

## **DEBATE PACK**

Number CDP 2016/0092, 25 April 2016

# Incentivising research and development of new antibiotics

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This pack has been produced ahead of the debate on **incentivising research** and **development of new antibiotics** to be held in Westminster Hall on Tuesday 26 April 2016 at 2.30pm. The Member in charge is Julian Sturdy.

Concern over antimicrobial resistance (AMR) has risen in recent years. A Westminster Hall debate was held on the issue on 15 October 2014. Amongst the current work on the issue, a Government-backed Review on Antimicrobial Resistance, set up last year and chaired by Lord Jim O'Neill, will report in May 2016.

#### Contents

١.	News items	3
2.	Press Releases	5
3.	Parliamentary	
	material	17
3.1	PQs	17
3.2	Debates	19
l.	Useful links and	20

The House of Commons Library prepares a briefing in hard copy and/or online for most non-legislative debates in the Chamber and Westminster Hall other than half-hour debates. Debate Packs are produced quickly after the announcement of parliamentary business. They are intended to provide a summary or overview of the issue being debated and identify relevant briefings and useful documents, including press and parliamentary material. More detailed briefing can be prepared for Members on request to the Library.

2 Number CDP 2016/0092, 25 April 2016

# 1. News items

The Independent

#### Antibiotic resistance 'could become bigger threat to mankind than cancer' [IND]

14 April 2016 |Jemma Crew

http://www.independent.co.uk/news/uk/politics/antibiotic-resistancecould-become-bigger-threat-to-mankind-than-cancer-a6983611.html

The Guardian

#### Mapping antibiotic resistance in real-time

11 April 2016 Sean Hargrave

http://www.theguardian.com/media-network/2016/apr/11/antibioticresistance-real-time-open-data

Financial Times

#### O'Neill 'superbug' review promotes wider use of vaccines

11 February 2016 Andrew Ward

http://www.ft.com/cms/s/0/aa52a020-cff4-11e5-831d-09f7778e7377.html?siteedition=uk#axzz46q7NXWQS

Daily Telegraph

#### Big pharma pushes for global alliance to fight antibiotic-resistant superbugs

21 January 2016 Bloomberg

http://www.telegraph.co.uk/finance/newsbysector/pharmaceuticalsandc hemicals/12112928/Big-pharma-pushes-for-global-alliance-to-fightantibiotic-resistant-superbugs.html

Daily Telegraph

#### First new antibiotic in 30 years discovered in major breakthrough

7 January 2016 Sarah Knapton

http://www.telegraph.co.uk/science/2016/03/14/first-new-antibiotic-in-30-years-discovered-in-major-breakthroug/

BBC Online

#### Analysis: Antibiotic apocalypse

19 November 2015 James Gallagher

http://www.bbc.co.uk/news/health-21702647

**BBC News** 

## Call for \$2bn global antibiotic research fund

14 May 2015 Fergus Walsh

http://www.bbc.co.uk/news/health-32701896

4 Number CDP 2016/0092, 25 April 2016

Financial Times **Big pharma risks public backlash on antibiotics, says Jim O'Neill**May 14, 2015 Andrew Ward

<a href="http://www.ft.com/cms/s/0/8a6f6cf6-f95e-11e4-ae65-00144feab7de.html#axzz46TNV8MgE">http://www.ft.com/cms/s/0/8a6f6cf6-f95e-11e4-ae65-00144feab7de.html#axzz46TNV8MgE</a>

# Press Releases

Review on Antimicrobial Resistance Jim O'Neill highlights the power of simple measures to prevent infections and slow the rise of drug-resistant superbugs 22 March 2016

Fundamental changes are needed to better prevent and monitor the spread of drug-resistant infections globally, according to a new report published today by Jim O'Neill's independent Review on Antimicrobial Resistance (AMR). Addressing the root causes of infections by improving access to water and sanitation reduces the demand for antibiotics as well as the opportunities for bacteria to become drug-resistant. Prevention is the most permanent, sustainable solution to slow down the rise of superbugs.

The paper, Infection prevention, surveillance and control: limiting the development and spread of drug resistance, is the last in a series of interim reports by the Review, before it presents its final recommendations to the UK Prime Minister in May 2016, which will set out a package of actions to tackle drug-resistant infections globally. It makes the case that many countries made the greatest progress in tackling infectious diseases in the 19th century, long before modern antimicrobial drugs were available, by focussing on disease prevention and investing in public sanitation infrastructure.

