

## EU competence to tackle antimicrobial resistance

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### 1.Introduction: AMR as a global public health concern

Antimicrobial resistance (AMR) happens when micro-organisms (such as bacteria, fungi, viruses and parasites) change when they are exposed to antimicrobial drugs (such as antibiotics, antivirals, antimalarials and anthelmintics). AMR occurs naturally over time, usually through genetic changes. However, the misuse and overuse of antimicrobials in the public health, food, agriculture and aquaculture sectors, and the existence of antimicrobial residues in soil, crops and water, accelerate this process. Antimicrobial resistant-microbes are found in people, animals, food, and the environment (in water, soil and air), and they can spread between people and animals, and from person to person. Loss of drug-effectiveness because of AMR is increasing in both developing and developed countries, and if this trend continues unchecked, the world will confront a reality where many infectious diseases have “no cure and no vaccine”.

AMR is present in every country and threatens the prevention and treatment of an ever-increasing range of infections caused by these micro-organisms, thus gravely challenging many medical and public health achievements of the 20<sup>th</sup> century. If AMR was left unchecked, it has been estimated that today's already large 700,000 deaths every year would become an extremely disturbing 10 million by 2050, and that the cost in terms of lost global production between now and 2050 would be an enormous 100 trillion USD.<sup>1</sup> Global GDP could fall short by 3.8% annually by 2050.<sup>2</sup> As a result, “AMR poses a serious threat to public health, growth, and global economic stability.”<sup>3</sup>

In September 2016, the Member States of the United Nations convened a high-level meeting to discuss AMR. The Political Declaration<sup>4</sup> they adopted recognises AMR as “the greatest and most urgent global risk, requiring increased attention and coherence at the international, national and regional levels”, and urges States to implement the World Health Organization (WHO) Global Action Plan on AMR which the World Health Assembly unanimously adopted in May 2015.<sup>5</sup> Importantly, the WHO Global Action Plan calls for “a coherent, comprehensive and integrated approach to AMR at global, regional and national levels, in a ‘One Health’ approach and beyond, involving different actors and sectors such as human and veterinary medicine, agriculture, finance, environment and consumers”. Member States are urged to implement multi-sectoral national action plans on AMR by May 2017.

In the European Union, it was estimated in 2009 that a subset of drug-resistant bacteria was responsible for about 25,000 deaths annually and that, in addition to avoidable deaths, this also translated into extra healthcare costs and productivity losses of at least EUR 1.5 billion (ECDC/EMA joint report).<sup>6</sup> These findings led the European Union to adopt a five-year Action Plan against the rising threats from AMR in 2011, organised around 12 key measures.<sup>7</sup> An evaluation report of the Action Plan was published on 24 October, highlighting the “clear added value” of an EU

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<sup>1</sup> The Review on AMR chaired by Jim O'Neill, final report and recommendations, May 2016.

<sup>2</sup> World Bank report, September 2016.

<sup>3</sup> G20 Declaration, 5 September 2016.

<sup>4</sup> UN Political Declaration on AMR, 21 September 2016.

<sup>5</sup> Resolution WHA 68.7.

<sup>6</sup> ECDC/EMA joint technical report “The bacterial challenge: time to react”, September 2009.

<sup>7</sup> COM(2011) 748.

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intervention on AMR and recommending that “the EU should build on progress already made and continue to play an active role in the area of AMR”.<sup>8</sup> The Commission is now reflecting on the follow-up. The publication of a second Action Plan in the form of a Commission Communication to the European Parliament and the Council is foreseen for the first semester of 2017.<sup>9</sup>

If all EU Member States have undertaken to implement a national action plan to address AMR by the May 2017 World Health Assembly, the question arises what the EU could do to support them. There is indeed a clear consensus that effective AMR containment strategies must involve a co-ordinated multilevel response, bearing in mind that Member States must be supported in their efforts by the international community, and the EU more specifically, not least because trade, migration, globalisation and European integration may reduce the effectiveness of unilateral interventions adopted at the local or national level. It is therefore necessary to enquire not only about which regulatory intervention should be adopted to contain AMR, but also who is competent – EU Member States, the EU or both – to do so. This enquiry adds a layer of complexity, in that it raises the controversial question of allocation of powers between different levels of governance.

This paper briefly reviews some of the EU competences which could be invoked to contain AMR. It does not purport to be exhaustive of all possible competences that the EU may have at its disposal to address the issue,<sup>10</sup> nor does it purport to provide a taxonomy of all possible AMR-containing measures that the EU may be competent to adopt. The purpose is more modest: to determine whether the EU could adopt legally binding measures at EU level in order to combat AMR as a major public health scourge with a cross-border dimension. After highlighting the significance for the EU legal order of the principle of attributed powers (2), it focuses on the competences of the EU in the field of health (3) and other relevant policies, and in particular the EU’s internal market, its common agricultural (and fisheries) policy, and its environmental policy (4).

