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Millions of people die each year because antibiotics are increasingly unable to cure many diseases such as TB, pneumonia, influenza and severe stomach ailments.

Antibiotic resistance has reached crisis proportions worldwide. Governments and WHO are preparing action plans. But are they too little, too late?
When medicines don’t work anymore

The crisis of antibiotic resistance has gotten worse, and a global action plan must be launched urgently.

By Martin Khor

The growing crisis of antibiotic resistance is catching the attention of policy makers, but not at a rate enough to tackle it.

More diseases are affected by resistance, meaning the bacteria cannot be killed even if different drugs are used on some patients, who then succumb.

We are staring at a future in which antibiotics don’t work, and many of us or our children will not be saved from TB, cholera, deadly forms of dysentery, and germs contracted during surgery.

The World Health Organization discussed a resolution in May at its annual assembly of Health Ministers on antimicrobial resistance, including a global action plan. There have been such resolutions before but little action.

This year may be different, because powerful countries like the United Kingdom are now convinced that years of inaction have cause the problem to fester, until it has grown to mind-boggling proportions.

The UK-based Chatham House held two meetings in October 2013 and in March 2014 (together with the Geneva Graduate Institute) on this issue, both presided over by the Chief Medical Officer of England, Prof. Dame Sally Davies.

This remarkable woman has taken on antibiotic resistance as a professional and personal campaign. In a recent book, “The drugs don’t work”, she revealed that for her annual health report, she decided in 2012 to focus on infectious diseases.

“I am not easily rattled, but what I learnt scared me, not just as a doctor, but as a mother, a wife and a friend. Our findings were simple: We are losing the battle against infectious diseases. Bacteria are fighting back and are becoming resistant to modern medicine. In short, the drugs don’t work.”

Davies told the meetings that antibiotics add on average 20 years to our lives and that for over 70 years they have enabled us to survive life-threatening infections and operations. “The truth is, we have been abusing them as patients, as doctors, as travellers, and in our food,” she says in her book.

“No new class of antibacterial has been discovered for 26 years and the bugs are fighting back. In a few decades, we may start dying from the most common place of operations and ailments that can today be treated easily.”

At the two Chatham House meetings, which I attended, different aspects of the crisis and possible actions were discussed. In one of the sessions, I made a summary of the actions needed, including:

- More scientific research of how resistance is caused and spread, including the emergence of antibiotic-resistance genes as in the NDM-1 enzyme, whose speciality is to accelerate and spread resistance within and among bacteria.
- Surveys in every country to determine the prevalence of resistance to antibiotics in bacteria causing various diseases.
- Health guidelines and regulations in every country to guide doctors on when (and when not) to prescribe antibiotics, and instructing patients how to properly use them.
- Regulations for drug companies on ethical marketing of their medicines, and on avoiding sales promotion to doctors or the public that leads to overuse.
- Educating the public on using antibiotics properly, including when they should not be used.
- Ban the use of antibiotics in animals and animal feed for the purpose of inducing growth of the animals (for commercial profit), and restrict the use in animals only for treating ailments.
- Promote the development of new antibiotics and in ways (including financing) that do not make the new drugs the exclusive property of drug companies.
- Ensure that ordinary and poor people in developing countries also have access to the new medicines, which would otherwise be very expensive, and thus only the very rich can afford to use them.

On the first point, a new and alarming development has been the discovery of a gene, known as NDM-1, that has the ability to alter bacteria and make them highly resistant to all known drugs.

In 2010, only two types of bacteria were found to be hosting the NDM-1 gene – E. coli and Klebsiella pneumonia.

It was found that the gene can easily jump from one type of bacteria to another. In May 2011, scientists from Cardiff University who had first reported on NDM-1’s existence found that the NDM-1 gene has been jumping among various species of bacteria at a “superfast speed” and that it “has a special quality to jump between species without much of a problem”.

While the gene was found only in E.
WHO sounds alarm bell on antibiotic resistance

In April 2014, the World Health Organization released the most comprehensive report to date on the alarming worldwide growth of antibiotic resistance, warning that we are already entering a world without antibiotics.

The World Health Organization has sounded a loud alarm bell that many types of disease-causing bacteria can no longer be treated with the usual antibiotics and the benefits of modern medicine are increasingly being eroded.

The WHO in April released a comprehensive 232-page report on antimicrobial resistance with data from 114 countries showing how this threat is happening now in every region of the world and can affect anyone in any country.

Antibiotic resistance -- when bacteria evolve so that antibiotics no longer work to treat infections -- is described by the WHO report as “a problem so serious that it threatens the achievements of modern medicine.”

“A post-antibiotic era, in which common infections and minor injuries can kill, far from being an apocalyptic fantasy, is instead a very real possibility for the 21st century,” said Dr. Keiji Fukuda, WHO assistant director general who coordinates its work on antimicrobial resistance.

“Without urgent, coordinated action, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill.

“Effective antibiotics have been one of the pillars allowing us to live longer, live healthier, and benefit from modern medicine. Unless we take significant actions to improve efforts to prevent infections and also change how we produce, prescribe and use antibiotics, the world will lose more and more of these global public health goods and the implications will be devastating.”

The report, "Antimicrobial resistance: global report on surveillance", shows resistance is occurring in many bacteria causing different infections.

The new WHO report on antimicrobial resistance.

The report focuses on antibiotic resistance in seven bacteria responsible for common, serious diseases such as bloodstream infections (sepsis), diarrhoea, pneumonia, urinary tract infections and gonorrhoea.

What is especially alarming is that the bacteria’s resistance has also breached “last resort” antibiotics, which are the most powerful medicines that doctors resort to when the usual ones do not work.

When patients do not respond to the usual medicines (known as first-line or first-generation medicines), doctors prescribe newer (second-line) medicines which also usually cost more.

When these also don’t work, newer and often more powerful (but sometimes with also more side effects) antibiotics are used, and they are even more expensive.

If these third-line or “last resort” medicines are not available or too costly for the patient, or if they don’t work on a patient because of antibiotic resistance, the patient remains ill or...
dies if the infection is a serious one.

New antibiotics have been discovered in the past to treat infections when the old ones became useless due to resistance. But these discoveries dried up in the past 25 years. The last completely new classes of antibacterial drugs were discovered in the 1980s.

Pathogens that are becoming increasingly resistant include E. coli, K. pneumonia, S. aureus, S. pneumonia, salmonella, shigella and n. gonorrhoeae.

Key findings from the report include:

- Resistance to the treatment of last resort for life-threatening infections caused by a common intestinal bacteria, K. pneumoniae -- carbapenem antibiotics -- has spread worldwide. K. pneumoniae is a major cause of hospital-acquired infections such as pneumonia, bloodstream infections, infections in newborns and intensive-care unit patients. In some countries, because of resistance, carbapenem antibiotics would not work in more than half of people treated for K. pneumoniae infections.

- Resistance to one of the most widely used antibacterial medicines for the treatment of urinary tract infections caused by E. coli -- fluoroquinolones -- is very widespread. In the 1980s, when these drugs were first introduced, resistance was virtually zero. In many countries today, this treatment is ineffective in more than half of patients.

- The sexually transmitted disease, gonorrhoea, may soon be untreatable unless there are new drugs. Treatment failure to the last resort of treatment for gonorrhoea -- third generation cephalosporins -- has been confirmed in several countries. In 2008, there were 106 million new cases of gonorrhoea.

- Antibiotic resistance causes people to be sick for longer and increases the risk of death. For example, people with MRSA (methicillin-resistant Staphylococcus aureus) are estimated to be 64% more likely to die than people with a non-resistant form of the infection. There are many cases of patients being infected by MRSA in hospitals.

The report also gives useful information on the worrisome building up of resistance in four serious diseases -- tuberculosis, malaria, HIV and influenza.

The re-emergence of TB is especially of great concern. Increasing cases of TB cannot be treated by most known antibiotics. In 2012, 8.7 million people developed TB and 1.3 million died; 3.6% of new cases and 20% of previously treated cases had multidrug-resistant TB.