Such an approach is still vital today. Yet the focus on prevention has weakened over recent decades, and public spending has shifted towards treatment as cheap and effective antimicrobial drugs have become more and more available, including antibiotics. But these drugs are losing their effectiveness because over time microbes evolve to resist them. For example, 500,000 people suffer from multi-drug-resistant tuberculosis today and 200,000 of them die every year. Global action to support the development of useful products like new antibiotics, rapid diagnostics and vaccines – as called for by the Review in earlier reports – remains essential, but it must be underpinned by more fundamental action to reduce the infectious disease burden and thus demand for these antimicrobials.

The report highlights three areas where decisive action has the potential to 'shift the demand curve' for antibiotics and other antimicrobials: Improved access to clean water and sanitation. Inadequate access to safe water and sanitation infrastructure increases the global burden of infections. This is particularly true given its impact on the burden of diarrhoeal disease, the second leading cause globally of death in children under five years old. The enormous number of preventable cases of diarrhoea is a major driver of antibiotic consumption (most of it unnecessary since diarrhoeal illness is most commonly caused by viruses, which do not respond to antibiotic treatment), and in turn the development of drug resistance. Analysis commissioned by the Review suggests that across India, Indonesia, Brazil and Nigeria, diarrhoeal illness could account for the consumption of at least 500 million courses of antibiotics today, growing to more than 622 million cases by 2030 –

a figure that could be reduced by more than 60% if these countries had universal access to improved water and sanitation.

Poor sanitation also plays a key role in fostering 'superbug' infections because exposure to unsanitary conditions provides greater opportunities for drug-resistant strains of bacterial infections to develop and move between humans and the environments, and substantially increases

Finally, the report presents analysis showing that, when national income and healthcare expenditure are controlled for, a 50% increase in access to improved sanitation is associated with an increase in national life expectancy of more than nine years.

A greater focus on infection prevention and control in healthcare settings. Hospitals and other care environments, like residential homes for the elderly, are high-risk environments for the spread of drugresistant infections. In high-income countries, at least one patient in 10 will contract a healthcare-associated infection whilst admitted to hospital, a figure that rises to one in three for patients in intensive care. MRSA (methicillin-resistant *Staphylococcus aureus*) is a well-recognised problem following worrying outbreaks in many countries over the past two decades, but for which infection rates have substantially fallen in recent years. The report argues that concerted efforts to prioritise infection prevention – led by governments, regulators and other health system leaders – are key to fending off existing and newly-emerging superbugs. These efforts must be supported by empowering the staff who lead infection control efforts within hospitals. Better research is also important into behavioural interventions that can 'nudge' doctors, nurses and other carers to follow what are sometimes simple steps such as washing hands and following checklists.

Substantial improvements to the global surveillance of emerging drugresistant infections. To manage the rise of drug resistance we must be able to effectively measure it and monitor it. This is far from the case at present. There is no globally-coordinated system that allows us to track the consumption of antimicrobials, or identify the emergence and spread of new drug-resistant strains of infections, not even in the most advanced economies and the gaps are much worse in developing countries. The report identifies many promising initiatives—such as the UK Government's 375m USD Fleming Fund, and work by the WHO and non-government organisations like the Gates Foundation, Wellcome Trust, and Institut Pasteur – but stresses that much more needs to be done to build adequate global capabilities. As well as building conventional lab-based infrastructure, efforts also need to take account of the emergence of new rapid diagnostic technologies. These new diagnostics have the potential to deliver real-time surveillance of resistance on an unprecedented scale in all parts of the world. Governments, industry and civil society need to consider how to best make use of this information, tackling questions of data sharing, ownership and intellectual property today, to realise the potential of these new technologies tomorrow.

Action on all three fronts represents a vital part of a broader series of interventions the world needs to make to tackle drug resistance. 2016

will be critical in making this happen with the G7, G20 and UN General Assembly all gearing up to discuss the global response to this challenge. The Review will spend the coming months engaging with governments, NGOs and industry globally to discuss and develop these proposals further, with input from an international advisory group, before presenting a final report in the May 2016, covering the whole AMR landscape.

#### Quotes about the report

Lord Jim O'Neill. Chairman of the Review on AMR. said: "The challenges of antimicrobial resistance are complex, but some of the most effective and permanent solutions will lie in getting the basic things right. There is nothing new or controversial in saying that we should look to prevent infections from spreading from person to person, and not overly rely on our ability to cure them. But in the age of effective and relatively cheap antimicrobials, we have too often lost sight of this simple idea. Investment in public infrastructure like water and sanitation can reap enormous benefits for individual countries by improving the health of their populations and their economic prosperity, and for the whole world by reducing unnecessary use of antibiotics and the development of drug resistance.

