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Antimicrobial Resistance Increased by Antibiotic Residue in Food: The Need to Strengthen the Legal Framework in India

SANTHIYA KS¹

ABSTRACT

Antimicrobials are antibiotics, antivirals, antifungals and anti-parasites, medicines used to prevent and treat infections in plants, animals, and humans. Antimicrobial resistance is when any viruses, fungi, bacteria and parasite no longer reacts to medications, making infections more difficult to manage and raising the risk of disease transmission, serious illness, and death. The World Health Organization has listed antimicrobial resistance as one of the top 10 threats to global health in 2019. Apart from causing being a threat to global health, it also affects the economies of the States as it disrupts the working cycle of patients and their caretakers while also increasing the burden on the healthcare systems. There are multiple reasons behind the spreading and emerging of the antimicrobial resistance and one of them is the extensive use of antimicrobials in agriculture, animal husbandry practices. The sale of anti-microbial drugs in India is regulated under the Drugs and Cosmetics Rules 1945, however animal feed laced with antibiotics are not medicines and do not fall under the purview of these rules and are not regulated by the Central Drugs Standard and Control Organization. The Food Safety and Standard (Contaminants, Toxins and Residues) Regulations, 2011 prescribes the maximum limits on contaminants present in the food sold in the market including antimicrobial drugs, while there are no regulatory mechanisms to check the residue limits in food sold. This paper deals with the problems existing with increased usage of antimicrobial drugs for veterinary purposes and the same translating to affecting public health of humans. The paper concludes with suggestions to address the issue ranging from classification of drugs for veterinary purposes and humans, periodical surveys, enhancing research institutes and creating public awareness.

I. BACKGROUND

Antimicrobials are antibiotics, antivirals, antifungals and anti-parasites, medicines used to prevent and treat infections in plants, animals, and humans. Antimicrobial resistance (AMR) is

¹ Author is a student at Tamil Nadu National Law University, India.

when any viruses, fungi, bacteria and parasite no longer reacts to medications, making infections more difficult to manage and raising the risk of disease transmission, serious illness, and death. Because of AMR, the medicines used to treat antimicrobial infections do not work on them and making treatment more complex and sometimes impossible. Surgeries such as caesarean sections, organ transplantations, chemotherapy become more difficult to handle in absence of antimicrobial drugs that are effective.

Antibiotics are drugs that are used to prevent and treat infections caused by bacteria. Antibiotic tolerance develops as bacteria evolve in response to antibiotic treatment. Bacteria, not humans or animals, develop antibiotic resistance. These bacteria can infect humans and animals, and their infections are more difficult to treat than those caused by bacteria that are not immune to antibiotics. Antibiotic resistance is the product of resistance to antibiotics.²

The World Health Organization (WHO) has listed antimicrobial resistance as one of the top 10 threats to global health in 2019.³ Apart from causing being a threat to global health, it also affects the economies of the States as it disrupts the working cycle of patients and their caretakers while also increasing the burden on the healthcare systems⁴. November 18-24 is the World Antimicrobial Awareness Week.

There are multiple reasons behind the spreading and emerging of the antimicrobial resistance⁵. They are one, misuse or overuse of antimicrobials, this is either because of excess or inappropriate prescription by medical professionals, or unauthorized antimicrobials being sold in the market for consumption. Two, humans and animals lack of access to clean water, sanitation and hygiene. Three, poor disease control and prevention mechanisms. Four, lack of access to appropriate medicines, vaccines, diagnostics. Five, extensive use of antimicrobials in agriculture, animal husbandry practices. The fifth reason will be the focus of the paper.

Antibiotics kill or suppress susceptible bacteria in food-producing animals, allowing antibiotic-resistant bacteria to survive. Humans are exposed to resistant microorganisms through the food supply as they consume animal produce and products that carry them.⁶ This is the chain of transmission of resistant microbes to humans from animals through food supply.

² *Anti-biotic resistance*, WHO, <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>.

³ *Ten threats to global health in 2019*, WHO, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>.

⁴ *Antimicrobial resistance*, WHO, <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>.

⁵ *Ibid.*

⁶ Centers for Disease Control and Prevention, Office of Infectious Disease Antibiotic resistance threats in the United States, 2013. Apr, 2013. Available at: <http://www.cdc.gov/drugresistance/threat-report-2013>. Accessed January 28, 2015.

