PLANO NACIONAL
DE COMBATE À RESISTÊNCIA A ANTIMICROBIANOS:
A VISÃO DO PPCIRA/DGS

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Grupo de Infecção e Sepsis

Presidente do Colégio de Especialidade de Medicina Intensiva da Ordem dos Médicos

AMR is a serious social and economic burden

- Between 2007 and 2015, in the EU/EEA, the health burden of infections due to bacteria with AMR has increased.
- The number of deaths attributable to infections due to *K. pneumoniae* resistant to carbapenems increased six-fold.
- The number of deaths attributable to infections due to third-generation cephalosporin-resistant *E. coli* increased four-fold
- AMR is estimated to be responsible for 33,000 deaths per year in the EU alone and 750,000 deaths per year globally.
- In the EU alone, it is estimated that AMR costs EUR 1.5 billion annually in healthcare costs and productivity losses.
- Currently, close to one in five infections in the EU/EEA is due to antibiotic-resistant bacteria.

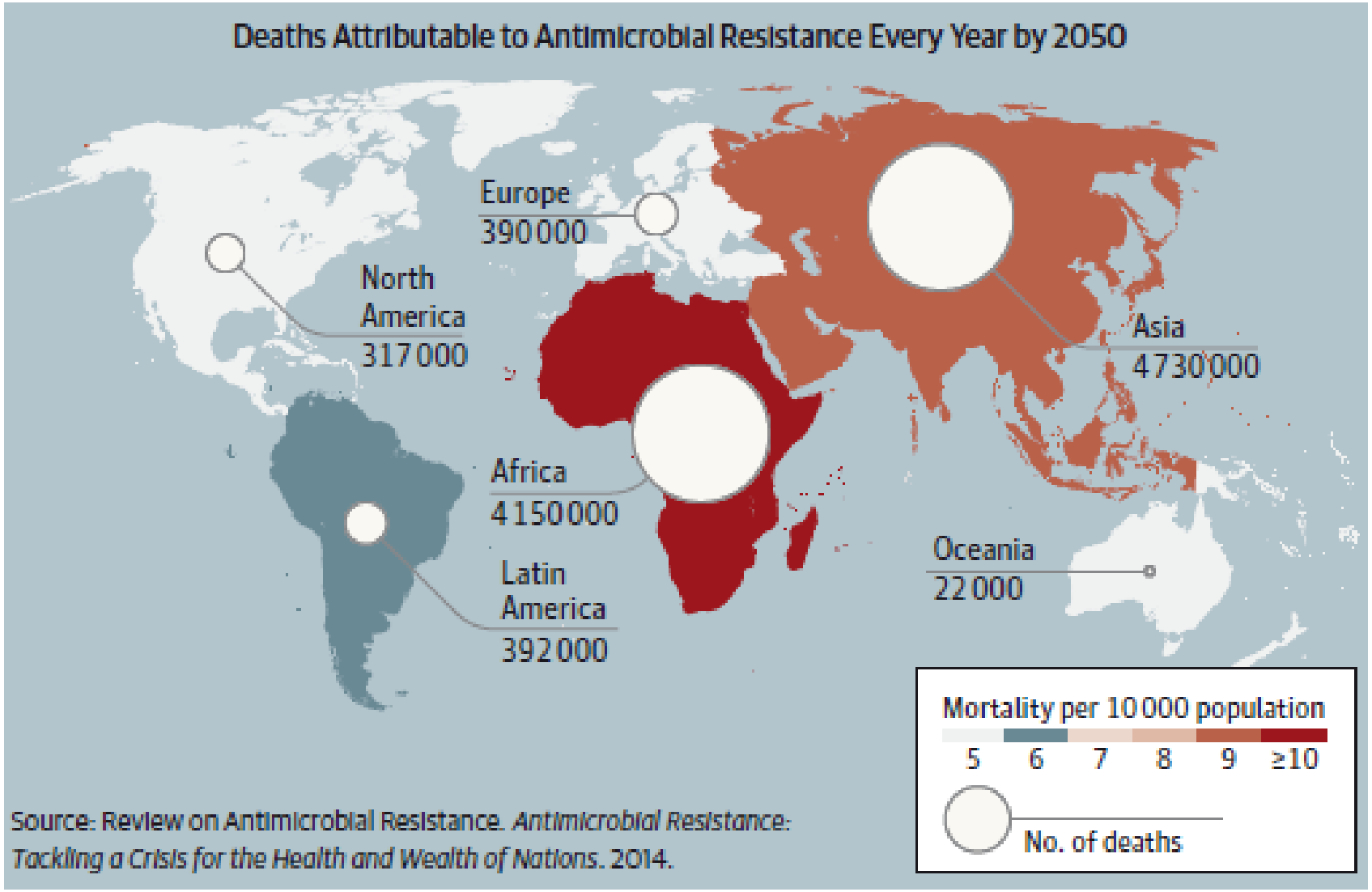
ECDC; OECD. Antimicrobial Resistance—Tackling the Burden in the European Union—Briefing Note for EU/EEA Countries; OECD: Paris, France, 2019

Inaction is projected to cause millions of deaths globally

- If no effective action is put in place, AMR to second-line antibiotics will be 72% higher in 2030 compared to 2005, in the EU/EEA
- In the same period, AMR to last-line treatments will more than double
- It also pushes up the cost of treatment and diminishes productivity due to illness.
- The World Bank has warned that, by 2050, drug-resistant infections could cause global economic damage on *a par* with the 2008 financial crisis.
- It also threatens the achievement of several of the United Nations' sustainable development goals, particularly the targets for good health and well-being
- AMR might cause more deaths than cancer by 2050

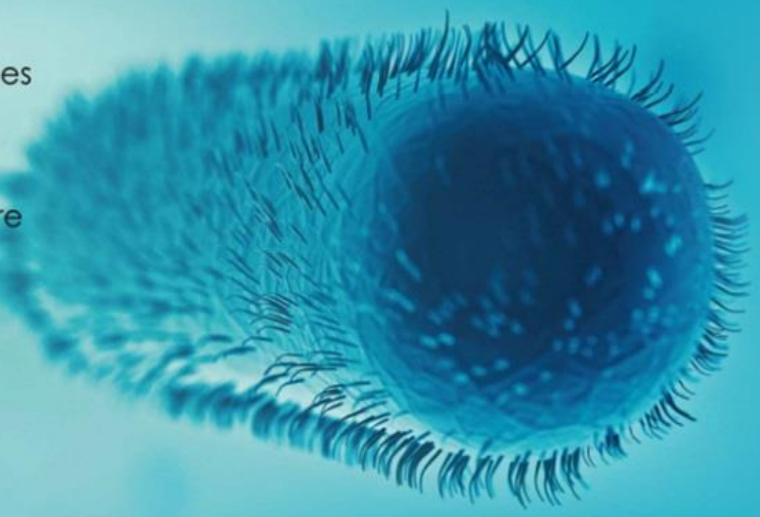
ECDC; OECD. Antimicrobial Resistance—Tackling the Burden in the European Union—Briefing Note for EU/EEA Countries; OECD: Paris, France, 2019

Mortality attributable to antimicrobial resistance in 2050
10 million deaths due to AMR in 2020



The causes of the fast increasing global resistome and the resulting AMR crisis:

1) Overpopulation, enhanced global migration and global misuse of antibiotics by laymen and professionals
2) Excessive use of antibiotics in animals (food, pets, aquatic)
3) Inadequate hygiene standards in health care, agriculture, food industries and stock farming, etc.
4) Senseless cost reduction or ignoring necessary investigations in health care (e.g. hospitals)
5) Increased number of class 3 medical devices - potential risk of foreign material-associated infections
6) Grossly negligent not to continue research and development of new antibiotics
7) Lacking knowledge about AMR mechanisms, particularly in context of FBR-associated colonization, biofilm formation and infection
8) Missing or delayed translation and implementation of alternative, complementary drug-free antimicrobial strategies



AMR: Antimicrobial crisis, particularly antibiotic crisis
FBR: Foreign body reaction

Antibiotic consumption is considered the main force driving the increase in AMR

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The association between antibiotic consumption and resistance is well documented across spatial and temporal scales at individual hospitals, communities and countries.

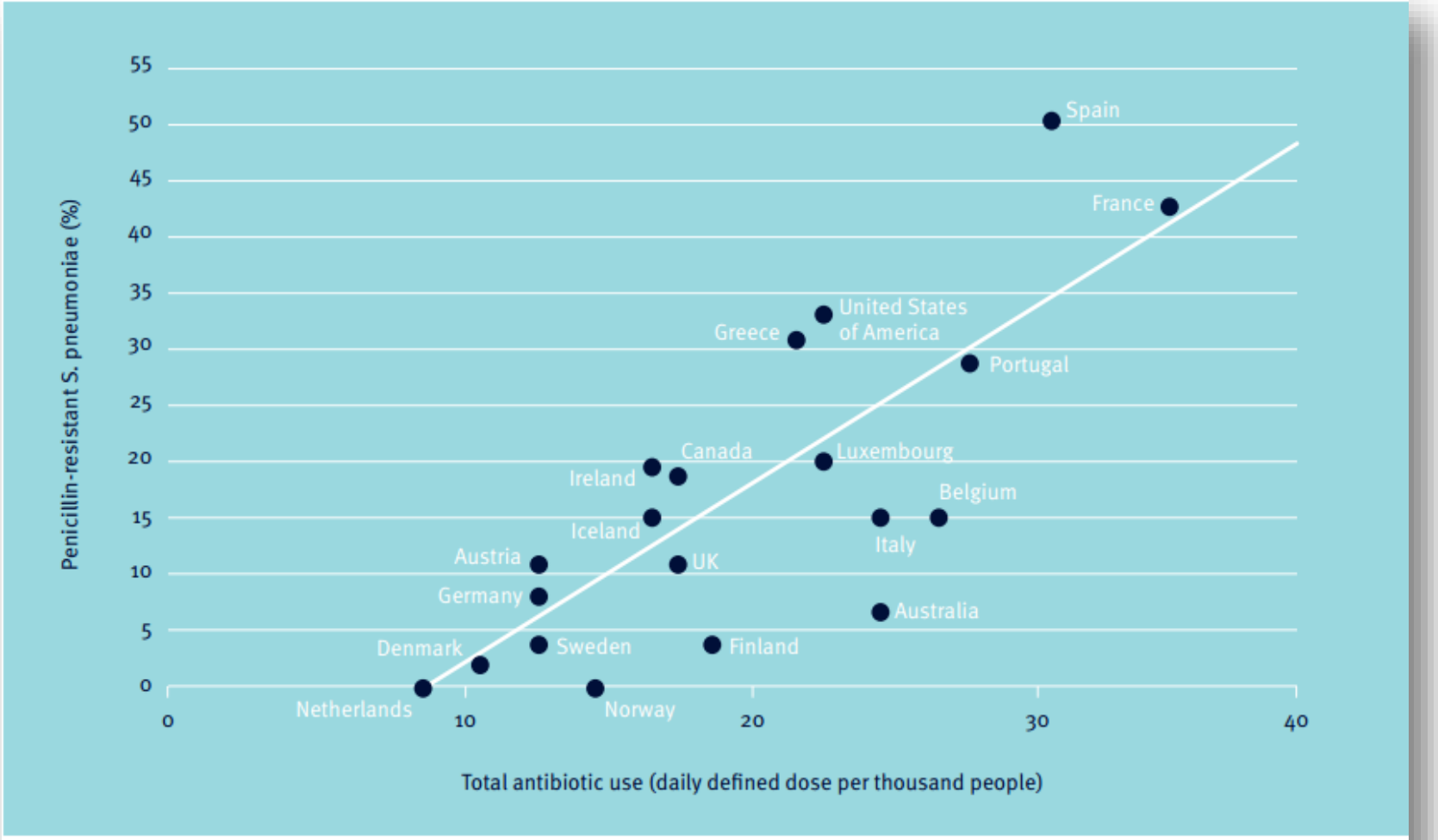


EXHIBIT 6: Correlation between antibiotic use and resistance[55]

