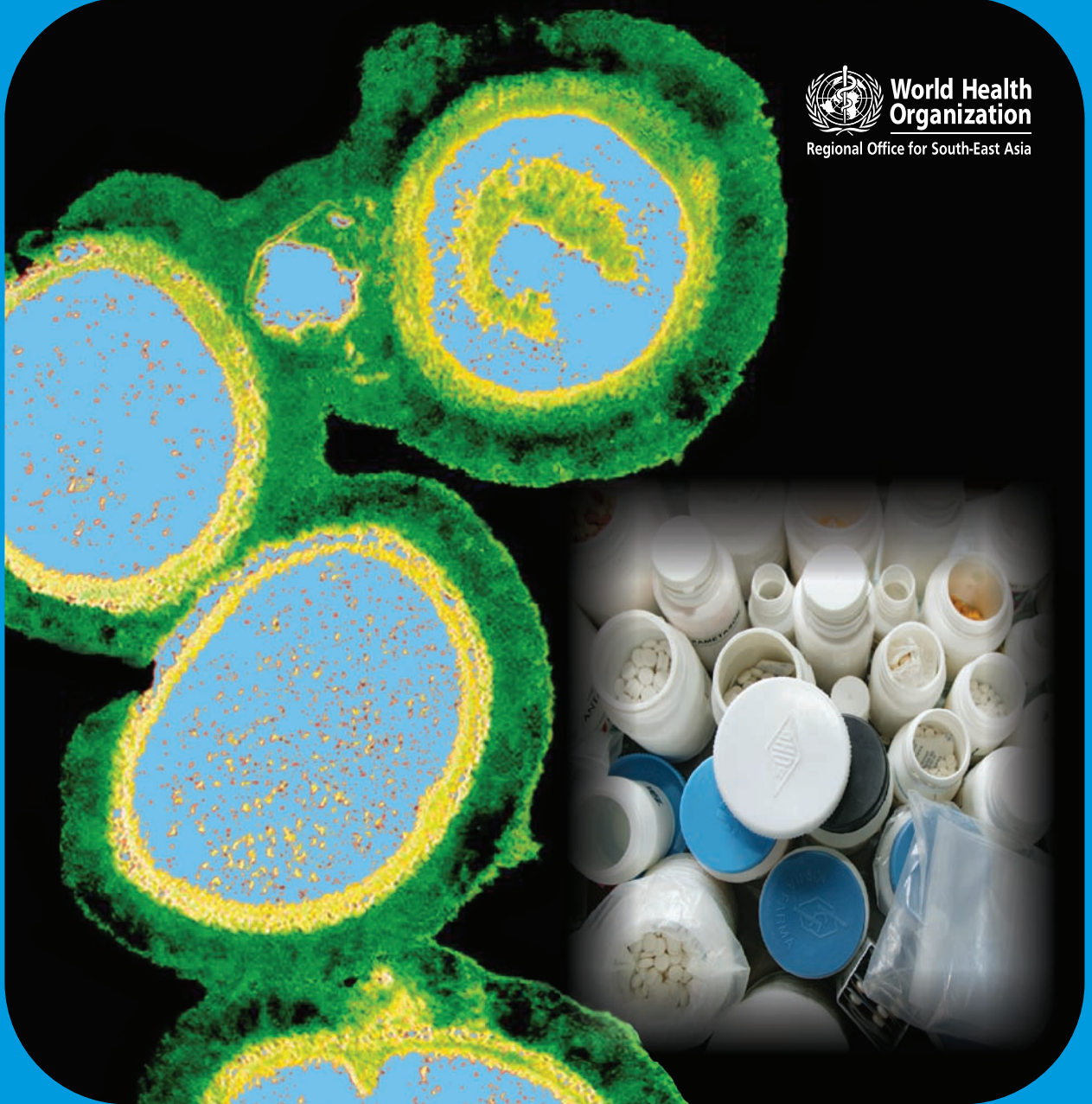




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Regional strategy on prevention and containment of antimicrobial resistance

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Regional Strategy on Prevention and Containment of Antimicrobial Resistance

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Foreword



During the past seven decades, antimicrobial agents have saved millions of lives, substantially reduced the burden of diseases that were previously widespread and improved the quality of life as well as helped increase life expectancy. In the recent past, emergence and spread of resistance in several microorganisms has rendered the management of many infectious diseases difficult. The development of resistance to drugs commonly used to treat malaria, TB and HIV is of particular concern and an impediment in achieving the related Millennium Development Goals by 2015.

