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Leaving the EU: Antimicrobial Resistance

Summary

There are multiple areas where the United Kingdom's departure from the European Union may affect how antimicrobial resistance (AMR) is addressed. AMR is a global health issue, with strategic coordination occurring at several levels to address the issue—from the World Health Organisation, to the EU, and in the UK's national health strategy. The World Bank has predicted that, globally, AMR will lead to increases in morbidity and mortality, increase the burden on healthcare systems, increase extreme poverty, and that it could inflict heavy losses on the global economy.

Access to the latest effective antibiotics is important for the treatment of patients and the mitigation of resistance development, and may be affected by changes in the development and regulation of new medicines—both of which pose particular challenges with regards to antimicrobials, and especially antibiotics. The UK has been heavily involved in medicine development and regulation in the EU, and the European Medicines Agency is currently based in London (though it will relocate to Amsterdam following the UK's departure from the EU). The UK Government has stated that it wishes to continue to participate in the European Medicines Agency under new arrangements that recognise the UK will not be a member state.

Trade agreements regarding food and agriculture have been highlighted by commentators as presenting both risk and opportunity in the context of AMR. Responsible antimicrobial use on farms is a key issue for AMR, and whether the UK maintains or reduces regulation in this area may be dependent on future trading arrangements. Michael Gove, Secretary of State for Environment, Food, and Rural Affairs, has stated there should be no compromise on animal welfare and environmental standards, and that the high levels of antibiotic use in agriculture in the United States are a concern. The UK Government has argued that being outside the EU Common Agricultural Policy would provide the freedom to apply higher animal welfare standards.

A key part of the EU's strategy against AMR is the development of epidemiological surveillance infrastructure across the member states. The UK Government has proposed continued close collaboration with the European Centre for Disease Prevention and Control including access to alert systems, databases, and networks.

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1. Introduction

The use of and access to antimicrobial medicines in the UK is affected by EU-level policy and both EU and UK antimicrobial resistance (AMR) strategies. The UK's departure from the EU has potential implications for areas such as medicine regulations and development (exemplified by the European Medicines Agency's move from London to Amsterdam), trade agreements (for example relating to animal welfare in agricultural production), access to cross-national AMR surveillance data and infrastructure, and the interpretation of law regarding the 'do no harm' principle.[1]

This Briefing begins with an introduction to areas of concern regarding AMR, an outline of the issue of AMR, and an explanation of the 'One Health' strategic policy focus that has become a cornerstone of AMR strategies. The Briefing then outlines the EU and UK strategies on AMR, and notes aspects of the UK strategy that were drawn from the EU roadmap. Finally, the Briefing examines the potential implications of the UK leaving the EU on AMR.

1.1 Antimicrobial Resistance

Antimicrobial drugs are medicines that are used against infections caused by bacteria (antibiotics), viruses (antivirals), fungi (antifungals) and parasites (antiparasitics). AMR develops when micro-organisms survive exposure to a medicine that would normally kill them or stop their growth.[2] This allows strains that are capable of surviving exposure to a particular drug to grow and spread. This has led to the emergence of 'superbugs', such as methicillin-resistant *Staphylococcus aureus* (MRSA), that are difficult to treat with existing medicines. The Department of Health and Social Care has argued that the emergence and spread of resistant and multidrug-resistant organisms is increasingly important because it is coinciding with a decline in the development of novel therapies to replace those rendered ineffective.[3]

The development of resistance to antimicrobial medicines is accelerated by several factors relating to antimicrobial use, including inappropriate prescribing practices (in both human and veterinary medicine), overuse of antimicrobials in agriculture (for example, prophylactic mass-medication in feed, or the use of antimicrobials as growth-promoters), and poor infection control practices.[4]

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[1] The 'do no harm' duty is enshrined in Article 168 of the Treaty on the Functioning of the European Union, and provides that new legislation must not be detrimental to public health.
[2] Review on Antimicrobial Resistance, *Tackling Drug-Resistant Infections Globally: Final Report and Recommendations*, May 2016, p 10.
[3] Department of Health, *Antimicrobial Resistance Empirical and Statistical Evidence-Base*, September 2016, p 8.
[4] Professor Dame Sally Davies, *The Drugs Don't Work: A Global Threat*, 2013, pp 38–41; and Department of Health, *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018*, September 2013, p 8.

The Chief Medical Officer, Professor Dame Sally Davies, has argued that "it is the re-emergence in the West of classic diseases such as tuberculosis that foreshadows the global threat of antimicrobial resistance".[5] Looking to the future, Professor Davies predicts:

> […] an ageing society will inevitably lead to an increased number of patients with one or more comorbidities. This will necessitate the use of a range of strategies to prevent infectious diseases and reduce their burden, and may actually lead to higher antibiotic prescribing rates than would be necessary in a younger and healthier society.[6]

There is a growing trend of antimicrobial resistance across the different types of antimicrobial medicines, however in the UK the immediate concern is for antibiotics.[7]

1.2 Consequences of Antimicrobial Resistance

The Review on Antimicrobial Resistance, commissioned by the Coalition Government in 2014 and chaired by economist Jim O'Neill (now Lord O'Neill of Gatley (Crossbench)), estimated that about 700,000 people die every year from drug-resistant strains of common bacterial infections, HIV, tuberculosis, and malaria.[8] The review further observed that "we are down to using our 'last line' antibiotic to treat gonorrhoea" following the rapid development of drug-resistant strains of gonorrhoea. Further, drugs previously side-lined due to their side effects have had to re-enter medical use as last resort treatments.[9]

Analysis by the World Bank has argued that "unchecked AMR is likely to inflict heavy losses on the global economy in the period 2017–2050".[10] AMR, the World Bank argued, would impact trade due to untreatable diseases and fear, impact upon livestock production due to worse animal health, and increase the burden on healthcare expenditure. This would result "in a pronounced increase in extreme poverty".[11] The World Bank further claimed "the annual economic damage from AMR during much of the projection period could be of the same order of magnitude as the impact during the major financial crisis", illustrated in Figure 1.[12] The difference in

