsibility.

National Development & Reform Commission and its subordinate organizations promote the R&D and industrialization of antibacterial agents; Ministry of Science & Technology and its subordinate organizations support the overall innovative research of antibacterial agents and antimicrobial resistance by setting up science and technology projects (e.g., special funds, grants, etc.); Ministry of Finance and its subordinate organizations arrange budget for antimicrobial resistance control and strengthen the budget for regulation and supervision; State Drug & Food Administrative and its subordinate organizations enhance the management of drug approval, production and circulation, particularly **strengthen the regulation of antimicrobials sales** with prescription in retail pharmacies; Ministry of Industry & Information Technology and its subordinate organizations optimize the policy of medicine industry and promote industrialization of green manufacturing of antibacterial agents; National Health & Family Planning Commission and its subordinate organizations are responsible for strengthening the **regulation of clinical use of antibacterial agents**, and coordinate and supervise implementation of the antimicrobial resistance control plan; State Administration of Traditional Chinese Medicine (TCM) and military healthcare authorities are responsible for the **regulation of clinical use of antibacterial agents in TCM institutions and army healthcare facilities**, respectively; Ministry of Agriculture and its subordinate organizations strengthen the regulation of producing, sale and usage of antibacterial agents in animal sector to decrease veterinary antimicrobial resistance; Ministry of Land & Resources and its subordinate organizations enhance capacity building of environmental surveillance of antibacterial agents in soil; Ministry of Environmental Protection and its subordinate organizations strengthen the prevention and control of environmental contamination, law enforcement, and capacity building of environmental surveillance associating with antibacterial agents, and stimulate the setup of the evaluation system for the indicators of antibacterial drug contamination; Ministry of Education and its subordinate organizations are responsible for including the knowledge of rational use of antibacterial agents into the health education in primary and secondary schools; Ministry of Culture and its subordinate organizations, State Administration of Press, Publication, Radio, Film and Television and its subordinate organizations rely on public media to promote public awareness and understanding of rational use of antibacterial medicines.

2.To increase investment in research and development of antimicrobials

1)To encourage the **research of molecular epidemiology and resistance mechanisms of antimicrobial resistant bacteria**. To timely track the development, spread and prevalence divergence of antimicrobial resistant bacteria in different geographic areas, population, medical institutions, and animals. To increase investment in fundamental research to elucidate bacterial pathogenicity and resistance mechanisms, and subsequently provide scientific evidence for making strategies of resistance control and the R&D of new drug and technology.

2)To Support the R&D of new anti-infection drugs, apparatus and instruments, and vaccines. To strengthen the deployment of prevention and control for antimicrobial resistant bacteria, and support the R&D of new anti-infection drugs, especially the drugs with diverse action mechanisms and molecular structures; **To support the R&D of rapid** diagnostic tools for the infections of antimicrobial resistant bacteria, especially the ones able to rapidly distinguish bacterial infections from non-bacterial infections, **to rapidly identify antimicrobial resistant bacteria**, and the microbial identification instrument suitable for use in primary medical institutions; To support the R&D of vaccines for antimicrobial resistant bacteria. To promote the **R&D of veterinary-use antimicrobials**, **new disease-prevention strategies and products of growth promotion for animals to replace antimicrobials**.

3)To support the **research of diagnosis, treatment and control for the infections of antimicrobial resistant bacteria**. To improve the capacity of clinical treatments for infectious diseases, the strategies include novel treatment regimen for antimicrobial resistant bacterial infections, dosage optimization, and **reevaluation of antimicrobials that are rarely used in clinics**.

4)To conduct the **research on controlling environment contamination** caused by antibacterial agents, including the development of de-contamination technology, and renewal technology for antimicrobial contaminated water and soil.

3.To **strengthen the management of antibacterial agents supply security**.

1)To improve the administration of **antibacterial agent registration**. According to the reform of the evaluation & approval system for drugs, the pre-market approval of antibacterial agents will be stringent. At the same time, the **novel innovative drugs, equipment, and vaccines used for antimicrobial resistant bacterial infections** will be prioritized for the pre-market evaluation & approval. **To setup the evaluation system for the antimicrobial-caused environmental hazards, and conduct the evaluation of antimicrobial-caused environmental hazards** for the registration of medicine, veterinary drugs and fertilizers.

2)To strengthen the management of production and circulation of antibacterial agents. To enhance the **regulation of antibacterial agents on production** and circulation. To implement measures of antimicrobials sales with prescription in retail pharmacies, forbid antimicrobials sales online, and combat the sales of counterfeit and shoddy antimicrobials. Retail pharmacies are required to keep prescriptions for inspection, and any actions to evade the rule of antimicrobials sales with prescription will get increased punishment.