Resistance to antimicrobials is a natural and inevitable biological phenomenon that can be amplified or accelerated by a variety of factors and practices that facilitate “selective pressure”. The selection pressure is highest when antimicrobials are used irrationally in the health and veterinary sectors.

The consequences of resistance are severe. Infections caused by resistant microbes fail to respond to treatment, resulting in prolonged illness and greater risk of death. Treatment failures also lead to longer periods of infectivity, which increase the number of infected people moving in the community and thus expose the general population to the risk of contracting a resistant strain of infection. It is also a threat to patient safety due to the rapidly growing pandemic of antimicrobial resistance.

The prevention and containment of resistance has a common approach and requires integrated and well coordinated efforts at the national level. It is a biological, behavioural, technical, economic, regulatory and educational problem, and requires a comprehensive response employing an evidence-based strategy.



Accordingly, the WHO Regional Office for South-East Asia has developed a Regional Strategy which is simple and practical, can be adapted by Member countries, and acceptable to multiple stakeholders. It is believed that it shall act as a powerful tool to prevent negation of the progress made in the field of communicable diseases. The Regional Strategy aims to comprehensively address interventions involving the introduction of legislation and policies governing the use of antimicrobial agents, establish laboratory-based networks for the surveillance of resistance, and assure rational use of these drugs at all levels of health-care settings. It also advocates ownership and active participation by several stakeholders.

I am sure this strategy shall facilitate our efforts in minimizing the morbidity and mortality due to antimicrobial resistant infections and preserving the effectiveness of antimicrobial agents.



Dr Samlee Plianbangchang
Regional Director

Background

Communicable diseases continue to be a major public health problem in Member States of the South-East Asia (SEA) Region of the World Health Organization (WHO). Each year, of 14 million deaths that occur in the SEA Region, six million—or about 40 per cent—are due to communicable diseases, which also contribute to 42% of the total disability-adjusted life years (DALYs) lost¹. The continuous interplay between complex socioeconomic, environmental and behavioural factors – as well as unrelenting population movements in an interconnected world – provides a milieu conducive to persistence and spread of communicable diseases² both within and across borders, thereby threatening international health security.

Emerging diseases continue to challenge public health as never before. With an estimated 3.5 million people currently living with HIV/AIDS, the Region's HIV/AIDS burden is next only to sub-Saharan Africa. The generic antiretroviral (ART) drugs produced by the pharmaceutical industry in the Region are contributing greatly to improve survival of patients worldwide and in rendering HIV a chronic manageable condition. Although response to ART is excellent when delivered at health facilities³, emergence of resistance in HIV can destroy the hopes of survival for millions of people living with the disease.

The Region also suffers disproportionately from the global burden of tuberculosis; 34% of all TB patients across the globe are from this Region⁴. The level of multidrug-resistant TB, however, remains low at below 3%, reflecting good quality of TB programmes. The need for preserving the efficacy of first-line antituberculous drugs has been widely felt since the drugs used in the management of MDR-TB cases are not only expensive but also toxic.



Furthermore, resistant malaria has already become a major issue for a population of 400 million living in areas with high risk of contracting it⁵.

In spite of these challenges, the Region has witnessed significant achievements over the past decade towards combating old diseases as well as new and emerging ones, and in health outcomes. During the past decade leprosy has been eliminated from all countries of the Region except one and the elimination of yaws has been achieved in India. The Region has now targeted selected neglected tropical diseases for elimination, namely leprosy, lymphatic filariasis, visceral leishmaniasis (kala-azar) and yaws due to unique epidemiological, technological and historical factors⁶. One of the most critical factors that will facilitate the elimination of these diseases is the availability of effective antimicrobial agents against the causative agents of these diseases.