## 2. The principle of attributed powers and the importance of determining the relevant legal basis for any EU action

Article 5(1) TEU provides that “the limits of Union competences are governed by the principle of conferral”, whereas their use “is governed by the principles of subsidiarity and proportionality”. The question of EU competence is fundamental in that it circumscribes EU intervention and thus determines its legality in all areas of policy-making. It is all the more relevant when dealing with issues such as AMR which require a coordinated action in a wide range of policy areas to be dealt with effectively. A corollary of the principle of conferral is that, if the EU is given the necessary powers to regulate certain fields of activity, these powers are defined by the provisions of the EU Treaties. The general power to act rests with Member States, subject to the transfer of their sovereign rights which they have operated to the benefit of the EU in specific areas only.<sup>11</sup>

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<sup>8</sup> Commission Staff Working Document, “Evaluation of the Action Plan against the rising threats from AMR”, SWD(2016) 347 final.

<sup>9</sup> The EU has published a roadmap for a Commission’s Communication on a One-Health Action Plan to support Member States in the fight against AMR, 24 October 2016.

<sup>10</sup> For example, it does not address the exclusive competence of the EU to ensure “the conservation of marine biological resources under the common fisheries policy” (Article 3(1) (d) TFEU) or the competence of the European Parliament and the Council to adopt directives to improve the working environment to protect workers’ health and safety (Article 153(2) TFEU).

<sup>11</sup> Article 4(1) TEU: “competences not conferred upon the Union in the Treaties remain with the Member States”. Article 1(1) TEU reiterates this principle: “By this Treaty, the High Contracting Parties establish among **themselves** a European Union, hereinafter called ‘the Union’ on which the Member States confer competences to attain objectives they have in common” (emphasis added).

The Treaties constrain EU action both from a substantive and from a formal point of view. The substance is governed by Articles 2 and 3 TEU and by Articles 2 to 6 TFEU. Article 2 TEU sets out the EU's values and objectives, whereas Article 3 TEU lists the tasks it has been assigned. These provisions provide a basis to interpret the scope of the specific legal bases which are found later on in the Treaties.<sup>12</sup> The Treaty of Lisbon expressly classifies EU competences. In particular, Article 2 distinguishes between exclusive, shared and supporting competences, whilst Articles 3, 4 and 6 TFEU defines these competence headings and provide a list of subjects falling within each one of them. The exact scope of EU competences is detailed in the third part of the TFEU, as interpreted by the Court of Justice of the European Union (CJEU).<sup>13</sup> The difficulties therefore reside in the need to draw the boundaries separating what is permissible from what is not. As discussed more specifically below, the EU policies which are likely to be the most relevant to AMR include: public health, the internal market, consumer protection, the common agricultural (and fisheries) policy, and environmental protection.

Apart from the substantive areas of EU action, the EU Treaties also define which instruments and procedures should be used for each of them. From a formal point of view, they empower EU institutions to adopt measures which must comply with their provisions.<sup>14</sup> Article 288 TFEU lists and defines the different categories of Union acts. The main distinction it establishes is between binding and non-binding EU acts: regulations, directives and decisions are binding legislative instruments ("hard law"),<sup>15</sup> whereas recommendations and opinions are not ("soft law"). This distinction is crucial, as the powers of the Union are more or less extensive and their intensity varies depending on each policy area under consideration.

One of the corollaries of the principle of conferral is that legal acts adopted by EU institutions must state the reasons on which they are based.<sup>16</sup> They must therefore have an appropriate legal basis which identifies the Treaty article(s) allowing such action to be taken. This requirement is intended to make EU institutions more accountable and the legislative process more transparent. It also facilitates judicial review. If the EU is granted the necessary powers to adopt binding legislation in a given policy area, the legal basis relied upon will also determine the legislative procedure to be followed. The TFEU distinguishes different legislative procedures, which give different powers to different institutions. In particular, the procedures vary depending on the role assigned to the European Parliament (e.g. whether it can act as the Council's co-legislator) and the voting mechanisms applicable in the Council (e.g. whether qualified majority voting or unanimous voting is required).

The rest of this paper attempts to delineate which legal basis the EU could rely on to adopt measures intended to contain AMR, bearing in mind – once again – that the principle of conferral requires that the assessment should be carried out policy area by policy area. We will first assess the extent to which the public health competence of the EU laid down in Article 168 TFEU could be relied on to contain AMR at EU level, before considering other relevant policy areas.

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<sup>12</sup> Article 3(6) TEU provides that "the Union shall pursue its objectives by appropriate means commensurate with the competences which are conferred upon it in the Treaties".

<sup>13</sup> Article 2(6) TFEU read together with Articles 26 to 212 TFEU.

<sup>14</sup> In other words, primary legislation (provisions of the TEU and the TFEU) takes precedence over secondary legislation (measures adopted on the basis of the Treaties), which means, for example, that a directive (secondary legislation) must not contravene any Treaty provision (primary legislation).

<sup>15</sup> Article 288 TFEU does not establish any hierarchy between various acts. However, they are of a different nature and their legal effects may differ, which explains why they should be distinguished.

<sup>16</sup> Article 296 TFEU.

### 3.AMR as a public health issue: the scope of EU powers under Article 168 TFEU

As AMR is regarded as a major public health concern, a good starting point to assess the regulatory powers the EU enjoys in this field is to consider the tools which it has at its disposal in the area of public health policy.

The role of the EU has evolved in this field. It was only with the Treaty of Maastricht in 1992 that the EU was formally granted some competence to deal with health matters. Its powers were further extended by the Treaty of Amsterdam and the Treaty of Lisbon. The insertion of a new title on health in the TFEU (then the TEC) resulted from the growing perception that certain health concerns could not be resolved by Member States acting unilaterally. Title XIV, which is composed of a single article: Article 168 TFEU, is devoted to public health. As this article is both complex and important for the development of an EU AMR strategy, it is quoted in full in the box below.

