



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

## **European One Health Action Plan against Antimicrobial Resistance (AMR)**

*Factual report of the online public consultation*

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# FACTUAL REPORT

## 1. INTRODUCTION

This report covers data and input received in the context of an open public consultation (OPC) on possible activities under a Commission Communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (AMR). This new Communication follows the Commission's 2011 action plan against the rising threats from AMR<sup>1</sup> which evaluation<sup>2</sup> was published in October 2016.

The OPC took place between 27 January 2017 and 28 April 2017<sup>3</sup>. It consisted of two parts, one addressed to citizens and one addressed to administrations, associations and other organisations (hereinafter stakeholders). It targeted citizens and stakeholders with an interest in human and animal health policy, public health, animal health, healthcare and/or the environment in Europe. The questionnaire for citizens was published in 23 official EU languages<sup>4</sup>. The questionnaire for stakeholders was published in English.

The OPC received replies from 584 participants: 163 stakeholders and 421 citizens.

The stakeholders represented a great variety of sectors. Over a fifth of the respondents were public or private administrations, followed by non-governmental organisations (NGOs), pharmaceutical industry stakeholders and human healthcare providers ([Annex – Graph 1](#)). More than half of the respondents (52%) were umbrella organisations or associations representing the interests of stakeholders.

As for the citizens, 406 came from 22 Member States while 15 came from non-EU countries ([Annex – Graph 2](#)). The vast majority were highly educated (87% had tertiary education) and admitted to being very well or well informed about AMR and its consequences (48% and 40% respectively), making the sample highly qualified to respond to the OPC. Additionally, whilst academically homogenous, the sample was very diverse professionally. There was a high prevalence of participants employed in the public and private human healthcare sector (39%), as these outweighed participants from the animal healthcare sector (12%) more than three to one. Generally participants were well distributed between the public, private and other sectors (44%, 35% and 21% respectively) ([Annex – Graph 3](#)).

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<sup>1</sup> [http://ec.europa.eu/dgs/health\\_food-safety/amr/docs/communication\\_amr\\_2011\\_748\\_en.pdf](http://ec.europa.eu/dgs/health_food-safety/amr/docs/communication_amr_2011_748_en.pdf)

<sup>2</sup> [http://ec.europa.eu/dgs/health\\_food-safety/amr/docs/amr\\_evaluation\\_2011-16\\_evaluation-action-plan.pdf](http://ec.europa.eu/dgs/health_food-safety/amr/docs/amr_evaluation_2011-16_evaluation-action-plan.pdf)

<sup>3</sup> The cut-off date is 28 April 2017. Contributions received by the European Commission after that date could not be taken into account in preparing this report.

<sup>4</sup> The citizens' questionnaire was not translated to Gaelic.

The OPC involved collecting input on the three main pillars of the new One Health action plan against AMR, namely: (1) making the European Union (EU) a best practice region; (2) boosting research, development and innovation on AMR, and (3) shaping the global agenda.

This report summarises the contributions received. Based on the analysis of the data, it puts forward the areas regarded as priorities for stakeholders and citizens in the fight against AMR. The contributions received have been used to inform policy-making in the area of AMR.

## **2. MAKING THE EU A BEST PRACTICE REGION**

The OPC sought to examine which actions with a strong EU added value for Member States would be most appropriate to tackle AMR effectively. Stakeholders and citizens answered questions which examined possible courses of action. Stakeholders were also invited to propose further actions.

Interestingly, almost half of the citizens (46%) attributed equal importance to conducting actions against AMR in the human health, animal health, and environmental sectors and more than a quarter (27%) were in favour of actions in both the human and animal health sectors. This highlighted their awareness on the need of a multi-sectorial approach, including a One Health<sup>5</sup> approach ([Annex – Graph 4](#)). Stakeholders' views also corresponded to a One Health approach addressing actions in all three sectors (human health, animal health, and environmental sectors).

### **2.1. BETTER EVIDENCE AND AWARENESS OF THE CHALLENGES OF AMR**

In terms of surveillance, stakeholders considered that a sound evidence-based AMR surveillance is the cornerstone for targeted and successful policy development. In this regard, stakeholders familiar with the EU surveillance systems<sup>6</sup> ([Annex – Graph 5](#)) believed to a great extent that the data collected on AMR in the human health sector (64% strongly agreed or agreed) and antimicrobial consumption (58% strongly agreed or agreed) is sufficient to support actions aimed at preventing and controlling AMR in humans. Nevertheless, in the animal health sector, only a slight majority considered that the data collected on AMR (52% strongly agreed or agreed) and antimicrobial consumption (50% strongly agreed or agreed) is sufficient to support actions aimed at preventing and controlling AMR in animals.

Stakeholders pointed to the following possibilities for improvement of surveillance:

- Moving towards a standardised system of data collection (or even data formats) in order to reduce disparities in the quality of national data;
- For antimicrobial consumption data:
  - In the human health sector, more granularity in the collection of data, e.g. at regional, sub-regional, or even local level or stratified by healthcare sector to

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<sup>5</sup> One Health recognises that the health of humans is connected to the health of animals and the environment.

<sup>6</sup> The percentages expressed were calculated based on stakeholders' replies after the answer 'I do not know / NA' was removed. These answers represented 23% to 33% of the total sample.

monitor better healthcare-associated infections (HAIs). Age/gender-specific data would also be welcome;

- In the animal health sector (including aquaculture), stakeholders strongly called for consumption data by species to be able to establish inter-species comparisons and targeted, sector-specific actions. Data by target population (e.g. fattening pigs or breeding sows and boars rather than all pigs); by farming system (e.g. intensive farming); and to start collecting data on antimicrobial use in companion animals (e.g. cats and dogs) would also be welcome;
- In both sectors, some stakeholders called for collecting data on the diagnoses or reasons for prescription;
- For antimicrobial resistance data, stakeholders called for broadening the scope of the surveillance systems to cover more pathogens in the human health sector. In both sectors they advocated for a database of resistance genes and for the use of genetic methods to improve data quality.

In order to strengthen the evidence base, stakeholders advocated for estimating the economic and health burden of AMR and for generating evidence on the outcomes of the actions that are being carried out. Finally, multiple stakeholders called for assessing the economic and health impacts of vaccines against major infectious diseases in humans and the effectiveness of vaccination schemes, infection control measures, farming systems and nutrition practices in animals.

In terms of awareness, stakeholders were very positive about the European Commission complementing Member States' AMR awareness-raising activities. Almost four times as many (79%) rated the Commission's efforts as helpful or very helpful compared to those who found these to be less helpful (21%). Stakeholders also pointed to the importance of country-specific, tailor-made campaigns as targeted as possible to citizens and consumers, but also to pharmacists, doctors, dentists, patients, veterinarians and farmers. These campaigns could also encompass awareness-raising on the importance of vaccines as preventive measures for humans and animals, and the potential risks of antimicrobial discharges to the environment.

Among citizens, a vast majority identified healthcare professionals and veterinarians as the most important actor in raising public awareness on AMR and the consequences of inappropriate use of antimicrobials (89% considered they should make high efforts) followed by Member States (78%). Citizens also valued the importance of international organisations (75%) and of the European Commission (68%) in public awareness-raising ([Annex – Graph 6](#)).

## **2.2. BETTER COORDINATION AND IMPLEMENTATION OF EU RULES TO TACKLE AMR**

To improve coordination of Member States' action on AMR, stakeholders considered it important holding regular discussions within a One Health dedicated network on AMR, gathering experts from the human health, animal health and environmental sectors. 96% of stakeholders considered it very helpful or helpful. Another 96% of stakeholders called on the European Commission to coordinate and facilitate the sharing of best practices and exchange of information on Member States' national action plans (NAPs) against AMR. Stakeholders from the pharmaceutical industry and the animal feed industry strongly advocated for private sector

engagement in the context of the One Health network and would welcome the set-up of a platform to track NAPs.

87% of the stakeholders considered that it would be either very helpful or helpful for Member States to define measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human health and animal health sectors and AMR in all three sectors. The human and animal health pharmaceutical industry stakeholders highlighted that reduction of AMR-related infections should be the primary end-point and not quantitative reduction targets for the use of antimicrobials. They argued that consumption-related reduction targets can have unintended consequences, in particular in the animal health sector, as they might induce a shift to more potent compounds, often used as critically important antimicrobials in human medicine, and hence compromise human and animal health, welfare and food safety.

To better implement EU policies, 90% of the stakeholders regarded as very helpful or helpful the use of EU funds to complement and help Member States in developing and implementing their NAPs against AMR and 80% believed that the European Commission should implement training programmes on AMR for Member States' competent authorities.

### **2.3. BETTER PREVENTION AND CONTROL OF AMR**

To reduce antimicrobial use and prevent the spread of AMR, stakeholders favoured new EU initiatives from the European Commission in humans (61% considered it very helpful and 28% helpful), followed by new EU initiatives from the European Commission in animals and agriculture (55% viewed it very helpful and 22% helpful).

With regards to infection prevention and control, stakeholders consistently called for:

- Supporting activities in the human health sector, including prevention of HAIs; infection control programmes; training and policies for all healthcare professionals to control HAIs; better hand hygiene and other control activities to prevent the transmission of microorganisms during healthcare delivery;
- Promoting initiatives, including legislative initiatives, in the animal health sector to improve animal husbandry practices for infection prevention and control (e.g. hygiene and management procedures, biosecurity measures, density of animals in holdings) and to re-think livestock production systems to reduce inherent disease risk and enhance the health of animals;
- Promoting feeding and animal nutrition strategies developed by national authorities in collaboration with feed industry experts (these strategies should ideally be part of NAPs) and stimulating the development of an incentive system for livestock farmers to implement optimised feeding strategies to help reduce the need for antimicrobials;
- Increasing the uptake of vaccination in the human and animal health sectors to prevent bacterial infections and reduce unnecessary antibiotic use for viral diseases.

While stakeholders identified human and animal healthcare providers as the most important actors to promote vaccination, most of their proposals concerned Member States (rated second in importance) and the European Commission (rated third in

importance in the human health sector and fourth in the animal health sector) ([Annex – Graph 7](#)).

