To: Jagat Prakash Nadda; Union Minister of Health and Family Welfare for the Government of India

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RE: Pharmaceutical Distribution Reform Recommendations for Decreasing Antimicrobial Resistance in India

**Executive Summary:**

As India endeavors to lose its United Nations designation as a developing country, the population is growing and average income is increasing.[[1]](#footnote-1) However, prices of antibiotics are decreasing and a high rate of infectious disease continues, leaving India as a country with overwhelming rates of antimicrobial resistance due to the overuse of antibiotics.[[2]](#footnote-2) Current programs focus on national and international collaboration, addressing broad issues that implicate antimicrobial resistance, but more specific strides must be made in over-the-counter prescriptions of antibiotics and the role of pharmacists in the drug distribution system. Moving forward two major recommendations are made to deal with these situations: decreasing self-medication by increasing community awareness of it and promoting the status of pharmacists to that of physicians to increase their involvement in the distribution of antibiotics to the citizens of India.

**Background:**

As the Government of India is aware, India has the highest burden of infectious disease in the world, due to a lack of expenditure on public health initiatives and high population density in many areas.[[3]](#footnote-3) Consequently, in 2010 India was the largest consumer of antibiotics in the world.[[4]](#footnote-4) Antibiotics are typically an effective treatment for these diseases, but with their increasing and inappropriate use in India, antimicrobial resistance has become a significant problem. With growing antimicrobial resistance, common antibiotics are losing their ability to treat infectious diseases, so drugs at the country’s disposal are becoming useless. The major implications of this issue involve the distribution and prescription of the drugs in hospital, clinical, and pharmacy settings.[[5]](#footnote-5) Specifically, antibiotics are frequently prescribed in incorrect doses, duration, frequencies, for the wrong diseases, and without regard to possible interactions that may occur with other drugs. A common example of this is the prescription of antibiotics for common cold and diarrheal diseases in which they are ineffective and inappropriate.[[6]](#footnote-6) India is a country with such high instances of similar diseases that mis-prescription of antibiotics is creating major health issues for its citizens, but the Government has recently taken major interest in addressing this problem.

The first major action by the Ministry of Health and Family Welfare on antimicrobial resistance in India, was the National Policy for Containment of Antimicrobial Resistance set in 2011.[[7]](#footnote-7) However, the program was put on an indefinite hold when the over-ambitious goals could not be realized as they were broad and difficult to tackle.[[8]](#footnote-8) Such goals included: gathering data on antibiotic use in the country at that time, creating a surveillance system for resistance as well as a monitoring system for drug prescription, enforcing regulations in veterinary and industrial use of antibiotics, and implementing interventions on using antibiotics appropriately in health settings.[[9]](#footnote-9) Following the downfall of this program, the Government of India worked with Indian medical societies to establish the Chennai Declaration. Put in place in late 2012, this was a roadmap set out to establish antimicrobial stewardship in India by regulating over-the-counter prescription of antibiotics. However, the diversity of the health care system across India has made it increasingly hard to uniformly implement its major initiatives, as the quality and commitment of drug dispensaries across the country vary greatly.[[10]](#footnote-10) Nonetheless, it should not be ignored that this declaration sparked a major increase in awareness and concern amongst Indian medical societies and programs on the issue of antimicrobial resistance.

The Ministry of Health and Family Welfare has past experience working with the World Health Organization and contributes to the Global Action Plan on Antimicrobial Resistance (GAP-AMR) that is currently underway across the globe. The focus of the GAP-AMR is to improve awareness of antimicrobial resistance, improve surveillance and research, reduce incidence of infection, use antimicrobials appropriately in animal and food sectors, and create sustainable economic conditions in all countries to deal with this problem.[[11]](#footnote-11) An additionally ongoing program is the National Action Plan on Antimicrobial Resistance in effect from 2017-2021 with the same goals as the GAP-AMR with an additional intention to strengthen India’s own leadership and autonomy in dealing with their own antimicrobial resistance problem at the national, state, and local level.[[12]](#footnote-12) Although it is too early to see this plan actualized, there are good intentions by the Indian Government.

**Analysis:**

A major cause of this issue is that many antibiotics are still attainable as over-the-counter drugs. The current justification for non-prescription drug use is to allow those who cannot receive medical attention to still utilize medications, however, this has ultimately led to widespread use in all socioeconomic populations in India.[[13]](#footnote-13) A study in Bangalore, India found that in two-thirds of the pharmacies they observed within inner city areas, non-prescription antibiotic distribution occurred which ultimately increases resistance and costs of health care.[[14]](#footnote-14) So the current rationalization of non-prescriptions antibiotics pertaining only to poor, rural areas is untrue and it is occurring throughout the country.