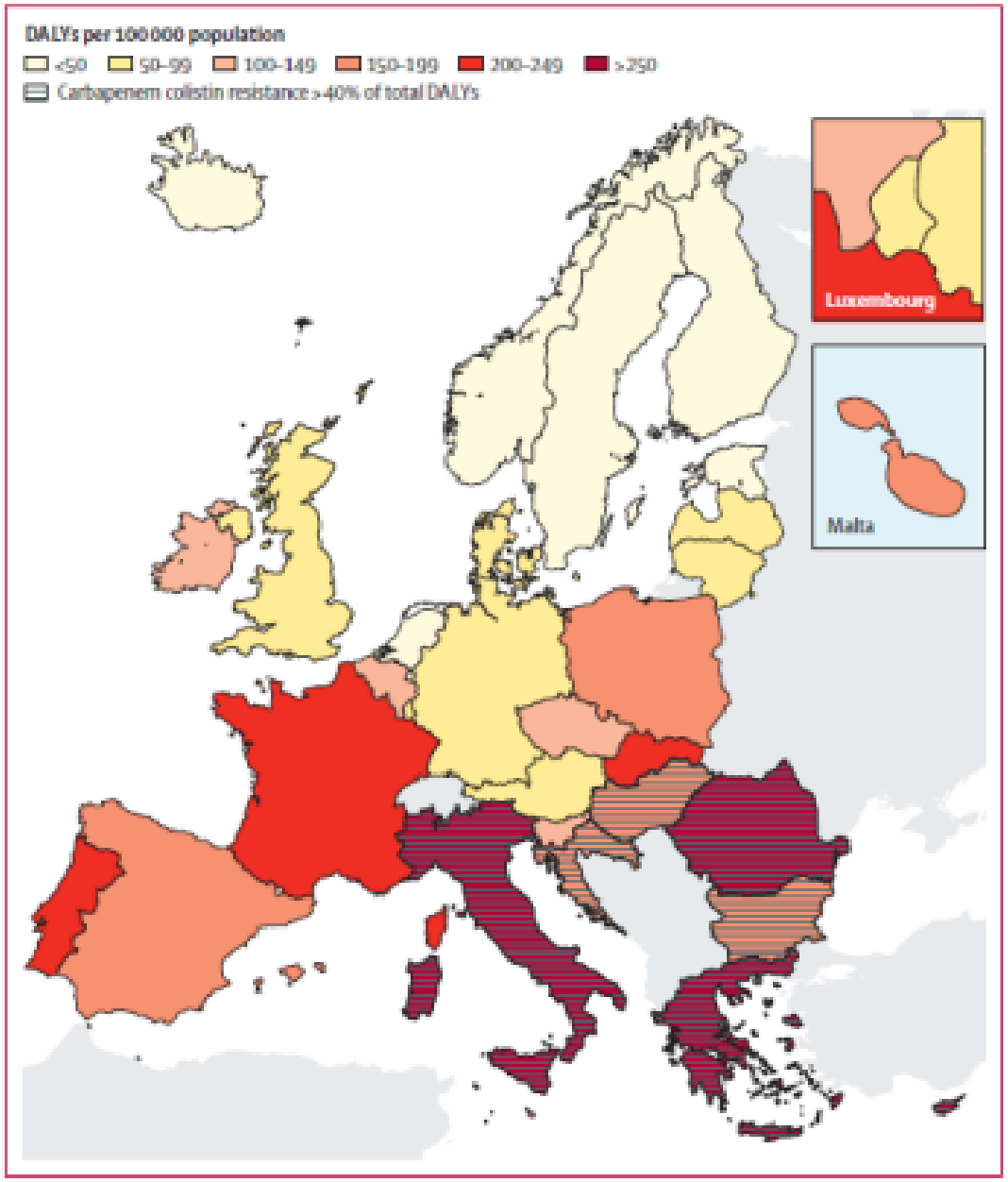


Figure 4: Model estimates of the burden of infections with selected antibiotic-resistant bacteria of public health importance in DALYs per 100 000 population, EU and European Economic Area, 2015

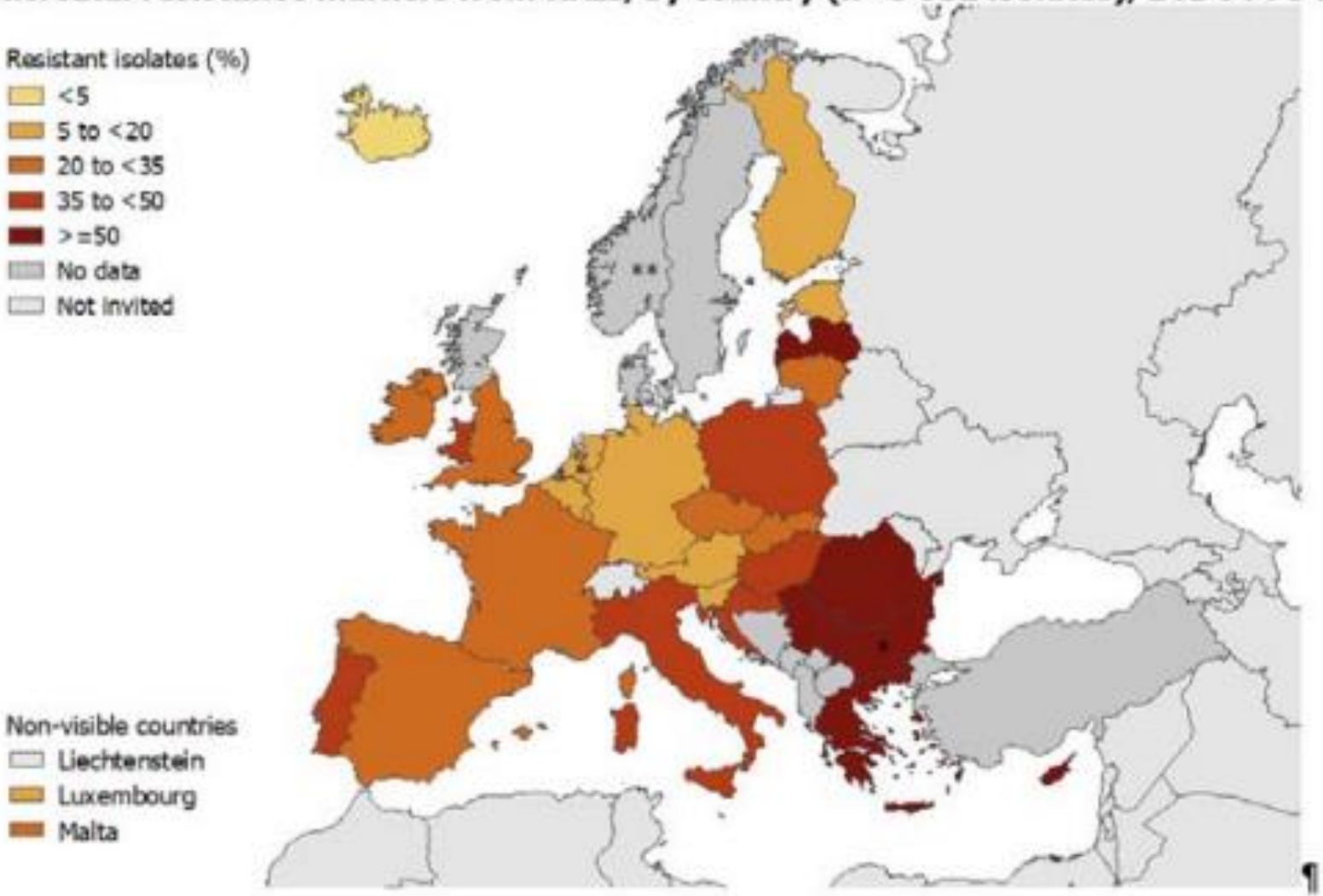
Model estimates of the burden of infections with selected AB resistant bacteria per 100 000 popualtion (DALYs)

DALY= Disability-adjusted life years

Cassini et al. Lancet Infect Dis 2019;19:56-66

Composite index of antimicrobial resistance

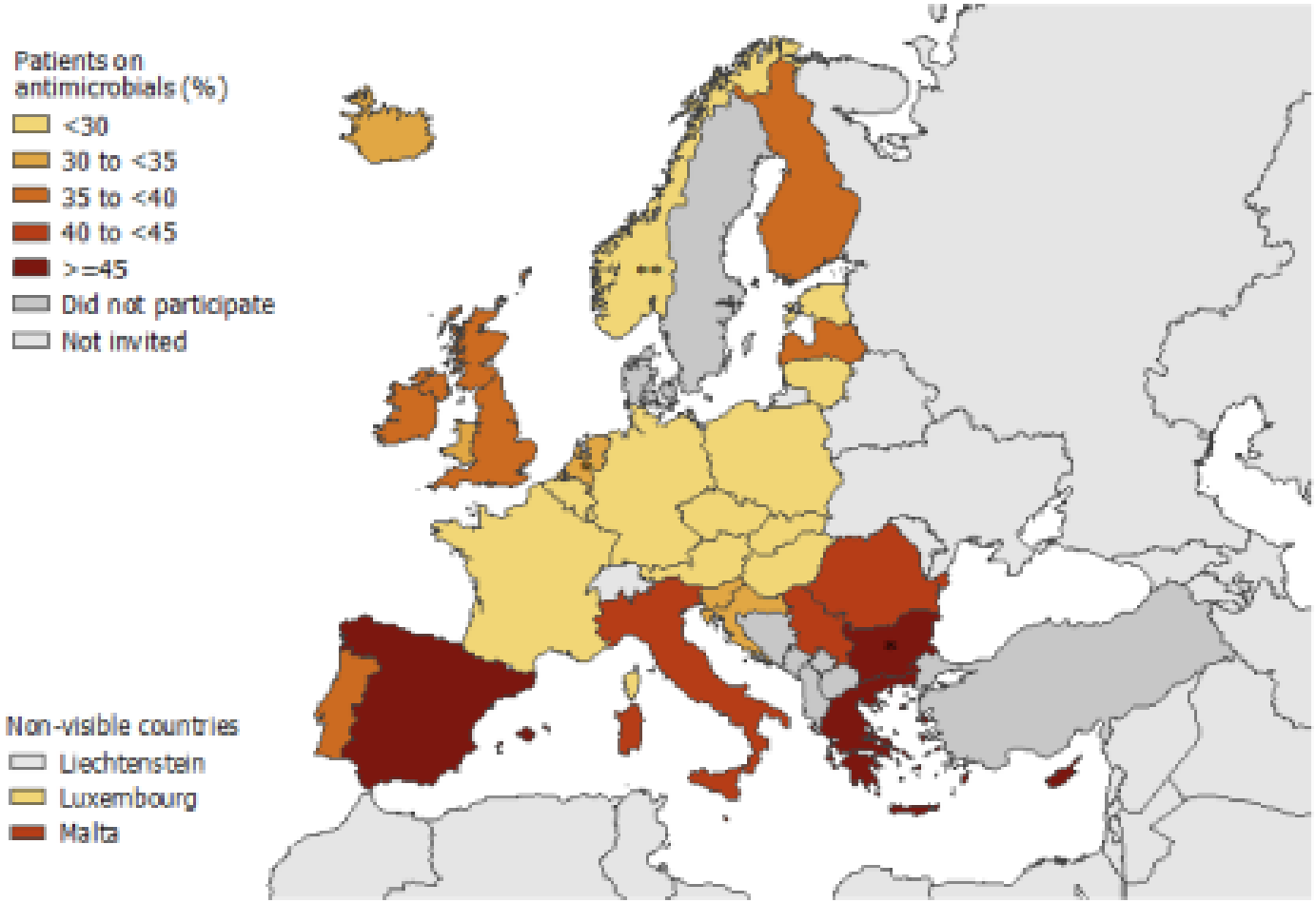
- Figure 40 Composite index of antimicrobial resistance: percentage of isolates resistant to first-level antimicrobial resistance markers from HAIs, by country (n=8 031 isolates), ECDC PPS 2016–2017



Composite index of antimicrobial resistance:
MRSA, VRE, Enterobacteriaceae resistant to 3rd gen. cephalosporins,
Pseudomonas aeruginosa
and
Acinetobacter baumannii
resistant to carbapenems