Emergence of resistance and factors influencing it

Resistance against antimicrobial agents has now become a huge problem. Though during the past seven decades antimicrobial agents have saved millions of lives, substantially reduced the burden of diseases that were previously widespread and improved both quality of life and human longevity, in the recent past the emergence and spread of resistance in several microorganisms has rendered the management of many infectious diseases using the common anti-infective drugs difficult. According to the European Centre for Diseases Control (ECDC), *antimicrobial resistance is possibly the single biggest threat facing the world in the area of infectious diseases.*

Resistance to antimicrobials is a natural consequence of exposure to antimicrobials and not a new phenomenon. Even with appropriate antimicrobial use, the rates of emergence of resistance can increase⁷. The progress is more rapid when there is inappropriate use. Several reports have shown the association between heavy use of antimicrobials and drug resistance because of selection pressure exerted by these agents⁸. The selection pressure is utmost when antimicrobials are used irrationally in health and veterinary sectors.

The emergence and spread of antimicrobial resistance are complex problems fuelled by the knowledge, expectations and interactions of prescribers and patients, and the regulatory environment⁹. Patient compliance with recommended treatment is another major problem. Easy access of antimicrobials in developing countries and prevalent myths among communities about its use exert an equally important influence on the emergence of resistance.

While resistance can and does appear in any setting, hospitals – featuring the combination of highly susceptible patients, intensive and prolonged antimicrobial use, and cross-infection – have become a hot spot for highly



resistant bacterial pathogens. Veterinary prescription of antimicrobials also contributes to the problem of resistance. The largest quantities are used as regular supplements for prophylaxis or growth promotion, thus exposing a large number of animals, irrespective of their health status, to frequent sub-therapeutic concentrations of antimicrobials.

Resistance in microorganisms is costly in terms of money, livelihood earnings and lives lost, and also threatens to undermine the effectiveness of health delivery programmes. The WHO strategies for all major disease control programmes (HIV, TB, malaria, influenza) advocate for the monitoring of drug resistance and suggest appropriate activities. The international movement of resistant strains, especially when these are multi- or extensively resistant, can be considered as a public health event of international concern (PHEIC) as per the provisions of the International Health Regulations 2005 [IHR (2005)].

Unfortunately, combating antimicrobial resistance has not been accorded the priority and attention it deserves in Member States in spite of several resolutions to this effect by the World Health Assembly (WHA37.33, WHA51.17, WHA54.11 and WHA58.27) on the rational use of drugs and prevention of antimicrobial resistance.

The World Health Assembly resolution in 1998¹⁰ had urged Member States to develop measures to encourage the appropriate and cost-effective use of antimicrobials; prohibit the dispensing of antimicrobials without the prescription of a qualified health-care professional; improve practices to prevent the spread of infection and thereby the spread of resistant pathogens; strengthen legislation to prevent the manufacture, sale and distribution of counterfeit antimicrobials and sale of antimicrobials in the informal market; and reduce the use of antimicrobials in food-animal production. This message was reinforced in WHA58.27 in 2005¹¹ wherein Member States were encouraged to ensure the development of a coherent, comprehensive and integrated national approach towards implementing the strategies for containment of antimicrobial resistance, and to monitor regularly the use of antimicrobial agents and the level of antimicrobial resistance in all relevant sectors.

The South-East Asia Regional Strategy for Prevention and Containment of Antimicrobial Resistance is based on essentials enunciated in WHA resolutions.

Status of resistance in the WHO South-East Asia Region

No systematic studies have been done in the South-East Asia Region to understand the status of resistance, trends and consumption of antimicrobial agents. While multidrug resistance in *Mycobacterium tuberculosis*, because of well-performing national TB control programmes in the Region, is still at an acceptable low level of <3%, this figure is very high among several other bacteria.

Outbreaks of resistant salmonellae-causing typhoid fever and shigellosis-causing bacillary dysentery have been reported from the Region. Resistance to *Vibrio cholerae*, *Escherichia coli*, *Neisseria gonorrhoeae*, and *Streptococcus pneumoniae* has been on an increase^{12,13,14,15}. More than 50% of isolates of *Staphylococcus aureus* in hospital settings are now methicillin-resistant¹⁶. The emergence of community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA) as an increasingly frequent cause of skin and soft tissue infections or invasive infections is further compounding this problem. Multiresistant klebsiellae and *Acinetobacter species* have given a new dimension to the problem of hospital-associated infections. Around 400 million people live in areas which are at risk of resistant malaria. With rapid means of travel, international movement of resistant bacteria occurs frequently¹⁷. In Canada and the USA several outbreaks of resistant strains have been reported with these strains originating from the SEA Region. Studies have also been conducted on international spread of drug-resistant gonorrhoea. *Neisseria gonorrhoeae* resistant to penicillin, tetracycline and multiple other drugs, detected in South-East Asia during 1960s and 1970s, has been an emerging public health issue in the United States of America¹⁸.