The malaria-causing bacteria have become increasingly resistant firstly to chloroquine and pyrimethamine and now resistance to artemisinin has been identified in some cases in Cambodia, Myanmar, Thailand and Vietnam. In 2010, 219 million cases of malaria occurred worldwide and 660,000 died from the disease.

A major factor accelerating resistance is in the animal husbandry sector, where there is a liberal use of antibiotics mainly to promote the growth of the animals used for food, for commercial purposes.

This builds up resistance in the bacteria present in the animals. These resistant germs are passed on to humans who consume the meat.

The WHO report has a small section on the animal-food chain, which has been identified as a major problem. The European Union has banned the use of antibiotics as growth promoters in animals, but it is still allowed in other countries.

The WHO report mainly provides information on the prevalence and problems of microbial resistance, rather than what to do about the emerging crisis.

However, a WHO press release on the report calls for some actions. These include:

- Setting up basic systems in countries to track and monitor the problem.
- Preventing infections from happening in the first place to reduce the need for antibiotics.
- Only prescribing and dispensing antibiotics when they are truly needed; and prescribing and dispensing the right antibiotic(s) to treat the illness.
- Regulating and promoting appropriate use of medicines.
- Patients using antibiotics only when prescribed by a doctor and completing the full prescription, even if they feel better, and never using leftover prescriptions.
- Developing new diagnostics, antibiotics and other tools to stay ahead of emerging resistance.

By Martin Khor
Health Ministers decide on action to use medicines wisely

A resolution by Health Ministers at the World Health Assembly in May 2014 to formulate a global plan to deal with antibiotics resistance has given some hope that action may finally be forthcoming.

Momentum is building to get doctors to prescribe and patients to use medicines properly in order to slow down the increasing ineffectiveness of antibiotics to treat dangerous infections.

The World Health Organization was recently given the go-ahead to draw up a global plan of action to combat antibiotic resistance, which experts and health leaders have warned will cause “the end of modern medicine” if nothing is done.

Health Ministers asked the WHO to present them the plan within a year for adoption by the World Health Assembly (WHA) in May 2015. A draft will be reviewed in January 2015 by the WHO’s Executive Board.

In a resolution adopted at the WHA in May 2014, they also agreed to accelerate efforts to use antibiotics responsibly and develop national plans to contain the resistance of bacteria to antibiotics and other antimicrobials.

Resistance is making many antibiotics ineffective for increasing numbers of patients around the world who suffer from stomach, skin and respiratory infections and from serious diseases including TB, malaria, pneumonia and gonorrhoea.

Patients in hospitals are also commonly infected with dangerous “superbugs” such as MRSA which are difficult to treat, including when they undergo surgical operations.

Although this problem has been known for decades, little action has been taken at global or national level to prevent the over-use and wrong use of antibiotics, and the build up of resistance in the bacteria has now reached crisis proportions.

Health leaders such as WHO Director-General Margaret Chan and the United Kingdom’s Chief Medical Officer Dame Sally Davies have sounded the alarm bells about the crisis leading to a pre-antibiotic age where millions will die from presently treatable diseases or from non-dangerous operations because of the resistant bacteria.

At the WHA session, Malaysia was one of the countries speaking in favour of the resolution.

The Malaysian health delegate said there was need for awareness and action at the highest level, and need for concrete action including sanitation and hygiene, use of vaccines when possible, innovation in service delivery as well as health promotion and communication programmes to change the present culture on antimicrobials use.

India and Ghana, representing Africa, voiced a common concern of developing countries. The action plan must take account of the special needs of developing countries, including supporting the measures they have to take, and making sure they have access to the new antibiotics at affordable prices.

This touches on one of the crucial issues in the resistance discussion. The situation is very worrying because no new class of antibiotics has been discovered since the mid-1980s.

There is no guarantee that new ones will be found. Since the existing antibiotics may become ineffective in some years due to resistance, people worldwide will be defenceless against the superbugs.

Even if new antibiotics are discovered and sold, they will likely be under patent protection. The prices could be so high that most people, especially in developing countries, can’t use them.

The developing countries are asking the WHO to make sure its action plan deals with these issues. The United Kingdom, a champion of the resistance issue, assured India and Africa that their concerns would be addressed.

According to the WHA resolution, the action plan should contain proposals on a national plan to fight resistance, to strengthen surveillance and laboratory capacity, ensure access to medicines, enhance infection prevention and foster research to discover new antibiotics.

Importantly, the plan will also propose how to “regulate and promote rational use of medicines, including for animal husbandry, and ensure proper patient care”.

Just before the WHA, 50 health groups from Asian countries (including Malaysia), Africa, the United States, Europe and Latin America met at the South Centre in Geneva and formed a new alliance – the Antibiotic Resistance Coalition – to campaign for actions to be taken to curb the resistance trend.

The actions they call for include:

- End the use of antibiotics given to livestock to promote their growth. Much of the antibiotics are used for animals, and resistance in bacteria in the livestock are transferred to humans through the food chain.

- Promotion of antibiotics including incentivising medical personnel to overuse or inappropriately prescribe antibiotics is harmful and should be prohibited.

- Guidelines should be given to hospitals and private doctors on the proper use of antibiotics in treating patients.

- Introduce comprehensive monitoring of the medical and farm use of antibiotics and the trends of state of resistance in various pathogens.

- Support innovation towards new antibiotics, and in ways that de-link the costs of R&D from the price of medicines so that they can be affordable.

Although the move in the WHA towards a global plan was widely supported, there is also a danger that the plan may only be on paper and not implemented.

Thus the start of a campaign by civil society to highlight the dangers of resistance and the need for many types of action also gives hope.

With a global plan and NGO action, there is finally some hope that antibiotics resistance will be tackled more seriously in the future.
Governments at the recent World Health Assembly (WHA) have committed to a higher level of action to combat antibiotic resistance that is an increasing public health threat across the world.

On 24 May, a resolution was approved by health ministers on "Combating antimicrobial resistance, including antibiotic resistance" after an important exchange of country positions and one amendment put forward by Mexico with regard to conflict of interests.

The World Health Assembly (WHA) took place in Geneva from 19 to 24 May with six days of intense discussions on a large list of global public health topics.

More than 20 resolutions on public health issues of global importance were adopted and according to Dr. Margaret Chan, WHO's Director-General, in an official press release, "This has been an intense Health Assembly, with a record-breaking number of agenda items, documents and resolutions, and nearly 3,500 registered delegates."

India supported the antimicrobial resistance (AMR) resolution subject to the understanding that its concerns would be included in the proposed global plan of action. These included financial access of developing countries' patients to new antibiotics, new ways of funding research and development based on the delinkage principle in the context of developing countries, and the special needs of developing countries and their capacity-building to take on relevant activities. India's proposal was in lieu of making changes in the resolution text itself which was its first preference.

The United Kingdom, in its statement, also acknowledged the legitimate concern of developing countries on access to antibiotics, and the importance of support for technical capacities and affordable drugs.

All Member States agreed on the importance and magnitude of antimicrobial resistance and broad support was heard in the statements made by all delegations on the paramount need to take action. Both developing and developed countries agreed that this is of global magnitude and urged the WHO to develop the action plan and for Member States to build up their own national plans.

Developing countries stressed on the urgency of the problem but also on the importance of ensuring access to new antibiotics for developing countries and the mobilisation of resources so that they can implement action plans and surveillance.

Antimicrobial resistance is also addressed by the United Nations Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE). On 30 April, WHO launched its report "Antimicrobial resistance: global report on surveillance 2014". This is the organisation's first global report on antibiotic resistance with data from 114 countries. It revealed a serious, worldwide threat to public health posed by antibiotic resistance.

Below are the highlights of several country statements that supported the resolution. (A new civil society coalition, the Antibiotic Resistance Coalition, also made a statement presented by one of its founding members, Health Action International.)

Lebanon said that extensive use and misuse of antimicrobials in human and animal health has resulted in AMR which now constitutes a serious threat to health and global health security. It noted that the 2001 WHO Global Strategy for the Containment of AMR which now constitutes a serious threat to health and global health security. It noted that the 2001 WHO Global Strategy for the Containment of AMR has not been realised and expressed strong support for the strategy and next steps. It stressed the need for strong commitment from member states, international organisations and
the food industry. Particularly, Lebanon highlighted that self-medication and over-the-counter use of antibiotics are widespread in developing countries and need more attention.