I find it alarming that despite what we know about the scale of the threat posed by rising drug resistance, our ability to monitor its development and spread in a systematic, global way is extraordinarily limited. Much more needs to be done to fix the surveillance blindspots that exist across all parts of the world – because if we can't measure the growing problem of drug resistance, we can't manage it. A new generation of rapid diagnostics, combined with developments in technologies like artificial intelligence and cloud computing, have the potential to revolutionise this field, but the opportunity to realise these benefits will be missed if we don't start building a consensus now about how we can gather, share and use this data in a consistent and coherent way.

Even in healthcare settings, where the importance of infection prevention and control is well-recognised and well-understood, there is a lot more that we can do to break the chains of transmission between patients and deny superbugs the opportunities to develop and spread, starting with making it a priority in health systems around the world. At the front line, basic things like better handwashing can have a huge positive impact on this, but even with the best of intentions we know that healthcare workers don't do it as much as they should: we need to understand the behavioural factors that get in the way of best practice, and empower professionals to make this change happen."

Mr Yasuhisa Shiozaki, Minister of Health, Labour and Welfare for Japan, said:

"Japan welcomes this report. It rightly recognises that effective disease surveillance is essential to counter the grave threat of drug-resistant infections that Jim O'Neill is outlining. Without good surveillance, we cannot effectively counter the threat that antimicrobial resistance poses to health systems and people all over the world. It is also vital that countries work together to make sure old and new technologies are

rolled out in a way that supports better global "One Health" AMR surveillance including animals and the environment.

Japan stands ready to work with other countries through our leadership as the G7 Presidency and the Tokyo Meeting of Health Ministers on AMR in Asia this year. We support other countries by sharing my country's expertise in developing the state-of-the-art JANIS system, Japan Nosocomial Infections Surveillance system."

Dame Sally Davies, Chief Medical Officer for England, said: "As Jim O'Neill's latest report shows, it is crucial that we remember to get the basics right as the foundations of the global response to antimicrobial resistance: good sanitation, safe water, cleaner hospitals, and better surveillance are all fundamental parts of the problem of drug-resistant infections. Building an effective, comprehensive global surveillance system to monitor the spread of antibiotic resistance will take time, but I'm pleased that through the leadership of the WHO and initiatives like the UK Government's 265m GBP [375m USD] Fleming Fund, we are making the important first steps towards this ambitious but vital goal."

Dr Jeremy Farrar, Director of the Wellcome Trust, said: "Clean water, better sanitation, hand washing in hospitals and wider

surveillance are all critical elements in preventing the spread of drugresistant infections. But absolutely none of these measures will be a surprise to those working in any area of medicine, who have been discussing them for decades. The time for talk is over. People are dying of infections that doctors are unable to treat now, and millions more lives are at risk. All countries must translate these recommendations into national policy and, above all, action, as a matter of urgency."

Dr Keiji Fukuda, the Director General's Special Representative for Antimicrobial Resistance at the World Health Organization (WHO), said: "The basics of public health – clean water, good sanitation and hygiene, infection prevention and control and surveillance – are as critical for reducing the impact of antimicrobial resistance as they are for infectious disease control. While we also need new technologies and medicines, and better use of existing medicines, we cannot let attention to fundamental public health practices suffer, or else antimicrobial resistance will continue to thrive."

Dr Val Curtis, Director of the Environmental Health Group, London School of Hygiene & Tropical Medicine, said:

"One of the best ways to prevent antimicrobial resistance is to prevent infections in the first place, so antimicrobials aren't needed. We won't solve this problem properly until we tackle the problem in the countries with the biggest burden of infection. We need to act to get toilets to the two billion that don't have them, and new norms of behaviour to the four out of five people on the planet who don't wash their hands with soap at key times. That's possibly the most cost effective way to rid us of both disease and the AMR that is its consequence."

#### Notes for Editors

1. AMR or 'antimicrobial resistance' is the term used to describe drugresistant infections, sometimes referred to as 'superbugs'. Antimicrobials include antibiotics (which act only on bacteria), antivirals, antiparasitics and antifungals.

