

# Patient Empowerment Training Session - What we need to know about antibiotics and antimicrobial resistance

Malta - 27 January 2023, 6:00 pm - 8:30 pm

The commitment of the EU Institutions against Antimicrobial Resistance & how to advocate with policymakers

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# Introduction: "Fighting paradoxes on AMR in the age of Covid-19 from a citizen perspective"

Good evening and welcome also from myself and my organization, very proud not only to support this initiative but first of all to provide a citizen's perspective on the topic of Antimicrobial Resistance (AMR).

We are talking about one of the ten most urgent threats for Global Health but totally underestimated among the populations; more impactful than car accidents<sup>1</sup> but not enough prioritized in the EU and National public health policies. Interlinked with Covid-19 pandemic but almost ignored by the media. The world is losing its most powerful tool in healthcare, antibiotics,

<sup>&</sup>lt;sup>1</sup> Road accidents: 20,000 fatalities in Europe in 2021 (IT language). www.aci.it/archivio-notizie/notizia.html?tx\_ttnews%5D=2555&cHash=3ea251c1c72893be884adc50ab8267df#:~:text=Nel%20 2021%2C%20nell%27Unione%20Europea,Transport%20Safety%20Council%20(ETSC)%20.



and in the meantime, research is still waiting for EU incentive mechanisms as well as an overall strategy to integrate the development of - and access to - affordable and of quality antimicrobials<sup>2</sup>. Despite the fight against Antimicrobial Resistance (AMR) requires policies focused on the prevention and extension of vaccinations, the health expenditure for prevention programmes is the "Cinderella" of the public health budget, and in several countries the National Plan on AMR is still missing or expired.

Patient engagement efforts on increasing awareness on AMR are not accompanied by more widespread initiatives targeted to citizens: how do we behave at the supermarket with regards to foods produced "without any use of antibiotics"?

These are some of the paradoxes on AMR that we still need to address, and justify the commitment of <u>Active Citizenship Network</u> (ACN), the European branch of the Italian NGO <u>Cittadinanzattiva</u>, established in 1978 to promote citizens' activism for the protection of rights, the care of common goods, the support for people in conditions of weakness.

Coming from Italy, please let me remember that before the pandemic, the phenomenon caused about 33,000 deaths in Europe each year from infections caused by antibiotic-resistant bacteria<sup>3</sup>: of these, more than 10,000, or one-third of the total, occur in Italy. This is the sad record held by my country, which tops the continental rankings for the number of deaths linked to antimicrobial

<sup>2</sup> Un antimicrobico è una sostanza chimica, naturale o di sintesi, che uccide i microorganismi, o ne inibisce la crescita. Gli antimicrobici possono essere suddivisi in base alla loro attività e al tipo di microorganismo che ne subisce l'azione. Tra gli antimicrobici che uccidono i microorganismi si avranno battericidi, fungicidi e virocidi.

Gli antimicrobici trovano largo uso nella pratica medica per combattere e prevenire le infezioni. Gli antibiotici sono sostanze naturalmente prodotte da alcuni microorganismi allo scopo di eliminare altri microorganismi competitori. Sono le sostanze più largamente usate come antimicrobici in medicina.

An antimicrobial is a natural or synthetic chemical substance that kills microorganisms or inhibits their growth. Antimicrobials can be divided according to their activity and the type of microorganism affected by them. Among the antimicrobials that kill microorganisms are bactericides, fungicides and virocides.

Antimicrobials are widely used in medical practice to fight and prevent infections.

Antibiotics are substances naturally produced by some microorganisms in order to eliminate other competing microorganisms. They are the substances most widely used as antimicrobials in medicine.

<sup>&</sup>lt;sup>3</sup> Quotidiano Sanità: Antimicrobial resistance, draft Plan expected in 2021. 40 mln euro funding each year. The announcement at Camerae Sanitatis, October 2021 (IT language). <a href="www.quotidianosanita.it/studi-e-analisi/articolo.php?articolo\_id=99360">www.quotidianosanita.it/studi-e-analisi/articolo.php?articolo\_id=99360</a>



resistance, according to a report published by the Italian National Health Istitute (Istituto Superiore di Sanità) on the occasion of the annual 2019 World Antimicrobial Awareness Week<sup>4</sup>.