These proposals asked for:

- Member States to develop clear national vaccination programmes in the human health sector with vaccination goals, which acknowledge the role of vaccines in the fight against AMR;
- Member States to identify and address key barriers to the introduction and roll-out of national vaccination schedules;
- Member States to establish national vaccination programmes in the animal health sector that reflect the diversity in livestock species and husbandry conditions;
- Member States to include vaccination schedules in their NAPs against AMR;
- The European Commission to support Member States in enhancing vaccination coverage against vaccine-preventable diseases and to encourage Member States to ensure that their vaccination schemes are updated and that a high percentage of the target population receives the recommended vaccines.
- Finally some stakeholders in the homeopathic and alternative medicine sectors called for the promotion of homeopathic and alternative medicinal products (traditional, complementary and alternative medicine) in the fight against AMR.

Stakeholders also voiced wide support for initiatives addressing prudent use of antimicrobials and requested:

- Including educational and training programmes on AMR and appropriate antimicrobial use in the human health and animal health sectors as well as in agricultural practice;
- Promoting antimicrobial stewardship teams in hospitals and healthcare facilities and enhancing antimicrobial stewardship policies for all clinicians in primary healthcare and hospitals;
- Promoting the uptake of diagnostic tests as a measure to increase appropriate use. Stakeholders identified human and animal healthcare providers as the most important actors to promote their uptake, as they are the ‘gatekeepers’ for use of antimicrobials. A few stakeholders called for obligatory susceptibility testing before prescription. Again, most of their proposals concerned Member States (rated second in importance) and the European Commission (rated third in importance in the human health sector and fourth in the animal health sector) ([Annex – Graph 8](#)). Stakeholders’ proposals called for:
  - Member States to encourage prescribers’ access to rapid diagnostics in order to help their decision-making;
  - Member States to set up measures targeting human and animal health providers to promote the use of rapid diagnostics (together with international or European institutions);
  - Member States to include the use of rapid diagnostics in educational, training and antimicrobial stewardship programmes;

- The European Commission to support Member States in producing treatment guidelines and decision-support tools based on evidence on the effects of the use of rapid diagnostic tests.

#### **2.4. BETTER ADDRESSING THE ROLE OF THE ENVIRONMENT**

Stakeholders expressed strong support (83% considered it very useful or useful) for initiatives aiming to monitor antimicrobials and resistant microorganisms in the environment (e.g. surveillance and data collection of active pharmaceutical ingredient (API) discharges, presence of resistant bacteria in ground and surface water). A few stakeholders pointed out that health and economic impact studies should be conducted before defining limitations on antimicrobial discharges to the environment.

Stakeholders familiar with antimicrobial discharge pathways to the environment<sup>7</sup> ([Annex – Graph 9](#)) had the opinion that action should be taken to limit antimicrobial discharges from the pharmaceutical manufacturing process (83% of stakeholders considered it very useful or useful). Pharmaceutical industry stakeholders highlighted their commitment<sup>8</sup> to implement concrete measures to reduce the environmental impact of antimicrobial manufacturing. Several stakeholders urged the European Commission to adopt an EU strategic approach to pharmaceuticals in the environment. This approach could include:

- Minimum manufacturing standards to prevent pharmaceutical waste that leads to AMR. These would encompass limitations to risk-based and science-driven discharge concentrations of APIs by industrial/pharmaceutical waste streams and transparency regarding the source of APIs and emissions of manufacturing waste containing APIs;
- Environmental risk assessment of the impact of APIs in the environment;
- New legal environmental requirements in the authorisation procedure of antimicrobial medicinal products.

In addition, 90% of these stakeholders viewed the limitation of antimicrobial and resistant microorganisms' discharges to the environment from other possible hotspots as very useful or useful and 66% also considered very useful or useful that the use of sewage sludge and animal manure and slurry as soil amendments is limited unless they have been subject to composting or similar measures. Several stakeholders advised that hotspots (e.g. hospitals, wastewater treatment plants, manure and slurry stores) should be clearly differentiated when establishing limitations as the discharges produced are very different.

Finally, further proposals included:

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<sup>7</sup> The percentages expressed were calculated based on stakeholders' replies after the answer 'I do not know / NA' was removed. These answers represented 10% to 27% of the total sample.

<sup>8</sup> <http://www.ifpma.org/resource-centre/industry-roadmap-for-progress-on-combating-antimicrobial-resistance/>

- Promoting and strengthening take-back schemes and systems, which could be obligatory and harmonised, for unused or out-of-date antimicrobials across the EU to prevent these from reaching the environment;
- Expanding the scope of actions to include heavy metals, disinfectants and biocides discharges;
- Exploring expanding the monitoring of antimicrobial consumption and resistance to plant agriculture.

## **2.5. A STRONGER PARTNERSHIP AGAINST AMR AND BETTER AVAILABILITY OF ANTIMICROBIALS**

Success against AMR depends on efforts from all levels of governance and multitude of societal actors. Stakeholders considered that the promotion of dialogue between all relevant stakeholders is crucial in order to discuss human and animal antimicrobial development challenges, with 55% viewing it as yielding high benefits and 31% medium benefits. Similarly, 85% and 83% considered that dialogue between stakeholders would bring high or medium benefits in discussing the regulatory framework for alternatives to antimicrobials and in accelerating vaccine development for multi-resistant pathogenic bacteria, respectively.

To optimise development plans, pharmaceutical industry stakeholders strongly advocated for early and continuous dialogue with all relevant stakeholders (e.g. regulators, HTA/NITAG<sup>9</sup> bodies, pharmaceutical industry, payers) throughout the entire product development cycle and called for dialogue on:

- A regulatory framework that prioritises the development of antimicrobial medicines, vaccines and diagnostic tests, further enables efficient pathways for medicinal product development and accelerates review pathways for antimicrobial medicinal products targeting serious and life-threatening infections;
- Broadening the definition of ‘unmet medical needs’ to recognise the public health value of having a variety of treatment options for specific bacterial infections;
- Harmonising regulatory requirements between agencies on approaches, standards and guidelines for antimicrobial medicinal product approval.

Stakeholders in the animal health sector asked to properly differentiate in the development phase which new antimicrobials are intended for human use and for use in animals.

Stakeholders had multiple constructive suggestions on how to guarantee the availability of effective antimicrobials. These asked to ensure that antimicrobials for humans and animals are only sold under prescription (better control of over-the-counter sales); to safeguard Internet sales of antimicrobials; and to improve and reformulate older antimicrobials in order to be kept longer on the market. A few stakeholders also called on Member States to take measures to support sustainable pricing levels and procurement practices to ensure continued supply of essential antimicrobials.

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<sup>9</sup> HTA: Health Technology Assessment, NITAG: National Immunisation Technical Advisory Group

Stakeholders in the animal health sector highlighted that although the need for new antimicrobials in human medicine is unquestioned, the availability of existing antimicrobials is as vital in veterinary medicine. They also expressed concern over the unavailability of vaccines and urged the European Commission to take measures to ensure that vaccines have EU-wide marketing authorisations and are available in Member States with small-sized markets.

### **3. BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION ON AMR**

Research, development (R&D) and innovation are essential strategic pieces in the fight against AMR. The consultation questions in this area aimed to gather opinions and views of stakeholders and citizens on potential actions to reduce barriers to the development of new antimicrobials, alternative therapies, vaccines and diagnostic tests; on funding instruments to stimulate R&D and on knowledge gaps on AMR in the environment.

#### **3.1. IMPROVE KNOWLEDGE ON DETECTION, EFFECTIVE INFECTION CONTROL AND SURVEILLANCE**

In order to contain and limit resistance dissemination, stakeholders involved in R&D called for funding of basic research (e.g. biochemical knowledge of virulence, mechanisms underlying resistance, epidemiology and immunology of pathogens and HAIs, molecular mechanisms underlying resistance gene transmission, host-microbiome and host-pathogen interactions), but also for research on communication, behavioural sciences and methods to promote a change in how antimicrobials are used.

#### **3.2. DEVELOP NEW THERAPEUTICS AND ALTERNATIVES**

In terms of making greater efforts to develop new effective antimicrobials and products, citizens attributed greatest importance to the pharmaceutical industry, followed by academia and international organisations ([Annex – Graph 10](#)).

In turn, stakeholders familiar with medicinal product development<sup>10</sup> indicated as primary challenges to bring new antimicrobials to patients in Europe the lack of funding in AMR R&D (91% considered it very important or important), followed by the lack of economic models incentivising R&D on AMR (90% considered it very important or important, this point is addressed in section 3.5.) and a challenging regulatory environment (70% considered it very important or important, this point is addressed in section 2.5.) ([Annex – Graph 11](#)).

In view of prioritising research, 76% of the stakeholders agreed that the EU should develop a list of R&D priorities for resistant pathogens, i.e. a priority pathogens list. They argued that it would provide real added-value by directing industry investment in R&D to the greatest threats and it could be the basis for supporting the status of priority antimicrobials. Several stakeholders

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<sup>10</sup> The percentages expressed were calculated based on stakeholders' replies after the answer 'I do not know / NA' was removed. These answers represented 15% to 23% of the total sample.

stressed the need for increased research on new therapeutics and alternatives for multidrug-resistant tuberculosis (MDR-TB).

Finally, in order to facilitate efforts in the development of new antimicrobials – given the challenge to find new candidate medicinal products – and novel alternatives and to address scientific challenges, stakeholders called for:

- Supporting scientific communities to easily access, share resources and use existing data to convert into new knowledge (e.g. setting up a shared data repository with rules ensuring intellectual property protection);
- Supporting scientific research on novel alternatives to antimicrobials such as medicinal product repurposing, combinatorial therapies, innovation in the natural products domain, bacteriophage therapies, immunomodulatory treatments, probiotics, microbiome modulation and traditional, complementary and alternative medicine approaches, which could offer the basis for new therapeutic options in both the human and animal health sectors.