 As an original intention of the Chennai Declaration previously mentioned; in March 2014, the Central Drugs Standard Control Organization (CDSCO) increased antibiotics to a stricter distribution schedule from H to H1. Now, a prescription by a registered medical practitioner is needed, the packaging contains warning labels, and pharmacists are required to register details of the drug distribution including who, by what medical professional, and how much of the drug was given, which were not previously common.[[15]](#footnote-15) However, only 213 pharmacies have adopted this and it only includes 24 antibiotics at this point, excluding several common antibiotics that are first-line drugs.[[16]](#footnote-16) In terms of antimicrobial resistance, a current concern is that antibiotic distribution must be controlled but still made accessible to the people who actually need them as it was found that lack of access to effective and affordable antibiotics still kills more children in India than does drug resistance.[[17]](#footnote-17)

Although the Government of India is making major strides with its current initiatives such as GAP-AMR and National Action plan on Antimicrobial Resistance, anticipated issues pertain to the pharmacists and community pharmacies that disseminate drugs. Neither are directly addressed in these programs, as they focus more on broad-scale issues which are also very important. The current structure of drug distribution in India is titled community pharmacy and includes: legally acknowledged drug stores (without a working registered pharmacist), chemists and druggists (with a registered pharmacist that distributes ready-made drugs), and pharmacies (have a registered pharmacist working that can give prescriptions).[[18]](#footnote-18) Many community pharmacies are owned by non-pharmacists and pharmacists hired are not available much of the time resulting in lack of pharmacist over-sight when selling drugs.

 The general history of pharmacists in India has been one in which they are often not taken seriously. In the recently accepted union government’s sixth pay commission report, pharmacists have been placed in the lowest band and structure along with other non-technical persons.[[19]](#footnote-19) Additionally, a government committee declared in 2002 that pharmacists were not necessary for drug distribution and sales, so this contributed to a downplay of the profession, which is hurting the country today as pharmacists are an integral part of addressing antimicrobial resistance.[[20]](#footnote-20) With this in mind, this community pharmacy and pharmacist has potential to interact with the community in a more effective way.

**Recommendations:**

 The first recommendation that is not yet being addressed in a current governmental movement is that of limiting self-medication in India. Self-medication is defined as an action to “treat self-diagnosed disorders without consulting a medical practitioner and without any medical supervision”.[[21]](#footnote-21) The majority of the drugs used to self-medicate are obtained over-the-counter. This can be dealt with by increasing the H1 schedule requirements of the Chennai Declaration to include all pharmacists and all antibiotics. Additionally, the Ministry of Health and Family Welfare should contribute to this issue by targeting families and lay-people by engaging them in comprehensive educational programs that explain the harm of self-medication. Common reasons that people migrate towards self-medication are having similar experiences in the past, down-playing the seriousness of disease, saving money, misunderstanding of antibiotics, and suggestions from others.[[22]](#footnote-22) As such, an increasing awareness among the community on this health harming behavior may decrease the prevalence of self-medication.

As a leader in both national and international programs addressing antimicrobial resistance, the Ministry of Health and Family Welfare will be best able to address the problems at the pharmacy-level within the country. The first recommendation to resolve this issue is that of improving the community-pharmacist relationship. More specifically, by requiring pharmacists at all depots of drug sales, people who come in for medications will be better used to interacting with these professionals. By building relationships similar to that of physician-patient, pharmacists can be a form of support and trust. With this, pharmacists will be able to inform patients of the risks of taking antibiotics when unnecessary and the general distribution of educational materials will be helpful. In a focus group discussion of retail pharmacists, public-sector pharmacists, and people working within pharmacist associations, “Many pharmacists believed that if a patient was aware of the importance of taking a full course, this would have significant effect on use of antibiotics”.[[23]](#footnote-23) A simple piece of information explained can change the minds of a medication-user.

As a part of this, the Government of India should treat pharmacists more like physicians by offering them collaboration and support. This could simply be by hosting discussions and events, or it could go so far as including them in the public health sector and considering them government employees. If pharmacists are given governmental support, that support can recapitulate onto those seeking medications. Not only that, but community pharmacies would be better able to include pharmacists in their structure if they did not have the responsibility of paying them. A current issue is that of the poor pay of pharmacists, and this may contribute to their sometimes lackadaisical approach to giving people medications without proper prescriptions from doctors, with old prescriptions, without proper instruction, and with financial temptation from pharmaceutical companies.[[24]](#footnote-24) As previously mentioned, the general attitude towards pharmacists has viewed them as less than in the Indian health care paradigm, but they are of paramount importance at current with the antimicrobial resistance issue growing steadily.

**Conclusion:**

 The Government of India has the right idea in applying programs such as the Global Action Plan on Antimicrobial Resistance and National Action Plan on Antimicrobial Resistance which are currently underway to solve the antimicrobial resistance problem. However, while we are able to recognize holes in these plans, it is necessary to act now. In doing such, the Ministry of Health and Family Welfare in particular should initiate the discussed recommendations of limiting self-medication via antibiotics through community awareness and increased integration of pharmacists in the health care field. These two plans of action will not only hold community members more accountable, but will also reintroduce a major player, the pharmacist, as an influential actor in solving this issue. Collectively, these recommendations will spread awareness and action in fighting antimicrobial resistance at the community level within India.

 With the leadership of a Ministry responsible for the health of the Indian community, these recommendations can be actualized to result in a healthier India. The first step is to make local connections between the government and community pharmacies and community programs that will invite pharmacists and community members to feel that they too can help improve the antimicrobial situation. Without action from the Ministry of Health and Family Welfare, major attention will remain on large-scale international and national agendas that skip over key stake-holders in this issue. By connecting the community to the country’s health leaders the two will be enabled to work together and acknowledge that all Indian citizens can make an impact on this current health issue.

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