Among the causes is certainly an inappropriate use of antibiotics, not only in the human but also in the veterinary field, and still today the epicenter of this drama is the hospital, where a series of incorrect behaviors, such as infrequent hand washing by healthcare workers, also affect it. According to the European Centre for Disease Prevention and Control (ECDC), in 2019 the risk - in Italy - of contracting infections during a hospitalization was about 6%. On an absolute level we are talking about 530 thousand cases each year, data that put Italy in last place among all countries in Europe<sup>5</sup>.

To all this should be added that antibiotic consumption in Italy is higher than the European average (both at the territorial and hospital level, especially in the age groups between 2 and 5 years old, and over 85 years old) and that, above all, in my country antibiotics are inappropriately prescribed in a quarter of cases, according to the 2020 National Report on Antibiotic Use in Italy, edited by the Italian Medicines Agency (AIFA)<sup>6</sup>.

In a nutshell, experts warn that by 2050, globally, antimicrobial resistance (AMR) could cause more deaths than cancer<sup>7</sup>, but more importantly, without effective action, AMR will take us back to a preantibiotic era when death from infection was much more common: and this is for all of us a first key message not to be overlooked.

It would be enough to become aware of this scenario to recognize its urgency and thus the need for action, also in light of the principles established by the European Charter of Patients' Rights<sup>8</sup>, including:

the right to compliance with quality standards<sup>9</sup>;

<sup>&</sup>lt;sup>4</sup> Il Fatto Quotidiano: "Antibiotic resistance, ISS: "Italy first among EU countries in number of deaths"", November 2019 (IT language). <a href="www.ilfattoquotidiano.it/2019/11/19/antibiotico-resistenza-iss-italia-prima-tra-i-paesi-dellue-per-numero-di-morti/5571058/">www.ilfattoquotidiano.it/2019/11/19/antibiotico-resistenza-iss-italia-prima-tra-i-paesi-dellue-per-numero-di-morti/5571058/</a>

<sup>&</sup>lt;sup>5</sup> Quotidiano Sanità: Antimicrobial resistance, draft Plan expected in 2021. 40 mln euro funding each year. The announcement at Camerae Sanitatis, October 2021 (IT language). <a href="www.quotidianosanita.it/studi-e-analisi/articolo.php?articolo.id=99360">www.quotidianosanita.it/studi-e-analisi/articolo.php?articolo.id=99360</a>

<sup>6</sup> Italian Medicines Agency (AIFA): 2020 National Report on Antibiotic Use in Italy (IT language). www.aifa.gov.it/documents/20142/1664282/Rapporto Antibiotici 2020.pdf

<sup>&</sup>lt;sup>7</sup> Epicentro Istituto Superiore di Sanità: Epidemiological Aspects, 2021 (IT language). <a href="www.epicentro.iss.it/antibiotico-resistenza/epidemiologia-europa">www.epicentro.iss.it/antibiotico-resistenza/epidemiologia-europa</a>

Active Citizenship Network: European Charter of Patients' Rights. <a href="https://www.activecitizenship.net/files/patients\_rights/charter-of-rights/the-charter-in-several-languages/full-text/Italy.pdf">https://www.activecitizenship.net/files/patients\_rights/charter-of-rights/the-charter-in-several-languages/full-text/Italy.pdf</a>

<sup>&</sup>lt;sup>9</sup> "Everyone has the right to access high-quality healthcare services, based on the establishment and adherence to precise standards. The right to quality healthcare services requires that healthcare facilities and professionals practice



- the right to information<sup>10</sup>;
- above all, the right to safety<sup>11</sup>: "Everyone has the right to be free from harm resulting from the malfunction of healthcare services, malpractice, and medical errors, and has the right to access healthcare services and treatment that ensure high standards of safety". In order to guarantee this right, the Charter claims "hospitals and health services must continuously monitor risk factors. All healthcare professionals must be fully responsible for the safety. Doctors must be able to prevent the risk of errors through background monitoring and constant education".