China stressed on how the WHO and Member States have conducted a series of work on fighting AMR but the situation remains daunting. It also emphasised the need for rational clinical use and stressed that in the case of China, supervision of marketing and a surveillance network have been established. It also placed emphasis on the need to examine the role of animal husbandry and the food industry on this issue and the importance of raising awareness among medical institutions and health workers on rational use.

In supporting the resolution, China said that we need to take action to conduct multi-country, multi-channel, and multi-sectorial cooperation.

Singapore said that AMR is a global problem of a large magnitude, requiring a global solution. It said further that the WHO Global Surveillance Report 2014 on AMR released just before the WHA was a good sign, adding that the United Kingdom and Sweden had done a lot in terms of putting the AMR on the global agenda.

Thailand appreciated the international cooperation and collaboration amongst WHO, FAO and OIE and strongly supported the resolution. It said that the size of the problem is big and global collective action is needed, and stressed that both human health and agricultural sectors have to be addressed. Irrational use and overuse of antimicrobials in agriculture is a matter of serious concern, said Thailand, adding that human antimicrobials used in agriculture can lead to reservoir of resistant bacteria. It stressed that the management of AMR needs strong political support and also called for new antibiotics and rational use of them. It asked the WHO to develop a global action plan.

Qatar reiterated that the threat of AMR is great and the issue of lack of new medicines to combat AMR. It also noted the need to have policy guidance, monitoring and research.

Mexico recognised the need to strengthen measures on AMR and noted how AMR is the main cause of health problems that have major impacts on the economy. It emphasised the need to deal with AMR at the global level respect specificities at each level and called for new strategies and new models to deal with use of antibiotics. Mexico proposed an amendment to the second paragraph, subparagraph six of the resolution (OP2.6) which was adding at the end the phrase: ‘taking into account the need to manage possible conflicts of interest’.

(OP2.6 refers to “a multi-sectoral approach to inform the drafting of the global action plan, by consulting Member States as well as other relevant stakeholders, especially other multilateral stakeholders, such as FAO and OIE; ...” Engagement with “non-state actors” was one of the important issues addressed at the WHA where conflict of interest in the relationship between industry and WHO has been raised by several Member States and civil society organisations.)

Malaysia stressed on the need for awareness and action at the highest level, and the need for concrete action including sanitation and hygiene, use of vaccines when possible, innovation in services delivery as well as health promotion and communication programmes to change the present culture on antimicrobial use.

India noted the emergence of new AMR mechanisms and how this is making it difficult or impossible to treat certain infections. It also expressed support for the global action plan which should be developed in close collaboration with all relevant partners and stakeholders, while avoiding conflict of interests. In stressing that AMR has been a priority for India, it also said that the South East Asia regional strategy on prevention and containment of AMR and the Jaipur Declaration of Health Ministers of the region on AMR are the guiding principles for building capacity to combat AMR.

India said further that the prevention of transmission of infectious disease gains new urgency in the face of resistance to chemotherapy for tuberculosis, HIV and hepatitics. A fresh and strong initiative around infection control in healthcare settings is, therefore, urgent. It strongly believes that ways to ensure financial accessibility of people to new antibiotics have to be better addressed in the global action plan; otherwise new antibiotics may be prohibitive for patients in developing countries, similar to the situation for second and third line antiretroviral drugs.

New ways of funding research and development based on the delinkage principle need to be explored in the context of the developing world, India emphasised. It added that the challenge of AMR adds weight to the proposed R&D Treaty and supporting transfer of technologies to ensure access to medicines for low-income countries.

India also stressed the need to address the specific needs of developing countries and their capacity-building to undertake the relevant activities. It is important to help mobilise financial and technical resources to support the developing countries and their special
needs for strengthening national laboratory-based surveillance capacities; as well as forging networks to produce comparable data and inform evidence-based treatment guidelines. Its understanding is that the proposed global plan of action would take into account these concerns paving the way for an effective global action on containment of AMR. Subject to this understanding, India supported the draft resolution.

Ghana spoke on behalf of the African Region (AFRO) and underlined that the growing prevalence of AMR poses challenges and threats to health security especially for countries with low surveillance and laboratory capacity. It emphasised that AMR threatens the security of public health control particularly for TB, malaria and HIV control.

Ghana also pointed out that a number of countries have developed national action plans on AMR and urged Member States that do not have action plans to develop them. It also reiterated the need for regulations to ensure new innovations for new antibiotics and the importance of collaboration between policymakers, academia and industry to develop new antimicrobials. It said that field epidemiology and laboratory programmes in Africa are being developed.

AFRO is convinced that coordinated efforts are necessary and encouraged the WHO to lead and support action plans in both human and animal health, adding that hygiene, infection control and rational drug use are crucial. Ghana emphasised the need for the global action plan to take into consideration the specific needs of developing countries, as well as access to new antibiotics and diagnostics. It supported the resolution as amended by Mexico.

South Africa supported the statement made by Ghana and the resolution. It pointed out that control of and adherence to antibiotics are key interventions. It underlined the particular challenges for developing countries on the optimisation of surveillance systems, within countries, but in particular in those countries where those systems do not exist. It emphasised the need for investments in those systems and that the agricultural sector must be addressed.

The Philippines supported the adoption of the draft resolution which will expedite and strengthen the implementation of national, regional and global evidence-based actions on AMR. It talked about implementation of its national policy and plan to control AMR and noted that AMR surveillance in the Western Pacific is a major development to handle AMR. It stressed its commitment to continue leading the surveillance for the Western Pacific region together with the WHO.

Tanzania aligned with Ghana's statement on behalf of AFRO and supported the global action plan as well as the work of the WHO strategic and technical advisory group (STAG). It expressed concern about losing the first-line antibiotic which is having impacts on treatment length, stressing that a major challenge is irrational prescribing and irrational use. It also urged the WHO secretariat to address the specific needs of developing countries and ensure access to new antibiotics and diagnostics.

Indonesia acknowledged the global efforts that have been taken to address AMR and shared information on its national efforts. It fully realised the importance of novel antibiotics and diagnostics in health care settings for addressing AMR and recognised that in order to address AMR many challenges need to be overcome such as finance and infrastructure issues.

Turkey pointed out that AMR is location specific and that it is necessary to understand regional dynamics, sharing information on its national and Central Asia efforts. It also supported the amendment proposed by Mexico.

Brazil, Bahrain, Libya and Vietnam also spoke in support of the resolution.

Most of the developed countries that spoke emphasised the global nature of the problem, the need for a global action plan and the importance of the WHO in guiding the process.

Australia noted the impact of AMR on all countries and said that it has committed resources to contain antimicrobial resistance, stressing that it is time to move from advocacy to action.

Norway called for the global action plan to be received in the next WHA and for the implementation of this action plan. Norway offered the possibility of co-hosting a meeting to discuss cooperation on actions to implement the global action plan on AMR.

Greece, on behalf of the European Union, stressed the growing public health threat of AMR, and emphasised the crucial role of the WHO in monitoring and surveillance of AMR and its effects for human health. The EU highlighted the need for global action and leadership on AMR of the WHO and the need for a One Health approach, involving human, animal, environment and agriculture. Adding that a multi-sectoral approach is needed, it said that there is an integrated action plan in the EU on these lines which supports the development of a global action plan.

Sweden also called for an inter-sectoral approach and said that AMR is a threat for low, middle and high income countries. It emphasised the
important leadership role of the WHO in the global action plan and also urged Member States to support the development of a Global Action Plan, facilitated by the WHO Secretariat. Sweden announced that it will co-host an expert meeting on surveillance with WHO which will build on the WHO Global Surveillance Report 2014. It also expressed its support for the resolution as amended by Mexico.

The UK underlined how the cross-regional support for the resolution demonstrated that is not only a developed or developing country issue but a global problem. The UK recognised the legitimate concern of developing countries on access to antibiotics and said that technical capacities as well as affordable drugs must be supported. (This was a reference to the statement by India). It approved the resolution with the amendment by Mexico.