### **3.3. DEVELOP NEW PREVENTIVE VACCINES**

In order to select the appropriate pathogens for the development of new vaccines against AMR pathogens and HAIs, stakeholders considered that it would be beneficial to clearly define priorities and to establish the necessary tools to support this development. In addition, stakeholders advocated for a priority pathogens list for vaccine development.

Stakeholders also highlighted the critical need to fund the development of new vaccines to address MDR-TB and to prevent multidrug-resistant infections, such as resistant infections from *Staphylococcus aureus*, *Clostridium difficile* and *Escherichia coli*.

### **3.4. DEVELOP NOVEL DIAGNOSTICS**

Stakeholders considered rapid diagnostic tests essential to inform prescribing and therefore to use antimicrobials appropriately in the human and animal health sectors. Some stakeholders mentioned the necessity of the pharmaceutical and diagnostics industries to work together.

In addition stakeholders called for:

- Supporting and funding targeted research for innovative, rapid and more mobile technologies (e.g. on-farm diagnostic tools), including manual and automated susceptibility tests and rapid diagnostics, to facilitate and accelerate the detection and identification of pathogenic agents;
- Horizon scanning to facilitate the development of clinical evidence for rapid diagnostics;
- Encouraging the uptake of rapid diagnostics in human and animal healthcare settings by creating a rapid diagnostic market stimulus in Europe;
- Promoting alternative reimbursement systems for rapid diagnostics in Member States;
- Developing diagnostics for measuring antimicrobials and AMR in the environment.

### **3.5. DEVELOP NEW ECONOMIC MODELS AND INCENTIVES**

As already mentioned, the lack of economic models incentivising R&D on AMR was viewed by 90% of stakeholders as either very important (61%) or important (29%).

Stakeholders widely supported the development of new funding and business models to encourage the development of new antimicrobials, alternative therapies, vaccines and diagnostic tests. The aim of these new economic models would be to improve access to innovative technological solutions to prevent and control AMR and HAIs. Stakeholders advocated that these models should align with the commitments Member States' governments made under the political declaration on AMR of the high-level meeting of the United Nations General Assembly, i.e. R&D should be needs-driven, evidence-based and guided by the principles of affordability, equity, effectiveness and efficiency; R&D should be considered a shared responsibility; and the cost of investment in R&D should be de-linked from the price and volume of sales. In addition, one stakeholder proposed that these models should promote the use of rapid diagnostics to reduce antimicrobial use.

In terms of incentives, stakeholders familiar with funding instruments<sup>11</sup> expressed considerable enthusiasm for funding possibilities under the European Framework Programme Horizon 2020 (95% considered it very important or important), followed by funding provided by the Innovative Medicines Initiative (IMI) public-private partnership (92% considered it very important or important) ([Annex – Graph 12](#)).

But whereas these push mechanisms were very well regarded, pharmaceutical industry stakeholders advocated for complementing them with pull mechanisms rewarding innovation earlier in the product life cycle and reducing the proportion of manufacturer revenue derived from antimicrobial sales volume in order to align with stewardship principles. Some examples of push mechanisms proposed included:

- Market entry rewards (or an EU market entry reward) granting pharmaceutical companies a prize for successful new antimicrobials (or new vaccines and rapid diagnostics) brought to the market;
- Transferable exclusivity incentives offering an extension of the supplementary protection certificate or an extension of regulatory exclusivity, which would provide a competitive return on investment of a medicinal product targeting a prioritised pathogen regardless of the volume of antimicrobial sold.

### **3.6. CLOSE KNOWLEDGE GAPS ON AMR IN THE ENVIRONMENT AND ON HOW TO PREVENT TRANSMISSION**

Stakeholders agreed that a clear understanding of the transmission dynamics between AMR in the environment and humans, animals and food is lacking.

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<sup>11</sup> The percentages expressed were calculated based on stakeholders' replies after the answer 'I do not know / NA' was removed. These answers represented 21% to 44% of the total sample.

In particular, stakeholders called for:

- Funding research on the impact of antimicrobial discharge (API residues) into the environment and the mitigation of the risk that this may pose. The findings could inform policy to set up concrete measures and recommendations to reduce the environmental impact of antimicrobial manufacturing;
- Gathering further knowledge on the factors that might have an important role in the spread of multidrug-resistant bacteria in the environment;
- Conducting research on how sub-inhibitory concentrations of antimicrobials and other substances (e.g. biocides) in the environment impact resistance rates.

#### **4. SHAPING THE GLOBAL AGENDA**

The challenges of AMR are globally shared. Due to travel and trade, the spread of AMR can be further facilitated. The OPC sought to gather views on European Commission international activities and mechanisms the European Commission could use to tackle AMR at global level. It also examined stakeholders' opinion on the regions on which the EU should focus its international efforts.

Citizens expressed strong support for both EU-centred and worldwide action on AMR (67% believed both were equally important, 24% considered worldwide action more important). This would indicate that the public is aware of the limited capacity to contain AMR within national borders, and that in order to effectively address AMR, global action is needed.

Stakeholders also considered global coordinated action crucial to address the AMR challenge. When asked in which region the EU should focus its international efforts, stakeholders expressed strongest preference for the non-EU European region, followed by the South Asian region and the North African region. ([Annex – Graph 13](#)).

##### **4.1. A STRONGER EU GLOBAL PRESENCE**

Stakeholders expressed clear support (91% considered it very useful or useful) for reinforcing cooperation with normative international organisations (e.g. WHO, OIE, FAO, UN<sup>12</sup> and Codex Alimentarius) to tackle AMR.

Stakeholders additionally pointed to the following international actions:

- Regarding trade, ensuring imports to the EU – particularly food and food-producing animals – meet standards equal to those within the EU and advocating for the international community to adopt similar standards;
- Collaborating with normative international organisations (e.g. WHO, OIE, FAO, UN and Codex Alimentarius), supporting existing international actions (e.g. WHO Global Action

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<sup>12</sup> WHO: World Health Organisation, OIE: World Organisation for Animal Health, FAO: Food and Agriculture Organisation of the United Nations (UN)

Plan on AMR), feeding into international standards and norms and addressing issues including access, inputting into the UN interagency coordination group on AMR, and engaging with all relevant stakeholders to tackle AMR and help achieve the Sustainable Development Goals<sup>13</sup>;

- Leading by example, sharing and exchanging information with a multi-stakeholder and multi-sectorial approach; regarding pharmaceutical manufacturing effluents, transparency in the production chain abroad, enforcement of on-site inspections and amending rules under the Good Manufacturing Practices<sup>14</sup> to include environmental and waste management criteria;
- Supporting establishment of international databases on monitoring of antimicrobials and resistances.

#### **4.2. STRONGER BILATERAL PARTNERSHIPS FOR STRONGER COOPERATION**

Stakeholders perceived positively (81% considered it very useful or useful) fostering bilateral partnerships with key EU trading partners and major regional and global players (e.g. USA, Canada, Brazil, China, India, and South-Africa). Stakeholders familiar with mechanisms which the European Commission could use to tackle AMR internationally<sup>15</sup> regarded capacity building as the most useful tool (56% very useful, 35% useful), followed by trade and partnership agreements (41% very useful, 37% useful) and non-binding cooperation (19% very useful, 51% useful).

In terms of EU contribution to capacity building (e.g. on surveillance and monitoring), it is interesting to note that stakeholders considered it equally useful to conduct action in the non-EU European region (i.e. EU candidate, potential candidate and neighbouring countries) and in developing countries (84% considered both options very useful or useful).

In the most favoured region for EU action, the non-EU European region, stakeholders indicated that the EU can have a very high impact in this region in terms of leveraging existing binding tools such as trade agreements and capacity building tools.

As for the second preferred option, the South Asian region, stakeholders called for a stronger partnership with strategic countries such as China and India. They argued that these countries not only have the highest population density and the bigger AMR challenges. In addition these countries represent a sizeable share of global antimicrobial manufacturing – exporting large volumes of APIs and finished dose antimicrobials to Europe, often as part of supply agreements with EU-based pharmaceutical companies – and are major exporters of food products to the EU without adequate surveillance structures for consumption and resistances, data collection, analysis and implementation of responsible principles.

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<sup>13</sup> <http://www.un.org/sustainabledevelopment/sustainable-development-goals/>

<sup>14</sup> [https://ec.europa.eu/health/documents/eudralex/vol-4\\_en](https://ec.europa.eu/health/documents/eudralex/vol-4_en)

<sup>15</sup> The percentages expressed were calculated based on stakeholders' replies after the answer 'I do not know / NA' was removed. These answers represented 11% to 15% of the total sample.

Additionally, stakeholders called for encouraging stronger regulatory convergence between the US Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

#### **4.3. COOPERATING WITH DEVELOPING COUNTRIES**

Stakeholders observed that the impact of EU action in low- and middle-income countries would largely help them to build resources to tackle AMR and preferred the North African region for EU efforts (third preferred region for EU action) due to its geographical proximity and share of immigrant population.

Moreover, stakeholders provided the following suggestions for international actions:

- Raising awareness of AMR globally and assisting countries that most require support with surveillance and stewardship capacity building;
- Promoting EU regulation and control systems with a ‘step-wise’ approach in developing countries.

#### **4.4. DEVELOPING A GLOBAL RESEARCH AGENDA**

Stakeholders expressed favourable opinions on research coordination. In terms of international action, they advocated for:

- Globally supporting R&D efforts, particularly regarding the WHO list of R&D priorities on AMR and addressing multidrug-resistant tuberculosis;
- Seeking strong political backing of the G20;
- Improving mapping and coordination of global R&D efforts, together with international organisations.

### **5. CONCLUSION**

Overall, stakeholders and citizens expressed in their replies very strong support for a new Commission Communication on a One Health action plan to support Member States in the fight against antimicrobial resistance (AMR). They believed that AMR is a major public health issue in which the EU can bring real added value and propose concrete measures in the human health, animal health and environmental sectors.

In order to make the EU a best practice region, stakeholders acknowledged the importance of developing sound monitoring and surveillance systems at EU level in order to inform policies. Although stakeholders rated positively the information collected by current EU surveillance systems on AMR and antimicrobial consumption, they particularly called for data collected amongst individual species in the animal health sector. To strengthen the evidence base they also advocated for generating evidence through health economics and evaluation studies which show the value of policies or interventions.

