The
Federal Government

DART 2020

Interim report on the occasion of the WHA 2016

Background

The German Antimicrobial Resistance Strategy (DART 2020)[1] was adopted by the Federal Cabinet in May 2015. DART is a joint initiative of the Federal Ministry of Health (BMG), the Federal Ministry of Food and Agriculture (BMEL) and the Federal Ministry of Education and Research (BMBF). The aim of DART 2020 is to slow the development and spread of antimicrobial resistances in human and veterinary medicine.

DART 2020 and the measures it contains adopt a stringent "One-Health" approach. The issue of resistance and the specific problems in the field of human and veterinary medicine are viewed and tackled in their entirety. DART 2020 brings together the various stakeholders with their differing areas of expertise and utilises the added value resulting from this cooperation. Important elements in this regard include raising the awareness of the population and medical professionals as well as improving rational antibiotic therapy and reducing the overall use of antibiotics. The ministries are also cooperating at international level with other partners and the relevant organisations, namely the World Health Organisation (WHO), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organisation of the United Nations (FAO), in efforts to further stem the spread of antimicrobial resistances.

One year after adopting DART 2020, this report describes the results achieved so far, gives examples of measures taken and provides an overview of the next steps.

1 http://www.bmg.bund.de/fileadmin/dateien/Publikationen/Ministerium/Broschueren/BMG_DART_2020_Bericht_dt.pdf

Focal areas and results

Cooperation at international level is crucial for successfully slowing down antimicrobial resistances globally. DART 2020 therefore focused on international measures in its first year, in particular via the German G7 Presidency. These efforts resulted in the Berlin Declaration on Antimicrobial Resistance[2] which provides an important basis for further action to be taken soon. The German G20 Presidency in 2017 plans to build on this basis.

By presenting this report, the ministries involved wish to show how antimicrobial resistance is being combated at national and international level.

In addition to the international efforts, national measures have also been launched and implemented in the strategy's various areas of action. The most important measures and results are outlined below under the six DART 2020 objectives.

OBJECTIVE 1: Strengthening the One Health approach nationally and internationally

Human and animal health must be viewed holistically. Multisectoral measures are needed if the development and spread of antimicrobial resistances is to be slowed.

It is vital to have close cooperation between all stakeholders and between the competent federal ministries and their higher federal authorities. Increased travel and the globalised nature of trade in animals and plants also make close coordination with our international partners, both in the EU and worldwide, indispensable if we are to achieve sustainable success.

2 Berlin Declaration on Antimicrobial Resistance (https://www.bundesgesundheitsministerium.de/presse/pressemitteilungen/pressemitteilungen-2015-4/g7-gesundheitsminister-verabschieden-berlin-erklaerung.html)

What has been achieved so far?

Germany has already implemented one of the main objectives of the WHO's Global Action Plan on Antimicrobial Resistance – to have national action plans in place by 2017 – by drawing up DART 2020.

The German government used the German G7 Presidency to put antimicrobial resistance on the agenda of the G7 summit in Elmau and to reach concrete agreements. To give substance to the results achieved there, the G7 Health Ministers' Meeting in Berlin in October 2015 addressed the subject and set out measures in the "Berlin Declaration". The Federal Minister of Food and Agriculture and the OIE were included in this process. At Germany's suggestion, the Northern Dimension Partnership[3] also addressed this subject at its conference in Berlin in November 2015 and adopted a declaration. Germany is consequently pressing ahead internationally in raising awareness and promoting cooperation on the subject of antimicrobial resistance, both within the G7 and beyond.

A brochure with Best Practice examples from the G7 states in the fields of human and veterinary medicine has been drawn up to support other countries in developing national action plans. Not all countries have yet developed the capacities necessary to successfully combat antimicrobial resistance in the long term. As Co-Lead Country of the Global Health Security Agenda's (GHSA)[4] AMR Action Package, Germany is cooperating with other countries to support partner countries in developing these capacities and consequently in implementing the WHO's Global Action Plan. One specific example of this is Germany's cooperation with Turkmenistan in preventing nosocomial infections.

Another important step is to renew the research agreement on zoonoses that has been in place since 2006 between the BMBF, the BMG and the BMEL, and the Federal Ministry of Defence (BMVg) as a new partner. The support schemes contained in this agreement also help implement DART 2020 by

3 http://www.ndphs.org/
4 http://www.ghsa.org/

further strengthening research on infections that are transmissible between animals and humans.

Outlook

In September 2016, the United Nations General Assembly will address the subject of antimicrobial resistance. Germany has cooperated with the other countries committed to the GHSA's AMR Action Package in developing principles for a resolution and is following and supporting the further process closely. The aim of the United Nations' focus on this field is, in Germany's view, to attract the political attention of the heads of state and government, in particular those in developing countries and threshold economies, and to reach agreement on the fact that combating antimicrobial resistance requires multisectoral cooperation between human and veterinary medicine, agriculture, environment and research. Only then will the WHO's Global Action Plan be able to be implemented in good time.