#### TITLE XIV PUBLIC HEALTH Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.

The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Even though they do not define “health”, it is clear that the EU Treaties, and Article 168 TFEU more specifically, adopt a broad approach of what is required to ensure a high level of human health protection, by focusing not only on the treatment of patients, but also on the prevention of illness and diseases as well as on health promotion. This is arguably reinforced by the provision in Article 3(1) TEU that “the Union’s aim is to promote peace, its values and the well-being of its peoples” (emphasis added) – well-being presupposes good health (among others).

It nonetheless remains that, at the heart of Article 168 TFEU, lies a tension between, on the one hand, the recognition that Member States are primarily responsible for the health of their citizens, and, on the other, the recognition that the EU may be better placed than its Member States acting individually to address major public health concerns, particularly major cross-border health scourges such as AMR. This tension is reflected earlier on in the TFEU: whilst Article 4(2) (k) grants a shared competence to the EU in relation to “common safety concerns in public health matters, for the aspects defined in this Treaty”, Article 6(a) merely grants a complementary competence

to the EU “to carry out actions to support, coordinate or supplement the actions of the Member States” to protect and improve human health.

Uncontroversial are the extensive “soft law” powers that the EU derives from Article 168 TFEU: in particular, it can provide research funding and other forms of support and can promote health through information and education (paragraph 1); it can establish guidelines and indicators, as well as fora where best practice is exchanged and common problems discussed (paragraph 2); it can adopt non-binding recommendations (paragraph 6); and it shall promote – alongside its Member States – international cooperation with third countries as well as the WHO and other relevant actors<sup>17</sup> to reinforce the weight of the EU and its Member States on the global scene (paragraph 3).<sup>18</sup>

Uncontroversial too is the fact that Member States remain primarily responsible for the definition of their health policies and the organisation and the delivery of health services and medical care on their territories, particularly in relation to the management of such services and care and the allocation of the resources assigned to them (paragraph 7).

What is not as straightforward is the scope of EU powers under the fourth and the fifth paragraphs of Article 168 TFEU where the tension highlighted above really lies.

Article 168(4) TFEU grants powers to the EU to adopt legally binding measures, including regulations or directives, to meet common safety concerns.<sup>19</sup> In particular, it allows the EU to adopt EU-wide standards relating to the veterinary and phytosanitary fields to protect public health, and regulate medicinal products and devices for medical use to ensure high standards of quality and safety. This is significant for AMR containment, as demonstrated by the very recent “Animal Health Law”, which the EU adopted in the form of Regulation 2016/429 on 9 March 2016<sup>20</sup> and which is based – among other Treaty provisions – on Article 168(4) (b). It is discussed further below.

However, the scope of this power should not be interpreted too extensively, in light of the wording of the provision: it is indeed presented as a derogation – “by way of derogation from Article 2(5) and Article 6(a)” – and, therefore, it does not detract from the fact that EU competences in relation to public health are considered to be, above all, complementary of Member States’ powers. Furthermore, the provision is subject to the condition that a “direct” link must exist between the measure adopted and the objective of protecting public health.<sup>21</sup> Finally, Member States retain their freedom to adopt more protective standards where they see fit. The measures adopted on Article 168(4) must be of minimum harmonisation only: they require Member States to implement, as a minimum, the EU standard adopted on the basis of Article 168(4) without, however, preventing them from increasing the level of health protection they seek to pursue on their territory.

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<sup>17</sup> As far as AMR is concerned, these actors include the Food and Agricultural Organization (FAO) and the World Organization for Animal Health (OIE), with which the WHO formally collaborates to share responsibilities and coordinate global activities to address health risks at the animal-human-ecosystems interfaces.

<sup>18</sup> See also Article 21 TEU on the EU’s external action: “The Union shall seek to develop relations and build partnerships with third countries, and international, regional or global organisations which share the principles referred to in the first subparagraph. It shall promote multilateral solutions to common problems, in particular in the framework of the United Nations.”

<sup>19</sup> The applicable procedure if the EU decides to legislate on the basis of Article 168(4) TFEU is the ordinary legislative procedure, requiring a qualified majority vote in the Council.

<sup>20</sup> OJ 2016 L84/1.

<sup>21</sup> On the notion of measures having “as their direct objective the protection of public health”, see the decision of the Grand Chamber of the CJEU in Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 ABNA and Others [2005] ECR I-10468.

In relation to the public health measures which do not fall within the scope of Article 168(4), Article 168(5) TFEU explicitly excludes the adoption at EU level of “any harmonisation of the laws and regulations of the Member States”. Consequently, the EU does not have the authority, on the basis of this provision, to impose an EU-wide standard which would replace existing national standards (even on a minimum harmonisation basis). However, this should not be read as depriving the EU of any powers to adopt measures – even legally binding measures – which could contribute to the containment of AMR in the EU. On the contrary, Article 168(5) explicitly empowers the EU to adopt “measures concerning monitoring, early warning of and combating serious cross-border threats to health”. Even though the actual scope of this power has not, as far as we know, been tested before the CJEU, it does not prevent the EU from adopting legislation intended to ensure that Member States report key data to the EU in such a way as to facilitate EU-wide and international comparisons and improve monitoring and surveillance of AMR. This interpretation finds further support in Article 2(5) TFEU which provides that “legally binding acts of the Union adopted on the basis of the provisions of the Treaties relating to [the areas where the EU has complementary powers] shall not entail harmonisation of Member States’ laws or regulations”. This clearly suggests that the EU may adopt legally binding measures which do not entail the harmonisation of the laws of the Member States under Article 168(5) TFEU.