Stakeholders were also very vocal on the relevance of slowing down the emergence of AMR by developing infection prevention and control measures, antimicrobial stewardship programmes and prudent use policies. Stakeholders in the human health sector called for priority actions on infection prevention and patient safety in hospital environments (healthcare-associated infections prevention). They also called for the promotion of vaccination, in particular at Member State level, as an effective public health measure to prevent infections and consequently reduce the need for using antimicrobials. In turn, stakeholders in the animal health sector asked for new initiatives on infection prevention, animal husbandry practices and best practice feeding regimes, and expressed their concern over the reduced availability of existing antimicrobials and the poor availability of vaccines in certain markets.

Stakeholders strongly supported initiatives aiming to monitor antimicrobials and AMR in the environment, provided these are backed by a sound science-driven evidence base. They urged the European Commission to adopt an EU strategic approach to pharmaceuticals in the environment looking in particular at minimum manufacturing standards and risk assessments on the impact of active pharmaceutical ingredients in the environment.

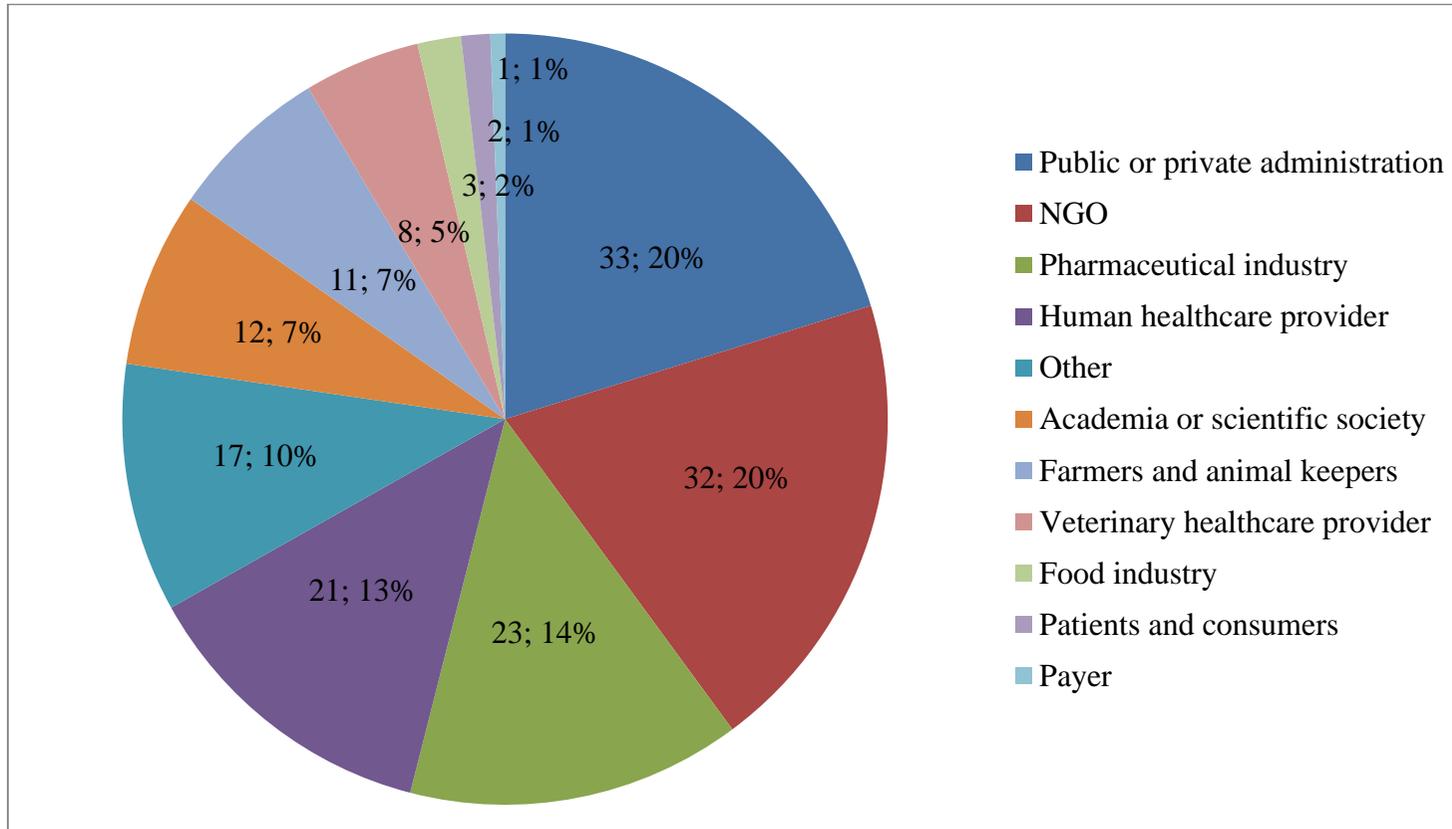
In terms of research, development (R&D) and innovation on AMR, citizens highlighted that the pharmaceutical industry and academia should make the greater efforts to develop new effective antimicrobials and products. Stakeholders were largely in favour of developing a list of priority pathogens at EU level to prioritise R&D and direct pharmaceutical industry R&D investment to the greatest threats. Pharmaceutical industry stakeholders strongly advocated for early and continuous dialogue with all relevant stakeholders throughout the entire product development cycle, and for a regulatory framework that prioritises the development of new antimicrobials, alternatives, vaccines and diagnostic tests. Stakeholders involved in R&D also asked for increased sharing of resources and better use of existing data. As regards the development of new diagnostics, stakeholders asked for targeted funding for innovative, rapid technologies but most prominently for actions to encourage their uptake and include them in antimicrobial stewardship programmes.

Stakeholders expressed support towards the development of new funding and business models to encourage the development of new antimicrobials, alternatives, vaccines and rapid diagnostics in order to prevent and control resistant infections and in particular HAIs. They conveyed great importance to push mechanisms such as the European Framework Programme 2020 and the Innovative Medicines Initiatives, but pharmaceutical industry stakeholders also advocated for pull mechanisms rewarding innovation earlier in the product life cycle.

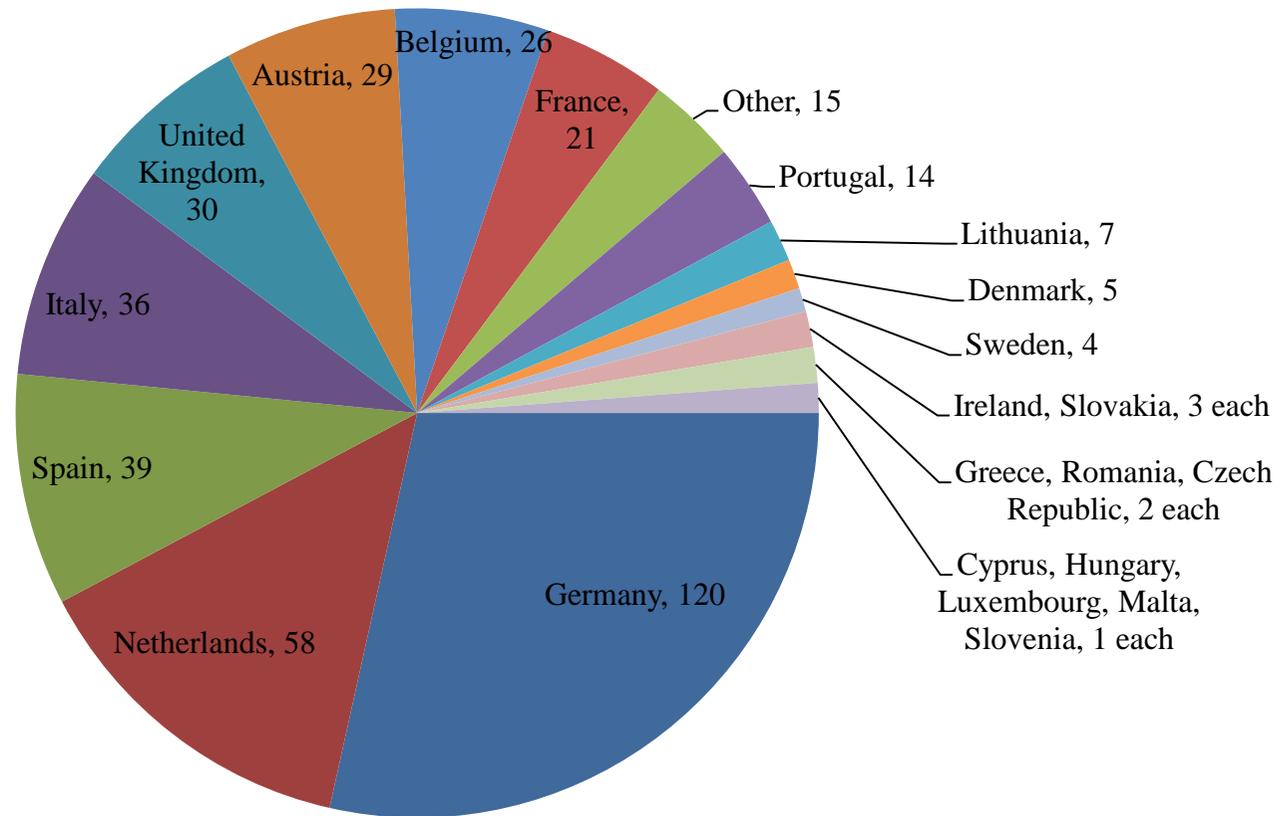
At international level, stakeholders were largely in favour of reinforcing cooperation with international organisations to tackle AMR and fostering bilateral partnerships with key EU trading partners and major regional and global players. Stakeholders indicated preference for capacity building and cooperation in the non-EU European region but also called for stronger partnerships with China and India, given their role in antimicrobial manufacturing and as major exporters of food products to the EU. Finally, stakeholders called for more capacity development and cooperation activities in low- and middle-income countries.