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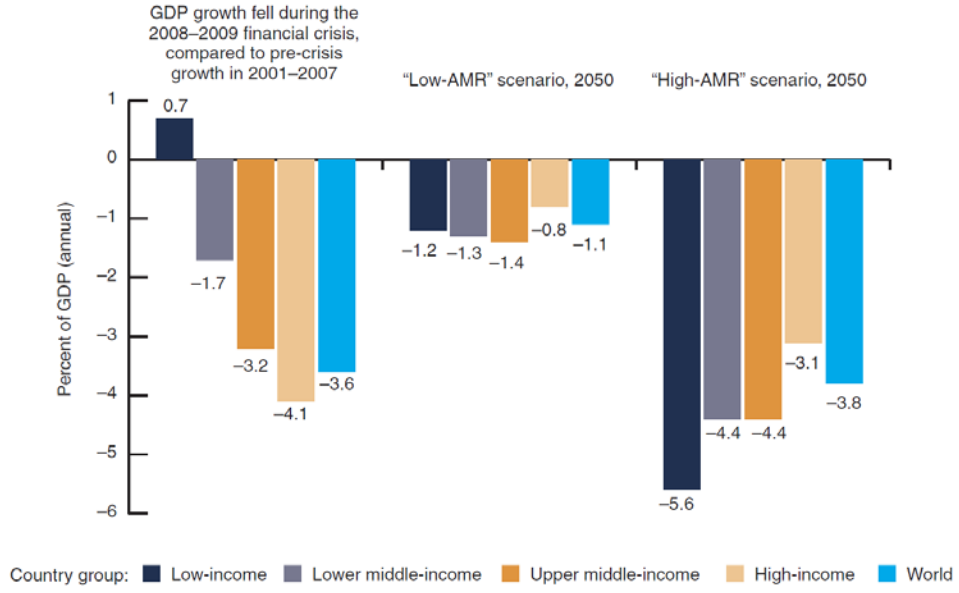
[5] Professor Dame Sally Davies, *The Drugs Don't Work: A Global Threat*, 2013, p 43.
[6] Professor Dame Sally Davies, 'Reducing Inappropriate Prescribing of Antibiotics in English Primary Care: Evidence and Outlook', *Journal of Antimicrobial Chemotherapy*, vol 73 issue 4, p 834
[7] Department of Health, *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018*, September 2013, p 8.
[8] Review on Antimicrobial Resistance, *Tackling Drug-Resistant Infections Globally: Final Report and Recommendations*, May 2016, p 10.
[9] ibid.
[10] World Bank Group, *Drug-Resistant Infections: A Threat to Our Economic Future*, March 2017, p 22.
[11] ibid.
[12] ibid, p 18.

impact between lower and higher income countries are reported as being due to the higher incidence of infectious disease and higher dependence on labour incomes in low-income countries.[13] The World Bank warned that impacts in low-income countries "might cancel decades of progress in global economic convergence".[14]

Figure 1 Economic Costs of AMR Compared to the Financial Crisis



(Source: World Bank Group, *Drug-Resistant Infections: A Threat to Our Economic Future*, March 2017, p 19)

1.3 'One Health' as a Strategic Policy Focus

Antibiotics are used in both humans and animals, and resistant bacteria can cross between human and animal populations.[15] Different bacteria species—for example, those causing disease in humans and those causing disease in animals—are also able to transfer genetic material between one another, such as genes coding for resistance. In short, antibiotic use in one sphere of medicine can impact upon prevalence of resistance in the other sphere. This has prompted the labelling of AMR by a group of academics as the "quintessential"[16] 'One Health' issue, requiring what Public Health England describes as a "joined up approach to surveillance and action".[17] One Health was initially proposed as a concept to foster interdisciplinary collaboration

[13] World Bank Group, *Drug-Resistant Infections: A Threat to Our Economic Future*, March 2017, p 18.
[14] ibid.
[15] Review on Antimicrobial Resistance, *Tackling Drug-Resistant Infections Globally: Final Report and Recommendations*, May 2016, p 10; and Public Health England, *UK One Health Report: Joint Report on Human and Animal Antibiotic Use, Sales, and Resistance, 2013*, July 2015, p 15.
[16] T Robinson et al, 'Antibiotic Resistance is the Quintessential One Health Issue', *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2016, vol 110, pp 377–80.
[17] Public Health England, *UK One Health Report: Joint Report on Human and Animal Antibiotic Use, Sales, and Resistance, 2013*, July 2015, p 15.

on combined human and animal health issues ranging from food safety, to mental health, through to antimicrobial resistance.[18] The concept of One Health has been made a cornerstone of strategies to address AMR, including the UK's Five Year AMR Strategy,[19] the European One Health Action Plan Against Antimicrobial Resistance,[20] and global strategies exemplified by the World Health Organisation (WHO), Food and Agriculture Organisation (FAO), and World Organisation for Animal Health (OIE) joint statement on the need for a "holistic and multisectoral" One Health approach to AMR.[21]

2. EU and UK Strategies to Address Antimicrobial Resistance

2.1 EU Strategy

The EU has a history of policy making about antimicrobial resistance, including regulatory actions such as banning the use of antibiotics as growth promoters in animal feed in 2006.[22] In June 2017, the European Commission adopted a "new and comprehensive EU action plan on AMR based on the One Health approach".[23] This plan continued the work of the previous plan adopted in 2011,[24] which was published in response to the WHO Europe Strategic Plan[25] of the same year. The new European Commission plan extended the 2011 approach in particular to include the environment, and aimed to improve data collection, monitoring, and surveillance.[26] The objectives of the new plan were constructed around three pillars, subdivided into actions as follows:

1. **Making the EU a Best Practice Region**
    a. Better evidence and awareness of the challenges of AMR
    b. Better coordination and implementation of EU rules to tackle AMR
    c. Better prevention and control of AMR

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[18] Paul Gibbs, 'The Evolution of One Health: A Decade of Progress and Challenges for the Future', *The Veterinary Record*, 25 January 2014, vol 174, pp 85–91.
[19] Department of Health, *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018*, September 2013, p 13; and HM Government, *Government Response to the Review on Antimicrobial Resistance*, September 2016, p 5.
[20] European Commission, *A European One Health Action Plan against Antimicrobial Resistance (AMR)*, June 2017.
[21] World Health Organisation, Food and Agriculture Organisation and World Organisation for Animal Health, 'WHO, FAO, and OIE Unite in the Fight against Antimicrobial Resistance', 2015, p 1.
[22] European Commission, 'Ban on Antibiotics as Growth Promoters in Animal Feed Enters into Effect', 22 December 2005.
[23] European Commission, *A European One Health Action Plan against Antimicrobial Resistance (AMR)*, June 2017, p 5.
[24] European Commission, *Action Plan Against the Rising Threats from Antimicrobial Resistance*, 15 November 2011.
[25] World Health Organisation, *European Strategic Action Plan on Antibiotic Resistance*, 10 June 2011.
[26] European Commission, *A European One Health Action Plan against Antimicrobial Resistance (AMR)*, June 2017, p 5.

d. Better addressing of the role of the environment
e. A stronger partnership against AMR and better availability of antimicrobials.