3.1 Consequences of resistance

The consequences of resistance are severe and several. Infections caused by resistant microbes fail to respond to standard treatment, resulting in prolonged illness and greater risk of death. Treatment of infections with resistant strains may require use of expensive and potentially toxic second line of drugs. Treatment failures also lead to longer periods of infectivity, which increase the numbers of infected people moving in the community and thus expose the general population to the risk of contracting a resistant strain of infection. It is also a threat to patient safety due to the rapidly growing pandemic of antimicrobial resistance^{19,20}.

Rationale for the strategy

Resistance is a biological, behavioural, technical, economic, regulatory and educational problem and requires a comprehensive response. Antimicrobial resistance has been an unrecognized and neglected problem which is not only cross-cutting but also has far-reaching implications as an emerging public health problem with huge risk to international health security. Newer drugs are being discovered only slowly. Efforts need to be made to slow down or delay the resistance, thus preserving the available antimicrobials. Several success stories of reversing resistance through the rational use of antimicrobials have been written in the SEA Region. These need to be scaled up to combat the problem comprehensively.

It was hence essential to develop a regional strategy that is acceptable to multiple stakeholders, is simple and practical, can be adapted by Member States, and also acts as a powerful tool to prevent negation of progress made in the field of communicable diseases. This regional strategy aims to accord particular attention to interventions involving the introduction of legislation and policies governing the use of antimicrobial agents, establish laboratory-based networks for the surveillance of resistance, and assure rational use of these drugs at all levels of health-care settings.

Antimicrobial resistance is a cross-cutting issue which is influenced by several factors. Accordingly, it requires ownership and active participation by several stakeholders, some of which are: the ministry of health, the ministry of animal husbandry, the ministry of education, the national regulatory authorities, medical and veterinary professional bodies, medical and veterinary councils, national medical and veterinary research councils, health facilities in public, private and other sectors, international agencies, NGOs, laboratory professionals, mass media and community champions.



The regional strategy shall address the following issues which continue to plague the process of prevention and containment of antimicrobial resistance and preserve the efficacy of these drugs to maintain their “wonder” status. Some of these are:

- Neglected problem of antimicrobial resistance with profound impact on health and economy.
- Inadequate visibility at the decision-making level in spite of WHA resolutions.
- Absence of a national approach/direction to combat the emerging problem of antimicrobial resistance.
- Lack of education among prescribers and users.
- Weak collaboration between stakeholders.
- Poor or no systematic surveillance of resistance and consumption of antimicrobial agents.
- Ineffective regulatory mechanisms.
- Lack of economic potential/incentives for pharmaceuticals to invest in the development of new drugs.
- Abysmal infection control practices.

The Strategy

The strategy shall have following guiding principles:

5.1 Guiding principles

- Understand the emergence and spread of resistance.
- Rationalize the use of available antimicrobial agents.
- Prevent emergence of resistance by reducing selection pressure by appropriate control measures.
- Bring about a change in behaviour of prescribers of antimicrobial agents and communities to ensure their rational use.
- Combat antimicrobial resistance by promoting discovery, development and delivery of new drugs/tools.
- Combat antimicrobial resistance through nationally coordinated efforts with defined functions by different sectors/programmes.

5.2 Goal

To minimize the morbidity and mortality due to antimicrobial-resistant infection and to preserve the effectiveness of antimicrobial agents in the treatment and prevention of microbial infections.



5.3 Objectives

- To establish a national alliance for prevention and control of antimicrobial resistance.
- To institute a surveillance system that captures the emergence of resistance, trends in its spread and utilization of antimicrobial agents in different settings.
- To promote rational use of antimicrobial agents at all levels of health-care and veterinary settings.
- To strengthen infection control measures to reduce the disease burden.
- To support research to develop and/or improve use of antimicrobial agents.