Antibiotic usage in hospitals during EU PPS 2016/17

Figure 51 Prevalence of antimicrobial use (percentage of patients receiving antimicrobials) in acute care hospitals, ECDC PPS 2016–2017



**PPS data representativeness was poor in Bulgaria and the Netherlands. **Norway used a national PPS protocol*

Programa de Prevenção e Controlo de Infecção e de Resistência Antimicrobiana
PPCIRA

Direcção Geral da Saúde

Saúde humana

PPCIRA / DGS

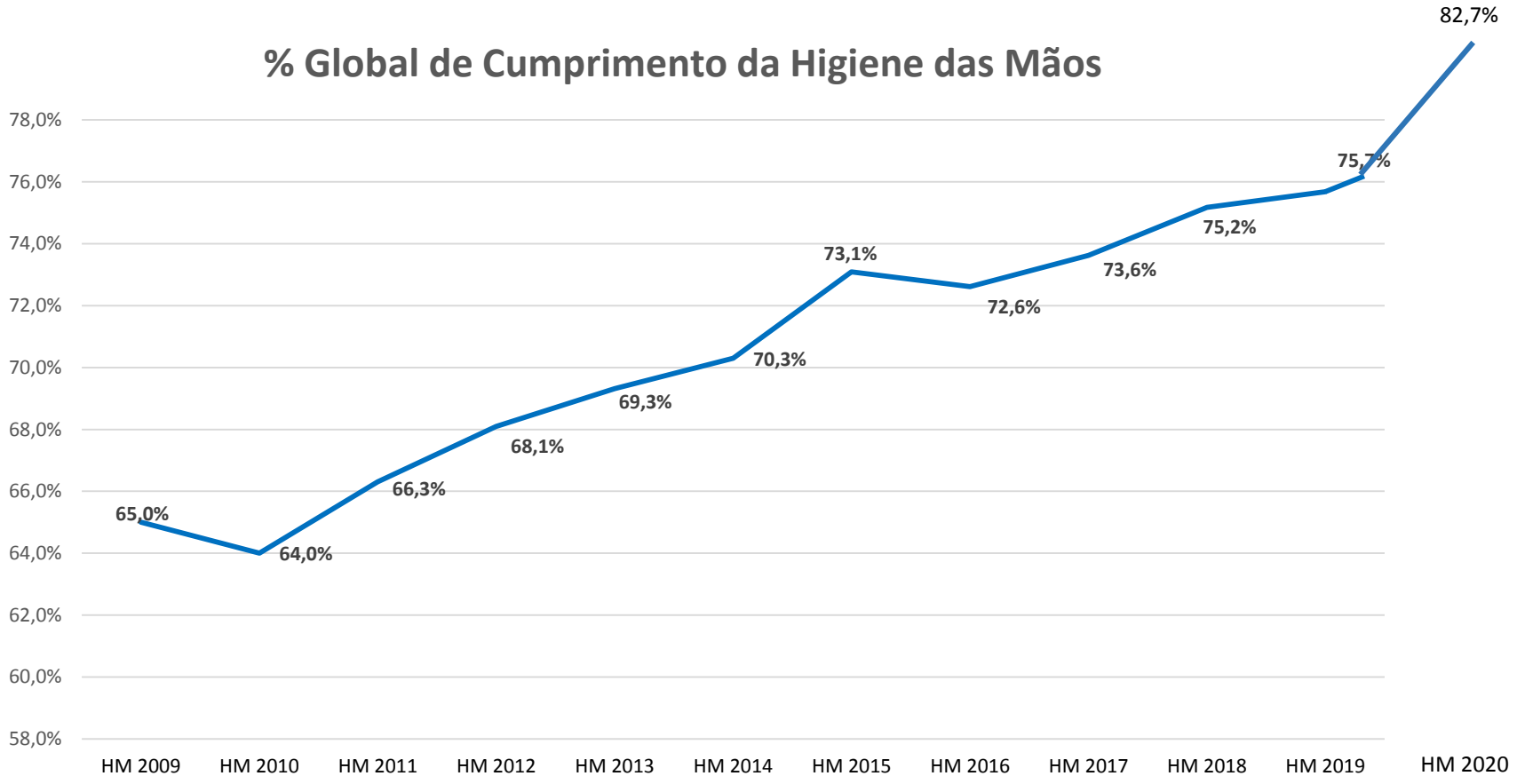
Criado em Fevereiro 2013, pela fusão do PNCI e do PNPRAM

Tem como atividades fundamentais:

- Vigilância epidemiológica de infeções associadas a cuidados de saúde, consumo de antimicrobianos e resistências a antimicrobianos.
- Promoção de adesão e cumprimento de precauções básicas de controlo de infeção e de precauções baseadas na via de transmissão.
- Promoção e implementação de feixes de intervenções (*bundles*) de prevenção de infeções associadas a cuidados de saúde.
- Promoção e desenvolvimento das atividades de apoio à prescrição antimicrobiana (*antimicrobial stewardship*).
- Produção de Normas e Orientações e de atividades educacionais de capacitação pedagógica de profissionais.
- Formulação e desenvolvimento de metodologias comportamentais de capacitação, nomeadamente *feedback* comentado de dados e facilitação de intervenções de melhoria de qualidade.
- Desenvolvimento de atividades promotoras da literacia do cidadão sobre esta temática.

Reduzir
infecções associadas a cuidados de saúde

Adesão às precauções básicas de controlo de infeção



Fonte: PPCIRA/DGS

Incidência de IACS entre 2015-2019

Fonte: PPCIRA/DGS

- Quanto à **vigilância de IACS em Unidades de Cuidados Intensivos de nível 3,** verificou-se uma **redução** da densidade de incidência de:

  - **Pneumonia associada à intubação**: em 22,6% (de 8,4 para 6,5 por 1000 dias de exposição a tubo endotraqueal);

  - **Bacteriemia associada ao cateter central**: em 28,75% (1,4 para 1,0 por 1000 dias de cateter venoso central).

- No que se refere à **vigilância da infeção do local cirúrgico (ILC),** verificou-se uma **redução** da incidência global por 100 doentes, em 12,78% (de 4,93 para 4.30).

  - ocorreu redução da infeção em artroplastia de anca (em 47,7%); na artroplastia do joelho (em 27,8%); nas cesarianas (em 5,9%) e,

  - em sentido inverso, verificou-se aumento nas cirurgias de colon e reto (em 9,6%) e na colecistectomia (em 12,0%);

- No que se refere à **vigilância da IACS em Unidades de Cuidados Intensivos Neonatais**, registou-se:
  - **Redução** da densidade de incidência de pneumonia associada a tubo endotraqueal em 2,78% (de 8,6 para 6,0 por 1000 dias de exposição a tubo endotraqueal);
  - A densidade de incidência de sépsis associada a cateter vascular central, aumentou em 28% em igual período (de 12,5 para 16 por 1000 dias de exposição ao dispositivo).

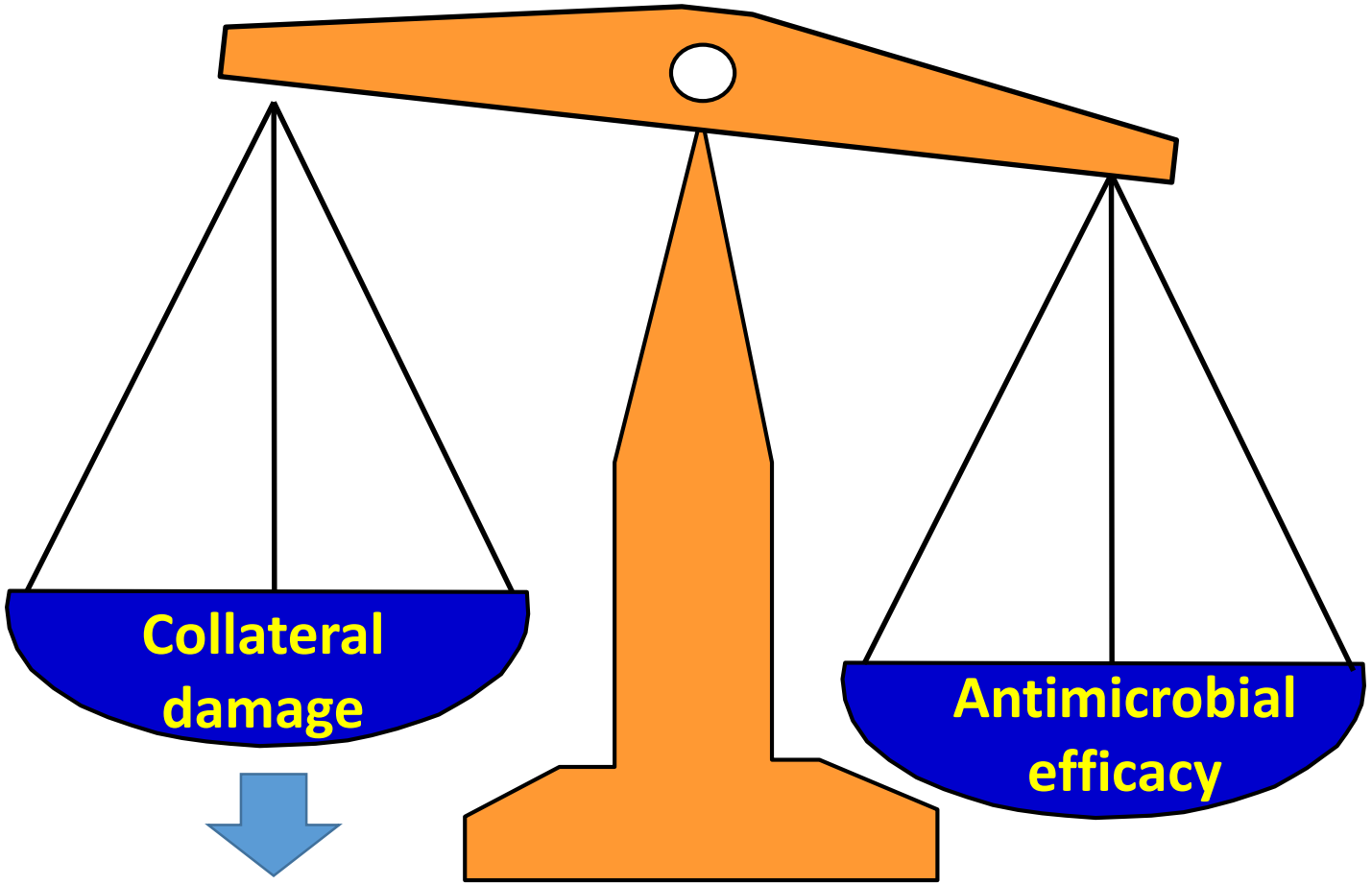
- No que se refere a **Infecções nosocomiais da corrente sanguínea,** houve **redução** de:

- densidade da incidência de INCS por 1000 dias de internamento em 15,38% (de 1,3 para 1,1);
- densidade de incidência de INCS por 1000 dias de cateter vascular central em 30,0% (de 2,0 para 1,4);
- densidade de incidência de INCS por *Staphylococcus aureus* meticilina.