The Russian Federation, speaking on behalf of the CIS (Commonwealth of Independent States - comprising Russia, Belarus, Ukraine and several former Soviet Republics), underscored the need for a comprehensive approach for AMR with veterinary, agriculture and human medicine sectors. Dealing with AMR needs comprehensive action and measures within the healthcare system, including boosting access to laboratory research on AMR; monitoring antibiotic resistance research on key microorganisms, quality control; and reducing the unnecessary consumption of antibiotics.

The United States supported the action plan with stakeholders and multi-sectoral action (human and animal health). It also supported innovative collaboration especially public-private partnerships. It underlined the importance of surveillance and said further that the US, the EU and the Trans Atlantic Task Force is a model to follow that the US, the EU and the Trans Atlantic Task Force is a model to follow. He said further that political will, technical support and funding are essential. Other pathogens apart from bacteria must also be addressed. He also acknowledged that in order to have a successful global action plan, the specific needs of developing countries with each highlighting the importance of AMR. The way forward is to work collectively and develop a global action plan. The action plan needs to cross all sectors, have Member State voices and capture principles from the One Health approach.

Fukuda emphasised the need to close the gap using research and innovation and the need to highlight prevention. He also acknowledged that in order to have a successful global action plan, the specific needs of developing countries such as capacity-building have to be considered. There must be a balance of the different realities, but also common guidelines.

He said further that political will, technical support and funding are essential. Other pathogens apart from bacteria must also be addressed. He then read the amendment proposed by Mexico in paragraph 2.6 as follows: "to apply a multi-sectoral approach to inform the drafting of the global action plan, by consulting Member States as well as other relevant stakeholders, taking into account the need to avoid conflict of interest..."

The resolution with the amendment was accordingly approved.

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State of the world’s health

The pulse of the state of health in the world was taken at the recent World Health Assembly which promoted universal health coverage and pledged to act on antibiotic resistance and on several diseases.

By Martin Khor

The premier international conference on public health policy is the World Health Assembly, organised by the World Health Organization, which attracts Ministers of Health and other top health officials as well as NGOs to Geneva every year.

This is where the latest trends in public health problems are presented and debated on, and action plans for solutions are adopted.

This year’s Assembly, which closed on 24 May, had 3,500 participants and saw a record number of issues debated and resolutions adopted.

One of the key buzz words during the Assembly was “universal health coverage.” This is being promoted by the WHO and several governments to be one of the goals for the United Nations’ post-2015 Development Agenda.

There is no precise definition for the term, but it is widely taken to mean that everyone, including the poor, should have access to medical treatment and other health services.

Inability to pay should not prevent someone from being “covered” by the health system, and people should not become financially burdened by having to pay, or to pay so much, to get treatment.

The UHC concept is a great one, similar to the “health for all by the year 2000” slogan that the WHO adopted in the 1980s as its umbrella goal. It resonates with or is even rooted in the “right to health”, which is one of the human rights recognised by the UN.

UHC was the centre of discussion at the panel session on the post-2015 Development Agenda half way through the WHA. WHO Director General Margaret Chan stated that there are various ways to finance and achieve UHC and it is for each country to choose its own model.

If UHC is adopted, it will be a big step forward towards equity (another term much used at the Assembly) in the health system. How to make it happen, especially the method to finance it, will be a key question.

In a resolution on health in the post-2015 development agenda, the Assembly proposed priority for the health of the new-born, non-communicable diseases, mental health, neglected tropical diseases and completion of existing health Millennium Development Goals.

It also stressed the importance of universal health coverage and the need to strengthen health systems.

The Assembly also adopted a resolution on antibiotic resistance after many delegates expressed their concerns that the bacteria’s growing resistance to medicines was making it difficult to treat many diseases.

The WHO had recently issued a report showing increasing prevalence of resistance in many diseases including TB, pneumonia, diarrhoea, malaria, skin diseases, and gonorrhea. It warned of a post-antibiotic era, where drugs will no longer be able to cure infectious diseases.

The resolution urges governments to strengthen the proper use and management of drugs, support research to extend the lifespan of existing drugs, and to develop new antibiotics and diagnostic technologies.

The WHO was asked to develop a draft global action plan within a year to combat antimicrobial resistance, that includes rational drug use, better surveillance, access to medicines and discovery of new drugs.

The Assembly adopted the first-ever global plan to end preventable deaths of newly born babies and stillbirths by 2035, and called for all countries to aim for fewer than 10 newborn deaths per 1000 live births and less than 10 stillbirths per 1000 total births by 2035.

Every year almost 3 million babies die in the first month of life and 2.6 million babies are stillborn (they die in the last 3 months of pregnancy or during childbirth). Most of these deaths could be prevented.

The Plan’s goals will require every country to invest in high-quality care before, during and after childbirth for every pregnant woman and newborn.

The WHO’s strategy to help countries improve access to essential medicines. Key principles include selecting a limited range of medicines using best evidence, efficient procurement, affordable prices, effective distribution systems, and rational use.
Another new global strategy was adopted for tuberculosis (TB), aimed at ending the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% by 2035.

TB remains a deadly disease. In 2012, 8.6 million people fell ill with TB, 1.3 million died from it and 450,000 people developed multidrug-resistant TB.

Non-communicable diseases, including those caused by diet, were also discussed. At her opening speech, WHO Director-General Dr Margaret Chan highlighted the increase in childhood obesity, especially in developing countries and announced a Commission on Ending Childhood Obesity.

The health plight of the poor in middle-income countries was also a theme at the Assembly. Dr. Chan highlighted that 70% of the world’s poor live in middle-income countries and asked if there will be policies to ensure benefits are fairly shared, or else the world will see “a growing number of rich countries full of poor people.”

But it is not only domestic policy that affects the poor. A side-event by health NGOs focused on how the middle-income countries were being left out of schemes such as supply of free medicines or the relaxation of patent rules to help the poor, as these are often reserved for low-income countries.

However most of the poor people in the world live in middle-income countries, some of which have large populations.

Some developing countries voiced frustration on how they are being picked upon by the United States for having patent laws that prioritise making medicines affordable to the public.

Dr. Chan in another speech also criticised free trade agreements that enable tobacco companies to challenge measures taken by governments to curb cigarette sales.

Other issues the WHA discussed include autism, psoriasis, an action plan for disabilities, palliative care, financing for research and development for diseases that affect developing countries, strengthening of medicines regulations, and assessment of health technologies.

“Post Mortem” of the 67th WHA

By Germán Velásquez

The sixty-seventh session of the World Health Assembly (WHA) was held in Geneva from 19 to 24 May 2014. The delegations of 194 Member States of the World Health Organization (WHO) discussed around 75 agenda items, 15 decisions, and 20 resolutions during the week-long Assembly.

This article makes some “post mortem” comments based on the discussions on some of the critical issues on the agenda of the WHA.

The first general comment is that the agenda items reflected very little of what countries have been discussing since several years as WHO priorities. The agenda of the WHA should have 20, maximum 25 items reflecting the global health priorities. The least that can be said is that it is impossible to deal with 75 points, deeply and with seriousness.

With respect to the format and methodology of the event, substantive discussions were held in two large committees - Committee A (for technical issues) and Committee B (for administrative matters). While the substantive discussions were held in the Committees with the involvement of technical experts from various delegations, Ministers and heads of delegations simultaneously addressed their speeches to a few close friends in a largely empty plenary hall. However, this year there was a full plenary hall listening to the keynote speech of Melinda Gates to the WHA for over twenty minutes. The intervention of Melinda Gates was heavily criticized by NGOs present at the meeting: “We the undersigned organizations express our strong protest against the decision of the World Health Organization (WHO) to invite Melinda Gates (of the Bill and Melinda Gates Foundation - BMGF) as the keynote speaker at the 67th World Health Assembly, that began in Geneva on 19th May. This is the third time in the last 10 years that someone from the BMGF and of the family has been an invited speaker at
the WHA (Melinda Gates was preceded by her husband Bill Gates, in 2005 and 2011). Ms. Melinda Gates’ credentials as a leader in public health are unclear” (Open letter from Civil Society, 20 May 2014).