From 2016 BMG, in cooperation with the Robert Koch Institute (RKI), the Paul Ehrlich Institute (PEI), the Bernhard Nocht Institute for Tropical Medicine (BNITM) and the Federal Institute for Drugs and Medical Devices (BfArM), will join forces with other partner countries in combating antimicrobial resistances under the Global Health Programme. The primary aim of this cooperation is to establish and develop global capacities and strengthen health structures for combating antimicrobial resistance.

To facilitate sustainable delivery of the Resolution on Antimicrobial Resistance, which was adopted by the FAO Conference in 2015, Germany continues to call for this subject to be incorporated into the FAO's regular programme of work and budget.

Germany also calls for the international standards on food safety and product quality to be revised in respect of antimicrobial resistance (Codex Alimentarius Code of Practice to Minimise and Contain Antimicrobial Resistance CAC/RPC 61-2005).

As a result of Germany's commitment and the Berlin Declaration, the OIE has made antimicrobial resistance one of the main topics at its next General Session in May 2016. In 2017, the OIE plans to hold a second Global Conference

on Antimicrobial Resistance. Germany will actively support this conference, as it did the first in 2013.

Germany will hold the second Patient Safety Summit in the summer of 2017. The first meeting took place in London in March 2016. Antimicrobial resistance and nosocomial infections will remain at the top of the agenda in 2017.

OBJECTIVE 2: Recognising changes in resistance at an early stage

Therapy and hygiene recommendations need to be continually adapted to latest developments and targeted prevention strategies need to be developed; to do so requires having representative data on the development and incidence of new pathogens and resistances. At local level, these data help adjust the scope and extent of prescriptions by medical and veterinary practitioners. The development of resistance rates over time provides indications of the effectiveness of intervention measures.

What has been achieved so far?

Antimicrobial Resistance Surveillance (ARS) at the RKI has been further expanded. The number of participating laboratories was increased by almost 70% in 2015 over the previous year. This further consolidates the data base on antimicrobial resistance in Germany. Reporting requirements were also expanded on 1 May 2016 to include carbapenem-resistant gram-negative pathogens and clostridium difficile; this is also helping improve the data situation. These data enable the local authorities to take early action. Both of these measures are also helping institutions such as the European Centre for Disease Prevention and Control (ECDC) and the WHO improve the data base at European and international level.

Antimicrobial resistance monitoring in respect of zoonotic pathogens and commensal organisms has been continued and expanded (AmpC and the colistin resistance gene *mcr-1*). The test for *mcr-1* has also been incorporated into the resistance monitoring system in respect of animal pathogens.

Outlook

The surveillance system at the RKI will be further expanded in the years to come. One focus will be on improving the feedback of data to the physicians who will in this way receive important information enabling them to adjust how and when they prescribe antibiotics.

There are plans to expand the above monitoring programmes, to standardise the methods and to examine the possibilities for providing feedback to veterinarians regarding resistance data.

OBJECTIVE 3: Retaining and improving therapy options

To ensure that antibiotics remain efficacious in the long term, they must be used properly. In Germany, the use of antibiotics varies greatly from region to region; there may be a number of reasons for this. Improving understanding in this area requires data on the quantities of antibiotics prescribed and used. These data also form a basis for targeted intervention measures and provide support in assessing their effectiveness.

What has been achieved so far?

The Antibiotics Consumption Surveillance System (Antibiotika-Verbrauchs-surveillance - AVS) was set up at the RKI in 2014. Over 200 hospitals have since been enlisted to take part in the AVS. The aim is to support hospitals in implementing the statutory requirements contained in the Protection against Infection Act (Infektionsschutzgesetz – IfSG) and to promote local activities related to antibiotics stewardship.

In 2014, a statutory benchmarking system, which records therapy frequency in respect of fattening cattle, pigs, turkey and chicken, was introduced to minimise the use of antibiotics. Under this system, animal keepers must compare the frequency with which they treat their animals with nationwide data every six months. If they exceed the nationwide parameters, they must take measures to improve animal health and consequently reduce the use

of antibiotics. The first three review periods showed a downwards trend in therapy frequency.

Key issues for further regulations on administering antibiotics to animals were also presented; these regulations are intended to focus on antibiotics that are of particular importance in human medicine.

The quantities of antibiotics dispensed to veterinarians by pharmaceutical companies and wholesalers have been recorded since 2011; recording of these data continued. As of 2014, these quantities had decreased by 27%.

At international level, 2015 saw the OIE begin keeping records of the dispensing of veterinary antibiotics.