Reduzir / Adequar
consumo de antimicrobianos

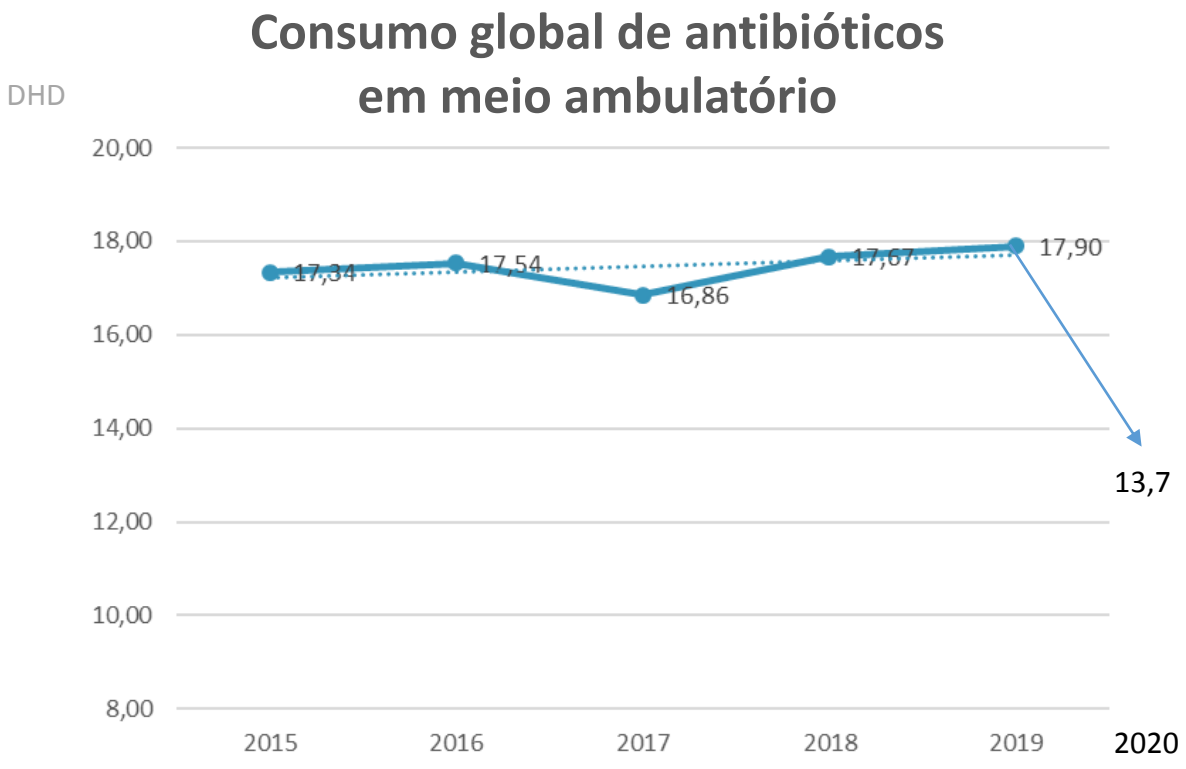
Goal of antimicrobial selection:

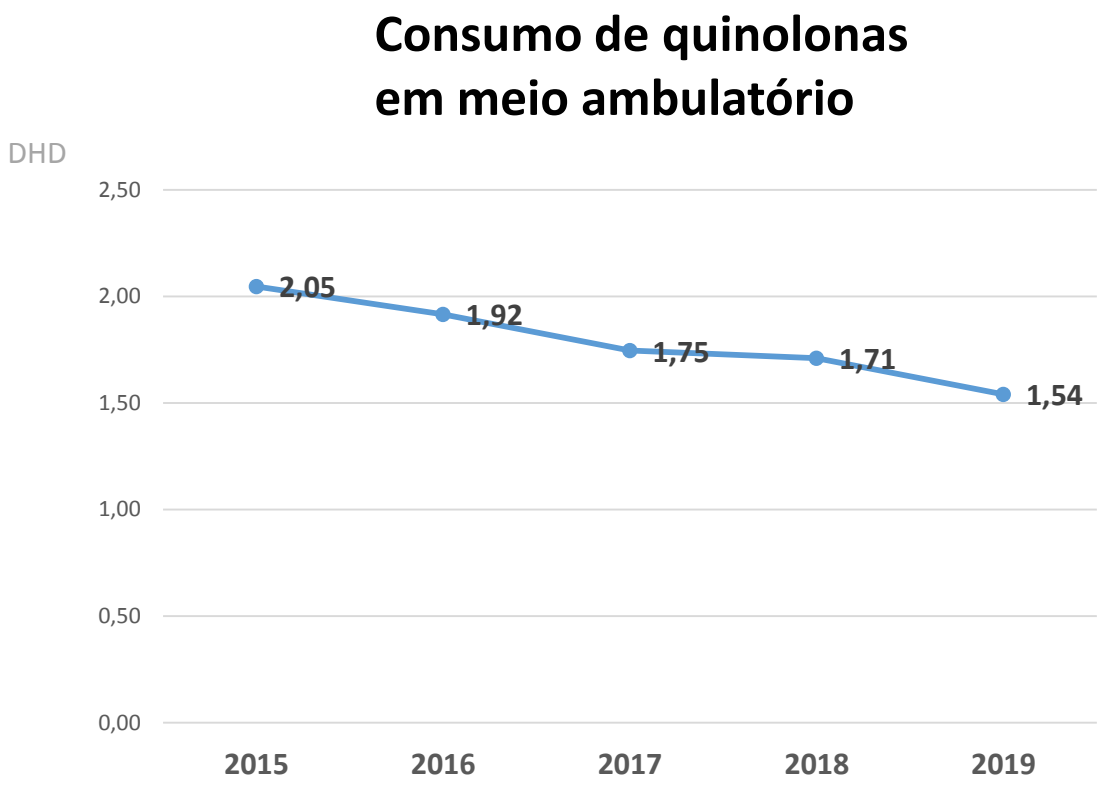
Treat adequately and with the least possible collateral damage



emergence of resistance
selection of pathogenic organisms
drug adverse events

Consumo de antibióticos em ambulatório



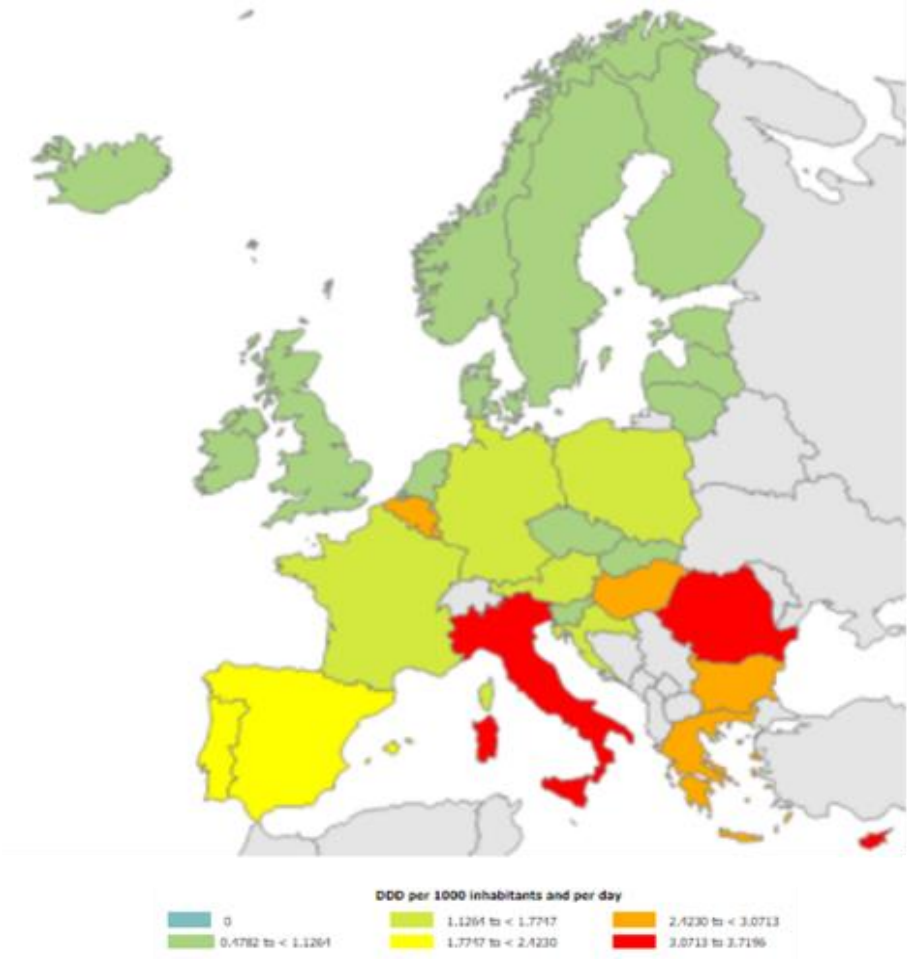


A utilização de antibióticos em Portugal registou uma descida entre janeiro e setembro de 2020, face ao período homólogo. Nas farmácias comunitárias, a dispensa destes medicamentos desceu 20%, passando de uma média de 17,46 doses diárias definidas por mil habitantes por dia (DHD) para 13,97 DHD