2. Boosting Research, Development, and Innovation on AMR

a. Improve knowledge on detection, effective infection control, and surveillance
b. Develop new therapeutics and alternatives
c. Develop new preventive vaccines
d. Develop novel diagnostics
e. Develop new economic models and incentives
f. Close knowledge gaps on AMR in the environment and on how to prevent transmission.

3. Shaping the Global Agenda

a. A stronger global EU presence
b. Stronger bilateral partnerships for stronger cooperation
c. Cooperating with developing countries
d. Developing a global research agenda[27]

The plan emphasised a focus on "the areas with the highest added value for member states",[28] such as the promotion of prudent antimicrobial use, enhancement of cross-sectorial work, improving infection prevention, and the consolidation of surveillance of AMR and antimicrobial consumption.

The European Commission has also pressed for specific areas of regulation to orientate towards a One Health approach to antimicrobial resistance. For example it addressed the Common Agricultural Policy (CAP) as follows:

> The CAP should become more apt at addressing critical health issues such as those related to antimicrobial resistance caused by inappropriate use of antibiotics. In line with an ambitious and encompassing approach with regard to human and animal health—as embodied by the "One Health" concept—it should also promote the use of new technologies, research and innovation to reduce risks to public health.[29]

Another example of the EU's work on AMR is the surveillance of AMR across member states through the European Antimicrobial Resistance

[27] European Commission, *A European One Health Action Plan against Antimicrobial Resistance (AMR)*, June 2017, pp 6–21.
[28] ibid, p 6.
[29] European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: The Future of Food and Farming*, 29 November 2017.

Surveillance Network (EARS-Net).[30] Surveillance across member states has found high levels of multidrug resistance in some types of salmonella[31], and associations between resistance to particular antibiotic agents found in bacteria from humans and bacteria from food-producing animals (which, in turn, was found to be associated with the consumption of the same kinds of antibiotics).[32]

2.2 UK Strategy

The Cabinet Office classes antimicrobial resistance, alongside climate change, as a long-term trend that is likely over the coming decades to change the overall risk landscape—making risks currently faced more severe or more likely—with the potential to lead to the emergence of completely new risks.[33]

The then Department of Health released the *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018* in September 2013.[34] A number of reports have been published since that document the progress of the strategy, with the latest covering the year 2016.[35] The overarching goal of the strategy is to slow the development and spread of AMR. The activity of the strategy is focused around three aims:

1. To improve the knowledge and understanding of AMR.
2. To conserve and steward the effectiveness of existing treatments.
3. To stimulate the development of new antibiotics, diagnostics and novel therapies.[36]

These aims are underpinned by activities in seven "key areas for future action", that focus the UK's response to the actions requested in the 2011 EU AMR Strategic Action Plan[37] and the 2012 EU Council

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[30] European Centre for Disease Prevention and Control, 'About the Network', accessed 8 June 2018.
[31] European Food Safety Authority and European Centre for Disease Prevention and Control, *The European Union Summary Report on Antimicrobial Resistance in Zoonotic and Indicator Bacteria from Humans, Animals and Food in 2016*, February 2018.
[32] European Centre for Disease Prevention and Control, European Food Safety Authority, and European Medicines Agency, *ECDC/EFSA/EMA Second Joint Report On The Integrated Analysis Of The Consumption Of Antimicrobial Agents And Occurrence Of Antimicrobial Resistance In Bacteria From Humans And Food-Producing Animals*, June 2017, pp 4–5.
[33] Cabinet Office, *National Risk of Civil Emergencies: 2017 Edition*, September 2017, p 8.
[34] Department of Health, *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018*, September 2013.
[35] HM Government, *UK 5 Year Antimicrobial Resistance (AMR) Strategy 2013–2018: Annual Progress Report, 2016*, 24 November 2017.
[36] Department of Health, *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018*, September 2013, p 7.
[37] European Commission, *Action Plan Against the Rising Threats from Antimicrobial Resistance*, 15 November 2011.

Conclusions[38] as follows:

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.
7. Strengthened international collaboration[39]

These "areas for future action" stemmed from key actions identified in the now-superseded 2011 EU strategy which, for example, called for activity to "strengthen infection prevention and control in healthcare settings" (Action 4), which lines up with key area 1 of the UK strategy, and to "strengthen surveillance systems on AMR and antimicrobial consumption in human medicine" (Action 9),[40] which lines up with key area 5.

The UK strategy was developed collaboratively with the devolved administrations of the UK, and each of the devolved administrations has responsibility for its implementation within their own jurisdictions in relation to human health.[41] The control of veterinary medicines, including antimicrobials, is currently a reserved power, and the Department for Environment and Rural Affairs (Defra) has UK-wide responsibilities in relation to animal health.[42] The strategies published by the devolved administrations generally address the same areas as the overall UK strategy, albeit with an emphasis on human health due to the reservation of powers. For example, NHS Scotland's *Scottish Management of Antimicrobial Resistance Action Plan 2014–18 (ScotMARAP 2)* "only contains human health initiatives",[43] whilst NHS Wales's *Together for Health: Tackling Antimicrobial Resistance and Improving Antibiotic Prescribing* cites the reservation of powers as the reason that its plan "will therefore largely focus on human healthcare and the

[38] Council of the European Union, *Council Conclusions on the Impact of Antimicrobial Resistance in the Human Health Sector and in the Veterinary Sector—A "One Health" Perspective*, 22 June 2012.
[39] Department of Health, *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018*, September 2013, pp 16–21.
[40] European Commission, *Action Plan against the Rising Threats from Antimicrobial Resistance*, 15 November 2011, pp 5–14.
[41] Nicole Redhead, Professor Dame Sally Davies and Tracy Parker, 'Building an International Coalition to Combat Antimicrobial Resistance', Civil Service Quarterly Blog (Cabinet Office), 14 February 2017.
[42] ibid; and NHS Wales, *Together for Health: Tackling Antimicrobial Resistance and Improving Antibiotic Prescribing*, October 2016, p 7; and Scottish Parliament, 'Written Answers: 31 October 2017', 31 October 2017, Question S5W-12115.
[43] Scottish Parliament, 'Written Answers: 11 September 2014', 11 September 2014, Question S4W-22368.

contributions Wales will make in that context".[44] In Northern Ireland, the Department of Health, Social Services and Public Safety's (DHSSPS) strategy also focuses on "improvement in the safety and quality of care related to human health", whilst noting that "there are wider issues including antimicrobial resistance in food and in animals".[45] The follow-up strategy to its 2012 to 2017 strategy will "be based on a One Health approach", the DHSSPS has stated.[46]