The year 2025 will mark 10 years since the adoption of the WHO Global Action Plan against AMR<sup>12</sup>, and despite the progress made to date, there is still a need to initiate concrete and effective actions to eradicate this phenomenon, which is still too little widespread in the collective consciousness, as already said: it is no coincidence that some experts label it with the name "silent tsunami"<sup>13</sup>, while others speak of a "neglected pandemic"<sup>14</sup>, and also this is another key message that should not be overlooked, and a more than valid reason to be daily engaged in the fights against AMR, and not only during the starting World Antimicrobial Awareness Week (WAAW) promoted by World Health Organisation<sup>15</sup>.

Against this background, this kind of training initiatives are welcome, so congratulations to Malta Health Network for this event supported by the Malta Medicines Authority, realized in the framework of a project funded by the Training Initiatives Scheme managed by the Malta Council for the Voluntary Sector. Thanks to all again for the invitation, and thanks to Gertrude.

satisfactory levels of technical performance". <a href="https://www.activecitizenship.net/charter-of-rights/rights/121-8-right-to-the-observance-of-quality-standards.html">www.activecitizenship.net/charter-of-rights/rights/121-8-right-to-the-observance-of-quality-standards.html</a>

<sup>&</sup>lt;sup>10</sup> "Everyone has the right to access all kinds of information concerning both his or her health status and health services and how to use them, as well as all the information that scientific research and technological innovation make available". www.activecitizenship.net/charter-of-rights/rights/126-3-right-to-information.html

<sup>&</sup>lt;sup>11</sup> "Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards".www.activecitizenship.net/charter-of-rights/rights/120-9-right-to-safety.html

<sup>&</sup>lt;sup>12</sup> WHO Global Action Plan against AMR. <u>www.who.int/publications-detail-redirect/9789241509763</u>.

The silent tsunami: stemming the tide of AMR in the Covid-era. www.youtube.com/watch?v=Ak8RzzFFNCE&ab channel=PublicPolicyProjects

<sup>&</sup>lt;sup>14</sup> Infezioni Obiettivo Zero: "The neglected pandemic of antimicrobial resistance", February 2022 (IT language). <u>www.infezioniobiettivozero.info/10-antibiotico-resistenza/139-pandemia-trascurata-antimicrobico-resistenza-ars-</u> 2022

World Antimicrobial Awareness Week (WAAW) runs in 2022 from 18 to November 24<sup>th</sup> www.who.int/campaigns/world-antimicrobial-awareness-week/2022



In my introduction I'll brief remember the commitment of the EU Institution on the topic, and then I'll show some concrete examples of how we can advocate on the topic of AMR and to open a dialogue with the Institutions.

#### Faithing AMR: the commitment of the EU Institutions

2001: Communication from the Commission on A Community Strategy Against Antimicrobial Resistance on 4 key areas of action: Surveillance: reinforcing occurrate surveillance systems on antimicrobial resistance in the human and veterinary sector and the consumption of antimicrobial agents. Prevention of communicable diseases and infection control: to reduce the needs for antimicrobial agents. Research and product development international co-operation: the antimicrobial resistance does not respect frontiers.

2011: This policy was reinforced with the "Action plan against the rising threats from Antimicrobial Resistance", notable for its One Health approach, addressing AMR in both humans and animals.

2017: The <u>European One Health Action Plan against AMR</u> is motivated by the need for the EU to play a leading role in the fight against AMR and to add value to Member States' actions. Its overarching goal is to preserve the possibility of effective treatment of infections in humans and animals.

Since 1999: the Commission has invested over EUR 1.3 billion in AMR research, making Europe a leader in this domain.

Well, in the last 20 years, the European Institutions increased a lot their commitment on AMR, starting with the Community strategy against AMR in 2001, then reinforced ten years later by the Commission action plan, notable for its One Health approach, addressing AMR in both humans and animals, and the European One Health Action Plan against AMR in 2017.

#### "One Health" according the WHO definition

'One Health' is an integrated, unifying approach to balance and optimize the health of people, animals and the environment. It is particularly important to prevent, predict, detect, and respond to global health threats such as the COVID-19 pandemic. The approach mobilizes multiple sectors, disciplines and communities atvarying levels of society to work together. This way, new and better ideas are developed that address root causes and create long-term, sustainable solutions.