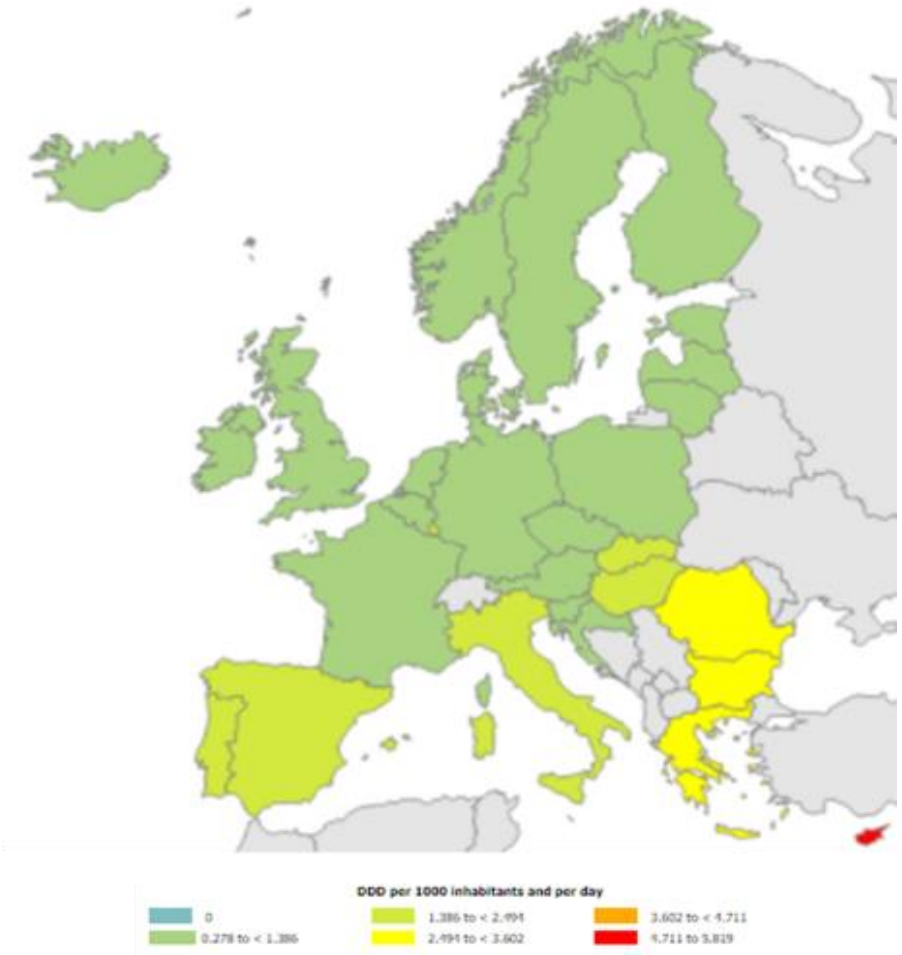
Fonte: INFARMED

Consumo de quinolonas em ambulatório

2014



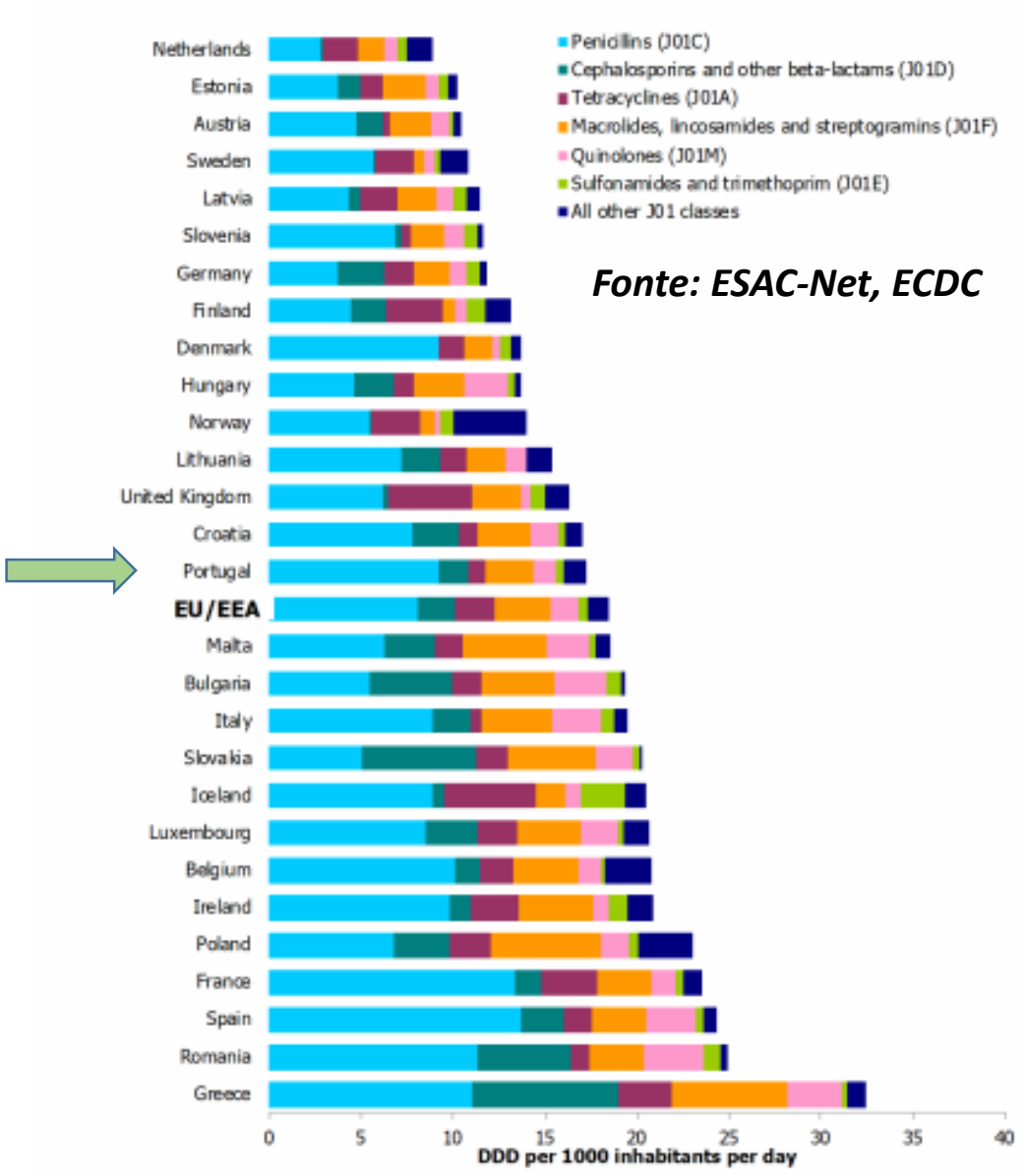
2019



Fonte: ESAC-Net, ECDC

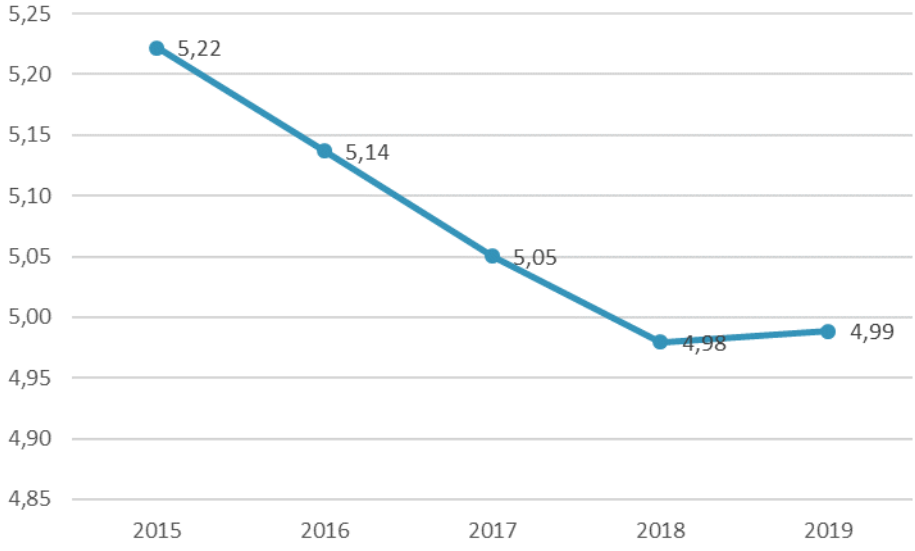
Consumo de antibióticos em ambulatório ECDC

Figure 2. Consumption of antibacterials for systemic use (ATC group J01) by country and ATC group level 3 in the community in EU/EEA countries in 2018 (expressed as DDD per 1 000 inhabitants per day)



Fonte: ESAC-Net, ECDC

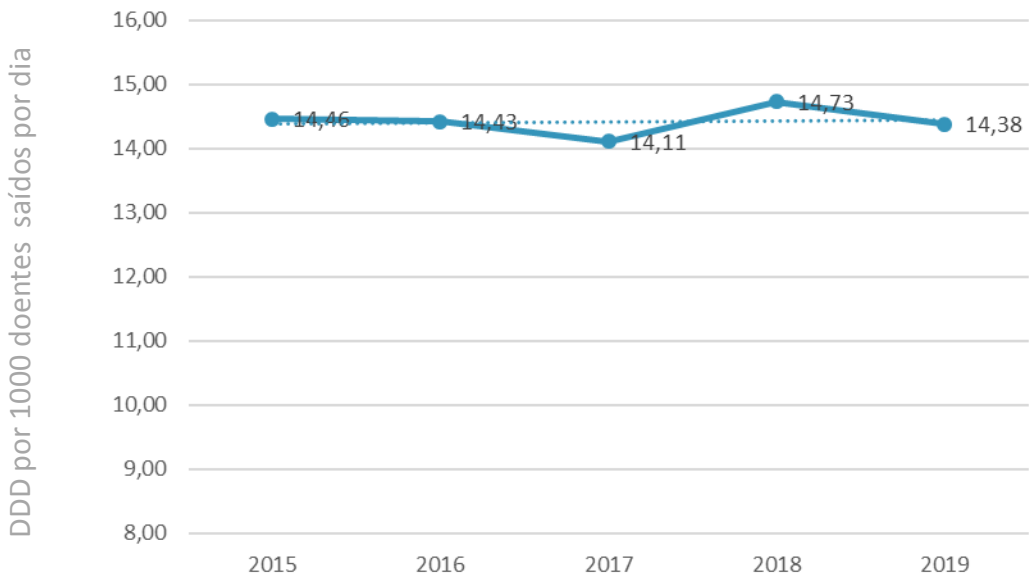
Rácio entre o consumo de antibióticos de largo espectro e espectro estreito em meio ambulatório



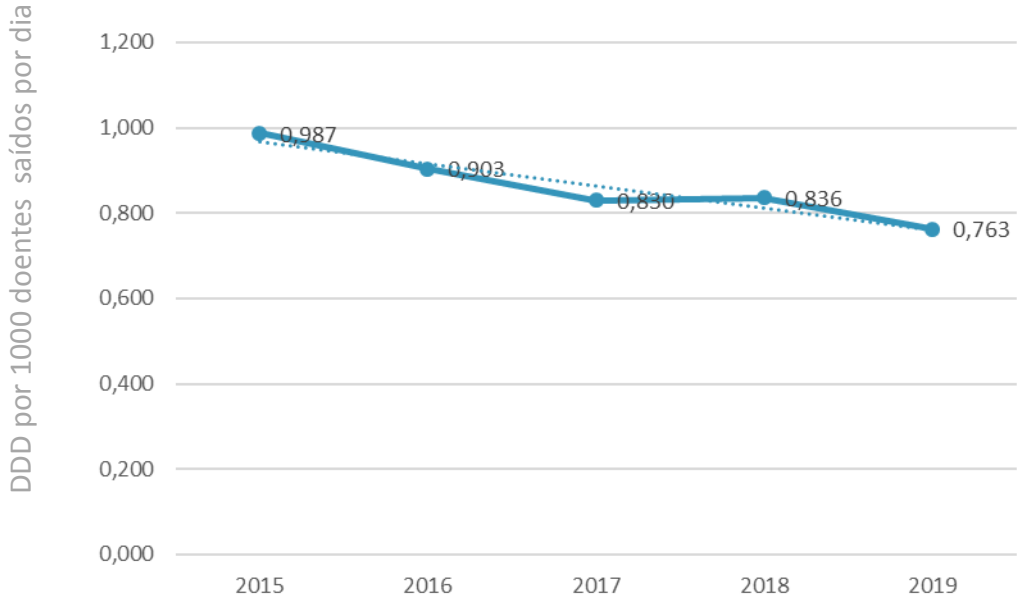
Fonte: INFARMED

Consumo hospitalar de antibióticos

Consumo global de antibióticos em meio hospitalar por 1000 doentes saídos por dia



Consumo de carbapenemes em meio hospitalar por 1000 doentes saídos por dia



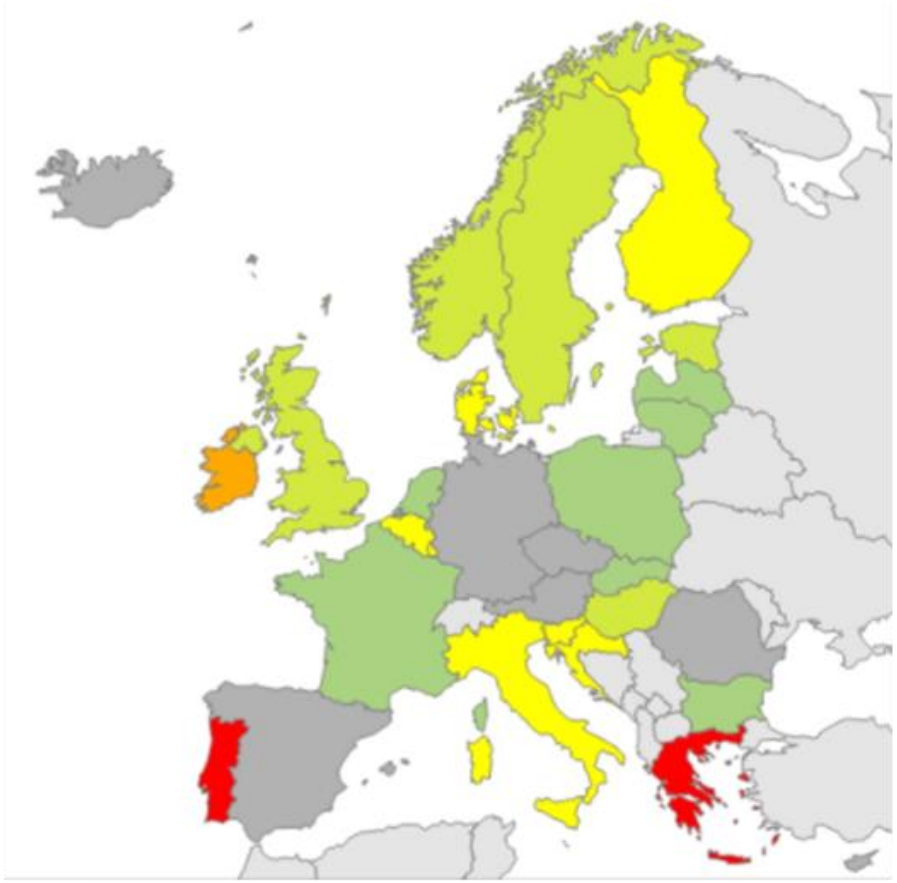
Apesar de Portugal se situar entre os países europeus com mais elevado consumo de carbapenemes, foi referido no último relatório do ECDC como **o único país, para além da Noruega, com redução do consumo desta classe de antibióticos estatisticamente significativa entre 2010 e 2019.**

No entanto, **entre janeiro e setembro de 2020**, registou-se aumento de consumo global de antibióticos e de carbapenemes por 1000 doentes saídos, nos Hospitais do SNS. entre janeiro e setembro de 2020, face ao período homólogo.