The results of this consultation have been largely taken into account to propose concrete actions under the three main pillars of the new Commission Communication on a One Health action plan to support Member States in the fight against AMR. Most of the contributions taken into account presented policy options which had a clear EU added value for Member States, which were relevant in terms of tackling AMR R&D-related challenges, or which would help ensure that the EU has a strong voice on AMR at international level. Contributions which went beyond the scope of EU competences were not taken into account.

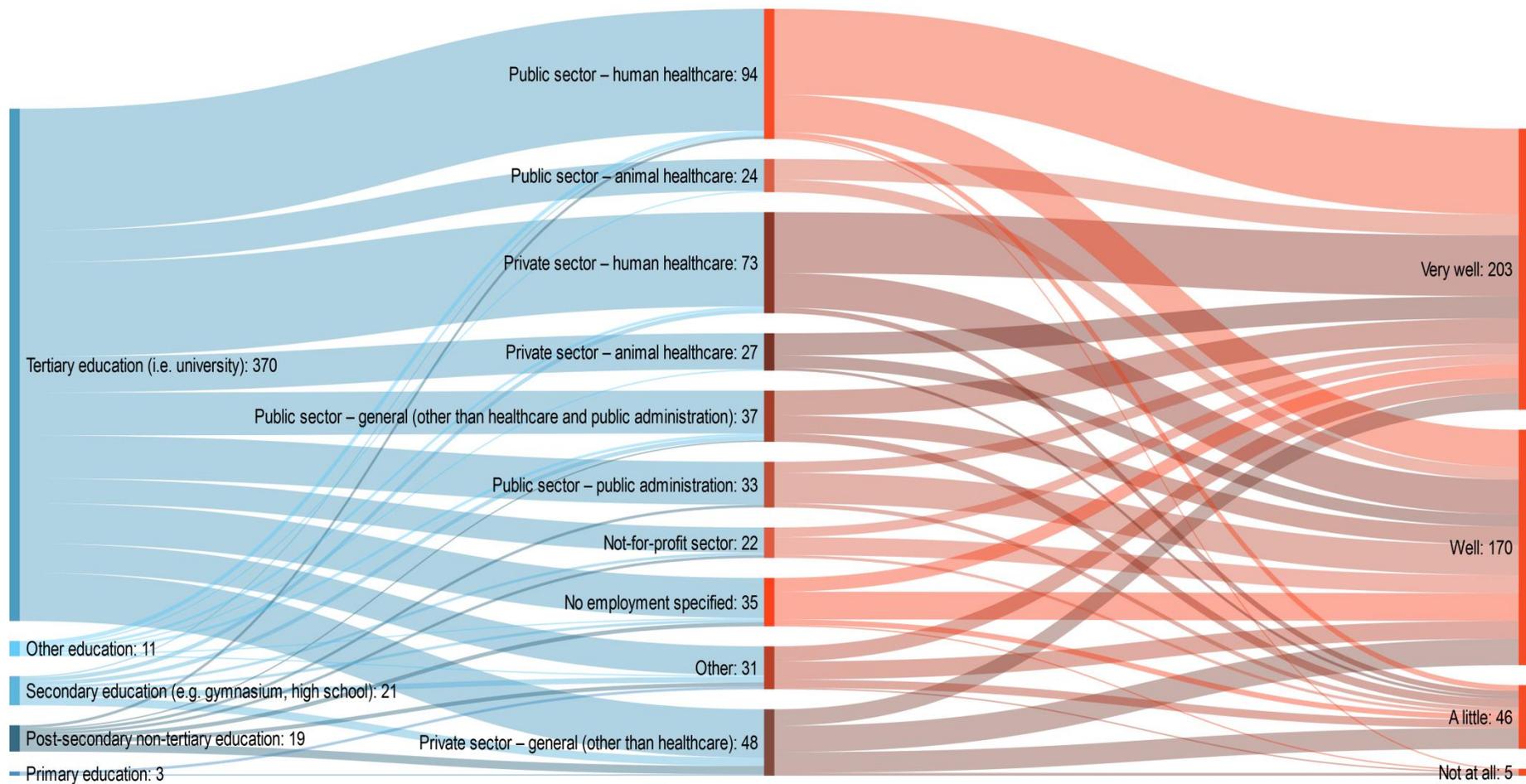
## ANNEX



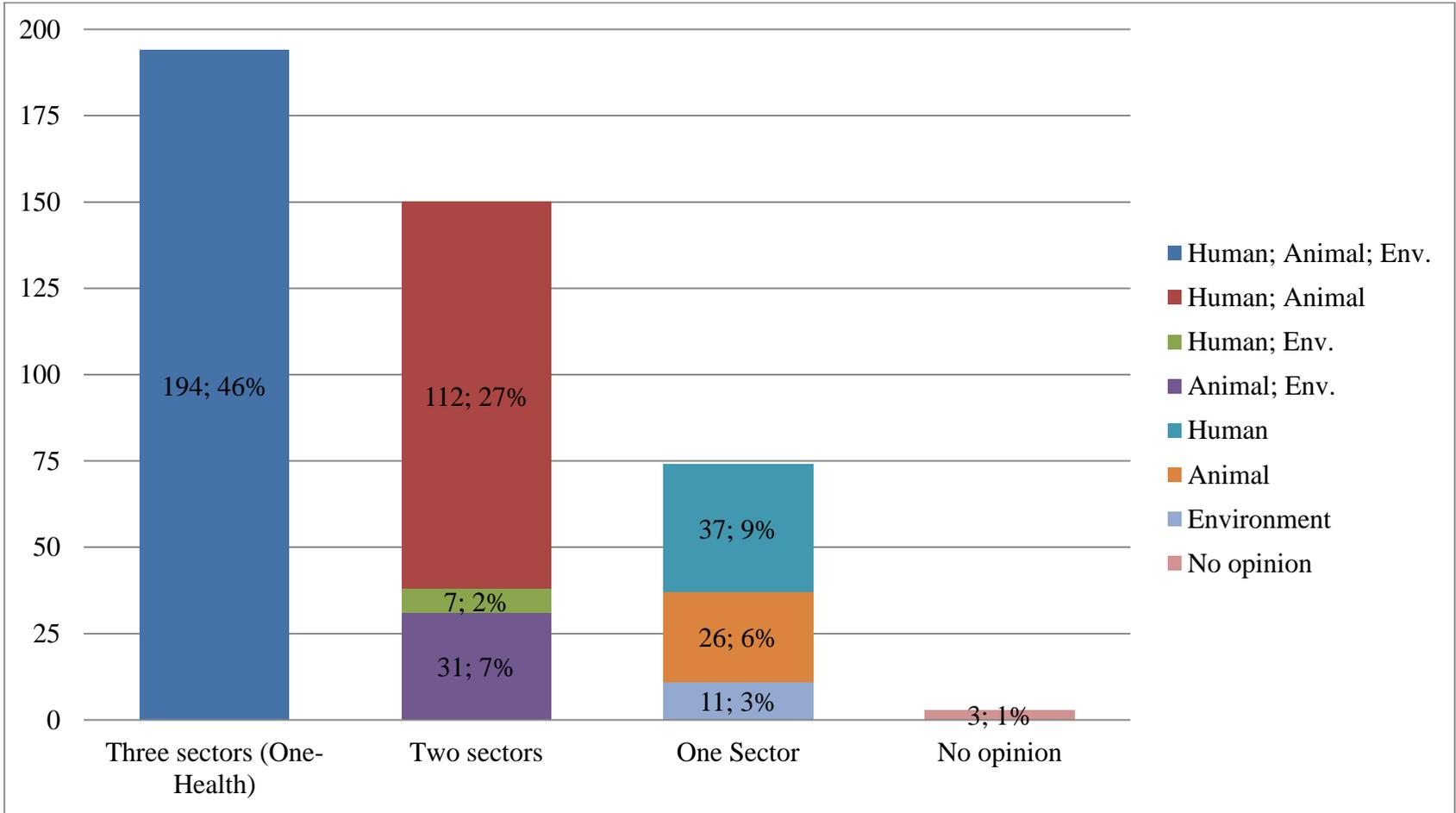
**Graph 1: Main sector of the respondents. Replies from stakeholders. (N=163)**



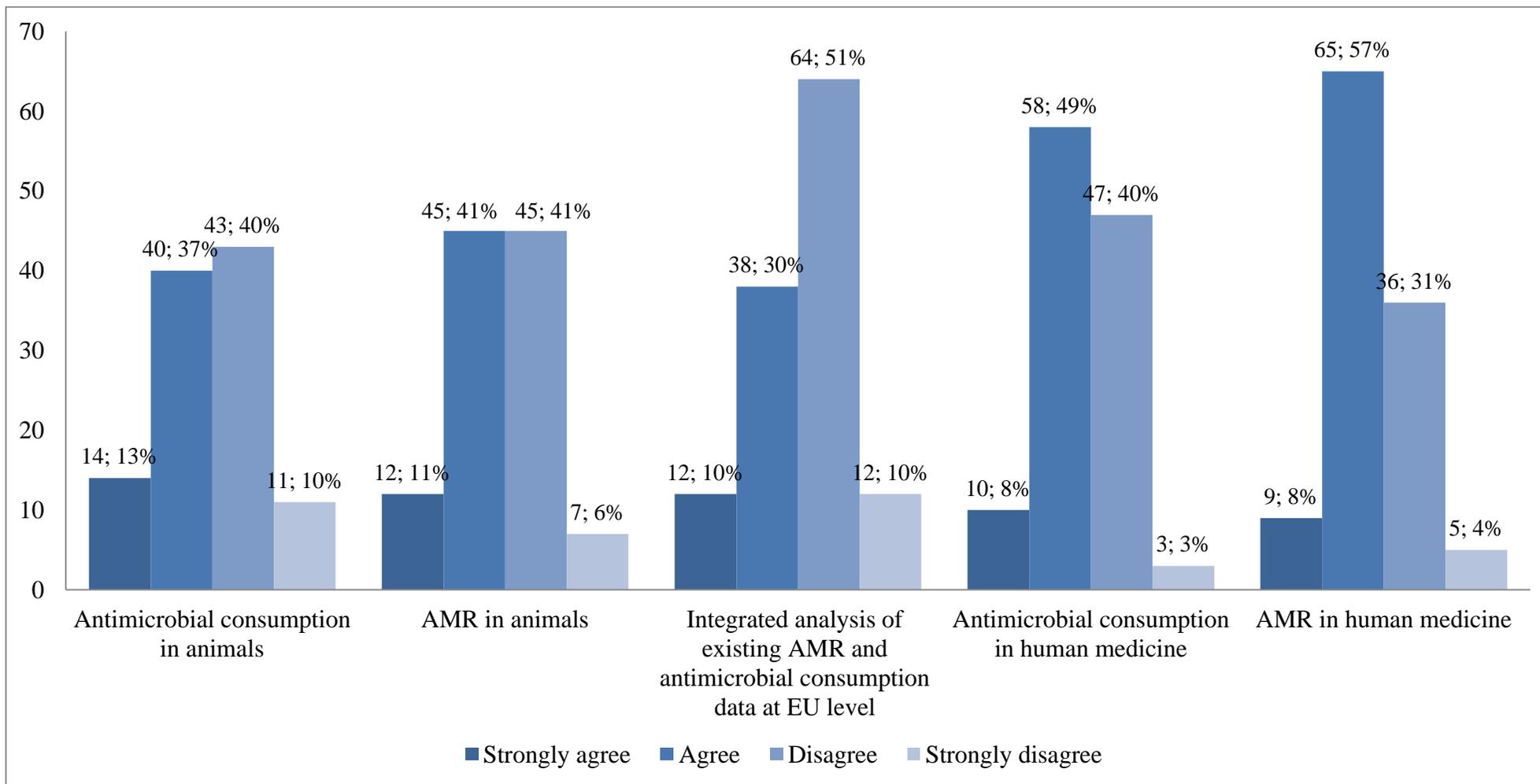
**Graph 2: Country of residence. Replies from citizens. (N=421)**