It is clear that the format and functioning of the WHA are not appropriate or effective for the annual deliberations that should guide the course of global health. Member States should consider the use of WHO’s treaty making powers (under Article 19 of WHO Constitution) in this context. Serious consideration needs to be put into whether and if so how WHO’s treaty making and regulation making powers could be used to mandate necessary standards governing the priority global health issues.

As it often happens in the WHO governing bodies, the meeting witnessed divergent points of view among a small group of countries of the North and countries of the South. Following are some comments on some of the most important items on the agenda:

Framework of engagement with Non-State actors (Document A67/6, WHA67 agenda item 11.3)

Two days of informal consultations were held in Geneva in March 2014 on this issue which concluded with the agreement to entrust the WHO Secretariat to submit to the 67th session of the WHA a new version of the policy on engagement with non-state actors (NSAs), taking into consideration the comments from Member States. After 2 days of intensive deliberations in a drafting group during the WHA, Member States were unable to agree on a draft framework and policy on the organisation’s engagement with “non-State” actors. According to the WHO draft, NSAs include non-governmental organisations, private sector entities, philanthropic foundations and academic institutions. The draft document submitted by the WHO secretariat was sent back to regional committees for further discussions. The failure to approve this policy will take one more year without clear guidance in this substantial item which is at the core of WHO reforms. There is a concern therefore that the unapproved draft framework and policies could continue to “legitimize the status quo” and the influence of the private sector in the WHO would continue to grow.

Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG, Documents EB134/26 and EB134/27, WHA67 agenda item 15.2)

Switzerland surprisingly, almost as a “coup d’état”, submitted a decision, which was not foreseen. Led by the delegation of Bolivia, developing countries managed to include the request that the demonstration projects should not be linked with starting the negotiations for a binding R&D treaty. Until now the demonstration projects, introduced by the EU, USA and Switzerland, seem to be a strategy to delay the central recommendations of the CEWG report.

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products (Document EB134/25, WHA67 agenda item 15.3)

No resolution was considered under this item and only a report was submitted to be noted by the Assembly. After more than 3 years of debate there has been very little progress in this process and doubts about the quality and legitimacy of generics persist.

Regulatory System Strengthening (Document A67/32, Resolutions EB134.R17 and EB134.R19, WHA67 agenda item 15.6)

On the issue of “Regulatory System Strengthening” two resolutions were approved. In the first resolution on “Regulatory System Strengthening for Medical Products” developing countries managed to delete reference to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH is basically an initiative of the US, Japan and the EU and the multinational pharmaceutical industry.

Most but not all references to harmonization were deleted. The preamble of the approved resolution said: “Noting with appreciation the many EXISTING national and regional efforts (...) such as the European Union regulatory framework for medical products, work under way in PAHO following its 2010 resolution CD50.R9, the African Medicines Regulatory Harmonization Initiative, and the regulatory harmonization and cooperation work in ASEAN”. Developing countries MUST watch that this is not a door left open to ICH in the next years.

Concerning the other resolution on the same agenda item - Access to biotherapeutic products including similar biotherapeutic products, acknowledging that national authorities may use different terminologies when referring to similar biotherapeutic products, under the leadership of Colombia and Argentina, developing countries managed to have the request to the Director for the revision of the “WHO Guidelines on evaluation of biosimilar products” issued by the WHO secretariat in 2009 approved, without the approval of the WHA.

Antimicrobial Drug Resistance (Documents A67/39 and EB134/2014/REC/1, WHA67 agenda item 16.5)

The WHA approved a resolution on antimicrobial resistance, which urges Member States to strengthen drug management systems, to support research to extend the lifespan of existing drugs, and to encourage the development of new diagnostics and treatment options. The WHA recognized the growing concern of antimicrobial resistance and urged governments to strengthen national action and international collaboration. The resolution also requested WHO Secretariat to develop a draft Global Action Plan to combat antimicrobial resistance, including antibiotic resistance for presentation to the World Health Assembly for approval next year.

It is time, better late than never, that WHO takes seriously an issue that NGO’s, like TWN, have been alerting the global community for more than 15 years.

Germán Velásquez is Special Advisor on Health and Development of the South Centre.
A new global coalition has been established by several NGOs to address the crisis of antibiotic resistance.

This decision was made at the end of a workshop on antibiotic resistance that was held in Geneva on 28 April to 1 May.

The South Centre hosted the workshop, and co-organised it with ReAct (a Sweden-based NGO specialising in antibiotic resistance) and the What Next Forum.

The Antibiotic Resistance Coalition (ARC) comprises civil society organisations from six continents and will act to demand policy shifts and actions. It called on policy makers to “Act Now or face a catastrophic post-antibiotic era.”

The coalition also issued a Declaration on Antibiotic Resistance which outlined comprehensively its analysis of the crisis as well as the measures needed to address it.

“Antibiotic resistance is the most pressing public health issue facing the global community,” said Otto Cars, founder of ReAct. “If the WHO and its members states do not act quickly, there will be disastrous global health consequences.”

According to an ARC statement, “researchers estimate that each year millions of people around the world are infected with antibiotic-resistant bacteria, and hundreds of thousands of them die. Without immediate action, that toll is expected to worsen.”

The ARC asserted that consumer protection and public health must trump the pursuit of profit, and that effective antibiotics are global public goods. The Coalition also calls for international leadership and action to, in part:

- Prohibit the promotion and advertising of antibiotics;
- Promote new, needs-driven and open research and development models based on the principle of de-linkage (divorcing price from research and development costs and sales volumes);
- Phase out the use of antimicrobials for routine disease prevention in livestock, and end their use, altogether, for growth promotion;
- Build robust systems, in all countries, to monitor and report antibiotic use and resistance trends in humans and animals; and
- Improve public awareness to support an ecological understanding of human-bacteria interaction and behaviour change around antibiotic use.

“Member States must deliver a strong mandate to the WHO to not only develop a pressing action plan on antimicrobial resistance, but also to ensure that public health is prioritised over commercial interests,” said Yoke Ling-Chee, program director with Third World Network. “Access to affordable and effective antibiotics is of particular importance for developing countries.”

The workshop which was held over four days was attended by civil society groups which mainly focus on health issues. They represented national and international groups based in India, Thailand, Malaysia, Indonesia, China, Sri Lanka, Ecuador, Costa Rica...

(Continued on page 19)
By the Antibiotic Resistance Coalition

Antibiotic resistance threatens to undermine the effectiveness of modern medicine. More and more strains of bacteria are resistant to an ever-rising number of antibiotics, with no new antibiotics on the horizon to treat some of the most serious infections. The change is global and accelerating. Millions of people are infected with antibiotic-resistant bacteria each year; hundreds of thousands lose their lives. The toll will increase.

Antibiotic use causes resistance to emerge, and their misuse and overuse accelerates its spread. Without a radical change in antibiotic usage, antibiotic resistance will become one of the greatest threats to humankind, to security and to the global economy.

The lack of effective antibiotics against resistant infections has the potential to affect us all – doctors and patients, farmers and consumers, humans and animals – without regard for international borders.

Efforts to slow the march towards this dire future have largely failed.

The Antibiotic Resistance Coalition (ARC), comprising civil society organisations from all sectors on six continents has therefore been formed to demand policy shifts and action.

We affirm that:

- Clinically useful antibiotics are a finite resource and a global, essential public good. Consumer protection and public health must not be subordinated by governments or international institutions to the pursuit of profit.
- An ecological understanding of bacteria and their importance for human, animal and ecosystem well-being must underpin all policy and practice concerning the use of antibiotics.
- Public leadership is needed to enact new, needs-driven research and development models, with open research and transparent data, which support rational use and equitable access to antibiotics.
- National-level action is paramount, international cooperation is essential, and the collective responsibility of all stakeholders is crucial in order to bring about a solution to the escalating healthcare crisis caused by antibiotic resistance.
- Effective action on antibiotic resistance requires that the social and economic determinants of infectious diseases be addressed. In many parts of the world, these are manifested through poverty, exploitation, international power relations and local inequities, as well as through poor access to nutrition, safe drinking water and sanitation.

The Antibiotic Resistance Coalition commits itself, according to the principles and actions in this declaration, to urgently work to avert the looming post-antibiotic catastrophe.