In a response to a written question in March 2018, Steve Brine, Parliamentary Under Secretary of State for Public Health and Primary Care, stated that "work is underway to consider the priorities and focus for a refreshed strategy and national action plan for publication at the end of 2018".[47]

2.3 Recent Progress on Strategic Actions in the UK

Good stewardship of antimicrobial medicines[48] is one way in which the development of resistance is mitigated in community settings, and the effectiveness of antimicrobial medicines is preserved.[49] Public Health England has argued that the stability of the proportion of resistant infections over the life of the UK strategy "likely reflects good antimicrobial stewardship", particularly in community settings.[50] There is significant regional variation in antibiotic use reported by Public Health England, though the total consumption of antibiotics in primary and secondary care fell by 5.1 percent between 2012 and 2016.[51] The number of prescriptions dispensed in the GP setting—which accounts for 74 percent of antibiotic prescriptions for humans[52]—decreased by 8.1 percent.[53] Sales of antibiotics for food producing animals has also fallen by 10 percent—the lowest level in four years.[54]

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[44] NHS Wales, *Together for Health: Tackling Antimicrobial Resistance and Improving Antibiotic Prescribing*, October 2016, p 7.
[45] Department of Health, Social Services and Public Safety, *Strategy for Tackling Antimicrobial Resistance (STAR) 2012–2017*, July 2012, p 6.
[46] G Armstrong, *Stock-take of Progress on Tackling Antimicrobial Resistance in Northern Ireland, 2012–2017*, April 2018.
[47] House of Commons, 'Written Question: Antibiotics: Drug Resistance', 16 March 2018, 132264.
[48] Antimicrobial stewardship has been defined as the "careful and responsible management of antimicrobial use […] the right antibiotic for the right patient, at the right time, with the right dose, and the right route, causing the least harm to the patient and future patients" (British Society for Antimicrobial Chemotherapy, *Practical Guide to Antimicrobial Stewardship in Hospitals*, 2013, p 6).
[49] William Hall et al, *Superbugs: An Arms Race Against Bacteria*, 2018, pp 97–8.
[50] Public Health England, *English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR): Report 2017*, October 2017, p 5.
[51] ibid, p 41.
[52] ibid.
[53] ibid, p 42.
[54] Global and Public Health Group, *UK 5 Year Antimicrobial Resistance (AMR) Strategy 2013–18: Annual Progress Report, 2016*, November 2017, p 5.

The most serious multidrug-resistant infections are in healthcare settings where vulnerable patients are subject to a high antibiotic selective pressure, though these infections are now also said to be spreading within the community.[55] Overall trends in reports of resistant organisms have been mixed. For example, decreases have been reported in MRSA bacteraemia (the presence of the bacteria in the blood potentially leading to sepsis, a type of infection with high mortality) as well as for the proportion of surgical site infections from the same pathogen.[56] However, there has been an observed increase in isolates of MRSA producing a particular toxin associated with an increased ability to spread and cause severe infection,[57] and there has been an emergence over the past decade of bacteria that are nearly resistant to the last-line carbapenem class of antibiotics.[58] Resistance to antifungals also continues to grow, complicating patient management because of opportunistic fungal infections following otherwise successful medical interventions.[59]

2.4 Commentary on EU Strategic Success

Some commentary has noted progress made in several areas of the European Action Plan. For example, improvements in the uniformity of surveillance activities have been attributed to European Centre for Disease Prevention and Control (ECDC) activities,[60] and it has been noted that, in general, "the UK and many EU member states have been successful in implementing their AMR strategies".[61] However, it has also been argued that the European Antimicrobial Resistance Surveillance Network (EARS-Net) remains "adversely affected by the heterogeneity among European countries"[62] in terms of the organisation of health-care systems and national surveillance efforts; that there is a lack of "publicly available information on important methodologic aspects and indicators measured";[63] and that there are different methodologies applied by different countries in many aspects of surveillance.[64]

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[55] Department of Health, *Antimicrobial Resistance Empirical and Statistical Evidence-Base*, September 2016, p 8.
[56] ibid, p 19.
[57] ibid.
[58] ibid, p 20.
[59] ibid, p 10; and Matthew Fisher et al, 'Worldwide Emergence of Resistance to Antifungal Drugs Challenges Human Health and Food Security', 18 May 2018, *Science*, vol 360, pp 739–42.
[60] M Núñez-Núñez et al, 'The Methodology of Surveillance for Antimicrobial Resistance and Healthcare-Associated Infections in EUROPE (SUSPIRE): A Systematic Review of Publicly Available Information', *Clinical Microbiology and Infection*, 2018, vol 24, p 108.
[61] Victoria Wells and Laura Piddock, 'Addressing Antimicrobial Resistance in the UK and Europe', *Lancet Infectious Diseases*, December 2017, vol 17, p 1230.
[62] Evelina Tacconelli et al, 'Surveillance for Control of Antimicrobial Resistance', *Lancet Infectious Diseases*, March 2018, vol 18, p 101.
[63] M Núñez-Núñez et al, 'The Methodology of Surveillance for Antimicrobial Resistance and Healthcare-Associated Infections in EUROPE (SUSPIRE): A Systematic Review of Publicly Available Information', *Clinical Microbiology and Infection*, 2018, vol 24, p 108.
[64] ibid.

A report led by Laura Piddock, Professor of Microbiology at the University of Birmingham and former Director of Antibiotic Action—a public awareness group,[65] on behalf of the Secretariat of the All-Party Parliamentary Group on Antibiotics (APPGoA) noted with regard to surveillance of antimicrobial consumption that:

> The UK has not fully implemented the EU Road Map recommendation[66] to assess ways in which to improve access to data on AMR at regional, local and hospital levels. In the UK, there are reliable data from National Health Services (NHS) prescriptions in primary care, but there are no data available from secondary or tertiary care or the private or voluntary sectors. As a result the UK remains reliant on point prevalence surveys as an indicator of antimicrobial consumption in secondary care. Future action should take this discrepancy with the EU Road Map into account and harmonize data from both the public and private sectors. This would allow for more informed preventative action.[67]

The report also highlighted concerns that there was an absence of evidence of specific activity to restrict the use of new or critically important antibiotics across EU member states.[68]

A particular weakness highlighted by the report was the use of subjective terminology throughout the UK, EU, and WHO strategies, such as 'improve', 'promote', 'strengthen', and 'assess', and the report suggested that this language "may have limited the impetus for definitive action by national and regional governments and authorities".[69]

3. Antimicrobial Resistance and Leaving the EU

This section examines three areas in which the UK's exit from the EU has potential implications for AMR. These areas are the life sciences and pharmaceutical industry (including access to new medicines), trade arrangements regarding agriculture and food, and access to data and surveillance. A further area considered relates to the influence of Article 168 of the Treaty on the Functioning of the European Union (TFEU), and the incorporation of this into UK law after the UK's exit.