One Health involves the public health, veterinary, public health and environmental sectors. The One Health approach is particularly relevant for food and water safety, nutrition, the control of zoonoses (diseases that can spread between animals and humans, such as flu, rabies and Rift Valley fever), pollution management, and combatting antimicrobial resistance (the emergence of microbes that are resistant to antibiotic therapy).

Among the global health problems, <u>AMR is the one that most clearly illustrates the One Health approach</u>. AMR is a critical global problem affecting humans the environment, and animals. This is related to each of these three components due to the irresponsible and excessive use of antimicrobials in various sectors (agriculture, livestock, and human medicine). Improper management of antimicrobials, inadequate control of infections, agricultural debris, pollutants in the environment, and migration of people and animals infected with resistant bacteria facilitate the spread of resistance.

The main characteristic is the so called "One Health" approach, so defined by the WHO: an integrated, unifying approach to balance and optimize the health of people, animals and the



environment. This approach mobilizes multiple sectors, disciplines and experts from public health, veterinary and environmental sectors.

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### The European One Health Action Plan against AMR

The key objectives of this new plan are built on three main pillars:

- making the EU a best practice region: this will require better evidence, better coordination and surveillance, and better control measures. EU action will focus on key areas and help Member States in establishing, implementing and monitoring their own national One Health action plans on AMR, which they agreed to develop at the 2015 World Health Assembly,
- boosting research, development and innovation by closing current knowledgegaps, providing novel solutions and tools to prevent and treat infectious diseases, and improving diagnosis in order to control the spread of AMR;
- intensifying EU efforts worldwide to shape the global agenda on AMR and the related risks in an increasingly interconnected world



In particular, with the <u>European One Health Action Plan against AMR</u> drafted in 2017, the EU Institutions are motivated to play in the world a leading role in the fight against AMR and to add value to Member States' actions. To date, since 1999 the Commission has invested over EUR 1.3 billion in AMR research, making Europe a leader in this field.



### **EU main initiatives on AMR (overview)**

- 2013: launch of the New Drugs for Bad Bugs (ND4BB) programme, the world's biggest public-private AMR research partnership, forming part of the Innovative Medicines Initiative (IMI): The EUR 650 million programme comprises 8 projects that are finding solutions to the scientific, regulatory, and business challenges that are hampering the development of new antibiotics.
- 2017/2021: Join Action on Antimicrobial Resistance and Healthcare-Associated Infections, a
  partnership of 44 partners and over 40 stakeholders, with the mission to foster synergies across
  all members using a One Health approach to influence policy to tackle Antimicrobial Resistance
  and Healthcare-Associated Infections.
- Ongoing since 2012: Joint Programming Initiative on AMR (JPIAMR) with the aim to better coordinate and align worldwide AMR research efforts. JPIAMR is an international collaborative platform engaging 29 nations and the European Commission to curb antimicrobial resistance (AMR). JPIAMR coordinates national public investments from member countries and supports collaborative action seeking new knowledge and supporting solutions to decrease the burden of AMR with a One Health approach. To date, JPIAMR has supported more than 1600 researchers in 112 projects and 44 networks with funding about 141 million Euro.

16 Jan. 2023: The <u>call</u> is open! A joint research call on AMR diagnostics and surveillance! Est. budget: 18.8 Million Euro. 18 countries participate, providing funding for researchers in national contexts.



This number of resources has been used to finance several multi-annual programmes, as the world's biggest public-private AMR research partnership, to foster synergies across Member States, to better coordinate and align worldwide AMR research efforts. And as you can see, days ago another call has been launched to support joint research.



Taking into consideration this background, what kind of initiatives can be taken by PAGs and civic organizations to help policy makers and other stakeholders to put/to guarantee high attention to AMR? In my second part of the presentation, I'll show you concrete examples, mainly but non only at the EU level, with the aim to encourage all of you to be more active on the topic: for instance, focusing of the EU Parliament elections that will take place in 2024.



What actions can be taken to help policymakers and other stakeholders? A collection of concrete examples (1)

Open letter to the Members of the European Parliament on the importance to sustain EU progress in fighting against antimicrobial resistance (AMR)

17 organisations active in human and animal health have sent an open letter to the Members of the European Parliament, urging them to bring antimicrobial resistance (AMR) to the forefront of EU interinstitutional discussions and to support the establishment of a dedicated AMR parliamentary group.