We call on international organisations, governments and concerned citizens to support us in this endeavour.

We invite civil society and other organisations to join us in signing this declaration, with the following analysis and action points.

Problem Statement

1. Lack of effective antibiotics is a global concern with the potential to affect all humans and domesticated animals. It threatens to undermine the effectiveness of modern health care. An ever-widening range of bacteria, causing a spectrum of diseases in humans and animals is becoming resistant to most available antibiotics.
Unchecked, escalating antibiotic resistance will lead to the global spread of untreatable infections and massive deterioration in health and loss of life. It will also make most surgery impossible and end organ transplantation and cancer chemotherapy.

2. Antibiotic resistance makes it difficult and sometimes impossible to treat even the most common bacterial infections. It prolongs recovery, greatly increases treatment costs and is leading to greater mortality and morbidity. It results in serious side effects, since antibiotics of last resort are often more toxic than drugs of choice.

3. While antibiotic resistance is a natural phenomenon, it has greatly accelerated with decades of unrestrained marketing by the pharmaceutical industry, which promotes overuse and misuse of antibiotics in human medicine, industrial food animal production and the food-processing sectors. For some infections resistance has already reached critical levels.

4. Inadequate regulation and control of the sale and use of antibiotics in animals and humans, including financial incentives for prescribers and dispensers, has been a major factor leading to this crisis.

5. International organisations, such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE), have so far failed to exercise effective leadership in the stewardship and responsible use of antibiotics. National bodies that set food standards and regulate pharmaceuticals have largely failed to control human and animal antibiotic use. Data systems for monitoring antibiotic resistance and use remain very fragmented. New trade and investment regimes threaten to place commercial interests above public health and consumer protection, thereby under-cutting effective control of antibiotic use and resistance.

6. The policy frameworks for research and development are further fuelling resistance without advancing innovation. They are failing to build on available scientific research in developing new antibiotics and diagnostics, and there is a severe antibiotic discovery gap. They are also failing to ensure access for all people who need treatment and are ineffective in limiting excessive and irrational use of antibiotics.

7. Inappropriate antibiotic use is also driven by public misunderstandings about the difference between bacterial and viral infections, and an ill-informed fear of bacteria in general. It is essential to promote understanding of the critical importance of bacteria for all life forms, in order to use antibiotics only when necessary to deal with the small fraction of bacteria that, at times, threaten to harm us. Prudence and restraint from excessive consumption must inform a new paradigm for how to live well and what ‘good health’ means.

Thematic Action: Access, Not Excess – Curbing excessive use while ensuring access for people in need

8. Antibiotic treatments and diagnostics should be considered global public goods – common resources requiring common stewardship.

9. Effective regulation and control of antibiotics must be exercised to ensure that existing and new antibiotics are made available and are affordable to those in need in all countries, while not being overused or misused. This calls for further strengthening of public health systems everywhere.

10. All countries should adopt a national policy on rational use of antibiotics, as well as taking necessary action to prevent excessive antibiotic use. Regulatory controls must address prescription and marketing practices.

11. Securing access for everyone in need is as vital as curbing overconsumption. Price should not be used as an instrument to ration use for humans. Limiting access leads to preventable suffering and death.

12. Activities to curb excessive use must include better training of health professionals through non-commercial, evidence-based programmes and sustained and targeted public education. Standard treatment guidelines should inform antibiotic administration. Antibiotic stewardship, involving optimal antibiotic drug regimens and appropriate duration of therapy and route of administration, as well as future effectiveness, should be incentivised, and unnecessary use should be disincentivised.

13. Hospitals, which are known to have a high degree of resistance, as well as other healthcare delivery centres should be encouraged to collect regular data on both hospital-acquired and community-acquired infections, to make the data publicly available and to follow infection control protocols to minimise such infections.

14. The public sector in every country needs to build a robust national system for monitoring antibiotic use and resistance trends in humans and animals, as well as contributing to the development of an effective global monitoring system. Essential inputs to a global surveillance system include data on prices, availability, affordability, sales and use of antibiotics, by drug and by indication, as well as drug resistance patterns and changes in antibiotic efficacy. These data for both human and non-human uses must be gathered and publicly disclosed in sufficient detail to enable effective action by stakeholders such
as civil society, medical professionals and governments.

15. Diagnostic uncertainty must be minimised through development and availability of rapid diagnostic tools and techniques. This is instrumental for timely determination of the nature of infection and to prevent irrational use of antibiotics. Such tools should meet WHO ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users) criteria, including being affordable and adapted to meet the needs of low- and middle-income countries.

16. Promotion and advertising of antibiotics, including marketing for inappropriate uses or incentivising medical and veterinary personnel to overuse or inappropriately prescribe antibiotics, is harmful to health and should be prohibited. Regulatory authorities should be funded out of general taxation, and fees from pharmaceutical companies and the livestock industry should be paid directly to governments rather than to these authorities. This is in order to avoid any conflicts of interest.

17. Enhanced attention should be given to preventing the occurrence and spread of infections, and to addressing infections in ecologically informed ways. An over-reliance on new antibiotics as the main solution should be avoided. Public health communication should focus on restraint and balance.

18. We should avoid seeing ourselves as being at war with bacteria and learn to live more harmoniously with them, except on the rare occasions when infectious strains threaten our health. Treatment of infections must be balanced with the importance of maintaining healthy populations of bacteria for humans and animals.

19. Civil society and governments should engage in raising broad-based public awareness and efforts to support behavior change in society, grounded in creativity, popular education, art, social movements and reformed school curricula.

**Thematic Action: Non-human Use – Tackling excessive non-human use in food and agriculture**

20. The preservation of effective antibiotics for human health should take priority over their use for commercial gain in food production. A disproportionately high amount of antibiotics is used in animals, particularly in the industrial production of food animals. Antibiotics should only be used for treating animals when indicated by a genuine therapeutic need and based on antibiotic therapeutic guidelines.

21. Antibiotic use for mass disease prevention must not substitute for good animal husbandry and welfare. Farm practices such as overcrowding, unhygienic conditions, inappropriate diets, and early weaning requiring routine antibiotic administration, must be prohibited. Similarly, antibiotic use for growth promotion must be banned.

22. All countries should participate in a global surveillance system that promotes and supports infrastructure and periodic survey data to assess animal antibiotic use and resistance patterns in farm animals and foods.

23. To help secure effective antibiotics for the future, the role of veterinarians should be delineated, to guide infection prevention and discourage non-therapeutic use of antibiotics.

24. Antibiotics considered critically important for humans must not be used for animals, except in specific circumstances in order to save life or prevent serious suffering.

25. Regulations should be instituted and enforced to ensure antibiotics are marked with appropriate warnings and clear distinctions between human and animal use, so as to help control and monitor antibiotic consumption.

26. Food produced without routine use of antibiotics and without antibiotic residues should be labelled through reliable, certified schemes to facilitate consumer choice. Food produced with routine use of antibiotics must be clearly labelled, until effective prohibition of such antibiotic use can be introduced.

27. Food produced without antibiotics in animal feed, or routinely used in any other way for its production, should be a prerequisite in all public procurement of food. Hospitals should take a leadership role in procuring food produced without routine use of antibiotics, as doing so is consistent with their core health mission.

28. Civil society and consumer movements should target the supply chain by exposing and boycotting corporations that produce or provide food with routine use of antibiotics.

29. Governments should initiate regulatory measures to control the environmental pollution that allows the spread of antibiotic-resistant genes across soil, water and air. Environmental movements have an important role in supporting and mobilising actions towards limiting such pollution.

**Thematic Action: Innovation – Developing an effective innovation system for new antibiotics, diagnostics and other tools that supports health, access and rational use**

30. Short of radical changes in our innovation system, we stand at the precipice of a post-antibiotic era. We call for public leadership promoting new, needs-driven research and development models based on the principle of de-linkage: divorcing price from research and development costs, as well as from sales volumes. Public funding is essential, and benefits of these investments should accrue to the public. Incentives should target new antibiotics with novel mechanisms of action or with significant public health value. We must couple these incentives with measures conserving antibiotics use.