Key strategic elements and major activities

Objective 1: To establish a national alliance for the prevention and control of antimicrobial resistance

Concerted and nationally coordinated efforts are needed to bring together various stakeholders and harness their expertise and the resources available within the country in different sectors to meet this Objective. Key elements and major activities that will accomplish Objective 1 are:

(1) Establish a national alliance against antimicrobial resistance

- Establish a cell in the Ministry of Health, preferably within the unit dealing with emerging infectious diseases (EID) or the implementation of IHR (2005) for coordinating national activities and sharing information with other countries in the Region.
- Designate national focal points for coordinating antimicrobial resistance-related activities.
- Forge national alliance of relevant programmes and stakeholders from both public and private sectors.
- Constitute an intersectoral steering committee under the chairpersonship of a high-level policy-maker.
- Establish national expert advisory committees.
- Develop a national strategic approach towards antimicrobial resistance with consensus of all stakeholders about their specific roles.

- Strengthen national regulatory mechanism.
- Allocate adequate resources to implement a strategy for the prevention and containment of antimicrobial resistance.
- Provide adequate representation to the private sector in the steering committee and advisory committees.

(2) Strengthen national networks

- Augment existing networks to fulfil Objective 2 (*see below*).
- Incorporate standards in the national regulatory framework.
- Establish/strengthen accreditation mechanism for hospitals which articulates the rational use of antimicrobials as an integral requirement.
- Enhance capacity and powers of the regulatory authority to implement national standards on the use of antimicrobials.
- Involve networks under IHR and World Alliance on Patient Safety (WAPS).

(3) Collaborate with stakeholders

- Develop linkages with stakeholders (potential stakeholders at Annex 1).
- Promote regular and formal interactions.
- Encourage the role of NGOs in community awareness and targeted education.

Objective 2: To institute a surveillance system that captures the emergence of resistance, trends in its spread and utilization of antimicrobial agents in different settings

Several networks may be operational in the country that generate and collate data on resistance in microorganisms and consumption of antimicrobial agents. These should be activated to support national efforts towards containment of antimicrobial resistance. If such networks are not functional, the same must be established. Key elements and major activities that will accomplish Objective 2 are:

(1) Monitor resistance in microorganisms

- Quantify resistance in microorganisms through networks of laboratories equipped with the capacity to perform quality assured antimicrobial susceptibility testing.
- Ascertain trends in emergence and spread of resistance.
- Detect and report new events.
- Assess effect of interventions on resistance.
- Communicate data to users and national focal points.
- Advocate the establishment of surveillance networks in the veterinary sector and develop linkages between human and veterinary networks.

(2) Monitor use of antimicrobials

- Evaluate prescription policies in health-care settings in the public and private sectors and the utilization of antimicrobial agents at various levels.
- Assess therapeutic and non-therapeutic use in animals.
- Appraise the impact of promotion of pharmaceuticals.
- Collate data and communicate to stakeholders.

(3) Monitor disease and economic burden due to resistant organisms

- Correlate data on utilization of antimicrobials and resistance.
- Determine impact of non-pharmaceutical factors on the emergence of resistance.
- Calculate economic losses due to resistance.
- Utilize data generated for policy formulation and programme development/improvement.



Objective 3: To promote rational use of antimicrobial agents at all levels of health-care and veterinary settings

This is the most complex and yet critical objective since it involves the strengthening of technical and regulatory requirements along with bringing about a change in the behaviour of the prescribers and users. Key elements and major activities that will accomplish Objective 3 are:

(1) Promote optimal prescription

- Develop standard national/local treatment guidelines (STGs) advocating evidence-based monotherapy or combination therapy.
- Train professionals in use of these STGs.
- Assure use of STGs through Hospital Committees.
- Provide effective curriculum on the rational prescription of antimicrobial agents in undergraduate and postgraduate education of medical, dental, veterinary and pharmacy students

(2) Make available quality laboratory data in real time

- Ensure quality-assured laboratory determination of resistance.
- Utilize locally generated data for immediate use as well as for developing/modifying use of antibiotics guidelines.
- Build capacity of health-care providers to utilize the resistance data efficiently.

(3) Rationalize use in veterinary sector

- Ban non-therapeutic use of antimicrobial agents using the IHR (2005) as the regulatory framework
- Develop standard treatment guidelines (STGs)
- Train professionals in use of STGs.