Of particular relevance to AMR containment is the establishment in 2005 of the European Centre for Disease Prevention and Control – an independent EU agency aimed at strengthening Europe’s defences against infectious diseases.<sup>22</sup> The evaluation report of the EU Action Plan on AMR concludes that the Action Plan has helped strengthen monitoring and surveillance systems, develop and fulfil bilateral and multilateral commitments and raise public awareness about AMR. However, it also calls on the EU to provide additional coordinated support to Member States and to ensure that the monitoring of AMR take a more holistic approach linking data resistance to and usage of antimicrobials to prescribing trends and other factors: better tracking AMR-related costs and benefits; considering the use of targets and related indicators, including, as appropriate, country-specific targets and indicators; and continuing to monitor public awareness. These measures could arguably be best implementing with the adoption of EU-level measures on the basis of Article 168(5) TFEU.

#### Mainstreaming public health in all EU policies: from 168(1) to Article 9 TFEU

By requiring that “a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”, Article 168(1) 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.

The EU’s duty to mainstream public health concerns in all its policies has been reinforced by the Lisbon Treaty in two ways. Firstly, it introduces Article 9 TFEU, which provides that “in defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of [...] protection of human health”. The mainstreaming provision is therefore given more prominence within the TFEU. Secondly, the EU Charter of Fundamental Rights – including Article 35 on health – has acquired the same legal value as the Treaties,<sup>23</sup> further reinforcing the importance of health protection to the EU agenda and the process of EU integration.

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<sup>22</sup> Regulation 853/2004 was adopted on the basis of Article 168 TFEU (then Article 152 EC); OJ 2004 L142/1.

<sup>23</sup> Article 6(1) TEU.

Mainstreaming provisions do not extend the competences of the Union as defined in the Treaties. However, they may help the EU ensure consistency between its policies and activities, taking all of its objectives into account, as required by Article 7 TFEU. Furthermore, they mandate the EU to ensure that it takes a high level of public health protection in all its policies (though not necessarily “the highest”), at all stages of the policy process, and they have been invoked as interpretation aid to help shift the balance in favour of public health protection over potentially competing interests. For example, in its recent *Philip Morris* decision, the CJEU upheld the validity of Directive 2014/40 on tobacco products and ruled:

156. [...] human health protection — in an area characterised by the proven harmfulness of tobacco consumption, by the addictive effects of tobacco and by the incidence of serious diseases caused by the compounds those products contain that are pharmacologically active, toxic, mutagenic and carcinogenic — outweighs the interests put forward by the claimants in the main proceedings.

157. Indeed, as is apparent from the second sentence of Article 35 of the Charter and Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU, a high level of human health protection must be ensured in the definition and implementation of all the European Union’s policies and activities.<sup>24</sup>

Article 114(3) TFEU – the provision that we have not yet referred to – refers to the EU legislature’s obligation when discussing internal market harmonising measures concerning health, safety, environmental protection and consumer protection, to take as a base a high level of protection, with particular regard for any new development based on scientific facts. We now turn to this key EU policy.

#### **4. Beyond Article 168 TFEU: the importance of a “One Health” Approach**

##### **a) EU internal market policy**

The internal market – the area in which the free movement of goods, services, people and capital shall be ensured in accordance with the provisions of the Treaties<sup>25</sup> – has always been central to the process of EU integration. Its rationale is that the broader the market, the more choice for consumers and the more opportunities for businesses. Article 114 TFEU is the key provision granting the powers to the EU to adopt the measures necessary for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.<sup>26</sup> From a formal point of view, measures may be adopted on the basis of Article 114 by qualified majority voting only in Council, i.e. without the need for the unanimous agreement of the Member States. Moreover, the ordinary legislative procedure applies in that both the Council and the European Parliament must reach a common decision. From a substantive point of view, measures may be adopted on the basis of Article 114 only if they have as their object the establishment or functioning of the internal market.

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<sup>24</sup> Case C-547/14, judgment of 4 May 2016.

<sup>25</sup> Article 26(2) TFEU.

<sup>26</sup> The TFEU also contains more specific internal market legal bases, not least Article 53(1) and 62 TFEU which allow the European Parliament and the Council, also acting in accordance with the ordinary legislative procedure, to issue directives to promote the freedom of establishment and the free movement of services within the EU.