31. Public leadership for innovation must also look beyond antibiotics. New avenues of treatment may provide entirely new opportunities and merit investment as well. Complementary technologies can reduce the selective pressure of antibiotic use on the microbiome. Diagnostics are an important tool to help reduce inappropriate use, aid surveillance and recruit patients to clinical trials. Vaccines can prevent the need to use antibiotics.

32. Innovation requires access to the building blocks of knowledge. We call for public leadership to establish pooled efforts and support open research. These might include enriching compound libraries with potential new drug candidates, providing specimen banks to aid developers of new diagnostics, building clinical trial networks to ease recruitment of patients, sharing pre-clinical and clinical data, and publishing findings in open access journals.
33. Screening of existing compound libraries has resulted in few promising drugs. We call for public leadership to establish a network of bio-repositories that can harness biodiversity for natural products that might become tomorrow’s antibiotics. This will require committing public funding, enlisting the informed participation of low- and middle-income countries, where much of this biodiversity exists, in the process of innovation, and ensuring returns through fair and equitable benefit-sharing arrangements with those countries.

34. Complete trial data and other information concerning the safety, efficacy and resistance profiles of antibiotics and diagnostics should be made publicly available, to advance scientific progress and rational use, with privacy protections in place.

35. We reject additional intellectual property measures. These are likely to compromise patient access and reward high sales volumes without altering the current failing incentives structure. The needs of one patient group should not be sacrificed to another, for example, via proposals for an Intellectual Property (IP) voucher that would transfer the cost of antibiotic development to other patient groups.

36. The paramount concern of regulatory review of new antibiotics must be the improved health outcomes and safety of patients facing multi-drug resistant infections. In recent years, drug regulatory agencies have amended regulations for antibiotics to approve them based on clinical trials with small sample sizes and surrogate endpoints. However, lowering standards of clinical trials only to incentivise drug companies to bring drugs to market without significant public health benefit is not acceptable.

37. A broad, holistic approach, based on an ecological understanding of bacteria, should be encouraged so as to spur innovative ways of discovering new antibiotics as well as finding solutions and approaches to infections other than through the use of antibiotics. From redesign of hospitals, to targeting inter-bacterial communication, to fecal transplants, a ‘reimagination’ of resistance and bacteria can open whole new avenues for solutions.

**International Action and Co-operation**

38. A global framework for action must be developed by governments through the United Nations system, in close collaboration with all stakeholders. Such a framework must include targets and ways of tracking their achievement that can be applied according to national circumstances.

39. National governments should formulate specific, measurable, achievable, realistic and time-bound targets for controlling antibiotic resistance.

40. International cooperation should support low- and middle-income countries financially and technically, including through capacity-building, to enable them to implement the set targets effectively.

41. International action should ensure that the terms of any global, regional and bilateral trade, investment or intellectual property rules do not undermine laws and policies that aim to implement effective controls over antibiotics.

42. International organisations, including both the United Nations system and other institutions, should scale up their actions and coordination to match the urgency of the crisis posed by antibiotic resistance.

- WHO should enhance its efforts to take a genuine leadership role by significantly expanding its in-house capacity, making a strong case for Member States to provide the necessary funds, providing enhanced training and policy guidance to developing countries, establishing closer collaboration with organisations and movements with non-profit, public health interests working against the containment of antibiotic resistance.

- The Codex Alimentarius, the joint WHO and FAO international food standards, should develop new sets of standards for antibiotic use in food animals which take into account not only residues in food, but also antibiotic resistance.

- FAO and OIE should prioritise efforts to ensure radical reductions of antibiotic use in food production and processing, and not shy away from the far-reaching implications this may have on the industrial agriculture model of food production.

- International organisations should work together with national governments to develop a robust system of surveillance of antibiotics usage and resistance.

The Antibiotic Resistance Coalition affirms that the principles and actions in this declaration are necessary to prevent a global catastrophe. Actions must be taken now.
South Centre calls for stop to unilateral US pressure against South’s use of TRIPS flexibilities

The South Centre issued a statement on March 2014 calling on WTO Members to respect the legitimacy of the use of TRIPS flexibilities for public health in light of new threats of unilateral trade measures by the United States against India over its intellectual property laws and regulations.

The South Centre is deeply concerned that developing countries, and more recently the government of India, are facing increasing pressure from the United States of America to reform their intellectual property (IP) laws. The Indian IP laws include balanced provisions to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health. These are fully in line with the TRIPS Agreement and reaﬃrmed by the Doha Declaration on TRIPS and Public Health.

The mere threat of sanctions by placing a country in any speciﬁc category in the US watch list would appear to violate the WTO Dispute Settlement Understanding. A WTO panel noted, in a dispute brought in 1999 by the EU against Section 301 of the US law, that “the threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures.”

The United States International Trade Commission (USITC) has initiated investigations against India on trade, investment and industrial policies in India particularly on intellectual property laws and regulations. Moreover, the United States Trade Representative (USTR) is being asked to include India as a priority foreign country in the Special 301 review for 2014, at the request of US industry associations including the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization (BIO), the National Association of Manufacturers (NAM), the National Foreign Trade Council (NFTC), the US Chamber of Commerce’s Global Intellectual Property Centre, and the Alliance for Fair Trade with India (AFTI), alleging lack of adequate and effective protection of intellectual property rights (IPRs).

The South Centre views these recent developments as most inappropriate, as it is against the spirit of the landmark Ministerial Declaration on TRIPS Agreement and Public Health. India and other developing and least developed countries have the right to use the flexibilities in the TRIPS Agreement to the fullest extent for advancing public health needs and other development priorities. The legal and regulatory measures that India has used for protecting public health are fully consistent with the WTO TRIPS Agreement. The continued threat of unilateral trade sanctions by the US to developing countries through USITC investigations and the Special 301 review undermines the legitimacy of the WTO, particularly the TRIPS Agreement and the WTO’s dispute settlement system.

It is regrettable that India or any other developing country may be designated as a “priority foreign country” under the “Special 301” provisions of the US Trade Act of 1974. Designation as a “priority foreign country” starts a 30-day period during which targeted countries must engage in good faith negotiations or make significant progress in bilateral or multilateral negotiations or face sanctions under the Section 301 process. Priority foreign country determinations are reserved for countries “that have the most onerous or egregious acts, policies, or practices,” that “have the greatest adverse impact (actual or potential) on the relevant US products,” and for which “there is a factual basis for the denial of fair and equitable market access as a result.” The USTR investigation may lead to unilateral trade sanctions that would be illegitimate under the WTO rules.

Below is the South Centre’s statement.

The South Centre made written submissions explaining why India’s patent law and policy are fully consistent with India’s obligations under the WTO TRIPS Agreement. The USTR in April 2014 decided to retain India’s status as a country in the priority watch list along with a number of other countries, but did not designate India as a priority foreign country (which would have resulted in a penalty).

In the USITC process, two Congress committees (as well as 17 industry associations) requested the USITC to prepare a report by 30 November 2014 whether Indian industrial policies had affected the US economy and jobs. The investigation is on-going and a report will be submitted by November.

The South Centre issued a statement on March 2014 calling on WTO Members to respect the legitimacy of the use of TRIPS flexibilities for public health in light of new threats of unilateral trade measures by the United States against India over its intellectual property laws and regulations.
The establishment by the government of a country of its criteria to grant patents (as provided for in section 3 (d) of the Indian Patent Act and interpreted by the Indian Supreme Court in the Novartis case), the right to issue compulsory licenses, and the use of patent pre-grant and post-grant opposition proceedings are, among others, important flexibilities that serve to protect public health, consistent with the TRIPS Agreement. None of the recent decisions in India to reject patents on known medicines or to issue compulsory licenses on anti-cancer medicines have been challenged before the WTO dispute settlement mechanism. In fact, the recent actions taken by India are not unique. Many other developing countries have issued compulsory licenses for ensuring access to affordable medicines to meet their public health needs, including Brazil, Ecuador, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, Thailand and Zambia.

The TRIPS Agreement also does not preclude that countries include in their patent laws a requirement to disclose the source and geographical origin of biological materials used in an invention that is the subject of a patent application. The disclosure requirement is conducive to the mutually supportive implementation of the TRIPS Agreement and the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit sharing.