- 2. The report, *Infection prevention, control and surveillance: Limiting the* development and spread of drug resistance, will be published on the Review's website at www.amr-review.org on Tuesday, 22 March. The UK Prime Minister, David Cameron, commissioned the Review on Antimicrobial Resistance in July of last year to address the growing global problem of drug-resistant infections. It is Chaired by Lord Jim O'Neill and backed by the Wellcome Trust and the UK Government.
- 3. Lord Jim O'Neill is the current Commercial Secretary to HM Treasury, as well as the Chairman of the Review on AMR. He is an internationally published economist and until 2013 was Chairman of Goldman Sachs Asset Management, having previously been the organisation's Head of Economic Research. Before chairing the Review on Antimicrobial Resistance, he led the Cities Growth Commission which played a central role in the Government's decision to devolve significant new powers to large urban centres in the UK starting with Manchester and the Northern Powerhouse project. He is particularly well known for his work in relation to developing and middle-income economies, having coined the BRIC (Brazil, Russia, India, China) acronym – meaning that he is especially well-placed to understand the broad range of international interests raised by antimicrobial resistance.
- 4. While action to encourage the use and development of vaccines and alternative approaches is crucial to tackling AMR, this represents one part of the solution to the diverse challenges of increasing drug resistance, as outlined in our previous papers and those still to be published in 2016. The Review will be covering health infrastructure in the coming months, before producing its final report in May 2016.
- 5. The Wellcome Trust is a global charitable foundation that spends more than £700 million a year on advancing human and animal health. It is the second highest-spending charitable foundation in the world, after the Bill & Melinda Gates Foundation, investing principally in biomedical science, the medical humanities and public engagement. The Trust is providing part-funding for the work of the Review, and hosting the team at its London headquarters.
- 6. The Review will be tweeting about the report via its official account, @ReviewonAMR

#### Antibiotic Research UK Antibiotic Research UK launches its first research programme to tackle superbugs with Antibiotic Resistance Breakers 2 March 2016

Research will use drug repurposing to test whether existing therapies for the treatment of any medical condition can extend the life of existing antibiotics

To meet the challenge of the rise in antibiotic resistant bacteria (superbugs), national charity 'Antibiotic Research UK (ANTRUK) is commissioning the first ever research programme to screen antibiotic resistance breakers against antibiotic resistance in Gram-negative bacteria. ANTRUK is asking scientific organisations and universities to submit tenders for this testing to see if therapies already in use and being safely administered in humans can be coadministered with antibiotics. This is the first of five projects to be carried out in the next 5 to 7 years, with the ultimate objective of developing new antibiotic therapies for use by the early 2020's to overcome superbugs. ANTRUK has ambitious goals to reverse the decline in antibiotic drug development particularly given the lack of appetite among 'big pharma' to find new therapies. This is critical as the WHO believes antibiotic resistance threatens a global situation as serious as the AIDs epidemic; this has been supported by the UK's Chief Medical Officer Dame Sally Davies and the Prime Minister.

In the first of its five projects – identified by ANTRUK's Scientific and Technical Advisory Committee, on which some of the UK's foremost experts in antibiotic resistance sit - up to 1500 drugs in use today for any therapeutic purpose, for example cancer treatment, heart disease and arthritis, will be tested to find out if any can reverse antibiotic resistance. The target antibiotic resistance bacteria to be examined in the screen are the so-called Gram-negative type. These species are responsible for urinary tract, skin and blood infections as well as pneumonia.

ANTRUK has raised funds to finance its first scientific programme from Trusts and Foundations, major donors and the general public. Professor Colin Garner, the Charity's Chief Executive said "We are delighted to have raised sufficient funds 20 months from formation to commence our research. Our Antibiotic Resistance Breaker programme could potentially find new ways of extending the life of our existing antibiotics at a fraction of the cost and time compared to conventional drug development".

Dr David Brown an ex-senior research executive who has worked for Pfizer, Roche and AstraZeneca and, Chair of the Charity's Scientific and Technical Advisory Committee said "Our Committee has been developing this programme for the past 12months. I believe it offers the possibility of finding new antibiotic therapies to meet our goal of bringing one into clinic by the early 2020's. The Charity is delighted to be starting real research now".

#### **Review on Antimicrobial Resistance** GLOBAL PHARMACEUTICAL INDUSTRY CALLS ON GOVERNMENTS TO WORK WITH THEM TO BEAT THE RISING THREAT OF DRUG **RESISTANCE** 21 January 2016

More than 80 leading international pharmaceutical, generics, diagnostics and biotechnology companies, as well as key industry bodies, have come together to call on governments and industry to work in parallel in taking comprehensive action against drug-resistant infections – so-called 'superbugs' – with a joint declaration launched today at the World Economic Forum in Davos, Switzerland. The

statement sets out for the first time how governments and industry need to work together to support sustained investment in the new products needed to beat the challenges of rising drug resistance. The Declaration on Combating Antimicrobial Resistance – drafted and signed by 85 companies and nine industry associations across 18 countries – represents a major milestone in the global response to these challenges, with commercial drug and diagnostic developers for the first time agreeing on a common set of principles for global action to support antibiotic conservation and the development of new drugs. diagnostics, and vaccines. The industry is calling on governments around the world to now go beyond existing statements of intent and take concrete action, in collaboration with companies, to support investment in the development of antibiotics, diagnostics, vaccines, and other products vital for the prevention and treatment of drug-resistant infections.