The question arises how far the EU can accommodate health concerns in the internal market harmonisation process. On the one hand, the CJEU clearly stated in its Tobacco Advertising I judgment that Article 114 should not be relied on to “circumvent the express exclusion of harmonisation” under Article 168(5) TFEU.<sup>27</sup> On the other hand, this should not be understood as meaning that harmonising measures based on Article 114(1) cannot have a strong impact on public health. On the contrary, as we have just seen, Article 114(3) explicitly mandates the EU to take a high level of health protection as a base for its internal market policy, supplementing other health mainstreaming Treaty provisions. As the Court observed in its Alliance for Natural Health ruling, “provided that the conditions for recourse to [Article 114 TFEU] as a legal basis are fulfilled, the [EU] legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made”.<sup>28</sup>

The crucial point for the EU legislature therefore is to ensure that the three conditions which the CJEU has restated in its more recent Vodafone judgment are fulfilled for a measure to be validly adopted on the basis of Article 114 TFEU:

- there must exist an “internal market barrier” resulting from the disparities in the legal systems of the Member States;
- this market barrier must not consist of an “abstract risk of obstacles”, but should be “such as to obstruct the fundamental freedoms” or create “distortions of competition” within the internal market; and
- the intended harmonisation should “genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market”.<sup>29</sup>

These conditions could be met by a range of measures intended to address AMR as a consumer protection, a food safety and/or a patient safety issue.<sup>30</sup> This is all the more so as the case law of the CJEU has interpreted these conditions generously.<sup>31</sup>

## EU competence and consumer protection

In June 2016, the Commission published the Eurobarometer results on Antimicrobial Resistance awareness. The main conclusion of this Eurobarometer was that knowledge across the EU remains low. One can therefore wonder the extent to which providing consumers with relevant information on the foods they buy for themselves and their families **could help reduce this “knowledge gap”**.

Consumer protection, and consumer information more specifically, has been at the heart of the EU internal market since the late seventies. This close relationship has become more explicit following the entry into force of the Lisbon Treaty with the introduction of Article 12 TFEU – another mainstreaming provision: it mandates the EU to take into account “consumer protection requirements” in defining and implementing other Union policies and activities, whilst Article 114(3) TFEU requires that the EU should take as a base a high level of consumer and health protection when using its internal market harmonising powers. Furthermore, Article 169 TFEU – the sole article of Title XV (Consumer Protection) – empowers the EU to adopt measures on the basis of

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<sup>27</sup> Case C-376/98 Germany v Council and the European Parliament (Tobacco Advertising I) [2000] ECR I-8419.

<sup>28</sup> Joined Cases C-154 and 155/04 Alliance for Natural Health [2005] ECR I-6451.

<sup>29</sup> Case C-58/08 Vodafone [2010] ECR I-4999.

<sup>30</sup> There can be significant overlap between these categories, but this does not have consequences to the extent that Article 114 TFEU (or a more specific internal market legal basis such as Articles 53-62 TFEU) could be invoked as the appropriate legal basis and the same formal conditions would apply irrespective of the sub-category identified.

<sup>31</sup> E.g., Case C-380/03 Germany v Council and the European Parliament (Tobacco Advertising II) [2006] ECR I-11573.

Article 114 TFEU in the context of the completion of the internal market in order to promote the interests of consumers and to ensure a high level of consumer protection, and in particular to contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests. It is therefore unequivocal that consumer and internal market policies are very closely related, and that the proper functioning of the internal market requires that the EU protect its consumers and their health effectively: it is only if it does so that the Four Freedoms on which the internal market is premised can be envisaged.

Consumer information is at the heart of EU consumer policy. Over the years, the EU has adopted a wide range of directives and regulations, based on Article 114 TFEU, to ensure that consumers could fully exercise their choice. “Consumer empowerment” – to use one of the EU’s recurring phrases – requires that the information that they are provided with is sufficient, clear and reliable (i.e. not misleading).<sup>32</sup> One could reflect on the adoption at EU level of harmonising legislation requiring the disclosure of whether antibiotics have been used in any of the ingredients (of animal or plant origin) composing a given food, and if so in which quantities. The EU would be in a better position than its Member States to regulate food labelling bearing in mind the extensive food trade taking place within the EU internal market, and such a rule would be in the same vein as the raft of legislation the EU has adopted to allow consumers to make more ethical, safer and more nutritious choices.

#### EU competence and food safety

Closely related to food information is the EU regulatory framework on food safety. There is no doubt that AMR can be viewed as a food safety issue. The WHO European Regional Office published a report specifically on “Tackling antibiotic resistance from a food safety perspective in Europe” in 2011, with a view to exploring the options for prevention and containment of antibiotic resistance in the food chain through national coordination and international cooperation, including the regulation and reduction of antibiotic use in food animals, training and capacity building, surveillance of resistance trends and antibiotic usage, promotion of knowledge and research and advocacy and communication to raise awareness of the issues. It is clear that the EU has extensive powers to implement some of these measures. Beyond the imposition of further food labelling and other food information disclosure requirements, a broad range of legislative measures could be adopted on the basis of Article 114 TFEU (possibly in combination with other legal bases) to ensure a high level of food safety, consumer and health protection across the EU.

The Food Safety Regulation, which provides a framework for EU food law, is an excellent example of the reach that EU law can have to facilitate the establishment and functioning of the internal market.<sup>33</sup> It was adopted following the outbreak of BSE (bovine spongiform encephalopathy), as the EU and its Member States identified a strong and urgent need for a cross-border response to what had become a cross-border problem – a problem with which analogies could be drawn to AMR.

The Food Safety Regulation is based on Article 114 TFEU, as well as other relevant legal bases, including Article 43 on the Common Agricultural Policy (discussed below) and Article 168 on public health (discussed above). Also reflecting the multi-sectoral approach required to address

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<sup>32</sup> For example, the Food Information Regulation of 2011 imposes several disclosure requirements with a view to ensuring that consumers are informed, via product labelling or other means, of several key characterising features of the foods they may decide to buy: Regulation 1169/2011, OJ 2011 L 304/18.