3)To promote upgrading of antibacterial drug industries. To improve the policy of medicine industries, guide enterprises to develop novel antibacterial

agents, and support the industrialization of novel antibacterial agents. To promote the merger and reorganization of antibacterial enterprise, and encourage the application of new technology and apparatus for the technological transformation and green manufacturing of antibacterial agents.

4.To strengthen the construction of antibacterial agent application and antimicrobial resistance control system.

1)To **standardize management of clinical application** of antibacterial agents and implement antimicrobials stewardship program. To strictly implement the relevant provisions such as Drug Administration Law, The Regulations of Medical Institutions, Prescription Administrative Policy, Pharmaceutical Affairs Management of Medical Institutions, The Administrative Regulations of Clinical Application of Antibacterial Drugs, Management of Hospital Prescription Evaluations (Trail), The Guidelines for Clinical Application of Antibacterial Drugs, and so on. To encourage the establishment of multidisciplinary cooperation mechanisms in hospitals. Multidisciplinary working groups consist of clinical departments; infectious diseases unit, clinical microbiology unit, pharmacy and hospital infection management unit to enhance the implementation of antimicrobial stewardship program. To continuously carry out the surveillance of clinical consumption of antibacterial agents and antimicrobial resistance. To timely release the survey results, and make effective use of the survey results. To strengthen the capacity building of clinical staff, especially personnel of primary healthcare institutions, in the rational use of antibacterial agents. To improve the environment of medical institutions and healthcare, and strengthen the management of hospital infections. To greatly enhance the construction of information systems of medical institutions for antibacterial agent management through information-based methods, and gradually achieve scientific and efficient management to establish a sustainable development system of resistance control.

2)To strengthen the supervision and management of veterinary antibacterial agents. To formulate the application guidelines and administrative regulations of veterinary antibacterial drugs, and timely revise application specifications of animal feed additives and banned drug list. To implement veterinary drug classification management system and practice system of veterinary antibacterial agents sales with prescription. To strictly manage various sale channels of raw antibacterial drugs. To implement clean animal breeding, strengthen animal farm sanitation management, improve the animal breeding manner and guarantee animal health. To strengthen the management of animal feed additives, reduce preventive use of sub-therapeutic concentration antimicrobials, forbid husbandry use of important human antibacterial agents, intensify risk assessment of veterinary antibacterial agents, and speed up the elimination of high-risk drugs. To establish the classification schemes of human and veterinary antibacterial drugs to define different types of antibacterial drugs, and classify the levels of these agents on the basis of drug importance, cross resistance and clinical application.

5.To optimize antimicrobials consumption and antimicrobial resistance surveillance system.

1)To optimize antimicrobials consumption and antimicrobial resistance surveillance network in clinics. To set up a national surveillance center for clinical antimicrobials consumption and antimicrobial resistance on the basis of existing resources. The center is responsible for the surveillance of antimicrobials use and antimicrobial resistance in healthcare settings. The center is also responsible for developing surveillance standards and protocols, and launching the surveillance into practice. In order to improve the performance, universal survey, active monitoring and target bacterial monitoring will be implemented. To obtain the comprehensive data of antimicrobial resistance epidemiology, the surveillance system is expected to cover the tertiary, secondary and primary healthcare institutions, and both inpatients and outpatients will be included in the monitoring objects.

2)To establish and improve the surveillance network of antimicrobials consumption and antimicrobial resistance in animal breeding. To set up a national surveillance center of animal antimicrobials consumption and antimicrobial resistance on the basis of existing resources. The center is responsible for surveillance of antimicrobials consumption and antimicrobial resistance in livestock, developing the surveillance standards and protocols, and launching the surveillance into practice. In order to improve the performance, universal survey, active monitoring and target bacterial monitoring will be implemented. To get the epidemiological data of animal origin antimicrobial-resistant bacteria, the surveillance will cover different geographic areas, various animal breeding methods, different farming sizes (households) and the markets of representative animal products (food).

3)To develop interactive mechanisms between health care system and breeding industry in the surveillance of antimicrobials consumption and antimicrobial resistance; to achieve the mutual reference of the data from the two areas. In order to provide the evidence for strengthening the management of antibacterial use in healthcare and animal industry, a scientific and reasonable evaluation system will be established.

4)To establish antimicrobial resistance reference laboratories and bacterial strain banks. The laboratories are responsible for identifying antimicrobial-resistant bacteria, standardizing the resistance research and surveillance technology, collecting and storing the antimicrobial-resistant isolates, and providing type strains for clinics and research.