In particular, the Declaration supports a continuation of efforts towards improved conservation of antibiotics, including a call for improved uptake of rapid point-of-care diagnostics to improve how antibiotics are prescribed, and changes to incentive structures within health systems that directly reward doctors, pharmacists and veterinarians for prescribing antibiotics in greater volumes.

In what the Review on Antimicrobial Resistance recognises to be a notable step for the industry, the signatory companies call on governments to work with them to develop new and alternative market structures that provide more dependable and sustainable market models for antibiotics, and to commit the funds needed to implement them. These mechanisms are needed to provide appropriate incentives (coupled with safeguards to support antibiotic conservation) for companies to invest in R&D to overcome the formidable technical and scientific challenges of antibiotic discovery and development. These include mechanisms to ensure that, where appropriate, the pricing of antibiotics more adequately reflects the benefits they bring; and novel payment models that reduce the link between the profitability of an antibiotic and the volume sold. An integral part of these models is a reduced need for promotional activity by companies.

As well as calling for continued progress by governments on these fronts, the Declaration sets out a commitment to further action on drug resistance by its signatories, which the Review warmly welcomes. These span across three broad areas:

#### Reducing the development of drug resistance.

The companies commit to encouraging better and more appropriate use of new and existing antibiotics, including through work that supports the antibiotic stewardship principles set out by the World Health Organization (WHO) Global Action Plan on antimicrobial resistance (AMR), and via improved education of clinicians. This support extends to promoting more judicious use of antibiotics in livestock, as part of a 'one health' approach.

Increasing investment in R&D that meets global public health needs. Recognising the need to increase research into new antibiotics, diagnostics, vaccines and other alternative treatments, the companies commit to a continuation and extension of collaborative initiatives between industry, academia and public bodies to improve how R&D in the field is done and provide greater opportunities for the scientific barriers to antibiotic discovery to be overcome.

Improve access to high-quality antibiotics for all. In light of the gaps that remain in global access to our existing antibiotics and vaccines, and the importance of ensuring that new generations of products are available to all those who need them, the signatories commit to supporting initiatives aimed at ensuring affordable access to antibiotics in all parts of the world, at all levels of income.

By bringing together such a wide range of companies in this unprecedented way, the Declaration provides a valuable roadmap to guide further collaborative efforts between industry, governments and NGOs in the global fightback against AMR. The Review will continue to work to drive progress towards a series of key international milestones in 2016 – including likely discussions on AMR at the UN General Assembly and as part of China's G20 programme in the autumn – and in support of progress against the WHO Global Action Plan on AMR.

#### **World Health Organisation** WHO multi-country survey reveals widespread public misunderstanding about antibiotic resistance 16 November 2015

As WHO ramps up its fight against antibiotic resistance, a new multicountry survey shows people are confused about this major threat to public health and do not understand how to prevent it from growing. Antibiotic resistance happens when bacteria change and become resistant to the antibiotics used to treat the infections they cause. Overuse and misuse of antibiotics increase the development of resistant bacteria, and this survey points out some of the practices, gaps in understanding and misconceptions which contribute to this phenomenon.

Almost two thirds (64%) of some 10 000 people who were surveyed across 12 countries say they know antibiotic resistance is an issue that could affect them and their families, but how it affects them and what they can do to address it are not well understood. For example, 64% of respondents believe antibiotics can be used to treat colds and flu, despite the fact that antibiotics have no impact on viruses. Close to one third (32%) of people surveyed believe they should stop taking antibiotics when they feel better, rather than completing the prescribed course of treatment.

"The rise of antibiotic resistance is a global health crisis, and governments now recognize it as one of the greatest challenges for public health today. It is reaching dangerously high levels in all parts of the world," says Dr Margaret Chan, WHO Director-General, in launching the survey findings today. "Antibiotic resistance is compromising our ability to treat infectious diseases and undermining many advances in medicine."