(A) Antibiotics residues in Honey from India

In 2010, the Centre for Science and Environment, India published a report on the presence of antibiotics residues in honey that was being sold to Indian Consumers in the market.⁷ It highlighted that antibiotics are being used by beekeepers at relatively high doses to treat clinical infection affecting the bees and in low doses as growth promoters.⁸ This use of antibiotics makes it less labor intensive for the beekeepers and more profitable the report remarked. The report clearly identified that the chemicals have been approved for use world-wide for fighting bee diseases and acceptable daily intakes have been established by one, Joint Food and Agriculture Organisation and WHO Meeting on Pesticide Residues (JMPR), two, the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Maximum residues limits have been established for all food producing species for certain chemicals but the maximum residue limits have not been prescribed for honey in India it noted. As a result of this report, matter was taken up by Food Safety and Standards Authority of India (FSSAI) which issued an advisory in this regard in 2010, to state that pesticide and antibiotic residues were not allowed in honey. In 2014, the Food Safety and Standard (Contaminants, Toxins and Residues) Regulations, 2011 was amended to set the tolerance limits of antibiotics residue in honey, beyond which the antibiotics shall not be found in honey sold in the market.

(B) Antibiotic residues in milk from India

The National Milk Safety and Quality Survey by FSSAI was carried out from May 2018 to October 2018 covering all states and Union Territories. A total of 6,433 sample were collected, which included organized sector such as the retailers and processors as well as from no organized sector such as the local dairy farms, milk vendors and milk mandis. The survey showed that 1.2% of the samples i.e., 77 samples had antibiotic residue beyond permitted limits. While 77 samples resemble a smaller sum on comparison, the sample was chosen from towns/cities with population above 50,000, which in conversion to say that milk supplied to around 38 lakh people has antibiotic residue than the permissible limit, which is a concern.

II. ACTION ON ANTIMICROBIAL RESISTANCE IN INDIA

(A) National Action Plan on Antimicrobial Resistance

Government of India framed a national plan for to fight antimicrobial resistance from 2017 to 2021. The plan was developed along with the support of World Health Organization. In India, the impact of AMR on livestock and food animals has been poorly reported notes the plan.

⁷ *Antibiotics in honey*, DOWN TO EARTH, <https://www.cseindia.org/antibiotics-in-honey-1727>.

⁸ Ibid. Pg.9, 4.3 Antibiotics authorized in Beekeeping.

Evidence that can be extrapolated to the national level is scarce, apart from intermittent, limited, localized studies. Given India's regulations prohibiting the use of antibiotics for non-therapeutic purposes is very few, AMR from antibiotic overuse in the animal sector is likely to be an unquantifiable threat remarks the report.

(B) National Programme on the Containment of Antimicrobial Resistance

It was launched under National Centre for Disease Control under the 12th Five Year Plan (2012-2017). The program's goals were to develop a laboratory-based AMR surveillance system with 30 network laboratories, producing high-quality data on AMR for pathogens of public health concern; to improve infection control guidance and procedures, promoting rational antibiotic use; and to raise antibiotic use awareness among healthcare providers and the general public.

(C) Antimicrobial Resistance Surveillance Research Network

The Indian Council of Medical Research developed a national network for antimicrobial resistance surveillance in tertiary care academic centres, with a focus on WHO-identified medically significant index microbes. In 2017, the Indian Council of Medical Research, in partnership with the Indian Council of Agriculture Research, launched a project to understand the gaps in antimicrobial susceptibility testing and to fill those gaps through capacity building activities using structured methodology.

III. LEGAL REGULATIONS IN INDIA

(A) Delhi Declaration on Antimicrobial Resistance

An inter-ministerial consensus endorsed by Ministries of Agriculture and Farmer Welfare, AYUSH, Chemicals and Fertilizers, Consumer Affairs Food and Public Distribution, Drinking Water and Sanitation, Environment and Forest and Climate Change, Finance, Food Processing Industries, Health and Family Welfare, Human Resource Development, Information and Broadcasting, and Science and Technology at the inter-ministerial consultation on antimicrobial resistance in New Delhi on 19th April 2017.

(B) Food Safety and Standard (Contaminants, Toxins and Residues) Regulations, 2011

The rules prescribe maximum residue limits of contaminants, toxins and residues allowed in food. It prescribes limits on metal contaminants, crop contaminants, naturally occurring toxic substances, insecticide residues, and antibiotic and other pharma – cologically⁹ active

⁹ Pharmacology means the properties and reactions of drugs especially with relation to their therapeutic value, definition by Merriam Webster.

substances¹⁰. The section 2.3.2. has four sub sections.¹¹ The first one deals with 4 antibiotics and the tolerance limits of these 4 antibiotics in sea foods, any fish variety and fishery products. The second one lists down 19 antibiotics which is prohibited from being used in any stage of processing meat, meat products, poultry and eggs, sea foods, fish and fishery products. However, the maximum residue limits have been prescribed on these 19 antibiotics as 0.001 mg/kg.¹² The third section deals with antibiotics limits in honey. The fourth section deals with antibiotics and veterinary drugs and the tolerance limits on food including but restricted to all edible animal tissues¹³, milk, fats derived from animal tissues. There are a total of 103 antibiotics/veterinary drugs for which the tolerance limits have been prescribed.