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[65] Antibiotic Action, 'Antibiotic Action', accessed 25 July 2018.
[66] This recommendation refers to Action 9 of the 2011 EU Strategy upon which the UK strategy's seven key areas for future action were based. Action 9 calls for member states to "Strengthen surveillance systems on AMR and antimicrobial consumption in human medicine", for example to "assess ways to improve access to data on AMR at all levels (regional, local and hospitals)" (European Commission, *Action Plan Against the Rising Threats from Antimicrobial Resistance*, 15 November 2011, p 11).
[67] Victoria Wells et al, *Implementing WHO, EU and UK AMR Strategies and Action Plans: Has the World Lived Up to the Challenge?*, All-Party Parliamentary Group on Antibiotics, November 2017, p 12.
[68] ibid, p 3.
[69] ibid, p 13.

3.1 Impacts on the Life Sciences, Pharmaceutical Industry, and Access to Medicines

In a book authored by three members of the Review on Antimicrobial Resistance—including the chair, Lord O'Neill—it is argued that "in order to truly stay on top of drug-resistant infections, it would be ideal to have new antibiotics while current ones are still working most of the time".[70]

Professors Bernard Golding and Michael Waring of Newcastle University have argued that:

> Given the crisis of the emergence of resistant pathogens, abrogating many current treatments, unabated drug discovery in Europe is too important to fall on the sword of political infighting. The Brexit negotiating teams must realise that all European citizens will suffer without the UK continuing to be being intimately involved in every aspect of drug discovery, evaluation, and regulation.[71]

The development and regulation of medicines is an area in which the UK has been heavily involved with the EU through the Department of Health and Social Care's executive agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), and the Department for Environment, Food, and Rural Affairs' executive agency, the Veterinary Medicines Directorate (VMD). The European Medicines Agency (EMA) will relocate from London to Amsterdam following the UK's departure from the EU.[72] All EU member states are part of the EMA, as are EEA countries, but only EU member states play a role in decision making and the operation of the EMA. The EMA has been a part of tripartite discussions with the United States' Food and Drug Administration (FDA) and Japanese Pharmaceuticals and Medical Devices Agency (PDMA) regarding the convergence of "clinical trial designs for evaluating antibacterial drugs and ways to further enhance collaboration in this therapeutic area among the Agencies".[73]

Both the British Medical Association (BMA) and the British Veterinary Association (BVA)—the professional bodies of the medical and veterinary professions in the UK—have highlighted access to medicine as an area of concern regarding the UK's departure from the EU.[74] The BMA has stated

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[70] William Hall et al, *Superbugs: An Arms Race Against Bacteria*, 2018, p 92.
[71] Bernard Golding and Michael Waring, 'The Consequences of 'Brexit' for Drug Discovery and Development, and the Regulatory Implications', *Expert Opinion on Drug Discovery*, April 2018, p 585.
[72] European Council, 'European Medicines Agency to be relocated to Amsterdam, the Netherlands', 20 November 2017.
[73] European Medicines Agency, *Tripartite Meeting Held between the PMDA, EMA, and FDA in Kyoto, Japan to Discuss Convergence on Approaches for the Evaluation of Antibacterial Drugs*, 17 November 2017.
[74] British Medical Association, *Brexit Briefing: Medicines and Medical Devices Regulation*, October 2017, p 2; and House of Commons Environment, Food and Rural Affairs Committee, *Written Evidence Submitted by the British Veterinary Association*, October 2017, p 7.

that a divergent approach to medicines licensing could lead to delays in access to new medicines and weaker pharmacovigilance, arguing that the UK Government should "work closely with the EMA through a formal agreement to continue to support and participate in its assessments for medicines approvals; and agree mutual recognition of the CE-mark scheme".[75] The BVA has argued that any new trade arrangement with the EU should "maintain the link with EU veterinary medicine approval systems",[76] and that post-EU life science research regulation "should not hinder the development and global application of novel therapeutics".[77] Concerns have also been raised in Parliament over the implications for research, and particularly clinical trials, of the UK's changing relationship with the EU.[78]

In its final report, Lord O'Neill's Review on Antimicrobial Resistance argued that "harmonised regulations and clinical trials networks can play an important role […] to lower drug development costs".[79] The review went on to explain why this was significant for antibiotic development:

> The greatest cost associated with new antibiotic development is that of running clinical trials—particularly during the later stages of testing. Analysis undertaken by the Review found that on average more than 80 percent of the costs of bringing an antibiotic to market are related to clinical trials, or 65 percent of the cost when you adjust for the risk of failure, which more realistically captures the all-in cost of drug development.
>
> […] Antibiotics face some particular challenges, which have contributed to the progressive decline of R&D efforts. For instance, even antibiotics intended for use as back-up defences for current generics to which resistance is rising need in principle to demonstrate clinical "superiority" versus the existing treatment. Identifying and enrolling large enough groups of patients with drug-resistant infections can be a technical and logistical challenge, not least due to limited diagnostics to identify patients quickly and dispersed populations.[80]

The Life Science Industry Coalition (comprising eleven associations representing the European and British life science industry) has argued that trade barriers could create delays or shortages in the medicine supply, with

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[75] British Medical Association, *Brexit Briefing: Medicines and Medical Devices Regulation*, October 2017, p 2.
[76] House of Commons Environment, Food and Rural Affairs Committee, *Written Evidence Submitted by the British Veterinary Association*, October 2017.
[77] British Veterinary Association, *Brexit and the Veterinary Profession*, June 2017.
[78] HL *Hansard*, 18 April, cols 1173–246. Lord Patel introduced an amendment to the Bill regarding clinical trials regulation, which is discussed at columns 1214 to 1218.
[79] Review on Antimicrobial Resistance, *Tackling Drug-Resistant Infections Globally: Final Report and Recommendations*, May 2016, p 6.
[80] ibid, p 54.

the implication of increasing costs for patients and governments:

> [There are] wide ranging implications, from scientific research, manufacturing processes, development of medicines including participation in clinical trials, and trade. Trade barriers, for example, could lead to a delay or shortage of supply of medicines for patients, thus causing a disruption in their treatment and potential risk to public health as may be the case for vaccines and antibiotics. Shortages of supply will increase costs both to the patients and costs to Governmental Health Budgets both in the UK and EU member states.[81]