The survey findings coincide with the launch of a new WHO campaign 'Antibiotics: Handle with care'—a global initiative to improve understanding of the problem and change the way antibiotics are used. "The findings of this survey point to the urgent need to improve understanding around antibiotic resistance," says Dr Keiji Fukuda, Special Representative of the Director-General for Antimicrobial Resistance. "This campaign is just one of the ways we are working with governments, health authorities and other partners to reduce antibiotic resistance. One of the biggest health challenges of the 21st century will require global behaviour change by individuals and societies." The multi-country survey included 14 guestions on the use of antibiotics, knowledge of antibiotics and of antibiotic resistance, and used a mix of online and face-to-face interviews. It was conducted in 12 countries: Barbados, China, Egypt, India, Indonesia, Mexico, Nigeria, Russian Federation, Serbia, South Africa, Sudan and Viet Nam. While not claiming to be exhaustive, this and other surveys will help WHO and partners to determine the key gaps in public understanding of the problem and misconceptions about how to use antibiotics to be addressed through the campaign.

Some common misconceptions revealed by the survey include:

- Three guarters (76%) of respondents think that antibiotic resistance happens when the body becomes resistant to antibiotics. In fact bacteria—not humans or animals—become resistant to antibiotics and their spread causes hard-to-treat infections.
- Two thirds (66%) of respondents believe that individuals are not at risk of a drug-resistant infection if they personally take their antibiotics as prescribed. Nearly half (44%) of people surveyed think antibiotic resistance is only a problem for people who take antibiotics regularly. In fact, anyone, of any age, in any country can get an antibiotic-resistant infection.
- More than half (57%) of respondents feel there is not much they can do to stop antibiotic resistance, while nearly two thirds (64%) believe medical experts will solve the problem before it becomes too serious.

Another key finding of the survey was that almost three guarters (73%) of respondents say farmers should give fewer antibiotics to foodproducing animals.

To address this growing problem, a global action plan to tackle antimicrobial resistance was endorsed at the World Health Assembly in May 2015. One of the plan's 5 objectives is to improve awareness and understanding of antibiotic resistance through effective communication, education and training.

**House of Commons Science and Technology Committee** Ministers must stop unnecessary use of antibiotics in healthcare and farming 07 July 2014

The Government's announcement of a review of the economics of antimicrobial research is a welcome step in addressing one aspect of antimicrobial resistance. However, current practice across both health and veterinary services is failing to prevent the inappropriate prescription of antibiotics. The Government needs to set clear responsibilities at all levels of the NHS and veterinary medicine to achieve better stewardship of the antimicrobial drugs vital in modern medicine, the Science and Technology Committee has warned.

- Report: Ensuring access to working antimicrobials
- Report: Ensuring access to working antimicrobials (PDF 425 KB)
- Inquiry: Antimicrobial resistance (AMR)
- Science and Technology Committee

Andrew Miller MP, Chair of the Science and Technology Committee: "Antibiotic resistance cannot be entirely prevented, but it is a problem made worse by inappropriate use and poor stewardship of antibiotics in healthcare and farming. We heard concerns, for instance, that antibiotics are often prescribed by GPs simply to achieve a placebo effect or placate patients with distressing symptoms. In farming meanwhile, we suspect that antibiotics may be routinely used on healthy animals.

"We're pleased that the Prime Minister has taken the opportunity just ahead of our report launch to reaffirm his commitment to action on antibiotic resistance, but publishing strategies and announcing reviews is not the same as dealing with the problem. A two year review of the incentives needed to develop new antibiotics may lead to necessary action, but what we really need from Government right now is decisive and urgent action to prevent antibiotics from being given to people and animals who do not need them."

#### Antibiotics in healthcare

The MPs argue that it is essential that the Government puts urgent measures in place to drastically reduce the unnecessary prescription of antibiotics. Better education of medical students and greater focus on antimicrobial resistance during clinical career development is also needed.

Fears were raised during the inquiry that major restructuring of the NHS may limit its ability to get to grips with growing antibiotic resistance in the short-term. The Committee is concerned that the implementation of new structures and chains of command may exacerbate difficulties in limiting the unnecessary use of antibiotics. It recommends that the Government outline, in its Action Plan for its Antimicrobial Resistance Strategy, how they will embed those responsibilities across all roles within the NHS and how compliance with the Strategic goals will be monitored and reported.

#### Andrew Miller MP added:

"All levels of the NHS must be given clear responsibilities for stewardship of antibiotics and better monitoring and reporting put in place to bear down on unnecessary use of antibiotics."

#### Antibiotics in farming

There is circumstantial evidence that antimicrobial resistance can be transmitted from animal pathogens to human pathogens. The use of tetracycline antibiotics and penicillin in farming as growth promoters has been already banned, but the Committee is worried that the total veterinary use of tetracyclines has increased nearly tenfold and that of penicillin type antibiotics has increased nearly fivefold Since the Swann Report in 1969. The MPs are calling on the Government to takes action to ensure the use of antibiotics in farm animals is strictly required for therapeutic use and that more research is carried out on the link between animal and human pathogens resistant to antibiotics.