(4) Promote compliance and proper public use

- Educate communities on proper compliance and non-self-medication.
- Prevent over-the-counter availability of antimicrobial drugs.
- Provide continuous education to pharmacists/chemists in appropriate use of antimicrobial agents.

Objective 4: To strengthen infection prevention and control measures to reduce the disease burden

Since all the factors that promote or influence communicable diseases also facilitate resistance, efforts made to reduce the disease burden are bound to mitigate the extent of resistance. Key elements and major activities that will accomplish Objective 4 are:

(1) Strengthen disease control programmes

- Develop standard treatment guidelines (STGs) and assure their implementation.
- Train professionals in the use of STGs.
- Support activities at the community level to assure adherence.
- Monitor resistance and effect of interventions.
- Promote private-public partnership (PPP).

(2) Augment infection-control practices in hospitals

- Establish infection control practices, especially universal/standard precautions, and provide an enabling environment.
- Ensure the availability of an adequate number of trained health-care staff.
- Provide personal protective equipment (PPE) and other infrastructural support.
- Institute and empower Hospital Infection Control Committees.



- (3) **Promote infection control practices in communities**
 - Launch comprehensive health education campaigns.
 - Promote hygiene in school curricula.
 - Collaborate with NGOs and local opinion leaders
- (4) **Promote and strengthen disease prevention interventions**
 - Strengthen immunization programmes.
 - Conduct educational campaigns on hygiene and non-pharmaceutical practices.
 - Strengthen disease prevention measures.
 - Collaborate with the mass media to create awareness.

Objective 5: To promote research in the area of antimicrobial resistance

- (1) **Encourage basic research**
 - Ascertain the dynamics of spread, and the drivers of, resistance.
 - Understand the mechanism of resistance.
 - Evaluate the impact of use of antimicrobials in agriculture and fishery on human health.
- (2) **Support operational research**
 - Develop optimum doses and duration of various drugs as monotherapy or in combinations.
 - Understand impact of resistance on illness and economy.
 - Develop rapid diagnostic tools.
 - Determine factors that influence prescription habits.
 - Elucidate behavioural aspects about self-medication and adherence, and develop interventions to bring about change.

(3) Support the development of new antimicrobial agents and vaccines

The development of new antimicrobial agents or alternatives thereof requires support from the government and from industry-supported research through:

- research grants, PPP, public contribution to research funding and R&D tax credits;
- remuneration for outputs from the R&D process, including advance purchase commitments or patent buyouts, and also through:
- reducing time to market entry through fast-track mechanisms of regulatory approvals.



Implementation

Resistance to antimicrobial agents is a cross-cutting problem that needs to be tackled by well-coordinated action. This Regional Strategy recognises the need for a wide range of activities which are required to support the control of antimicrobial resistance and the need for commitment from a wide variety of players. It needs to be endorsed by all countries of the SEA Region and will lead to sustained action to combat this problem. Microbes are dynamic organisms and so should be our approach to tackling their resistance to antimicrobial agents.

The Strategy also recognises the need for action across a wide range of interests and by many organizations and individuals. Since microorganisms do not recognise geographical boundaries and are increasingly spread through international travel and commerce, it also recognises the need for the WHO Regional Office for South-East Asia to play its part by providing appropriate technical support in step-wise implementation of the Strategy at the national and local level.

The implementation framework may include followings:

- (1) Obtaining national commitment towards prevention and containment of antimicrobial resistance.
- (2) Constitution of an intersectoral steering committee with all stakeholders from the public and private sectors represented, which is chaired by a senior policy-maker.