Professor Emma Cave, a specialist in medical law and the Director of Research and Deputy Dean of the Law School at Durham University, has argued that any advantages to divergence from aspects of EU law must be balanced with the advantages of harmonisation given the implications for the efficacy of global health initiatives:

> Exacerbating the differences between the UK and the rest of Europe has the potential to lead to isolationism. It could also limit the effectiveness of European and global health initiatives, such as pandemic responsiveness and the fight against antimicrobial resistance.[82]

The Government has said that it is aiming for close alignment and cooperation with the EU in the area of clinical trials. During the report stage of the European Union (Withdrawal) Bill, Baroness Goldie, Government Whip, stated the following with regards to impending changes to EU clinical trials regulation:

> If the CTR [Clinical Trials Regulation] (2014/536) comes into force during the implementation period, as it is currently expected to do in March 2020, it will apply to the UK. If this opportunity does not come to pass, the Government will seek to bring into UK law all relevant parts of the EU regulation that are within the UK's control. […]
>
> The two key elements of the regulation that are outside the UK's control, and therefore not covered by this guarantee or pledge, are, first, the use of a shared central IT portal and, secondly, participation in the single assessment model, both of which require a negotiated UK-EU agreement regarding UK involvement post-Brexit.[83]

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[81] Life Science Industry Coalition, *United Kingdom Exit from the European Union "Brexit"*, December 2017, pp 4–5. Further information regarding the Life Science Industry Coalition can be found on the Association of the British Pharmaceutical Industry (ABPI) website.
[82] Emma Cave, 'Brexit and the Regulation of Clinical Trials', *British Medical Journal* Blog, 20 April 2017.
[83] HL *Hansard*, 18 April 2018, cols 1215–16.

With regards to access to medicines and the avoidance of a disruption to supplies, the Government's white paper on *The Future Relationship Between the United Kingdom and the European Union*[84] outlined the Government's vision for future arrangements. The Government envisions an economic partnership that includes:

> [P]articipation by the UK in those EU agencies that provide authorisations for goods in highly regulated sectors—namely the European Chemicals Agency, the European Aviation Safety Agency, and the European Medicines Agency—accepting the rules of these agencies and contributing to their costs, under new arrangements that recognise the UK will not be a member state.[85]

Regarding the manufacture and marketing of medicines, the white paper elaborates further:

> In the context of a common rulebook, the UK believes that manufacturers should only need to undergo one series of tests in either market, in order to place products in both markets. This would be supported by arrangements covering all relevant compliance activity, supplemented by continued UK participation in agencies for highly regulated sectors including for medicines, chemicals and aerospace. This would be underpinned by strong reciprocal commitments to open and fair trade and a robust institutional framework.
>
> In order to achieve this, the UK's proposal would cover all of the compliance activity necessary for products to be sold in the UK and EU markets. This includes […] bespoke provisions for human and animal medicines which reflect their unique status […][86]

Following this, and more specifically addressing participation in the EMA "as an active participant, albeit without voting rights" and through "making an appropriate financial contribution", the white paper states that the Government would seek to ensure:

> [T]hat all the current routes to market for human and animal medicine remain available, with UK regulators still able to conduct technical work, including acting as a 'leading authority' for the assessment of medicines, and participating in other activities like ongoing safety monitoring and the incoming clinical trials framework.[87]

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[84] HM Government, *The Future Relationship Between the United Kingdom and the European Union*, July 2018, Cm 9593.
[85] ibid, p 8.
[86] ibid, p 20.
[87] ibid, p 22.

3.2 Trade Agreements

The impact of trade agreements on public health protections has been raised as an area of concern by the BMA,[88] BVA,[89] charity groups,[90] and in the press,[91] with implications for antibiotic use and for addressing antibiotic resistance.

The BVA has argued that responsible antimicrobial use on farms "must be incorporated into future trade deals" to avoid losing progress made in this area, as well as highlighting the risk of the UK Government undercutting its leadership position on the issue of antimicrobial resistance at home and abroad.[92] The BVA further argued that animal welfare is "inextricably linked with animal health, with public health, and with One Health issues such as antimicrobial resistance" and is "impacted by trading agreements".[93] In order to facilitate future trade with the EU, the BVA also noted that the UK should continue to promote best practice guidance and evidence-based targets for reducing antimicrobial use in line with EU requirements.[94] Written evidence to the House of Commons Environment, Food and Rural Affairs Committee from Sustain (who describe themselves as a "UK alliance for better food and farming and a registered charity")[95] argued that in countries outside the EU, such as Brazil and the US:

> [T]here is more acceptance that meat hygiene—such as contamination with faeces—can be less stringent in the production phases, if it can be 'cleaned up' at the end of the process through a system such as antibiotics, chemical treatment or food irradiation. Here, the focus is more on measuring contamination or residue levels at 'end of pipe', and less on reducing the risks of contamination along the supply chain, meaning less overall reliance on—for example—profligate use of antibiotics, which is an issue of international concern. There is also less acceptance that animal welfare, reduced farm antibiotic use, and worker welfare and safety can be legitimate issues for standards and public inspection, or as legitimate requirements in trade deals.[96]

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[88] British Medical Association, *Brexit Briefing. Health Protection and Health Security: Maintaining an Effective Working Relationship Between the UK and the EU*, January 2018, p 7.
[89] House of Commons Environment, Food and Rural Affairs Committee, *Written Evidence Submitted by the British Veterinary Association*, October 2017, pp 8–9; and British Veterinary Association, *Brexit and the Veterinary Profession*, June 2017, p 20.
[90] House of Commons Environment, Food and Rural Affairs Committee, *Written Evidence Submitted by Sustain*, 25 October 2017.
[91] George Monbiot, 'Resist a US Trade Deal. Your Life May Depend On It', *Guardian*, 14 February 2018; and Lee Williams, 'These Are the Right-wing Think Tanks Pushing for a Worse Deal than TTIP after Brexit—and Their Influence is Frightening', *Independent*, 12 March 2018.
[92] House of Commons Environment, Food and Rural Affairs Committee, *Written Evidence Submitted by the British Veterinary Association*, October 2017, pp 8–9.
[93] British Veterinary Association, *Brexit and the Veterinary Profession*, June 2017, p 20.
[94] ibid, p 28.
[95] House of Commons Environment, Food and Rural Affairs Committee, *Written Evidence Submitted by Sustain*, 25 October 2017, p 1.
[96] ibid, p 6.