<sup>33</sup> Regulation 178/2002, OJ 2002 L 31/1.

food safety effectively, the Food Safety Regulation lists a range of key objectives of “food law”, which the Food Safety Regulation defines broadly to include “any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals” (Article 3(1)); the protection of human life and health, the protection of consumers’ interests, fair practices in food trade, the protection of animal health and welfare, and the protection of plant health and the environment (Article 5(1)).<sup>34</sup> To ensure that these objectives are achieved, the Food Safety Regulation requires the use of appropriate risk analysis, which consists of “three interconnected components: risk assessment, risk management and risk communication” (Article 3(10)). To facilitate the implementation of such a risk-based analysis, the Food Safety Regulation establishes the European Food Safety Authority (EFSA), whose primary role is to provide scientific advice and scientific and technical support for the implementation of Union law and policy in all areas that have a bearing on the safety of food (Article 22). In particular, EFSA is a central actor in the Rapid Alert system for the notification of a direct or indirect risk to human health deriving from food or feed (Article 35).

Of particular interest for our purposes is the role which the Food Safety Regulation attributes to the precautionary principle. Even though the precautionary principle is not mentioned as a guiding principle of internal market or public health policy in the EU Treaties themselves (whereas it is in relation to environmental law, as discussed below), it is nonetheless enshrined in the Food Safety Regulation as central to the development of EU food law. Article 7(1) indeed provides that “in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the [Union] may be adopted, pending further scientific information for a more comprehensive risk assessment”. Article 7(2) specifies, however, that measures adopted on the basis of the first paragraph should be cognisant of trade imperatives and no more restrictive than is necessary to achieve a high level of health protection. If health concerns are very clearly central to the assessment, the question nonetheless arises what is meant by “scientific uncertainty”. What would constitute sufficient evidence and thus remove “scientific uncertainty” is defined neither by the Food Safety Regulation nor by the European Commission Communication on the precautionary principle.<sup>35</sup> However, the Court’s case law suggests that the EU should be granted a broad margin of discretion in its assessment of existing evidence and whether it can invoke the precautionary principle.<sup>36</sup>

### EU competence and patient safety

In line with the wording and spirit of Article 168 TFEU, and its fifth paragraph more specifically, the EU has used its “soft law” powers to issue some recommendation to Member States on patient safety, including recommendations on the prevention and control of healthcare associated infections.<sup>37</sup> Such instruments are particularly relevant in relation to AMR containment.

However, because people move from one Member States to another (with the bacteria, viruses and other micro-organisms they carry), the EU has exercised its internal market powers to ensure the application of patients’ rights in cross-border healthcare. Directive 2011/24 is based on Article

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<sup>34</sup> Article 8 adds that “food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume”.

<sup>35</sup> COM(2000) 1.

<sup>36</sup> See, for example, Case T-13/1999 Pfizer Animal Health v Council [2002] ECR II-3305 in which the EU prohibited the use of four previously approved antibiotics in animal feed (Regulation 2821/1998, OJ 1998 L 351/4).

<sup>37</sup> Council Recommendation 2009/C 151/01.

114 and Article 168 TFEU, and refers specifically to Article 114(3) TFEU.<sup>38</sup> Its preamble highlights that “systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technologies” (emphasis added).<sup>39</sup> Referring to “Union legislation on safety standards”,<sup>40</sup> the Patients’ Rights Directive extends the scope of the EU’s involvement in healthcare – without however exceeding the powers the EU has been granted by the EU Treaties, and Articles 114 and 168 TFEU more specifically. Although the organisation and delivery of health services within national health systems have not been affected, in compliance with Article 168(5) TFEU, the Member States have been required to reimburse cross-border care subject to defined exceptions. They have also been required to provide information about quality and costs, as well as providing for professional liability and damages. In addition, the Directive provides for enhanced cooperation on rare diseases and e-health. This model of enhanced cooperation could perhaps be reflected upon in the context of AMR containment.

#### b) The Common Agricultural (and fishery) Policy

The Common Agricultural Policy (CAP) is one of the EU’s oldest policies. It was set up in 1962 with the aim to provide food security, i.e. to ensure that food supplies were widely available at affordable prices. Even though the TFEU does not specifically refer to health, the CAP has evolved over the years to meet changing economic circumstances and citizens’ requirements. The challenges facing the sector, many of which driven by factors that are external to agriculture, have changed over the years. Today, they have been identified as economic (including food security and globalisation, a declining rate of productivity growth, price volatility, pressures on production costs due to high input prices and the deteriorating position of farmers in the food supply chain), environmental (relating to resource efficiency, soil and water quality and threats to habitats and biodiversity) and territorial (where rural areas are faced with demographic, economic and social developments including depopulation and relocation of businesses). As such, it seems that the CAP can (and has started to) play a potentially powerful role in containing AMR. This is all the more so as the EU has extensive competence in this field.