Fonte: INFARMED

Consumo hospitalar de carbapenemes em 2014 e em 2019,

nos países europeus (ESAC-Net, ECDC)



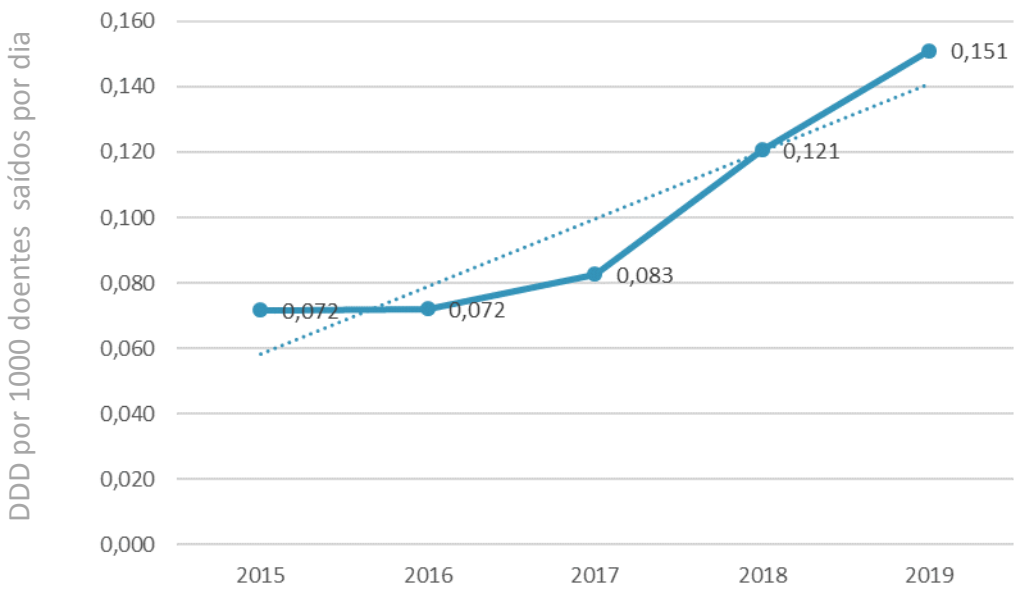
0,106 DHD

0,075 DHD

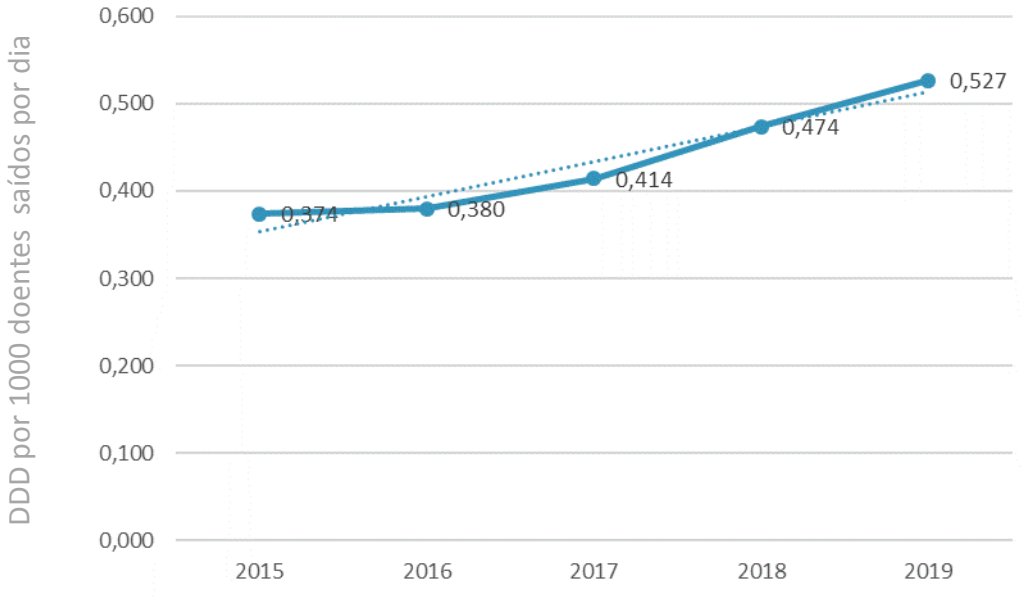
Fonte: ESAC-Net, ECDC

Consumo hospitalar de antibióticos

Consumo de polimixina B em meio hospitalar por 1000 doentes saídos por dia (ATC J01XB)



Consumo de antibióticos *Reserve* em meio hospitalar por 1000 doentes saídos por dia



Entre Janeiro e Junho de 2020, observou-se um aumento de +33,9% no consumo de polimixina B (colistimetato de sódio), em meio hospitalar (hospitais do SNS), por 1000 doentes saídos por dia, quando comparado com o período homólogo.

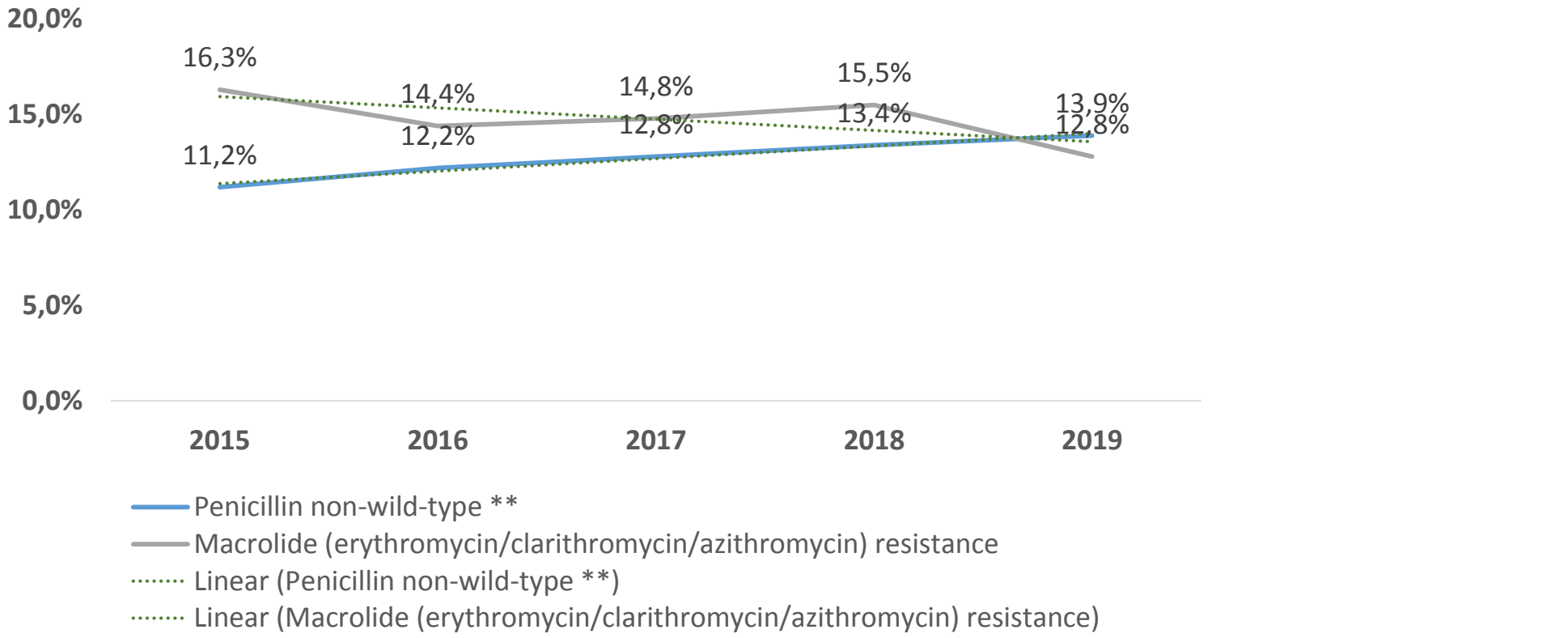
Fonte: INFARMED

Reduzir
resistências a antimicrobianos

Vigilância epidemiológica

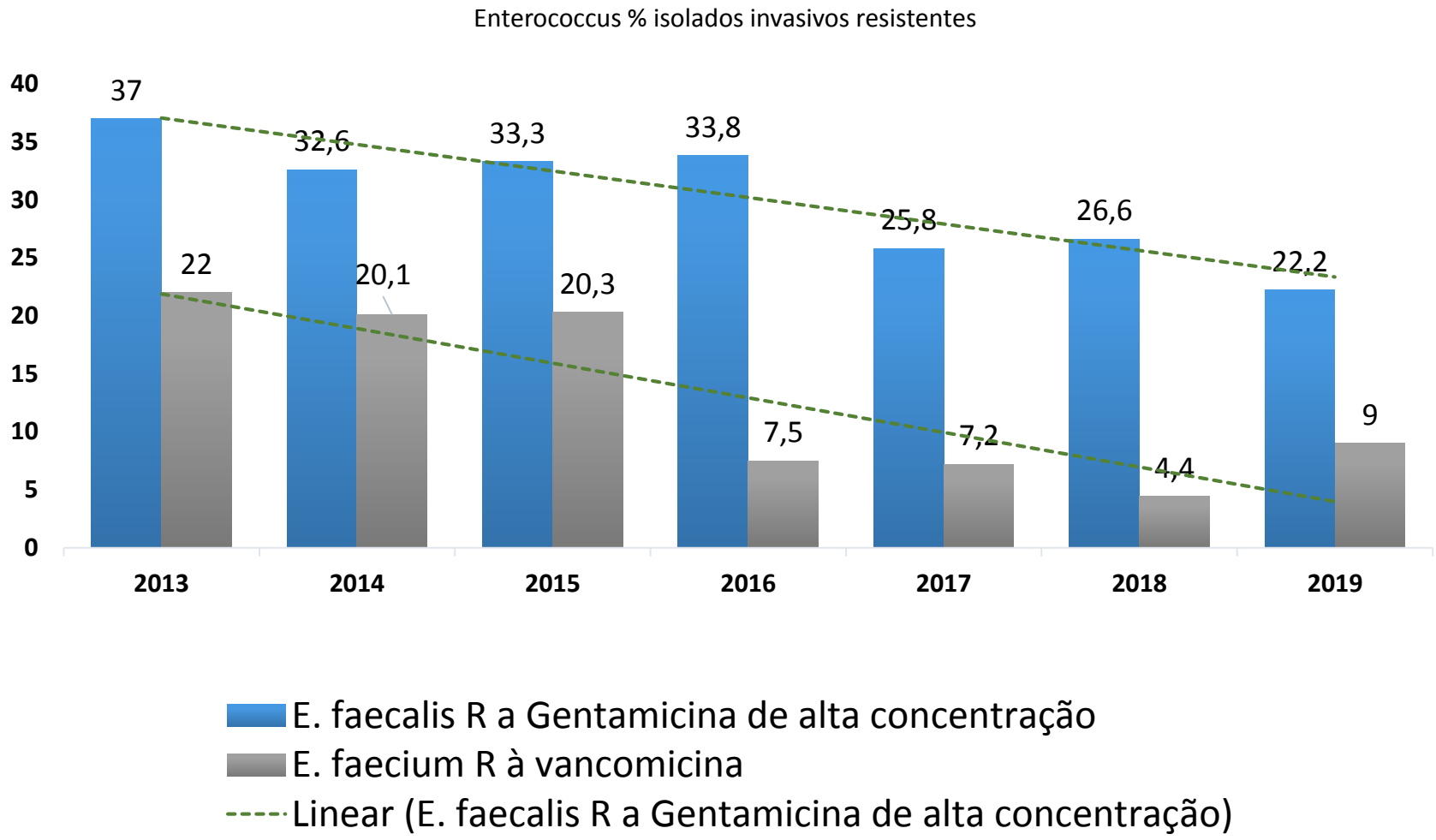
- Portugal é um dos 30 países que reporta dados de vigilância de resistências a antimicrobianos para o **European Antimicrobial Resistance Surveillance Network (EARS-Net)** do ECDC, acerca de: *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter species, Streptococcus pneumoniae, Staphylococcus aureus, Enterococcus faecalis e Enterococcus faecium*. (Decisão nº 1082/2013/EU), regulada em Portugal pela Norma 004/2013 (V. 2015) da DGS, no âmbito da colaboração entre o INSA e a DGS/PPCIRA.
- O ECDC categorizou a **representatividade de Portugal** no que se refere à amostra populacional, número de laboratórios hospitalares e isolados bacterianos, **como elevada**, participando nesta rede de vigilância cerca de uma centena de laboratórios, usando as orientações clínicas para determinação das categorias de suscetibilidade aos antimicrobianos definidas pelo EUCAST.
- Adicionalmente, temos sistema Lab/PPCIRA/DGS/INSA de relato imediato de microrganismos alerta e de analise de surtos