(C) Drugs and Cosmetics Rules 1945

The amicrobial are placed in the schedule H1 since 2014.¹⁴ On labelling of medicines belonging to Schedule H1, the drug has a warning that says it is dangerous to consume without medical advice and that it is not be sold without prescription of registered medical practitioner.¹⁵ This warning in itself creates a dilemma while it says it will not be sold without the prescription, it also warns that it is dangerous to consume without medical advice. If the drug is never going to be sold without a prescription, then the first warning that it is dangerous to consume without medical advice would become redundant and goes on to give an idea that there are instances that it may get sold without prescription which is an alarming issue in itself. The issue of medicines being sold without medical prescription is not new in India¹⁶.

The medicine container for treatment of food producing animals are to be compulsorily labelled with the withdrawal period of the drug¹⁷. *“The withdrawal period is the period of interval between the last administration of a veterinary medicine to animals under the normal conditions of use and the production of food stuff from such animals to ensure that foods do not contain the residues in quantities in excess of maximum residue limits laid down”*. In cases where the withdrawal period has not been mentioned, the withdrawal period should not be less

¹⁰ Section 2.3.2. in chapter 2 of the Food Safety and Standard (Contaminants, Toxins and Residues) Regulations, 2011.

¹¹ The compendium of contaminants of the regulation referred to is version – V (19.08.2020).

¹² Except for Chloramphenicol for which the MRL is 0.0003 mg/kg.

¹³ It includes fish.

¹⁴ Section: 1.2.5 on Use of antimicrobials, National Action Plan on Antimicrobial Resistance, Govt. of India, 2017.

¹⁵ Rule 97, (1) (e), Drugs and Cosmetics Rules 1945.

¹⁶ *Police ask pharmacies not to sell select drugs without prescription*, TIMES OF INDIA, <https://timesofindia.indiatimes.com/city/madurai/police-ask-pharmacies-not-to-sell-select-drugs-without-prescription/articleshow/75498109.cms>; *Karnataka to track sale of fever, cold medication*, MINT, <https://www.livemint.com/news/india/karnataka-sixth-state-to-bring-paracetamol-under-prescription-11587651517507.html>

¹⁷ Rule 97, (3A), Drugs and Cosmetics Rules 1945.

than 7 days in case of eggs or milk and 28 days in case of meat from poultry and mammals and 500 degree days for fish meat. The major challenge here is that there is no monitoring to check that the withdrawal period is being duly followed by the owners of animals who are dependent on animal husbandry/fisheries as a means of their livelihood¹⁸, or large scale of animal husbandry or fisheries for profit business¹⁹, and there is nothing to prevent them from selling the animal produces in the period of withdrawal prescribed. It is not that the consumer on buying the products check for the antibiotic residues, and that their awareness level on the subject can be minimal or null. In fact, the WHO has been focusing on spreading awareness regarding antibiotics resistance as part of its global action plan.

(D) National Livestock Policy 2013

The policy emphasizes on the need to ensure quality, safety and suitability of food for human consumption in the food sector. It states that the livestock origin food and food products have to be free of contaminants, toxin toxins, pathogens, pesticides and antibiotic residues, harmful additives and adulterants. It also states that the it would promote awareness among the farmers and consumers regarding food safety standards.

IV. SUGGESTIONS AND CONCLUSION

India needs to develop strict antimicrobial use policies for both humans and animals. In accordance with WHO recommendations, it would be in the national interest to control the use of antibiotics when they are absolutely required and to limit their use when they are not. The Food and Drug Administration of the United States had refused shrimp as they were anti-biotic contaminated which included the export stocks from various countries including China, India, Vietnam.²⁰ The report shows that the amount of shrimp refused by F.D.A in 2021 till april month has crossed the total of refusals in all of 2020.²¹ India's Marine Products Export Development Authority has given a shrimp hatchery in Andhra Pradesh a certificate of antibiotic-free production as per its statement in 27th April, 2021. This is the first such hatchery to receive the SHAPHARI certification which in Sanskrit means "superior quality of fishery

¹⁸ *Our daily dose of antibiotics*, DOWN TO EARTH, <https://www.downtoearth.org.in/news/food/our-daily-dose-of-antibiotics-71804>.