#### Andrew Miller MP:

"The link between human and animal pathogens antibiotic resistance has not been conclusively proven, but we believe the Government should be taking precautionary action to ensure that antibiotics are only being used on sick animals."

#### Public Awareness

The Committee says greater public awareness surrounding the necessity for stewardship of antibiotics is crucial in reducing pressure on practitioners to prescribe antibiotics. The MPs welcome the awareness of the Government of the need for sustained campaigns to educate new generations and the recent announcement by the Prime Minister. However, they point out that the previous Strategy appears to have had insufficient impact on public awareness and the current Strategy has no definitive targets or measures of success. The report recommends that the Action Plan set challenging targets for improvement of public awareness against which success may be measured and reported.

Potential delay while Prime Minister's review is conducted The Committee agrees with the Prime Minister that urgent work must be done with researchers, investors, pharmaceutical companies and other Governments to identify appropriate incentives to encourage the development of new antimicrobials. However, the review will take almost two years to report back with recommendations. The MPs warn that this must not delay work on any pricing alternatives that could be agreed with the pharmaceutical industry over a shorter timescale.

#### Backaround

Antibiotics are antimicrobial substances that target bacterial infections rather than infections caused by viruses and fungi. They are an essential tool in modern medicine as many procedures, such as chemotherapy for the treatment of cancer and invasive surgery, rely on the use of antibiotics.

In September 2013, the Department of Health and the Department for Environment, Food and Rural Affairs jointly published the UK Five Year Antimicrobial Resistance Strategy 2013 to 2018. This document set out action points in seven "key areas":

- 1. improving infection prevention and control practices in human and animal health
- 2. optimising prescribing practice

- 3. improving professional education, training and public engagement
- 4. developing new drugs, treatments and diagnostics
- 5. better access to and use of surveillance data in human and animal sectors
- 6. better identification and prioritisation of AMR research needs to focus activity
- 7. strengthened international collaboration

# 3. Parliamentary material

### 3.1 PQs

#### Antibiotics: Research

#### Asked by: Lefroy, Jeremy

To ask the Secretary of State for Business, Innovation and Skills, what information his Department holds on how many new antibiotics are in development by UK companies.

#### **Answering member: George Freeman | Department: Department** for Business, Innovation and Skills

The Department does not hold information on how many new antibiotics are in development by UK companies.

The independent review on antimicrobial resistance led by Lord O'Neill publication Securing New Drugs for Future Generations – the Pipeline of antibiotics, provides a high-level assessment of the development pipeline for new antibiotics:

#### http://amr-

review.org/sites/default/files/SECURING%20NEW%20DRUGS%20FOR% 20FUTURE%20GENERATIONS%20FINAL%20WEB 0.pdf

#### HC Deb 17 February 2016 | PQ 26571

#### Antibiotics: Research

#### Asked by: Cunningham, Mr Jim

To ask the Secretary of State for Health, what financial support his Department has provided for research into antibiotic resistance in each of the last five years; and if he will make a statement.

#### **Answering member: George Freeman | Department: Department** of Health

The information requested is not available. The Department funds research through the National Institute for Health Research (NIHR) and the Department's Policy Research Programme (PRP). Spend on research funded directly by the NIHR is categorised by Health Research Classification System (HRCS) health categories. There are no HRCS health sub-categories, and no category or sub-category for antibiotic resistance.

On 18 November 2015 the NIHR announced funding for 16 studies relating to antimicrobial resistance with an investment of over £15.8 million to date, with funding of further projects expected during 2015.

#### HC Deb 24 November 2015 | PQ 17038

#### **Antibiotics**

#### Asked by: Dakin, Nic

To ask the Secretary of State for Health, what assessment he has made of the potential merit of the production of NICE evidence summaries for new and emerging antibiotics as a means of supporting the decisions of local stewardship and medicines management committees.

#### Answering member: Jane Ellison | Department: Department of Health

The Government is determined to use the best available evidence and guidance to support the policy of improving antibiotic prescribing. To this end, the National Institute for Health and Care Excellence (NICE) will be publishing guidance this summer on systems and processes for effective antimicrobial medicine use. In addition, NICE is developing a new Quality Standard on Effective Antimicrobial Stewardship.

Consultation on this new Quality Standard will begin in November 2015 with final publication scheduled for April 2016.