The concern over the status of antimicrobial resistance within trade agreements has been echoed by Anna George, an associate fellow of the Centre on Global Health Security at Chatham House:

> Health and scientific experts already have evidence of AMR identified in animals, seafood, fertilisers, agricultural outputs, soil, water, pets and food—all important in trade and commerce. Resistance organisms in the food chain can have financial and other consequences for citizens, health systems, domestic food security, and, national strategic interests linked to development options, including export industries.
>
> It would therefore seem obvious that any strategic analysis of routes of the spread of AMR would identify food imports that fall outside of domestic regulation as important. Yet 'trade' is one of the key pathways for transmission of resistant organisms receiving little if any substantive attention in National AMR Action Plans—representing a significant gap in AMR containment and countermeasure strategies.[97]

The maintenance of an internal market in the UK is an example where divergence in animal health could arise.[98] Divergence in the area of animal health related to agriculture could have implications for antimicrobial use as a result of changes in hygiene standards or production methods that increase the likelihood of infections, and could consequently increase the use of antibiotics to compensate for farming methods. This could affect internal trade barriers if different parts of the UK have different animal welfare or antimicrobial usage regulations.

The Government has listed animal health and welfare (such as on-farm issues and the prevention and control of disease) as a policy area that will be "subject to more detailed discussion to explore whether legislative common framework arrangements might be needed".[99] Public health more generally is an area "where non-legislative common frameworks may be required".[100] The Institute for Government described the role of common frameworks in the following terms:

> [T]he devolved institutions are legally bound to comply with EU law. As a result, in some nominally devolved areas—such as environmental regulation, agriculture, state aid for industry, public procurement and aspects of justice, transport and energy—the policy autonomy of the devolved institutions is significantly constrained in practice.

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[97] Anna George, 'Antimicrobial Resistance, Trade, Food Safety and Security', *One Health*, November 2017, vol 5, p 7.
[98] House of Commons Public Administration and Constitutional Affairs Committee, *Oral Evidence: Devolution and Exiting the EU, HC 484*, 30 April 2018, p 4; and Alan Page, *The Implications of EU Withdrawal for the Devolution Settlement*, October 2016, p 20.
[99] Cabinet Office, *Frameworks Analysis: Breakdown of Areas of EU Law that Intersect with Devolved Competence in Scotland, Wales and Northern Ireland*, 9 March 2018, p 17.
[100] ibid, p 14.

> When the UK leaves the EU, if no changes were made other than to remove the statutory requirement to comply with EU law, these policy areas would fall completely under devolved control.
>
> This would allow policy differentiation within the UK in areas where EU law has previously provided a common legal framework.[101]

The Government's white paper on the future relationship with the EU emphasised the desire for future arrangements to be aligned within the UK internal market:

> Under the existing constitutional settlements in Scotland, Wales and Northern Ireland, each devolved administration and legislature generally has competence to make its own primary and secondary legislation in relation to agriculture, as well as in related areas such as animal health and welfare, food safety, plant health and fisheries. The UK Government will work closely with the devolved administrations, who share high ambitions for a sustainable agricultural industry in the UK, as the UK withdraws from the EU, and will ensure future arrangements within the UK work for the whole of the UK.[102]

In response to Defra's consultation *Health and Harmony: The Future for Food, Farming and the Environment in a Green Brexit*, the BVA argued that the design of a new agricultural policy could further the objectives of antimicrobial resistance strategies and build on previous successes in this area.[103] However, the BMA has expressed concerns over the safety of weakened regulation and market surveillance of imports and exports, citing the EU's rejection of US imports as an example:

> The EU has previously rejected certain US imported products on the grounds of public health safety. For example, beef from hormone treated cattle is currently deemed unsafe by the EU, while poultry dipped in chlorinated disinfectant is similarly banned.[104]

The US has stated that areas of divergence such as these would need to be overcome in order to secure future trade arrangements.[105]

The US has differences to the EU in its regulation of antimicrobial use in agriculture. For example, the US's Food and Drug Administration (FDA) has

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[101] Institute for Government, 'Brexit, Devolution and Common Frameworks', accessed 6 July 2018.
[102] HM Government, *The Future Relationship Between the United Kingdom and the European Union*, July 2018, Cm 9593, p 22.
[103] British Veterinary Association, *BVA Response to Defra: Health and Harmony the Future for Food, Farming and the Environment in a Green Brexit*, May 2018, p 10.
[104] British Medical Association, *Brexit Briefing: Health Protection and Health Security: Maintaining an Effective Working Relationship Between the UK and the EU*, January 2018, p 7.
[105] Richard Partington, 'Trump Adviser Ross Says UK-US Trade Deal Will Mean Scrapping EU Rules', *Guardian*, 6 November 2017.

taken steps to curb the unnecessary use of antimicrobial drugs in agriculture—notably for growth promotion—through voluntary changes by manufacturers to medicine labelling, since legally drugs administered through feed must be used according to approved labelling.[106] This approach has been criticised by Charlie Fisher, State Director for the Oregon State Public Interest Research Group (a consumer group concerned with a broad portfolio of issues),[107] for leaving multiple loopholes through which antimicrobials could still be used for the purpose of growth promotion in livestock.[108] Two states, California[109] and Maryland,[110] have passed laws that further restrict antimicrobial use in livestock, including prohibiting the use of medically important antimicrobial drugs in livestock for the purposes of growth promotion. The EU has banned the practice of using antimicrobial drugs to promote growth in livestock.[111] Other areas, such as hormone use, also impact upon antibiotic use in agriculture; for example, in the case of recombinant bovine somatotropin (rBST) used to boost milk production in dairy cows, which was banned in the EU as of 1 January 2000, partly on the grounds that its use caused a substantial increase in mastitis infections.[112] However, rBST is still in use in the US.[113]

Michael Gove, Secretary of State for Environment, Food and Rural Affairs, stated in oral evidence to the House of Commons Environment, Food and Rural Affairs Committee that the high levels of antibiotic use in US agriculture was an "issue of concern",[114] and that "the Cabinet has agreed that there should be no compromise on high animal welfare and environmental standards" from an animal welfare perspective, rather than a food safety perspective.[115] Again on the subject of animal welfare, the white paper on the future relationship with the EU argued the following:

> By being outside the CAP, and having a common rulebook that only applies to rules that must be checked at the border, the UK would be able to have control over new future subsidy arrangements, control over market surveillance of domestic policy arrangements, an ability to

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[106] US Food and Drug Administration, 'FDA's Strategy on Antimicrobial Resistance—Questions and Answers', accessed 15 June 2018.
[107] Oregon State Public Interest Research Group, 'About OSPIRG', accessed 11 July 2018.
[108] Tracy Loew, 'FDA Rule to Make it Harder to Give Antibiotics to Livestock', *Statesman Journal*, 5 January 2017.
[109] California Legislative Information, 'California Senate Bill 27: Livestock: Use of Antimicrobial Drugs', accessed 15 June 2018.
[110] General Assembly of Maryland, 'Keep Antibiotics Effective Act of 2017', accessed 15 June 2018.
[111] European Commission, 'Ban on Antibiotics as Growth Promoters in Animal Feed Enters into Effect', 22 December 2005.
[112] Scientific Committee on Animal Health and Animal Welfare, *Report on Animal Welfare Aspects of the Use of Bovine Somatotrophin*, March 1999, p 76; and Dirk Brinckman, 'The Regulation of rBST: The European Case', *The Journal of Agrobiotechnology Management and Economics*, 2000, vol 3 issues 2–3, p 168.
[113] US Food and Drug Administration, 'Bovine Somatotropin (BST)', accessed 26 June 2018.
[114] House of Commons Environment, Food and Rural Affairs Committee, *Oral Evidence: Brexit: Trade in Food, HC 348*, 20 December 2017, Q653.
[115] ibid, Q564.