¹⁹ *Reluctant game-changers: Why fast food cos in India drag their feet over antibiotics misuse*, DOWN TO EARTH, <https://www.downtoearth.org.in/news/food/reluctant-game-changers-why-fast-food-cos-in-india-drag-their-feet-over-antibiotics-misuse-70880>.

²⁰ *In First Quarter of 2021, FDA Refuses Almost as Much Antibiotic-Tainted Shrimp as All of 2020*, SHRIMP ALLIANCE, <https://www.shrimpalliance.com/in-first-quarter-of-2021-fda-refuses-almost-as-much-antibiotic-tainted-shrimp-as-all-of-2020/>.

²¹ *Through April, the FDA Has Already Refused More Antibiotic-Contaminated Shrimp Than All of 2020*, SHRIMP ALLIANCE, <https://www.shrimpalliance.com/through-april-the-fda-has-already-refused-more-antibiotic-contaminated-shrimp-than-all-of-2020/>.

product suitable for human consumption”. While this seems a positive move, the Authority is concerned with the export as is clearly understandable by its name and the authority is for export of marine products. It is clear that the U.S has clearly been taking serious efforts on the matter relating to anti-biotic resistance, while our country’s efforts have rather been slow and continues to remain non-implemented on multiple ends.

i. The poultry feed that come packed with antibiotics are not regulated in India as per the study published in Down to Earth.²² They are being used since such feed allow farm animals to attain maximum weight in few days, which would translate to lesser feed consumption. The issue is of serious nature as a variety of antibiotics such as Ciprofloxacin and levofloxacin are being used in these poultry feed, these are the drugs used to treat tuberculosis in humans and therefore antimicrobial resistance development fueled by these drugs is a life threatening issue. The antibiotics are regulated by the Central Drugs Standard and Control Organization (CDSCO) under the Ministry of Health and Family Welfare and as already discussed are placed in schedule H or H1 that makes prescription mandatory. However, the feed is not a medicine and it outside of the purview of the CDSCO. The suggestion therefore is that it should be either banned or restricted to a larger extent, which is a recommendation as proposed in a paper published in the Indian Journal of Medical Sciences²³ and available at Indian Council Medical Research - India's Antimicrobial Resistance Surveillance & Research Initiative, website’s publications.²⁴

ii. With new antimicrobial drugs in the pipeline, it would be necessary to reserve those antibiotic groups for human use, and these antibiotics should not be used in animals. This classification is backed by the findings of the research²⁵ by Indian Council of Medical Research along with Indian Council for Agriculture Research. In 2017, ICMR organized a meeting in this regard and observed that the antibiotics that are crucial for human use shall be not allowed to be for veterinary reposes. It can also be traced to the strategic priorities of the National Plan on AMR in which the goal number four deals with optimizing the use of antimicrobial agents in health, animals and food.

iii. Monitoring mechanisms such as expanding the lab facilities for checking for microbial residue in food would be essential. Conducting periodic surveys of the food being sold on the

²² *Perpetually on antibiotics*, DOWN TO EARTH, <https://www.downtoearth.org.in/news/health/perpetually-on-antibiotics-70353>.

²³ Kamini Walia, Monica Sharma, Sonam Vijay, & Bibek R. Shome, understanding policy dilemmas around antibiotic use in food animals & offering potential solutions, *Indian J Med Res* 149, February 2019, pp 107-118.

²⁴ Indian Council Medical Research - India's Antimicrobial Resistance Surveillance & Research Initiative, <http://iamrsn.icmr.org.in/index.php/publications>.

²⁵ Supra at 22.

market for antibiotic residue would prove crucial to identify the class of antibiotic that are being used in food producing animals, which then can help in regulating that particular drug or class of drugs being used as antibiotics in animals. The National Policy on AMR by Govt. of India recognizes 6 priorities, among which the second goal deals with strengthening knowledge and evidence through surveillance and fifth goal deals with promoting investments for AMR activities, research and innovations.

iv. Improving awareness among farmers, consumers, veterinarians, pharmacists, policy makers on this issue. The suggestion is backed multiple policies focusing on this issue such as the World Health Organization's goal as part of its Global Action Plan in which the first strategic objectives deals with improving awareness and understanding of antimicrobial resistance. This suggestion can also be traced to the strategic priorities of the National Plan on AMR to goal number one that deals with improve awareness and understanding of AMR through effective communication, education and training.

v. Although as per the labelling rule under the Drugs and Cosmetics Rules 1945, the antibiotics are noted as dangerous, the same is provided in English and that hampers the accessibility of the message on population that does use English as their language, in which the role of pharmacists and veterinarians become crucial to explain the consumers of these antibiotics regarding the effects of this drug.