The CAP (which includes fisheries) is dealt with in Title III of the TFEU, which contains Articles 38 to 44.<sup>41</sup> Article 39 TFEU lists the objectives for the CAP, including the objectives “to increase agricultural productivity by promoting technical progress and by ensuring the rational development of agricultural production and the optimum utilisation of the factors of production”, “to assure the availability of supplies” and to ensure that such supplies “reach consumers at reasonable prices”. In order to attain these objectives, Article 40 TFEU requires that a common organisation of agricultural markets shall be established, which may include in particular the regulation of prices and aids for the production and marketing of the various products, whilst Article 43(2) TFEU grants legislative powers to the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, to establish the common organisation of

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<sup>38</sup> OJ 2011 L 88/45.

<sup>39</sup> Recital 22.

<sup>40</sup> Article 4(1) (c).

<sup>41</sup> Article 38 TFEU defines “agricultural products” as “the products of the soil, of stockfarming and of fisheries and products of first-stage processing directly related to these products. References to the common agricultural policy or to agriculture, and the use of the term ‘agricultural’, shall be understood as also referring to fisheries, having regard to the specific characteristics of this sector”.

agricultural markets and the other provisions necessary for the pursuit of the objectives of the common agricultural policy and the common fisheries policy”.<sup>42</sup>

Following a range of consecutive reforms, the CAP now helps farmers to, among others, use eco-friendly farming techniques and meet public health, environmental and animal welfare standards. Thus, even though health is not expressly mentioned as an objective of the CAP, food safety concerns are nonetheless considered an integral part of it. Similarly, climate change concerns and issues such as biodiversity loss, water and soil quality mean that agriculture play an increasingly important role in the sustainable management of natural resources: environmentally sustainable farming, which uses natural resources prudently, is now considered essential for food production and for quality of life in the EU.

In pursuance of safe and high-quality food, the EU has developed over the years a range of tools. These include marketing standards, quality systems to identify products with a specific quality, certification systems and hygiene rules. For example, Regulation 1151/2012 on quality schemes for agricultural products and foodstuffs was adopted on the basis of Article 43(2) TFEU to “establish quality schemes which provide the basis for the identification and, where appropriate, protection of names and terms that indicate or describe agricultural products with added value attributes or characteristics” (Article 1(2)). This is intended “to help producers of agricultural products and foodstuffs to communicate the product characteristics and farming attributes of those products and foodstuffs to buyers and consumers, thereby ensuring – among others – the availability to consumers of reliable information pertaining to such products” (Article 1(1)).

The CAP therefore provides some scope to the EU to adopt legislation intended to contain AMR. For example, since 2006, the use of antimicrobials for animal growth promotion has been banned in the EU. Regulation 1831/2003 is based on both Articles 43 and 168 TFEU.<sup>43</sup> The legislation could arguably be revised to regulate the use of antibiotics in the treatment of animals too. In particular, the final report of O’Neill review on AMR, published in May 2016, has recommended that restrictions and/or bans on certain types of highly critical antibiotics be imposed as a priority area of regulatory intervention.<sup>44</sup> Bearing in mind the CAP and the EU internal market where animals, food and people can move from one Member State to another, there is no doubt that the EU would be in a much better position to implement this recommendation effectively than its Member States acting unilaterally could ever be.

Most recently, the EU adopted Regulation 2016/429 which lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans, referred to as “Animal Health Law”. It refers specifically to AMR and emphasises the preventive role this Regulation can play and the consequent expected reduction of the use of antibiotics in animals. As Recital 32 notes, “this resistance of microorganisms to antimicrobials to which they were previously responsive complicates the treatment of infectious diseases in humans and animals and may thus pose a threat to human or animal health. As a result, microorganisms that have developed resistance to antimicrobials should be treated as if they were transmissible diseases, and thus covered by the scope of this Regulation. This will enable action to be taken against antimicrobial-resistant organisms where appropriate and necessary.” The rules it lays down therefore aim to ensure: (i) improved animal health to support sustainable agricultural and aquaculture production

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<sup>42</sup> The Lisbon Treaty made the European Parliament the Council’s co-legislator in CAP matters, whereas it only needed to be consulted beforehand (ex-Article 36(2) EC).

<sup>43</sup> OJ 2003 L268/29.

<sup>44</sup> “Too many antibiotics that are last-line drugs for humans are being used in agriculture, sometimes without even professional oversight. These need to be in the prime focus of efforts to reduce consumption in animals and action should be taken on this now” (at page 26).

in the EU; (ii) the effective functioning of the internal market; and (iii) a reduction in the adverse effects on animal health, public health and the environment of certain diseases and the measures taken to prevent and control diseases, mentioning specifically the need to take into account the relationship between animal health and AMR (among others).<sup>45</sup>

It is therefore not surprising that this piece of EU legislation is based not only on Article 43(2) (CAP), but also on Articles 114 and 168(4) (b) (internal market and public health respectively) – as was the case for the Food Safety Regulation discussed above. Reliance on a multitude of legal bases reinforces the argument that animal health, and AMR containment in particular, is multi-faceted and requires a coordinated multi-sectoral response.<sup>46</sup> Such an approach was facilitated in this case as all the legal bases relied upon referred to the same category of EU competence (shared competence between the EU and its Member States<sup>47</sup>) and the same legislative procedure applied (the ordinary legislative procedure).

### c) EU environmental policy

The Evaluation of the EU AMR Action Plan has highlighted that, even though the Action Plan was overall coherent, “it could have been more coherent if it had covered environmental issues more broadly”. The final section of this paper therefore considers the powers that the EU derives from the EU Treaties to protect the environment.