- (3) Establishment of a cell and focal point in the MoH within the unit responsible for emerging infectious diseases or International Health Regulations (2005) to coordinate with the national alliance (comprising mainly of existing programmes) and empowered to provide evidence-based directives for rational use of antimicrobial agents and on disease prevention and control interventions.
- (4) Constitution of a national expert advisory committee.
- (5) Designation of subgroups in specialized areas.
- (6) Development of public information campaigns.
- (7) Establishment of a national surveillance system with a mandatory reporting system through efficient and quality laboratory networks and existing surveillance systems.
- (8) Development of and making available various national standards, guidelines for surveillance and treatment and strengthening regulatory support for their implementation.
- (9) Organizing continuing education for professionals and all health-care workers, and the like, through medical and health-related institutions and professional bodies.
- (10) Invoking IHR (2005) and other national measures to reduce or ban the use of antimicrobials as growth promoters in animals.
- (11) Collation of research findings for developing actions
- (12) Establishment of a national forum of multidisciplinary professionals (health, veterinary, agriculture, fishery, etc.) to share information to promote the understanding of the impact of use of antimicrobial agents on human health.
- (13) Collaborate with international agencies for technical support and to obtain information from other countries/sectors. WHO to coordinate the information exchange in the SEA Region.
- (14) Conducting regular meetings to review, assess and modify the action plans.

7.1 Indicators and targets

The following are suggested as regional indicators:

- Number of countries with national intersectoral steering committee for antimicrobial resistance monitoring (AMR).

Target: All countries of the SEA Region by 2013

- Number of countries with national alliances for prevention and control of antimicrobial resistance.

Target: All countries of the SEA Region by 2015

- Number of countries with national networks for surveillance of antimicrobial resistance through quality laboratory services.

Target: All countries of the SEA Region by 2015

- Number of countries with legislation banning over-the-counter sale of selected antimicrobial agents.

Target: All countries of the SEA Region by 2015

- Number of countries with a ban in place on non-therapeutic use of antimicrobial agents in animals.

Target: All countries of the SEA Region by 2015

- Number of antimicrobial agents for which resistance against nationally identified microorganisms has stabilized or decreased.

Target: At least five drugs for which resistance has stabilized or decreased by 2015.

- Number of antimicrobial agents of which the annual use has declined by 25% as indicated by defined daily doses (DDD) by 1000 patient days.

Target: At least five antimicrobial agents with annual utilization reduced by 25% as indicated by DDD by 2013.

- Per cent of hospitals that show a decrease in the rate of hospital-associated infections (HAI).

Target: More than 25% of hospitals in at least five countries of the SEA Region by demonstrated decrease in rate of HAI by 2015.



- Per cent of hospitals in the public and private sector in a country with a policy for rational use of antimicrobials.

Target: At least 75% of hospitals in public and private sector in at least five countries of the SEA Region having policy for rational use of antimicrobials by 2015.

- Number of countries with national Hospital Accreditation schemes with rational use of antimicrobials as an essential requirement for accreditation.

Target: All countries of the SEA Region by 2015

Monitoring and evaluation

A strong component of the monitoring and evaluation mechanism through an alliance utilizing the aforementioned indicators and targets shall be established. National baseline data should be established. The national steering committees must regularly review the data generated for this purpose and provide guidance for changes, if any, required to achieve the targets.

Regional annual reviews should be undertaken through the WHO intercountry coordination mechanism and mid-term assessment of the strategy plan period made.



Mainstreaming the national response

Given the cross-cutting nature of the problem and complexity of the response, it is essential that every stakeholder has clarity about its role in combating this menace, both within its own mandate as well as for those issues which have a bearing upon activities of other sectors. Ownership of the strategy by all stakeholders is critical for it to move forward and yield the desired results.

Antimicrobial drug failure may occur for many reasons, but it impacts not only patient care and safety but also threatens effective management of public health infectious diseases globally. A strategic approach is urgently needed to combat this emerging threat.



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Suggested stakeholders

- Ministry of Health, Ministry of Animal Husbandry, Ministry of Education.
- National Regulatory Agency/Authority.
- Medical, veterinary and pharmacy professional bodies.
- Medical and veterinary councils.
- National medical and veterinary research organizations.
- Corporate hospitals.
- NGOs.
- Community opinion leaders.
- Mass media.
- Pharmaceutical industry.
- International agencies.



Antimicrobial resistance has been an unrecognized and neglected problem which is not only cross cutting but also has far reaching implications as an emerging public health problem with huge risk to international health security. The consequences of resistance are severe and several. Resistance in microorganisms costs money, livelihood and lives and threatens to undermine the effectiveness of health delivery programmes. The emergence and spread of antimicrobial resistance are complex problems fuelled by the knowledge, expectations, and interactions of prescribers and patients, and regulatory environment. A strategic approach has been described in this document to combat this burgeoning problem.



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