Outlook

In 2016/2017, the surveillance system on the consumption of antibiotics will continue to be expanded. An intervention study is examining the differences in the regional consumption of antibiotics in Germany.

Once the discussion of the above key issues with the respective stakeholders has been concluded, these parameters will be incorporated into a corresponding draft regulation in 2016.

OBJECTIVE 4: Breaking chains of infection early and avoiding infections

Preventing infections is the most important step to reducing the consumption of antibiotics. Compliance with hygiene measures by qualified medical staff in hospitals and by well-informed animal keepers is crucial in this regard, but early diagnosis is also important in order to be able to use antibiotics in a more targeted manner and prevent the further spread of resistant pathogens. Regional networks for the prevention and control of resistant pathogens can help in identifying and eliminating local problems in applying and implementing these measures and objectives.

What has been achieved so far?

In 2015, the BMG developed a 10-point plan[5] to prevent treatment-associated infections and antimicrobial resistances in hospitals. When implemented, this plan will tackle key aspects of infection prevention. For instance, the hospital hygiene promotion programme has been extended until 2019 and expanded to include the field of infectiology. The hospital hygiene promotion programme supports medical institutions in implementing the requirements laid down in the Protection against Infection Act. The BMG has also supported research work carried out by regional networks; the results of this work were presented in a workshop.

Vaccinations are an important tool for disease prevention. In the field of human medicine, the Standing Committee on Vaccination (Ständige Impfkommission - STIKO) at the RKI is drawing up corresponding recommendations. The Standing Committee on Veterinary Vaccination was set up at the Friedrich Loeffler Institute in 2015. It assesses the use of vaccinations in animal medicine and makes corresponding recommendations. This is intended to support the targeted use of vaccines in animal medicine.

Support is being provided for a cooperative project that aims to develop products and elaborate measures that encompass the entire chain in order to reduce the transfer and development of multi-resistant pathogens within the poultry meat chain.

Outlook

As part of a European survey, it is planned to carry out another National Study on Nosocomial Infections and the Consumption of Antibiotics before the end of 2016 in order to obtain up-to-date data for this field. This will help identify trends and make measures more targeted.

It is also planned to continue and expand research on disrupting infection chains in and between animals stocks and along the food chain.

5 http://www.bmg.bund.de/fileadmin/dateien/Downloads/A/Antibiotikaresistenzstrategie/10-Punkte_Antibiotika-Resistenzen.pdf

OBJECTIVE 5: Raising awareness and strengthening skills

One key requirement for using antibiotics properly and dealing with multi-resistant pathogens correctly is to have sound knowledge and data. Medical and veterinary professionals, animal keepers and the population as a whole all have a great need for information and knowledge which must be supplied and imparted.

What has been achieved so far?

The Hospital Structure Act (Krankenhausstrukturgesetz – KHSG) requires hospitals to publish readily comprehensible information on hygiene standards in their quality reports. In 2015, the Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung – BZgA) developed an information sheet on antimicrobial resistance for the population to inform them about such resistance and the proper use of antibiotics and sent this sheet to doctor's surgeries, dispensing chemists and nursing homes. The BMG's current call for tender, issued to implement DART 2020, also includes the development and trialling of patient-orientated communication strategies.

The BMEL also supported the VetMAB project, which developed an internet-based training and data-management tool for veterinary practices designed to minimise the use of antibiotics in livestock husbandry. Antimicrobial resistance is one of the range of subjects addressed during counselling at funded demonstration farms.

Outlook

One focus in the coming year will be to further strengthen basic, further and advanced training of medical staff in treating infectious diseases and in particular on the subject of antimicrobial resistance. The projects carried out following the call to tender will result in greater knowledge about how, when and by what means appropriate information can be provided. It is also planned to conduct joint workshops with the BMEL and BMBF to develop ways of providing the targeted recipients with information.

The amendment that has been made to the rules concerning the licensing of veterinarians provides for the express inclusion of antimicrobial resistance in the "pharmacology and toxicology" section of the qualifying examinations.

OBJECTIVE 6: Supporting research and development

Data on the development and spread of resistant pathogens are needed to be able to slow down the spread of antimicrobial resistance. Research plays a crucial role in providing the necessary data. One objective of DART 2020 is therefore to strengthen all the corresponding research areas in human and veterinary medicine - from basic research, clinical research and research into public health issues to research carried out in cooperation with the health, agricultural, and food sectors, and to be an example to, and motivation for, the research community.

What has been achieved so far?