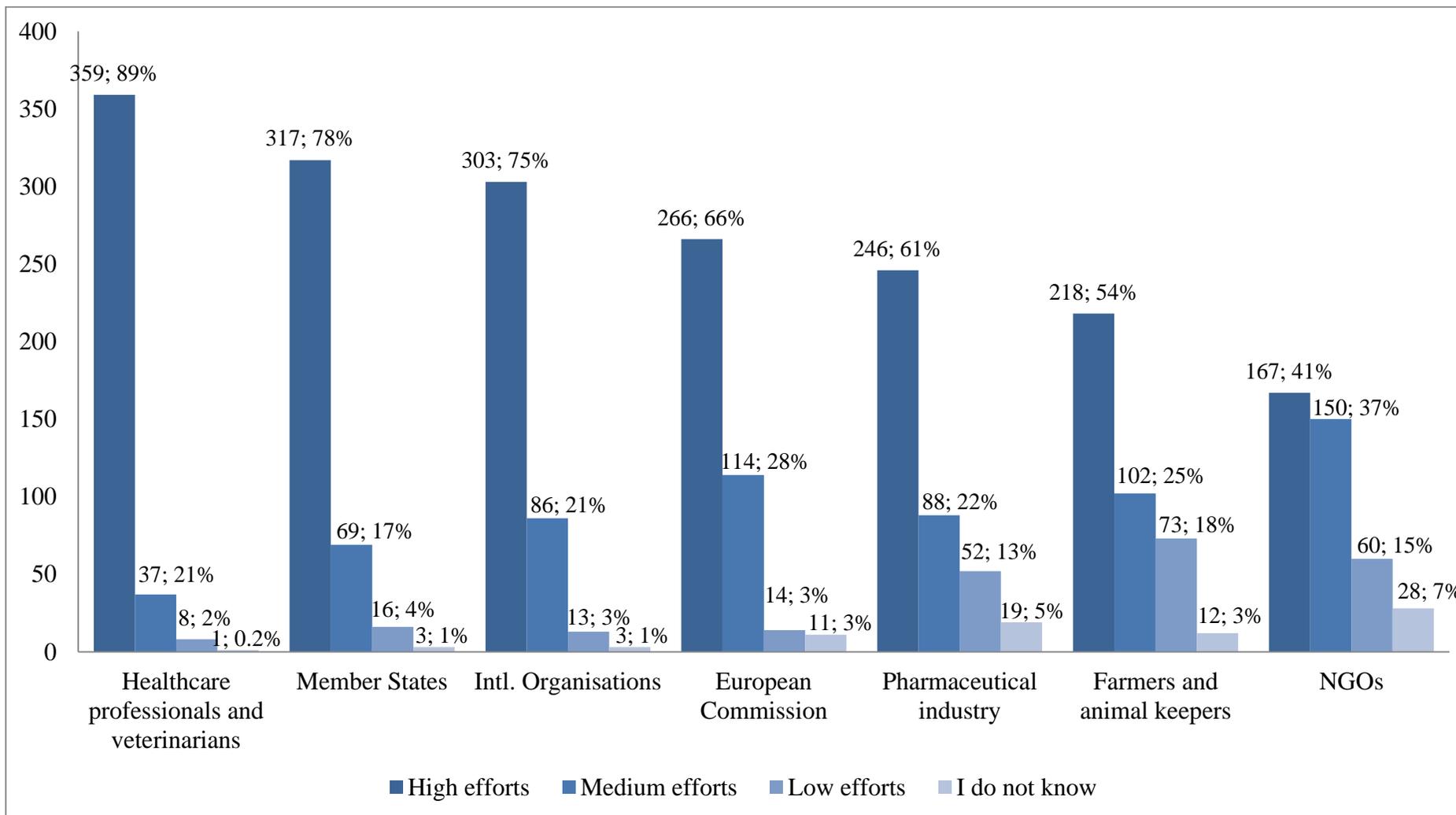
**Graph 3: Link between citizens' level of education (left), professional background (centre) and awareness on AMR (right). (N=421)**



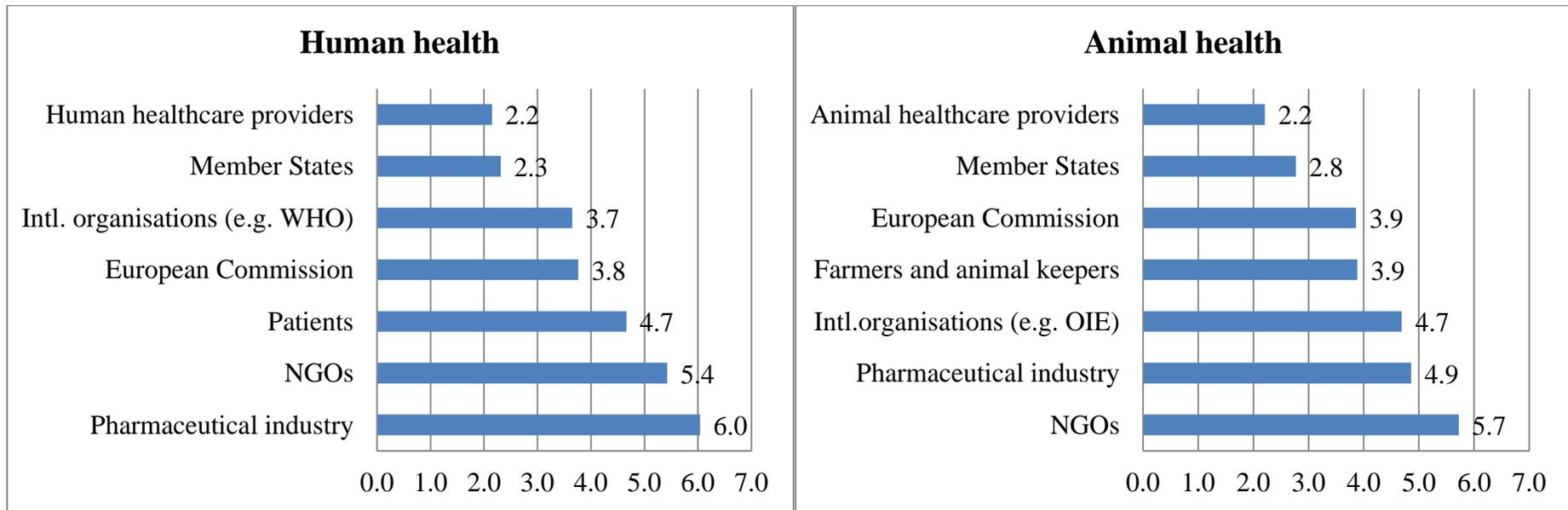
**Graph 4: Sectors in which action on AMR is deemed necessary. Replies from citizens. (N=421)**



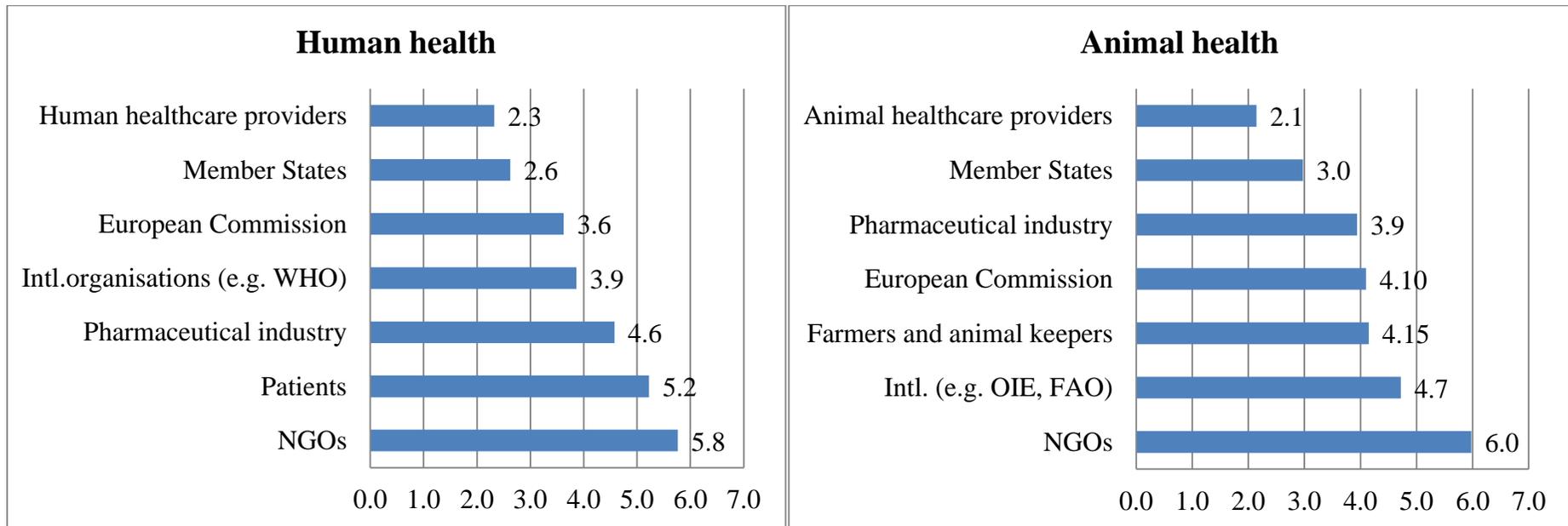
**Graph 5: Opinion on whether EU surveillance systems and analyses on AMR and antimicrobial consumption provide sufficient information to support actions aimed at preventing and controlling AMR in humans and animals. Replies from stakeholders.**  
 (N=108; N=109; N=126; N=118; N=115 respectively)