Resistência do *Streptococus pneumoniae* a penicilina e a macrólidos, 2015-2019



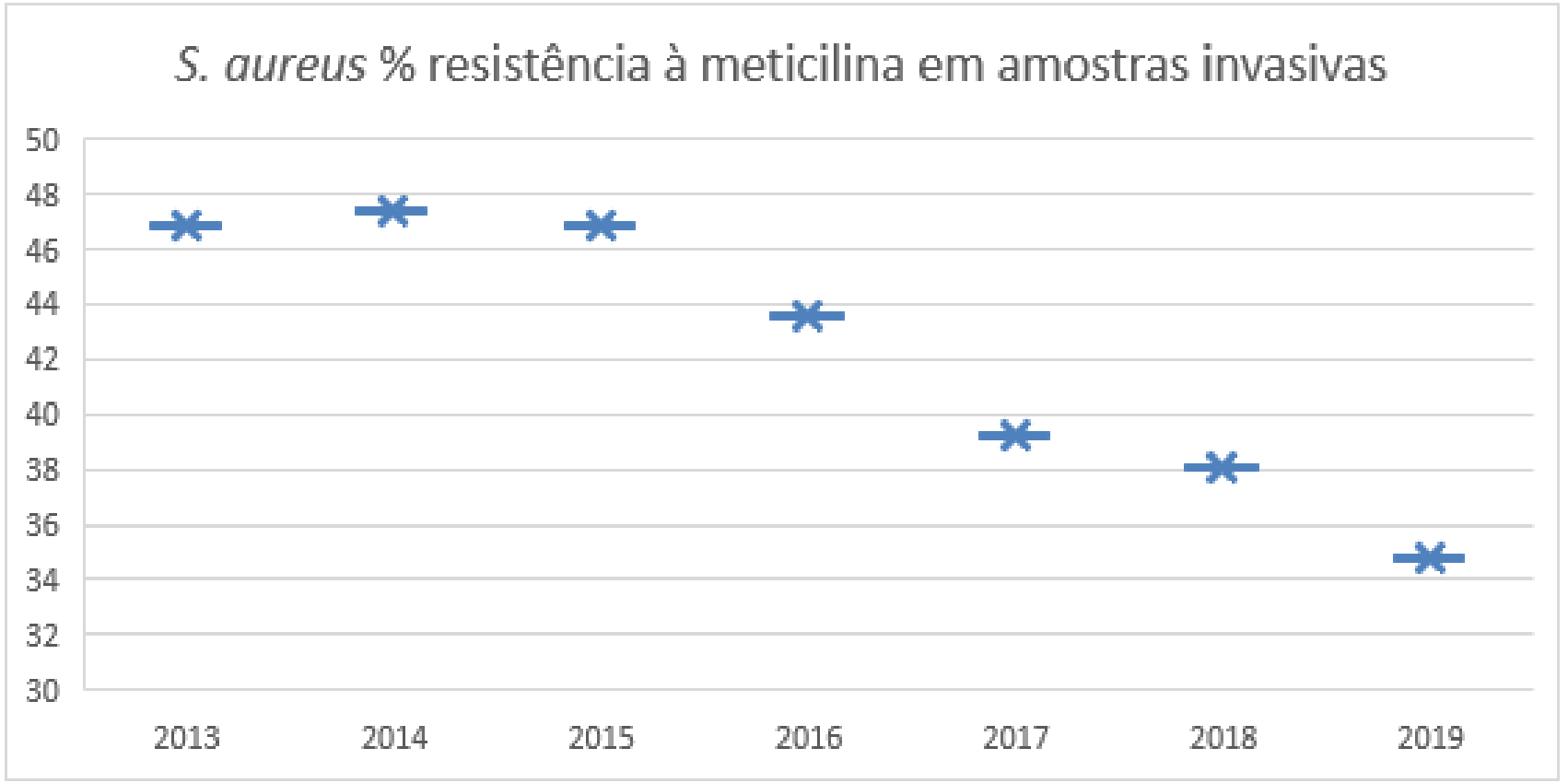
Fonte: Notificação pela Norma 004/2013 (V.2015)/DGS; INSA.

Enterococcus faecalis resistente à gentamicina de alta concentração e *Enterococcus faecium* resistente à vancomicina 2013-2019



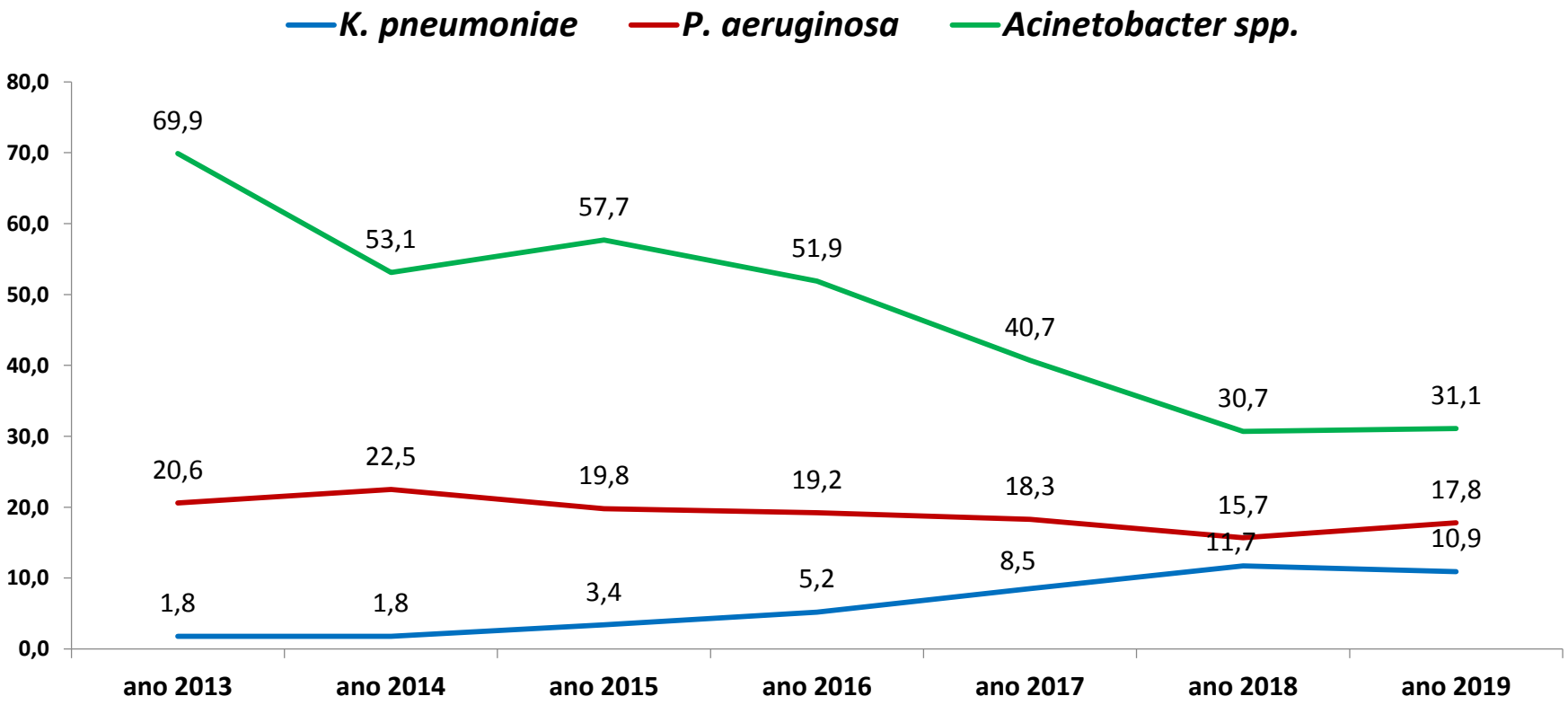
Fonte: Notificação pela Norma 004/2013 (V.2015)/DGS; INSA.

Taxa de resistência do Staphylococcus aureus à meticilina



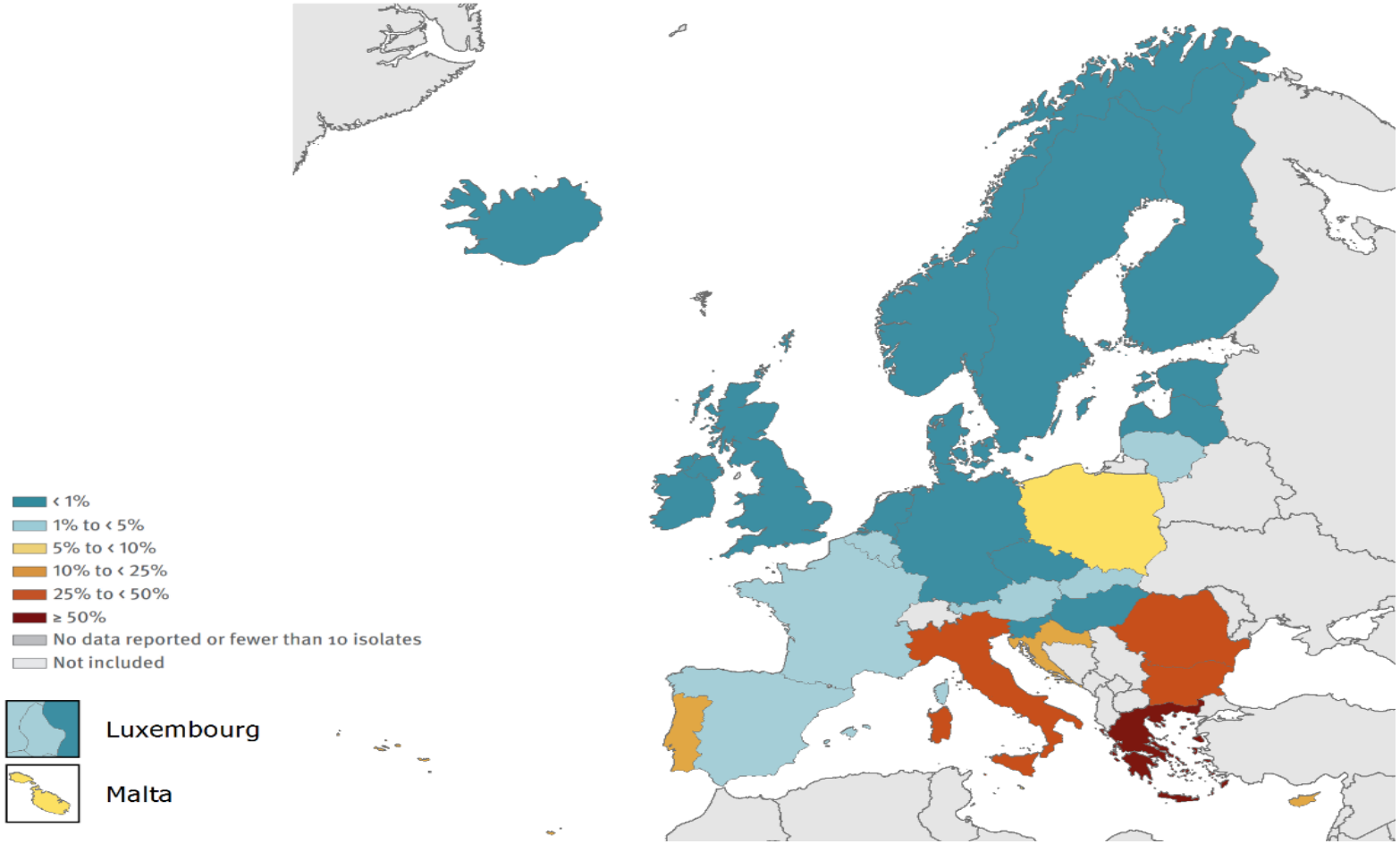
Fonte: Notificação pela Norma 004/2013 (V.2015)/DGS; INSA.