The EU Treaties explicitly acknowledge the importance of both environmental protection and sustainable development. Article 3(3) TEU states: “The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance.”<sup>48</sup> Combined with Article 11 TFEU, which lays down a mainstreaming provision mandating the EU to integrate “environmental protection requirements” into “the definition and implementation of the Union’s policies and activities”,<sup>49</sup> “in particular with a view to promoting sustainable development”, clearly reflects that the environment has become, over the years, a major EU concern.

The competence of the EU in relation to the environment is shared with its Member States. This is clear from the wording of Article 4(2) (e) TFEU. The scope of EU powers in this area are more specifically identified in Title XX Environment, which is itself made up of Articles 191 to 193 TFEU.

Article 191(1) TFEU makes it clear that there are clear linkages between the quality of the environment and human health protection, the latter being an explicit objective of the EU’s policy

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<sup>45</sup> Article 1(2).

<sup>46</sup> Laying down another mainstreaming requirement for the EU, Article 13 TFEU adds that “in formulating and implementing the Union’s agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage.”

<sup>47</sup> In particular, the EU was careful to rely on Article 168(4) specifically, as opposed to Article 168 more generally.

<sup>48</sup> See also the Preamble of the TEU: “DETERMINED to promote economic and social progress for their peoples, taking into account the principle of sustainable development and within the context of the accomplishment of the internal market and of reinforced cohesion and environmental protection, and to implement policies ensuring that advances in economic integration are accompanied by parallel progress in other fields.”

<sup>49</sup> Article 114(3) TFEU, which has been discussed above, also refers to the obligation resting on the EU to ensure a high level of environmental protection in its internal market policy.

on the environment, whilst Article 191(2) TFEU grants constitutional status to the precautionary principle, in that it requires that Union policy on the environment be based on the precautionary principle as well as on the principle that preventive action be taken.

Article 192(1) TFEU provides the specific legal basis on which the EU, acting in accordance with the ordinary legislative procedure, is empowered to “decide what action is to be taken by the Union in order to achieve the objectives referred to in Article 191.” The term of “action” is not defined, but seems to be even broader than the alternative term of “measures” often used in other Treaty bases. However, Article 193 TFEU specifies that “the protective measures adopted pursuant to Article 192 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. They shall be notified to the Commission.” The model of legislative harmonisation envisaged by Article 192 therefore is a minimum harmonisation model – similar to the model envisaged in, and previously discussed in relation to, Article 168(4) TFEU: the EU can impose a minimum standard below which no Member State can fall; however, Member States can decide to exceed this standard, subject to the limits imposed by EU Treaties, and particularly the general provisions on the free movement of goods and services.<sup>50</sup>

The potential of these provisions to AMR containment is significant. For example, the EU has adopted Directive 2013/39 on priority substances in the field of water policy on the basis of Article 193(2) TFEU whose objective is to achieve good surface water chemical status by laying down European-wide environmental quality standards for priority substances and certain other pollutants.<sup>51</sup> The link between environment and human health protection is explicitly established.<sup>52</sup>

## 5. Conclusion: distinguishing the limits on EU competence from the problem of political will

Overall, the EU Treaties, as interpreted by the CJEU, 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 the adoption of legally binding measures with other forms of policy intervention. The question is not only whether the EU has some competence to deal with AMR – AMR arguably is the archetypal issue envisaged by Article 168 TFEU (a “major health scourge with cross-border effect”).

Despite the limits enshrined in Article 168(5) TFEU, the EU does have a wide range of powers to contain AMR. Rather, the question is whether the EU will have the necessary political will to do so, and to do so quickly. It is hoped that the lack of political will that we have regrettably observed

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<sup>50</sup> Article 114 TFEU, which also has a strong environmental component by virtue in particular of Article 114(3) does not contain the same limit, allowing the EU to adopt a common standard – rather than a minimum standard – for all its Member States. This distinction may play an important role in determining whether the EU decides to legislate on the basis of Article 114 or Article 192 TFEU – only the former empowering the EU to adopt fully harmonised standards at EU level (i.e. one standard replacing 28 national standards – measures of minimum harmonisation may only contribute to the reduction of regulatory diversity in the EU). This is on the assumption, of course, that the measure under consideration pursues the dual objective of internal market integration and environmental protection: in the absence of the former, Article 114 could not provide an adequate legal basis, as discussed above.

<sup>51</sup> OJ 2013 L226/1.

<sup>52</sup> “The contamination of water and soil with pharmaceutical residues is an emerging environmental concern. In evaluating and controlling the risk to, or via, the aquatic environment from medicinal products, adequate attention should be paid to Union environmental objectives. In order to address that concern, the Commission should study the risks of environmental effects from medicinal products and provide an analysis of the relevance and effectiveness of the current legislative framework in protecting the aquatic environment and human health via the aquatic environment” (Recital 15).

in other health areas such as alcohol policy<sup>53</sup> will not hamper progress on AMR. We look forward to the publication of the Commission Communication laying down its second AMR Action Plan and hope that the measures envisaged will be apt to respond to AMR as “the greatest and most urgent global risk, requiring increased attention and coherence at the international, national and regional levels”.

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<sup>53</sup> In this field, it is fair to evaluate the EU Alcohol Strategy as a resounding failure: rhetoric aside, the EU has been virtually absent over the years, even though an effective EU response would have a significant added value for the EU, its Member States and its citizens alike.