#### HC Deb 23 July 2015 | PQ 7608

#### Medicine: Research

#### **Asked by: Lord Taylor of Warwick**

To ask Her Majesty's Government what assessment they have made of the case for a global fund to support research into antibiotics, Ebola and other neglected diseases.

#### **Answering member: Lord Prior of Brampton | Department: Department of Health**

The global funding of research and development of new antibiotics is part of the Independent review announced by the Prime Minister in June 2014 and chaired by Lord O'Neill of Gatley. The review is analysing the economics underlying all stages of the research and development of new antimicrobials and will propose concrete actions to tackle these internationally. The final recommendations from the review will be published in summer 2016.

There are now 15 vaccines under development for Ebola across the world. The Department for International Development, in partnership with the Wellcome Trust and the Medical Research Council, has supported the Phase 1 clinical trial of a vaccine candidate, and funded a number of other areas of Ebola research, through the Research for Health in Humanitarian Crises programme.

The United Kingdom is also providing over £10 million annually for research into neglected tropical diseases. This is through a range of initiatives, including development of new treatment and diagnostic products, as well as implementation research. Examples of products resulting from the research in recent years include the first ever rapid diagnostic test and the first new, improved treatment option for sleeping sickness.

HC Deb 20 July 2015 | HL1159

#### **Antibiotics**

#### Asked by: Baroness Manzoor

To ask Her Majesty's Government whether, as part of the triennial review into the National Institute for Health and Care Excellence and ongoing discussions relating to the institute's appraisal methods, they will consider creating modifiers or a special priority designation for qualified antibiotics.

#### Answering member: Earl Howe | Department: Department of Health

The National Institute for Health and Care Excellence (NICE) Triennial Review was announced on 30 October 2014 to review the form and functions of NICE. NICE's methods for the development of its technology appraisal guidance are outside the scope of the review. As an independent body, NICE is responsible for the methods it uses to develop its technology appraisal guidance and we have no plans at present to ask NICE to create modifiers or a special priority designation for qualified antibiotics. We continue to keep NICE's work programme under review.

We are commissioning an external review of the pathways for the development, assessment, and adoption of innovative medicines and medical technology. This review will consider how to speed up access for National Health Service patients to cost-effective new diagnostics, medicines and devices.

The development of new antimicrobial drugs is also the subject of the review on antimicrobial resistance announced on 2 July by the Prime Minister. The review will explore what actions may be taken by governments around the world to stimulate investment in new antimicrobial drugs. The review will present its initial findings during 2015 with a final report and recommendations to follow during 2016.

HC Deb 31 December 2014 | PQ HL3765

#### 3.2 Debates

Adjournment Debate - Antibiotics: Primary Care HC Deb 23 November 2015 | Vol 602 cc1165-1172

http://www.publications.parliament.uk/pa/cm201516/cmhansrd/cm151 123/debtext/151123-0004.htm#1511243000001

Westminster Hall debate - Antibiotic Resistance HC Deb 15 October 2014 | Vol 586 cc101-124WH

http://www.publications.parliament.uk/pa/cm201415/cmhansrd/cm141 015/halltext/141015h0001.htm#14101591000001

# 4. Useful links and further reading

Medical Research Council, Spotlight on: Antimicrobial resistance – meeting the challenge of resistant bacteria, 2016 https://www.mrc.ac.uk/research/spotlights/antimicrobial-resistance/

Review on Antimicrobial Resistance, Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance, January 2016

http://amr-

review.org/sites/default/files/Industry Declaration of support for comb ating AMR UPDATED SIGNATORIES APR 2016.pdf

House of Commons Science & Technology Select Committee Ensuring access to

working antimicrobials July 2014 HC509 2014-15

http://www.publications.parliament.uk/pa/cm201415/cmselect/cmsctech /509/509.pdf

Government response CM8919

https://www.gov.uk/government/uploads/system/uploads/attachment\_d ata/file/353295/42917 2902606 Cm 8919 WEB Accessible.pdf

Research Councils UK response HC643 2014-15

http://www.publications.parliament.uk/pa/cm201415/cmselect/cmsctech /643/643.pdf

Public Health England: Antibiotic Resistance 10 December 2015 https://www.gov.uk/government/publications/health-mattersantimicrobial-resistance/health-matters-antimicrobial-resistance

LSE Case Study: Reigniting Research and Development on Antibiotics http://www.lse.ac.uk/researchAndExpertise/researchImpact/PDFs/researc h-development-antibiotics.pdf

Antibiotic Research UK http://www.antibioticresearch.org.uk/

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# DEBATE PACK CDP 2016/0092

25 April 2016