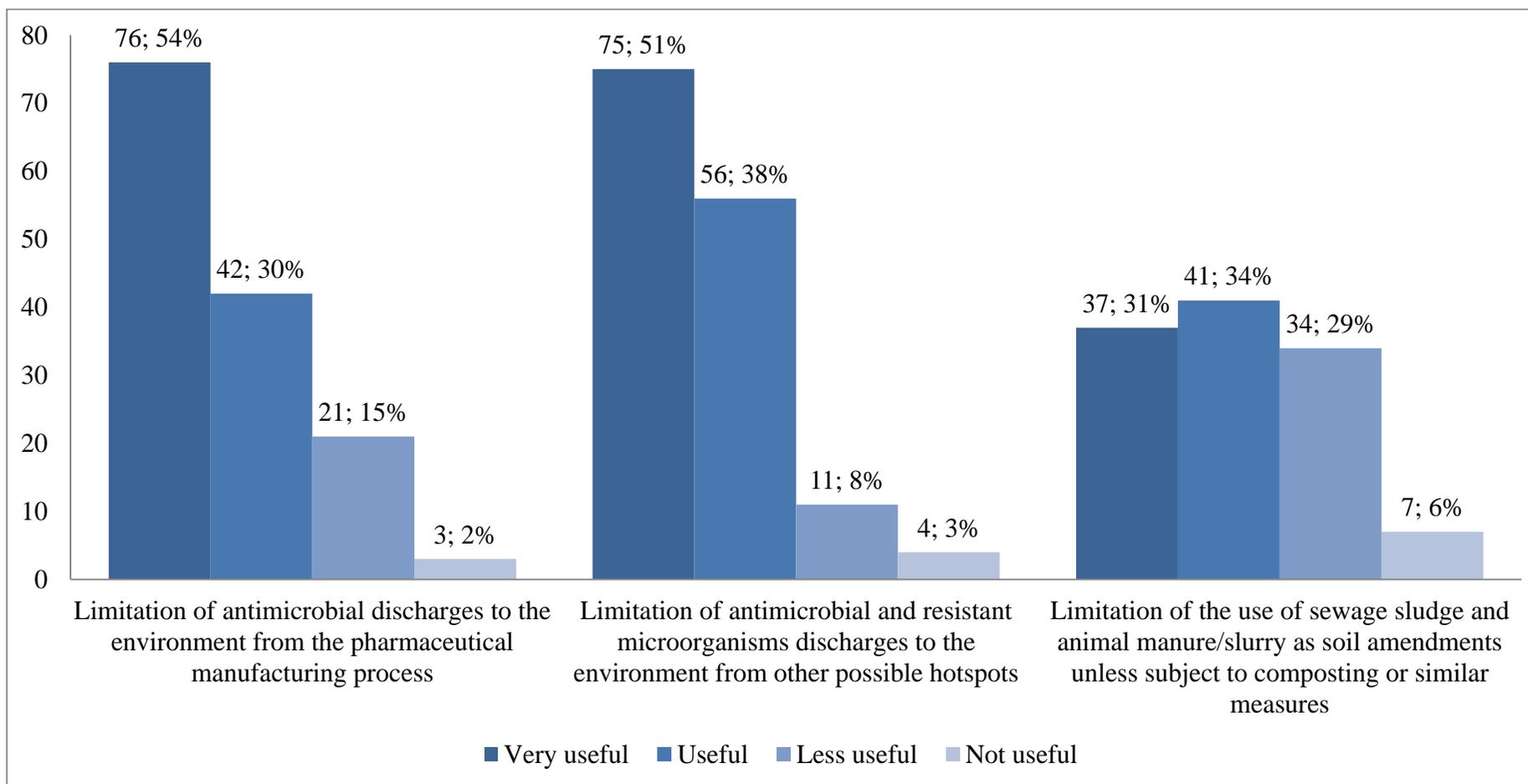
**Graph 6: Opinion on who should make greater efforts in raising public awareness on AMR and the consequences of inappropriate use of antimicrobials. Replies from citizens. (N=405)**



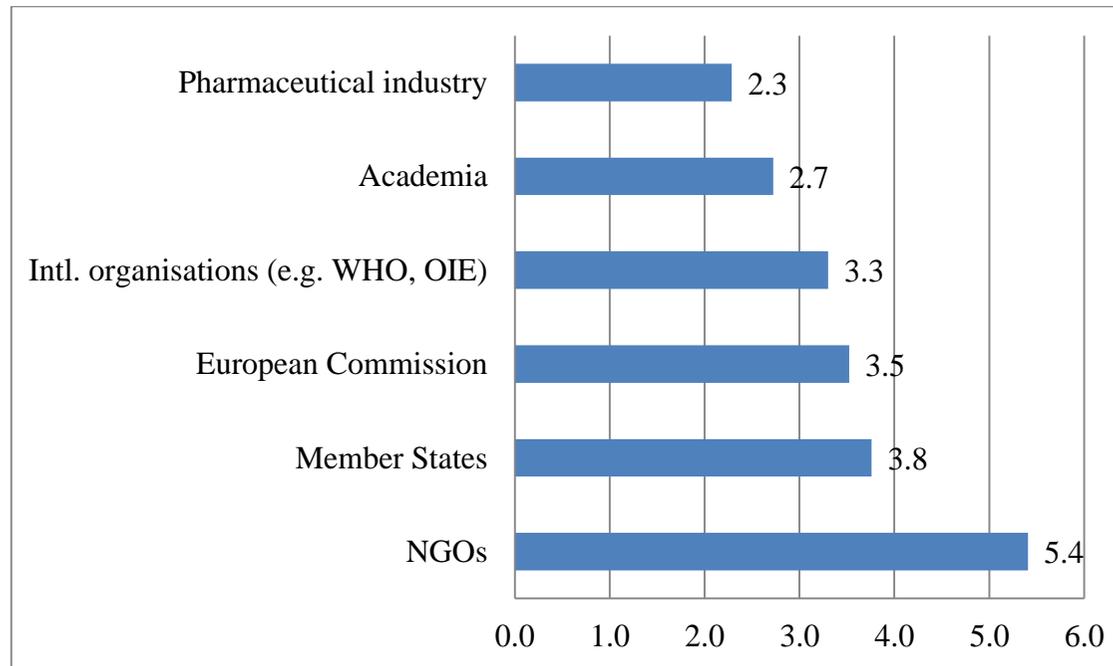
**Graph 7: Importance of different actors in promoting vaccination and the uptake / use of vaccines, in a scale of 1 ‘Most important’ to 7 ‘Least important’. Average calculated based on replies from stakeholders. (N=80 for human health, N=87 for animal health). Human healthcare providers include doctors, nurses, pharmacists, etc.; veterinary healthcare providers include veterinarians, etc.**