The South Centre encourages India and other developing countries to continue to make full use of the TRIPS flexibilities for public health and other public policy objectives, consistent with their rights and obligations under the WTO rules.

The US administration should also stop putting pressures on developing countries to prevent them from making use of their rights under the TRIPS Agreement to make use of policy measures to promote access to medicines, public health and other development objectives.

Civil society workshop...

(Continued from page 13)

Rica, Ghana, Tanzania, Egypt, the United States, Sweden, the United Kingdom, Denmark, Switzerland, the Netherlands and others.

The themes of the workshop included:

- State of Play of the resistance crisis: What does it look like, where is it heading?
- State of Play: Current actions by the UN, governments, experts and civil society
- Access (to medicines) but not excess (excessive use of antibiotics): Tackling excessive and irrational use of antibiotics in the health sector while ensuring equitable access
- Non-human use of antibiotics: Tackling excessive use in agriculture and food production
- Innovation: Collaborative approaches to ensure innovation of novel antibiotics
  - Re-imagining resistance: Holistic and ecological approaches to tackle ABR
  - Dialogue with officials from WHO

In the dialogue session with WHO, the workshop discussed presentations of the steps towards a global action plan on antimicrobial resistance by WHO Assistant Director General, Dr Keiji Fukuda, as well as Charles Penn, Carmem Pessoa Da Silva and Gilles Forte.

The participants urged the WHO to take the lead on this issue, while the WHO officials stressed that fighting the crisis required the efforts of all sectors, including the CSOs.

The United States’ Special 301 Interagency Panel hears testimony in Washington from industry and government representatives on the IPR situation in various countries.

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The US administration should also stop putting pressures on developing countries to prevent them from making use of their rights under the TRIPS Agreement to make use of policy measures to promote access to medicines, public health and other development objectives.

WHO officials at left table having dialogue with NGOs at the workshop in Geneva.

WHO officials at left table having dialogue with NGOs at the workshop in Geneva.
Reflections on the life of a `Gentle Caribbean Giant´, Dr. Norman Girvan, 1941-2014

By Mariama Williams

The South Centre pays tribute to the life of a dear friend, Dr. Norman Paul Girvan, a distinguished political economist, a public intellectual and a promoter of economic development grounded in the ethos of community development and social and economic justice in the Caribbean and in the Global South. His transition from this life is a great loss to all whose lives he had indelibly touched through his speeches, his academic writings and his political and social advocacy.

Norman P. Girvan (Nyak, to his close friends) was a long supporter of the South Centre, having served on the Board in 2002-2011, and as its Vice Chair in 2006-2011. Girvan was born in Jamaica (1941), lived for a while in Trinidad & Tobago and died on April 9, 2014 in Cuba where he was receiving medical attention from a terrible fall that left him paralyzed in Dominica. Norman is survived by his wife, Jasmine, a gifted artist, and his son, Alexander and daughter, Alatash.

At the time of his death, Prof. Girvan was a professorial research fellow at the Sir Arthur Lewis Institute of Social and Economic Studies (Mona Campus, Jamaica) and at the Graduate Institute of International Relations (St. Augustine campus, Trinidad and Tobago), both of the University of the West Indies. Dr. Girvan, a member of the UN Committee on Development Policy, had also been appointed by the Secretary General of the United Nations to mediate the border dispute between Venezuela and Guyana. Prior to that he was the second Secretary General of the Association of Caribbean States.

Girvan’s rich academic and devoted public service life was grounded in his quest for justice, his belief in the importance of ‘knowing your history, your roots, your heroes and your heroines’ and his profound belief in and lived experience of respect for his fellow human beings. He was noted for his commitment to principled positions that encouraged ‘compromise, but never betrayal’.

Girvan was committed to and dedicated his effort in the struggle for social and economic justice, culturally grounded and community based development and regional integration, the latter in particular with regard to the Caribbean and Latin America. He was a strong supporter and mentor of the Caribbean NGO community, whose leadership describes him as a ‘leading exemplar in the struggle for social and economic justice’, who worked tirelessly to ensure inclusiveness across the English, Dutch, French and Spanish speaking Caribbean. He loved Cuba and what it stood for in terms of an independent development path and avoidance of the machinations of external powers over development pathways, including the potential deleterious effect of multinational corporations on development.

Dr. Girvan’s distinguished career as a Caribbean and development scholar and a public servant has left a wonderful legacy of writings on the five dominant themes of his professional service: the impact of multinational corporations (as a mechanism of under-development) and extractive industries on development; the role of debt and IMF policies, including structural adjustment programmes in development; the central role of technology in development; the critical importance of regional integration in Caribbean development and the political economy of the South. He wrote eleven books, edited seven volumes and published over 100 articles and book chapters. He also founded the Association for Caribbean Economists.

His journey as a passionate and purposeful national, regional and international public intellectual (an engaged academic) ranged from early positions as Director of the National Planning Agency of Jamaica (1970s); to Dakar, Senegal, where he worked with the United Nations African Institute for Development and Planning in Dakar; Regional Coordinator of the Caribbean Technology Policy Studies Project of the University of the West Indies/University of Guyana; and he had worked as Senior Officer and Consultant at the now defunct UN Centre for Transnational Corporations. Norman was also a Visiting Fellow at the Universities of Chile, McGill, Northwestern. Ultimately, he served multiple
terms as a most beloved Board member of the South Centre, Geneva, for which, at the time of his death, he was undertaking research on the implementation process of the Economic Partnership Agreement between the EU and the Caribbean.

Dr. Girvan was a passionate intellectual giant and a beacon of scholarship in service of the Caribbean and the South in general. He worked tirelessly on the question of economic development that could be promoted by focusing on regional integration, community development and, above all, independent and critical thinking.

He recently wrote that:

I subscribe to the view that true sovereignty begins with independent and critical thought…this must remain the goal for those who have been subjected to centuries of colonization and metropolitan imposition of one kind or another.

Drawing on the reflections of one of his friends and colleagues at the University of the West Indies, Dr. Brian Meeks, it seems quite appropriate to end this reflection with two lines from Dylan Thomas that so well resonates with the life and passion of this gentle giant, Norman P. Girvan, and his ultimate lesson to us all.

Do not go gentle into that good night
Rage, rage against the dying of the light.

Dylan Thomas

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Norman Girvan – a personal reminiscence

By Yash Tandon

On 26 March 2008 the Sir Arthur Lewis Institute of Social and Economic Studies (SALISES) held its ninth annual conference in Jamaica in honor of Professor Norman Girvan and I was invited to give the keynote address in his honor. The conference called for ‘Reinventing the Political Economy Tradition of the Caribbean’ to which Norman had dedicated his whole life.

I had known Norman by reputation since the early 1970s whilst I was teaching at the University of Dar es Salaam. Norman had come out of the Latin American ‘Dependencia School’ to which he had made a distinct contribution. In essence this ‘School’ argued that the global economy was divided between the ‘Centre’ (comprising the developed countries of the west) and the ‘periphery’ (comprising the ‘South’); and that in order for the ‘South’ to develop they must adopt policies to protect their infant manufacturing built largely on domestic capital. One of the key proponents of this ‘school’ was the Argentinian Raul Prebisch, the main architect of the United Nations Conference on Trade and Development (UNCTAD). Norman’s book Foreign Capital and Economic Underdevelopment in Jamaica was part of the reading for my students on a course on the political economy of East Africa.

Some thirty years later we met at a conference in Nicaragua, and we became close friends and confidants. In 2004 I was appointed the Executive Director of the South Centre with some prodding, I might add, from Norman and political friends in Africa. Norman was on the Board of the South Centre. The Centre was at the time passing through some difficult time on account of the financial and governance problems following the sudden...
Alas, on April 10, 2014, Norman finally succumbed to the inevitable. Following his dreadful fall in the mountains of Dominica he survived only for three months. Norman, you have left behind an inspiring legacy. You will be missed, but your legacy, your dream, will live on. Rest in Peace!

Yash Tandon is former Executive Director of the South Centre (2005-2009).