The problem of increasing antimicrobial resistance is exacerbated by the pharmaceutical industry's decreasing engagement in researching and developing new antibiotics. This was addressed at national level in the German government's pharmaceuticals dialogue. At the German government's initiative, industry, science and policy makers met to jointly discuss urgent issues relating to the supply of medicinal products and to Germany as a location for the pharmaceuticals industry. A sub-working group on antibiotics conducted intensive discussions about research and development of new antibiotics. The final report[6] stated in respect of antibiotics that a list of the most important bacterial pathogens and resistances worldwide (List of threat organisms) would be drawn up in cooperation with the WHO. This list is intended to help in prioritising research. New reimbursement models are being developed for medicinal products that are important for medical care as reserve antibiotics. Preliminary work has begun on drafting corresponding statutory regulations.

6 http://www.bmg.bund.de/fileadmin/dateien/Downloads/P/Pharmadialog/Pharmadialog_Abschlussbericht.pdf

Under the German G7 Presidency, the G7 health ministers discussed incentive schemes for researching and developing new antibiotics, alternative therapies and diagnostics. Germany is taking action to progress the subject of antimicrobial resistance within the G7.

The development of new antibiotics must give consideration to the global need. New developments must also be accessible for developing countries and threshold economies. The WHO has therefore cooperated with the Drugs for Neglected Disease Initiative and launched the Global Antibiotic Research and Development Partnership (GARD). This focuses on product-development partnerships with the aim of developing antibiotics, vaccines, alternative therapies and rapid tests that are urgently required across the globe. It will also test ways of regulating the use of new medicinal products. Germany is a founding member of the initiative and provides financial support.

The German government has maintained its high level of institutional and project support for research on the development of new antibiotic substances. In early 2016, to further strengthen the One Health approach, work began on setting up a National Research Network on Infectious Zoonotic Diseases. This network will also cover research on the development and transmission of resistant pathogens between humans, animals, food and the environment. Research within the network will be based closely on the requirements in practice.

At international level, Germany has joined 21 other states in forming the Joint Programming Initiative on Antimicrobial Resistance (JPI AMR). Under this initiative, the BMBF launched a research initiative with the other JPI AMR members in early 2016 to research the transmission of antimicrobial resistances, paying particular regard to the One-Health approach.

Outlook

The further implementation phases in 2016/2017 will focus on the field of research support. In addition to the BMG's ongoing call for tender on antimicrobial resistance and nosocomial infections, which will support projects on diagnostics, patient-orientated communication strategies and the effectiveness of existing measures, the BMG is planning a further call for tender in late 2016 on the implementation of the zoonoses agreement.

The BMBF-funded National Research Network on Infectious Zoonotic Diseases will start its work in 2017. In addition to interlinked research, the network also plans to focus on support for junior research groups and a rapid-response module.

The BMBF will support the development of novel therapies and diagnostics for bacterial infections. It plans to focus in particular on supporting small and medium-sized enterprises in accelerating the transfer of research findings.

There are ten projects currently receiving support from BMEL; these are addressing possibilities for reducing the use of antibiotics for animals and preventative and innovative hygiene measures. It is also planned to support a research project on the use of antibiotics in fish intended for food production.

At Germany's initiative, a scientific conference is planned for 2016 to intensify international cooperation; at the conference , international scientists from different fields will be able to network and exchange thoughts and ideas on the research and development of antibiotics. Germany is consequently meeting its particular responsibility for the process initiated during the G7.

Conclusion

The excessive use of antibiotics is a highly-charged subject with far-reaching consequences. In the field of human medicine, for example, antibiotic therapy for acute upper respiratory tract infections is useless, as these are usually viral diseases. The use of antibiotics in this case has no added health value and promotes resistance formation.

The proper use of antibiotics is not just of immense importance from the point of view of health; it is also vital from an economic standpoint. Antimicrobial resistance may lead to bacterial infections becoming far harder, if not impossible, to treat because the antibiotics will lose their effectiveness. This will result in longer and more serious bouts of illness and disease and may lead to premature fatalities.

Resistances may be absorbed from the environment and via food across species and genera. Careful diagnosis for humans and animals is therefore not just important to the respective patient; it also prevents both excessive and inadequate use, prevents the spread of resistant pathogens and consequently protects everyone.

Enhanced research work is needed to slow the development and spread of resistances and develop new antibiotics, as many mechanisms are not yet understood and there is a lack of innovation for new active substances. The German government will therefore maintain its high level of support for research and development and will launch new, targeted initiatives.

The German government's dialogue on pharmaceuticals brought together industry, science and policy makers and succeeded in initiating joint concepts for researching and developing new antibiotics. This process is unique and provides impetus for the discussions necessary at international level.

The German government will use DART 2020 in coming years as the road map for addressing these challenges in both human and veterinary medicine. Thorough analysis, action and reviews are the necessary steps which will be combined under the One-Health approach.

The German government will not let up in its international efforts and will fight antimicrobial resistance at European level, with its G7 partners and under the GHSA.

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