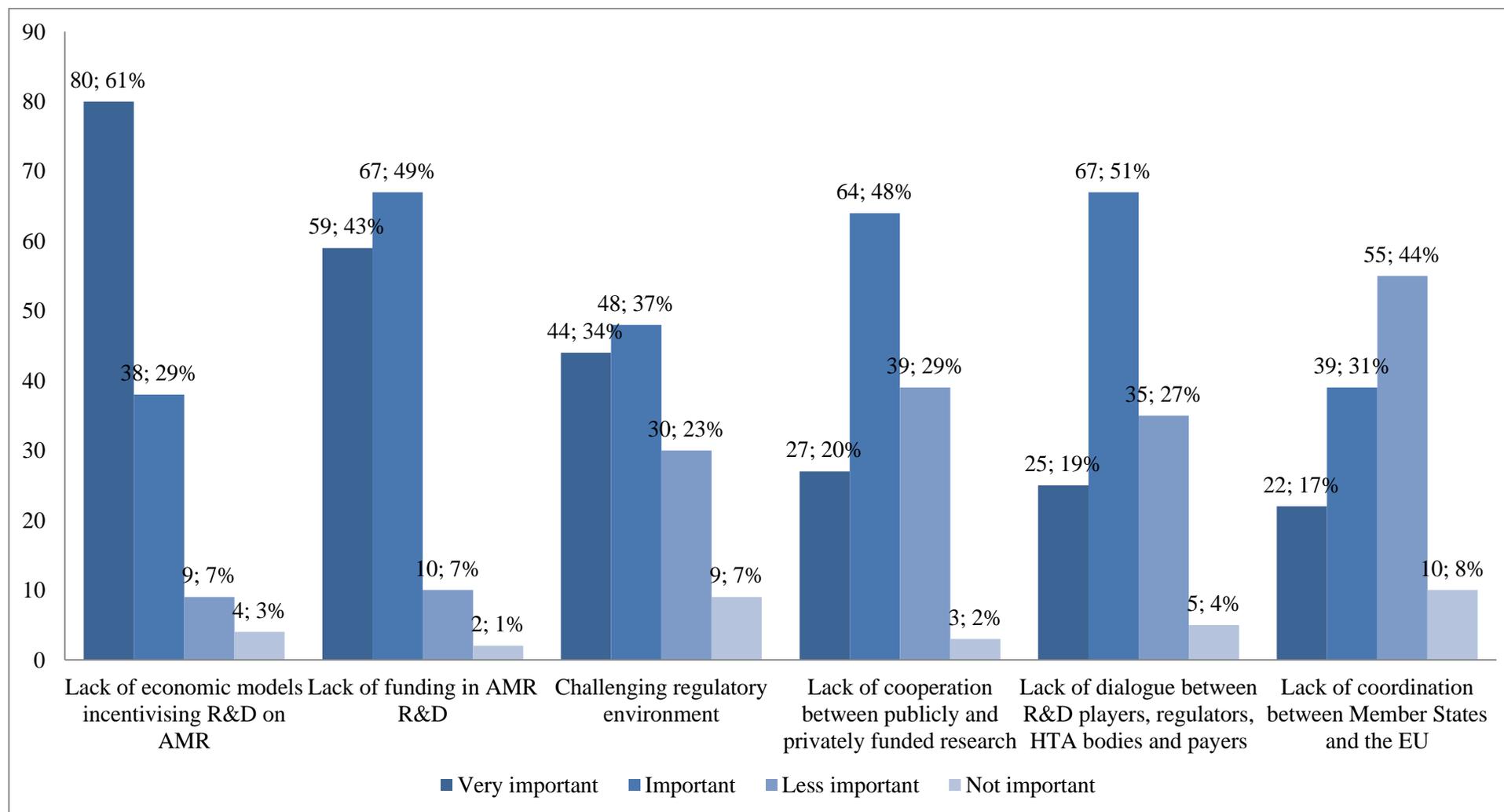
**Graph 8: Importance of different actors in promoting the uptake / use of rapid diagnostics, in a scale of 1 ‘Most important’ to 7 ‘Least important’. Average calculated based on replies from stakeholders. (N=80 for human health, N=82 for animal health). Human healthcare providers include doctors, nurses, pharmacists, etc.; veterinary healthcare providers include veterinarians, etc.**



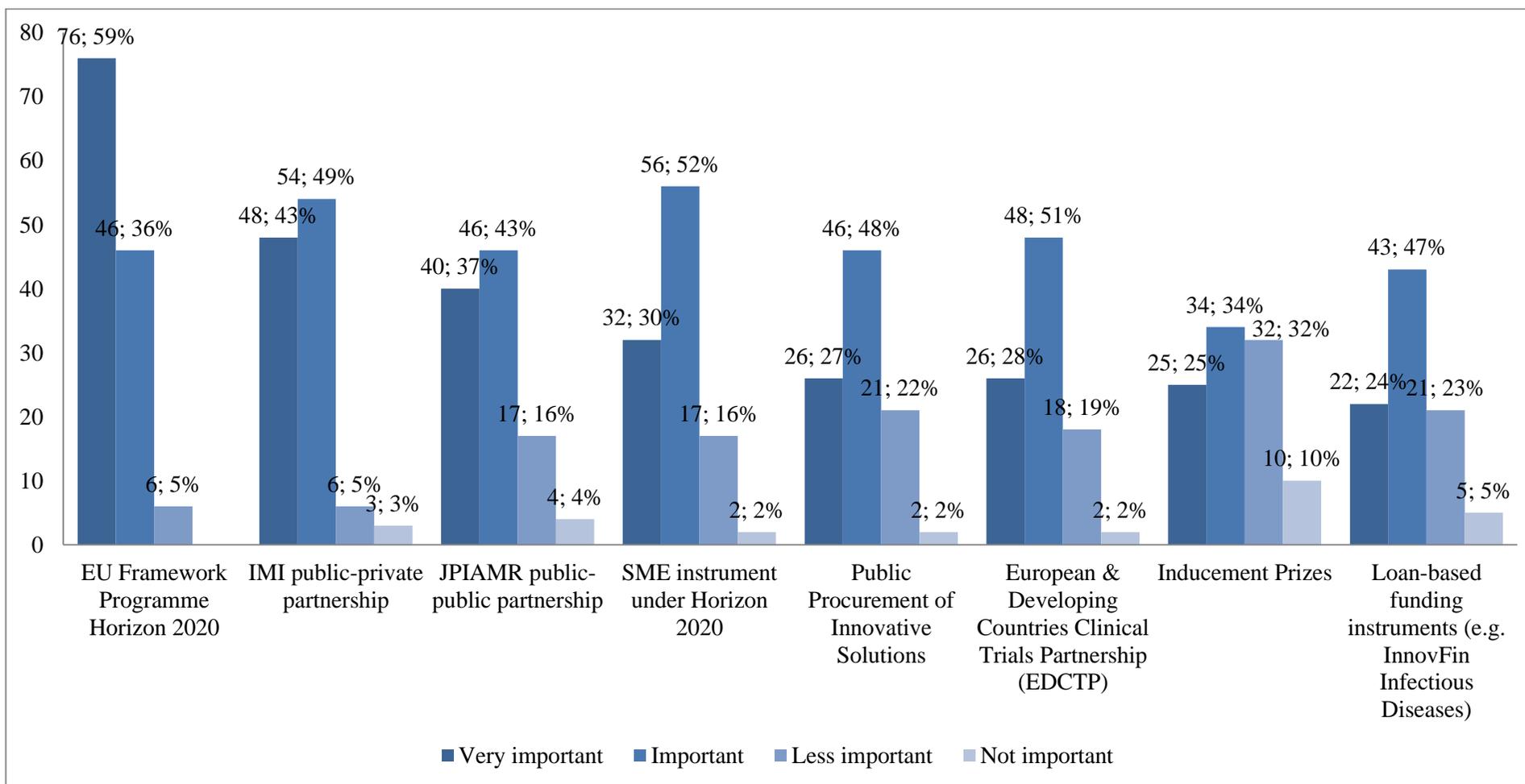
**Graph 9: Opinion on usefulness of actions to tackle AMR in the environment. Replies from stakeholders. (N=142; N=146; N=119; respectively)**



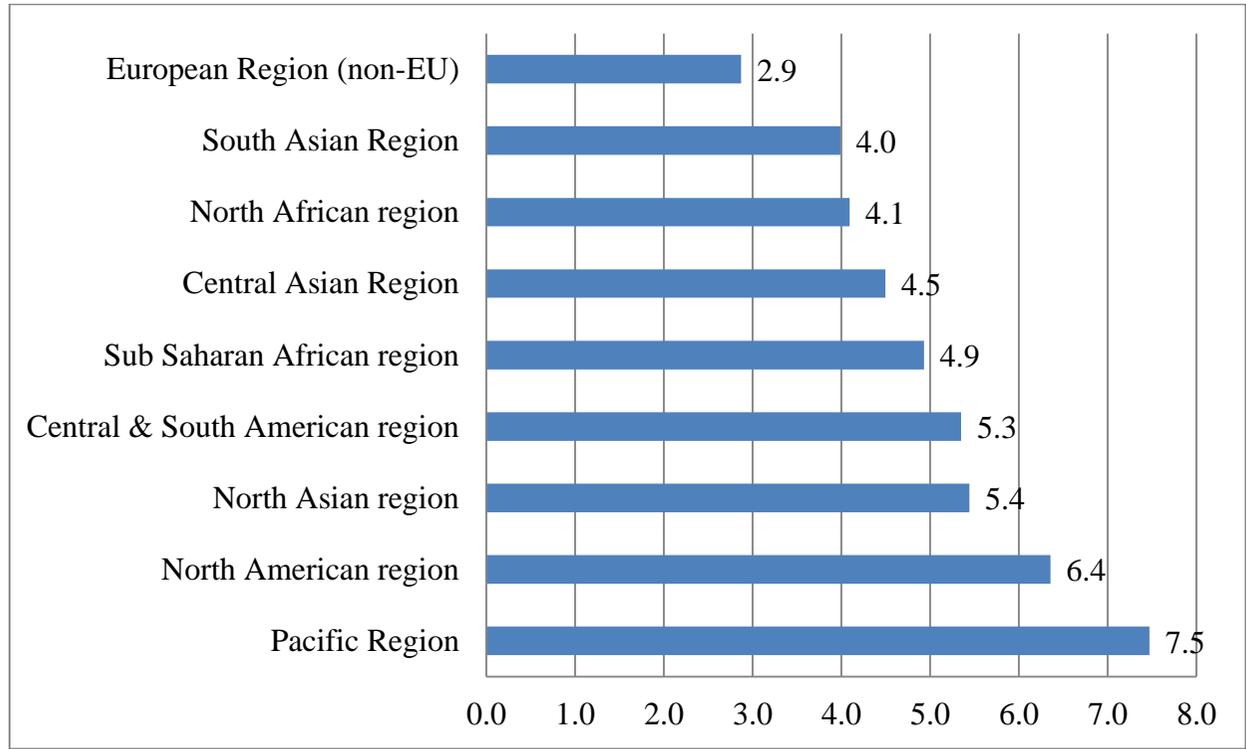
**Graph 10: Importance of different actors in making greater efforts to develop new effective antimicrobials and products, in a scale of 1 'More important' to 6 'Less important'. Average calculated based on replies from citizens. (N= 421)**



**Graph 11: Opinion on main obstacles to bring new antimicrobials to patients in Europe. Replies from stakeholders. (N=131; N=138; N=131; N=133; N=132; N=126 respectively)**



**Graph 12: Opinion on importance of different funding instruments to stimulate R&D in AMR. Replies from stakeholders. (N=128; N=111; N=107; N=107; N=95; N=94; N=101; N=91 respectively)**



**Graph 13: Preference on the region in which the EU should focus its international efforts, in a scale of 1 ‘Most preferred’ to 9 ‘Least preferred’.**  
**Average calculated based on replies from stakeholders. (N=163)**