6.To improve the capacity of professional personnel in antimicrobial resistance prevention and control

1)To strengthen the training of med-pharm students. To encourage med-pharm schools and universities to set up the course of rational use of drugs. To encourage agriculture and forestry universities to set up the course of animal infectious disease therapy.

2)To strengthen the training of professional healthcare staff. To enhance the training of professional personnel in rational use of antimicrobials and antimicrobial resistance, especially in infectious diseases, clinical pharmacy, and clinical microbiology, to meet the requirement of staffing healthcare institutions with proper number of practitioners. To strengthen continuing education of healthcare staff in rational use of antimicrobials and antimicrobial resistance. Healthcare staff should have a certain number of continuing education and get CME points.

3)To strengthen the education of the animal industrial practitioners and veterinarians. To train and strengthen the veterinary team. To enhance the education of rational use of antimicrobials among the veterinarians and breeding industrial practitioners. To promote the implementation of related regulations, and improve rational antimicrobials use in veterinary settings by conducting regular or irregular trainings.

7.To strengthen the prevention and management of environmental pollution of antimicrobials

From the perspective of planning and planning environmental impact assessment (EIA), to strictly choose the sites for antibacterial pharmaceutical companies and EIA must be strictly enforced in the new setup, reconstruction, extension of antibacterial pharmaceutical projects. To accelerate formulating the evaluation system for indicators of antimicrobial pollution, and strengthen environmental law enforcement on antimicrobials contamination. To improve the capacity-building of surveillance techniques and regulations about antimicrobials environmental pollution in water, soil, and solid waste. To carry out research on the ecological impact of antibacterial agent contamination, develop the prevention and management strategies of antimicrobials environmental pollution, and promote the emission reduction of antibacterial agents waste.

8.To strengthen publicity and education of antimicrobial resistance

To improve awareness and understanding of antimicrobial resistance through widely promoting the knowledge of rational use of antibacterial agents via traditional media (e.g., radio, television) and new media (e.g., Internet, micro-blog, WeChat, etc.). To combine the rational use of antibacterial agents with construction of a new socialism countryside project, bring scientific and literacy knowledge and medical services to rural areas, and integrate other policies of supporting and benefiting agriculture, rural areas and farmers to remove the unnecessary antimicrobials use. To conduct popular science education and publicity activities of rational antimicrobials use and antimicrobial resistance in primary and secondary schools to establish view of antimicrobials rational use from childhood. Healthcare institutions should strengthen education of rational antimicrobials use for patients and correct the behavior of self-medication of antibacterial agents. A publicity week on rational use of antimicrobials should be held regularly and promotion activities with the WHO should be carried out every year.

9.To conduct extensive international exchanges and cooperation

To actively participate in activities organized by international organizations such as WHO, OIE and FAO, including the development of prevention and control strategies and technical standards, antimicrobials consumption and antimicrobial resistance surveillance, and personnel training and seminars. To collaborate with other countries and regions in anti-microbial resistance surveillance to control cross-border spread of anti-microbial resistant strains. To share antimicrobial resistance surveillance data and research achievement with international community to develop joint global control strategies for international hazard antimicrobial-resistant bacteria. To participate in international collaborative research to support the development of novel techniques and drugs for resistance control. To actively assist countries and regions in need to carry out drug resistance control activities.

IV. Supporting and guaranteeing measures

1.To strengthen security investment. According to government health input policy, economic and social development and antimicrobial resistance trend, investment in the containment of antimicrobial resistance should be increased for the establishment of drug resistance control related facilities, equipment and personnel training. To link task completion and performance evaluation results of containment of antimicrobial resistance to government financial compensation.

2.To exert professional power. To set up National Consultative Expert Commission of Antimicrobial Resistance Containment, which consists of experts of medicine (basic and clinical medicine, TCM), veterinary medicine (veterinary drugs), microbiology, pharmacy, biological pharmaceuticals, health management, environmental protection, commercial circulation management, epidemiology, biological statistics, economics, education, media and information technology. The Commission provides consultation and policy recommendations for the management of antibacterial agents and containment of antimicrobial resistance. By referring to the organization of the Commission, local areas can set up local consultative committees for containment of antimicrobial resistance.

3.To strengthen supervision and inspection. According to the requirements of this action plan, the work objectives and tasks should be distributed to specific departments and implemented responsibly. Relevant authorities should regularly inspect annual work situation, especially the antimicrobials use in healthcare and agriculture, sales with prescription in retail pharmacies. Failure to comply and violations will be punished to ensure the effective implementation of the action plan.

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