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About it, I am glad to remember that on September 2019, just after the European election of the current EU Parliament, 17 organisations active in human and animal health have sent an open letter to the newly elected Members of the European Parliament, urging them to bring antimicrobial resistance (AMR) to the forefront of EU interinstitutional discussions and to support the establishment of a dedicated AMR parliamentary group.





Objective that has been achieved later on, involving Members of the European Parliament from different countries and political groups with the support of non-institutional actors, a good precondition to encourage and strengthen dialogue.



In the EU Parliament there are several informal Interest Group, so it was important to involve and converge on the topic also other Interest Groups, starting with the MEPs Interest Group "European Patients' Rights and Cross-border Healthcare", now at its second term. Here you can find some examples of initiative realized at the EU Parliament by my organization on ARM, the last on November.



To reinforce messages on AMR has been used also some fixed appointments on the European agenda, such as the European Patients' Rights Day, an annual appointment to be celebrated each



year across Europe as a common occasion to inform, discuss and commit to improving patients' rights in Europe and in each member State: 2 years ago, it was completely dedicated to the AMR.



We can find the way to interact with the Institutions promoting initiatives, but also trying to be recognize their stakeholder and so to join their initiative. Such as the EU-Join Action on Antimicrobial Resistance and Healthcare-Associated Infections already mentioned as one of the main programs led by the EU Institutions: for instance, as a Member of the EU-JAMRAI Stakeholder Forum, my organization Active Citizenship Network (ACN) was invited to join the EU-JAMRAI contest jury for a symbol representing the global threat of antibiotic resistance: the EU-JAMRAI Antibiotic Resistance Symbol Contest was officially launched on November 18th 2019, in the framework of the European Antibiotic Awareness Day.





Another example at the European level: as official member of the HERA Civil Society Forum, the expert group of the HERA Advisory Forum, we have encouraged and obtained by the new born European Health Emergency preparedness and Response Authority (HERA) to prioritize the topic on AMR in its 2023 Annual Workplan that has been officially announced last December.

This is a concrete example about how we can support the EU4Health programme for a healthier and safer Union linked to AMR.



In a parallel way with the advocacy initiative tailored to the policymakers, we need to invest in training sessions like the today's event, also because each one of us, when well-informed, represents a good antidote to the spreading of fake news.

And foster alliances, even among patient associations. Here you can find 2 recent initiatives:





Strengthen the alliance & enlarge the AMR constituency

The AMR Patient Group was officially launched on November 18th 2020, to coincide with European Antibiotic Awareness Day 2020; it is an initiative by Health First Europe and is comprised of national patient associations from across Europe, including Malta Health Network and my organization.



The key objectives of the AMR Patient Group are:

- Raising patient awareness about AMR and healthcare-associated infections to help reduce antibiotic misuse.
- Building a consistent patient voice across Europe to advocate for national policies to tackle AMR and healthcare-associated infections.
- Broadening the AMR debate to include infection prevention and control measures

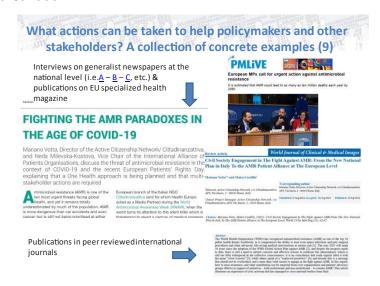
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The second initiative, AMR Patient Alliance<sup>16</sup>, aims to reach the same goals but its constituency is not only European but worldwide: among their more than 50 organizations, we can find also PAGs from Africa, USA and Canada.



Of course, another way to try to influence policymakers and stakeholder is to publish interview and articles: here you can find a selection of articles on AMR published on generalist newspapers at the national level, & publications on EU specialized health magazine and – also - publications in peer reviewed international journals.

<sup>16</sup> At the international level, together with the International Alliance of Patients' Organizations (IAPO) we are committed to the "<u>AMR Patient Alliance</u>", a global advocacy initiative of more than 50 PAGs from 22 Countries that aims to cooperate on patient empowerment, literacy and engagement for preserving the effectiveness of antibiotics.