> change tariffs and quotas in the future, and the freedom to apply higher animal welfare standards that would not have a bearing on the functioning of the free trade area for goods—such as welfare in transport and the treatment of live animal exports.[116]

3.3 Access to Data and Surveillance

Access to early warning and surveillance systems, a key part of the EU's strategy against AMR, has been raised as a concern by the BMA[117] and the BVA.[118]

The BMA has highlighted that access to systems such as the Early Warning and Response System of the European Union is restricted to EU and EEA member states.[119] Switzerland, for example, does not have routine access to the system, but can be granted temporary access to facilitate the management of outbreaks deemed threatening to the European region.[120]

The BVA has argued that "a robust surveillance system is vital to the health of UK livestock", and that the capacity and capability of surveillance systems must be maintained "irrespective of legislative requirements post-Brexit".[121] The BVA also argued that "public money to replace the EU CAP should be used to support and incentivise such public goods" as disease surveillance.[122] Existing infrastructure could be enhanced post-Brexit, the BVA suggested, to improve surveillance of companion animals and address areas with a potential impact on human health, such as antimicrobial resistance.[123]

Access to European surveillance systems after the UK leaves the EU has also been raised in Parliament by Baroness Walmsley (Liberal Democrat) during a House of Lords debate on the impact of Brexit on health and welfare. In response, Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health, stated:

> The noble Baroness, Lady Walmsley, asked about our desire to play a continued part in EU mechanisms such as ECDC, which provides surveillance, information sharing and action on antimicrobial resistance, where the UK has been in the lead. I can tell her that our desire is to continue to be part of those processes.[124]

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[116] HM Government, *The Future Relationship Between the United Kingdom and the European Union*, July 2018, Cm 9593, p 24.
[117] British Medical Association, *Brexit Briefing: Health Protection and Health Security: Maintaining an Effective Working Relationship Between the UK and the EU*, January 2018, p 6.
[118] British Veterinary Association, *Brexit and the Veterinary Profession*, June 2017.
[119] British Medical Association, *Brexit Briefing: Health Protection and Health Security: Maintaining an Effective Working Relationship Between the UK and the EU*, January 2018, p 6.
[120] ibid.
[121] British Veterinary Association, *Brexit and the Veterinary Profession*, June 2017, p 17.
[122] ibid, p 6.
[123] ibid, p 17
[124] HL *Hansard*, 29 March 2018, col 946.

An article written by Jeremy Hunt, then Secretary of State for Health and Social Care, in April 2018 stated that the UK is "proud to lead work in tackling the global threat of antimicrobial resistance", and stated that "we want to find an agreement that allows us to maintain the important and mutually beneficial collaboration with Europe on health issues".[125]

The Government's white paper on the UK's future relationship with the EU has proposed:

> [C]ontinuing close collaboration with the Health Security Committee and bodies such as the European Centre for Disease Prevention and Control (ECDC), including access to all associated alert systems, databases and networks, to allow the UK and the EU member states to coordinate national responses [and] collaboration with the European laboratory surveillance networks to monitor the spread of diseases across Europe.[126]

3.4 Influence of Article 168

Article 168 of the Treaty on the Functioning of the European Union provides that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".[127] Article 168 has had bearing on the development and structure of the European Union's approach to addressing AMR. In a paper commissioned by the European Public Health Alliance, Professor Amandine Garde noted:

> Article 168 recognises that public health should not be pursued only via ear-marked, distinct policies, but must be incorporated in all other EU policy areas. Such a "mainstreaming" provision is all the more relevant in areas such as AMR which require a coordinated, multi-sectoral response.[128]

Professor Garde further argued that:

> Overall, the EU Treaties, as interpreted by the Court of Justice of the European Union, grant a broad margin of discretion to the EU to use its existing powers to contain AMR. In particular, it can elect to develop an effective multi-sectoral AMR strategy which would combine

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[125] Jeremy Hunt, 'Britain Will Always Be a World Leader in Public Health—Here's Why', Politics Home, accessed 18 April 2018.
[126] HM Government, *The Future Relationship Between the United Kingdom and the European Union*, July 2018, Cm 9593, p 72.
[127] European Union, Consolidated Version of the Treaty on the Functioning of the European Union, Article 168, para 1.
[128] Professor Amandine Garde, *EU Competence to Tackle Antimicrobial Resistance*, November 2016, p 7.

> the adoption of legally binding measures with other forms of policy intervention.[129]

Professor Garde concluded that AMR, "arguably is the archetypical issue envisaged by Article 168 TFEU",[130] which allows for the adoption of measures "designed to protect and improve human health and in particular to combat the major cross-border scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health".[131]

In response to a point raised in the House of Lords about the retention of Article 168 in the application of law following the UK's departure from the EU, Lord Duncan of Springbank, Parliamentary Under Secretary of State at the Northern Ireland Office and the Scotland Office, stated:

> The Government fully expect that, after exit, Article 168 will continue to be influential to the interpretation and application of retained EU law. This may include the determination of legal challenges to which Article 168 is relevant, including the consideration of public health legislation before exit day. As was noted on Report in this House, although Article 168 is not a directly enforceable provision of the TFEU, it has nevertheless been influential on EU and domestic law in the area of public health. I reassure the noble Baroness [Finlay of Llandaff] that when retained EU law is interpreted and applied, any such influence will be preserved by this Bill.[132]

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[129] Professor Amandine Garde, *EU Competence to Tackle Antimicrobial Resistance*, November 2016, p 15.
[130] ibid.
[131] European Union, Consolidated Version of the Treaty on the Functioning of the European Union, Article 168, para 5.
[132] HL *Hansard*, 16 May 2018, col 708.