## What actions can be taken to help policymakers and other stakeholders? A collection of concrete examples (10a)



In Italy, the National Plan for Combating Antimicrobial Resistance (PNCAR) represents the tool to translate the national strategy into practice, providing a coordinated and sustainable direction to combat the phenomenon of AMR at national, regional and local level, through a "one health" multisectoral approach. Approved in November 2017, expired in 2020 and extended for 2021

On November 3, 2017, the PNCAR Technical Coordination Group (GTC) was established, with the task of coordinating, monitoring and updating the AMR National Countering Plan and Strategy, to harmonize the strategies already in place and facilitate the achievement of short and mediumlong term goals. In addition to the stakeholders who drafted the Plan (Ministry of Health, Italian Medicines Agency, Istituto Superiore di Sanità, AIFA, ISS and Scientific Societies & Regions), the following took part:

- The Ministry of Economy and Finance
- The Ministry of Agricultural and Forestry Policies
- · The Ministry of the Environment
- Cittadinanzattiva

My last example is at the national level, and I need to come back to talk about my country, Italy, where the National Plan for Combating Antimicrobial Resistance (PNCAR) was approved in November 2017, expired in 2020 and extended for 2021.

Please note that my organization was the only civic organization invited to join in 2017 the PNCAR Technical Coordination Group (GTC), established with the task of coordinating, monitoring and updating the AMR National Plan.

# What actions can be taken to help policymakers and other stakeholders? A collection of concrete examples (10b)



In Italy,Farmindustriahas promoted the AMR multidisciplinary Task Force, involving representatives of the academic-scientific world, civic & patients associations, and pharmaceutical industry, to provide recommendations on combating AMR:

- Role of vaccine prevention as a tool to combat antimicrobial resistance;
- Value, access and innovation of new antibiotics against bacterial resistance;
- Appropriateness of use of antibiotics.



In Italy, the <u>new National Plan for Combating Antimicrobial Resistance (PNCAR) 2022 -2025</u> was transmitted by the Presidency of the Council of Ministers to the Ministry of Health and the Economy and to the Regions last <u>September 2022</u>.



In order to contribute to provide suggestions for the new AMR National Plan 2022-2025, we worked closely with Scientific Societies and private sector<sup>17</sup>. Again, my organization was the only civic organization interested to the topic. And this is part of the problem, as appropriate antibiotic use is everybody's business, if we want to preserve the antibiotics and other antimicrobials effective for as many patients as possible, for as long as possible.

All we are aware that "One Health Approach" is planned, as well as multi-stakeholder actions are required and the collaboration is a key. According to me, to go further aiming higher, we need to involve as much as possible the number of the intermediate bodies of the society as well as to recognize - in support of initiatives, both institutional and non-institutional, to counter AMR - the active role of PAGs & citizen organization dealing with health as our main common good to be safeguarded.



Of course, we need to guarantee some pre-conditions about our commitment and not only our interest on the topic.

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<sup>&</sup>lt;sup>17</sup> at the national level in Italy, we joined the "AMR multidisciplinary Task Force" promoted by Farmindustria (involving representatives of the academic & scientific societies world, civic & patients associations, pharmaceutical industry), to provide - in occasion of the drafting the new National Plan to fight AMR - recommendations focused on the following three pillars: the role of vaccine prevention as a tool to combat antimicrobial resistance; the value, access and innovation of new antibiotics against bacterial resistance; the appropriateness of use of antibiotics.





If interested, in our webpage you can find more information about our long-term commitment on the topic.



To promote tailored actions to raise awareness on the issue of AMR also for all citizens as consumers:

- What is behind the "antibiotic-free supply chain" message?
- What about the difference between animal products being away from antibiotics "from birth" or "in the last 4 months"?
- What lies behind these labels, and why should they be considered for informed choices in all of our purchasing decisions?

Before to finish, I'd like to introduce a suggestion: to engage also the consumers' association on the topic on AMR, in order to promote tailored actions to raise awareness on the issue of AMR also for all citizens as consumers.







## **THANK YOU!**

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I thank you for the attention!