Evolução da resistência de *Pseudomonas aeruginosa*, *Acinetobacter* spp e *Klebsiella pneumoniae* aos carbapenemes, entre 2013-2019



Fonte: Notificação pela Norma 004/2013 (V.2015)/DGS; INSA.

Percentagem de isolados invasivos de *Klebsiella pneumoniae* resistente a carbapenemes (imipenem e/ou meropenem), nos países europeus, em 2019



Fonte: ECDC, EARS-Net 2019 data

Why didn´t the reduction in antimicrobial consumption produce a more significant reduction of the AMR rate?

AMR determinants go far beyond antimicrobial consumption

The causes of the fast increasing global resistome and the resulting AMR crisis:

1) Overpopulation, enhanced global migration and global misuse of antibiotics by laymen and professionals
2) Excessive use of antibiotics in animals (food, pets, aquatic)
3) Inadequate hygiene standards in health care, agriculture, food industries and stock farming, etc.
4) Senseless cost reduction or ignoring necessary investigations in health care (e.g. hospitals)
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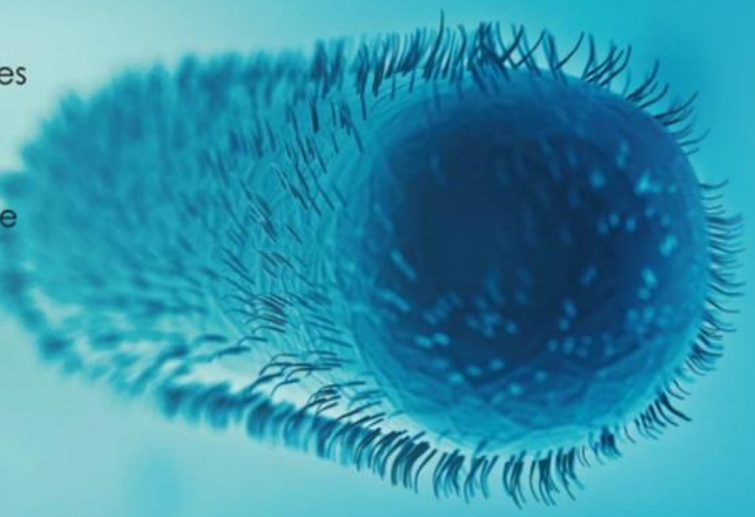


AMR: Antimicrobial crisis, particularly antibiotic crisis
FBR: Foreign body reaction

4 papers to help my thesis

antibiotics

MDPI

Article

Determinants of Antimicrobial Resistance among the Different European Countries: More than Human and Animal Antimicrobial Consumption

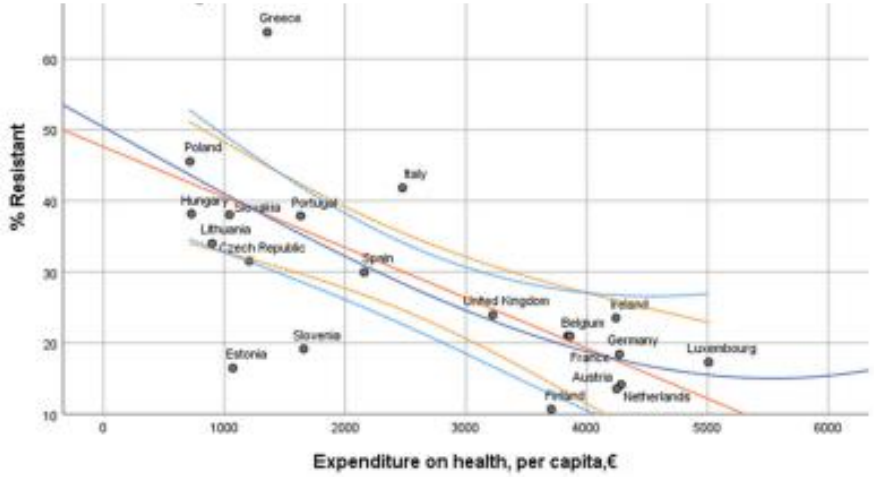
Ana C. Silva [1,2,*], Paulo Jorge Nogueira [1,3] and José-Artur Paiva [4,5,6,7]

- The study's goal was to assess AMR drivers across different European countries and quantify their possible contributions using the latest data available. Using the ESAC-Net (European Surveillance of Antimicrobial Consumption Network) database, the ESVAC (European Surveillance of Veterinary Antimicrobial Consumption) database and the OECD (Organisation for Economic Cooperation and Development) information, a dataset including 23 European countries was created.
- Associations between AMR and potential contributing factors were assessed using bivariate correlation and multiple linear regression models for multivariable analyses.

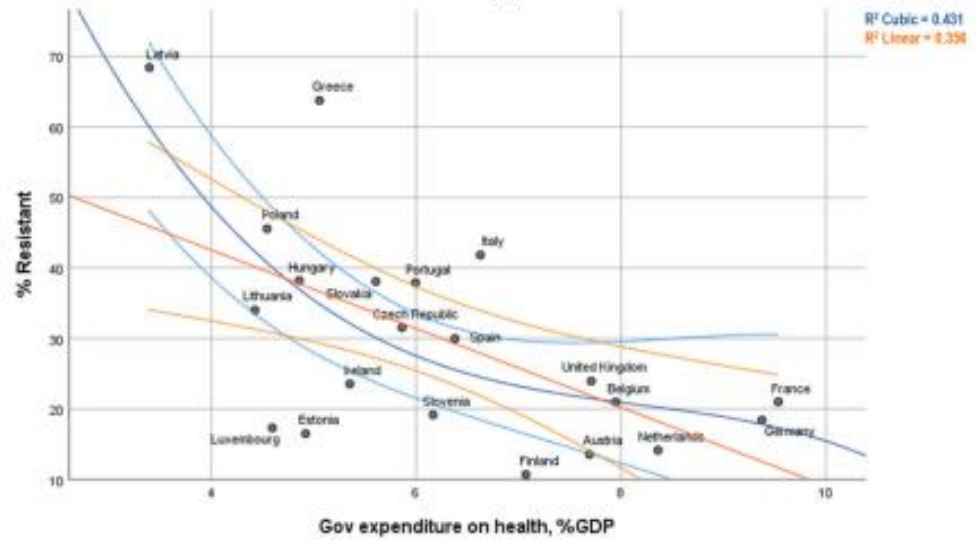
Conclusions

Study and understand the heterogeneity of socio-economic conditions and health systems across Europe and the huge variation in AMR rate among European countries may allow us to acknowledge better the relative importance of different possible drivers of AMR

- Factors associated with the rate of AMR among European countries are:
  - human ambulatory consumption of antibiotics
  - per capita expenditure on health.
- Meaning that the higher human ambulatory consumption of antibiotics and the lower the per capita expenditure on health are, the higher the AMR is.
- Both variables together explain 74% of AMR variation.
- Additionally, the higher the % of private health expenditure among global health expenditures, the higher the rate of AMR.



(a)



(b)

Other factors associated with AMR

- Our study shows that **higher human ambulatory consumption of antibiotics, lower per capita expenditure on health, and a higher percentage of private health expenditure** are associated with a higher rate of antimicrobial resistance.
- Low per capita expenditure on health may be a surrogate of worse healthcare conditions—infrastructure, human resources, and organization.
- A high percentage of private health expenditure may be a surrogate of less regulated antimicrobial prescriptions

- It may be that a quasi-total focus put on reducing antibiotic consumption as the most important factors contributing to antimicrobial resistance may be a deviant focus, as resistance transmission may be paramount for antimicrobial resistance levels.
- **Increasing public expenditure on healthcare, promoting interventions to improve sanitation, infection control and prevention, adequate human resources, better infrastructure are necessary to tackle antimicrobial resistance at the European scale.**

Ana C Silva, Paulo J Nogueira, José-Artur Paiva
Antibiotics 2021, 10, 834. https://doi.org/10.3390/antibiotics10070834

AMR determinants go far beyond antimicrobial consumption and include socioeconomic and health organisation factors

Although antibiotic usage is an important driver for increasing antimicrobial resistance levels, the spreads of resistant bacteria or the genes that encode resistance are likely to be at least as important in the dissemination and prevalence of antimicrobial resistance .

Holmes AH et al. Lancet 2016, 387, 176–187

The quality and performance of health systems and several socio-economic factors may significantly impact the rate of transmission of multidrug-resistant microorganisms and even in the etiquette of antibiotic utilization

Collignon P et al. PLoS ONE 2015, 10, e0116746

We need a One Society political vison and strategy

AMR determinants go far beyond antimicrobial consumption

The causes of the fast increasing global resistome and the resulting AMR crisis:

1) Overpopulation, enhanced global migration and global misuse of antibiotics by laymen and professionals
2) Excessive use of antibiotics in animals (food, pets, aquatic)
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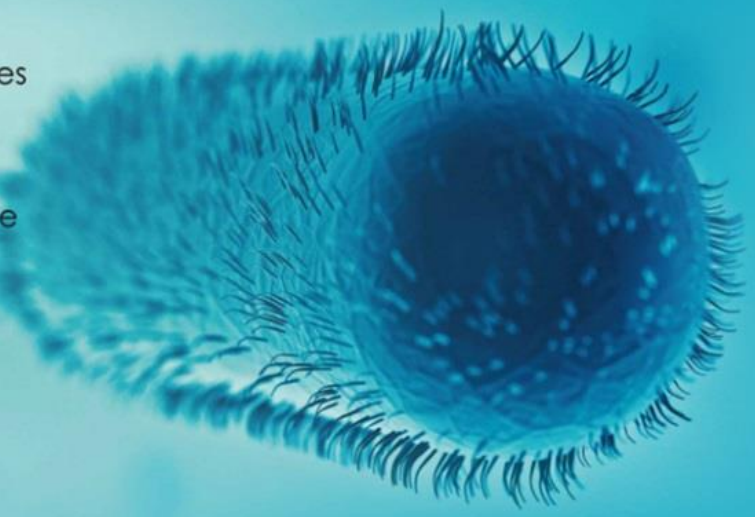
8) Missing or delayed translation and implementation of alternative, complementary drug-free antimicrobial strategies



AMR: Antimicrobial crisis, particularly antibiotic crisis
FBR: Foreign body reaction

PNAS

Global increase and geographic convergence in antibiotic consumption between 2000 and 2015

Eili Y. Klein[a,b,c,1], Thomas P. Van Boeckel[d], Elena M. Martinez[a], Suraj Pant[a], Sumanth Gandra[a], Simon A. Levin[e,f,g,1], Herman Goossens[h], and Ramanan Laxminarayan[a,f,i]

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Contributed by Simon A. Levin, February 23, 2018 (sent for review October 3, 2017; reviewed by Bruce R. Levin and Dominique L. Monnet)

PNAS 2018; 115 (15): E3463-70

Convergent antimicrobial consumption

- Between 2000 and 2015, **antibiotic consumption, expressed in DDD, increased 65%, and the antibiotic consumption rate increased 39%**
- **The increase was driven by low- and middle-income countries (LMICs),** where rising consumption was **correlated with gross domestic product per capita** (GDPPC) growth (P = 0.004).
- In high-income countries (HICs), although overall consumption increased modestly, DDDs per 1,000 inhabitants per day fell 4%, and there was no correlation with GDPPC.
- Of particular concern was the rapid increase in the use of last-resort compounds, both in HICs and LMICs, such as glycylcyclines, oxazolidinones, carbapenems, and polymyxins.
- Although antibiotic consumption rates in most LMICs remain lower than in HICs despite higher bacterial disease burden, **consumption in LMICs is rapidly converging to rates similar to HICs.**
- Reducing global consumption is critical for reducing the threat of antibiotic resistance, but reduction efforts must balance access limitations in LMICs and take account of local and global resistance patterns.

Klein EY et al. Proc. Natl. Acad. Sci. USA 2018, 115, E3463–E3470

Global antibiotic consumption by country

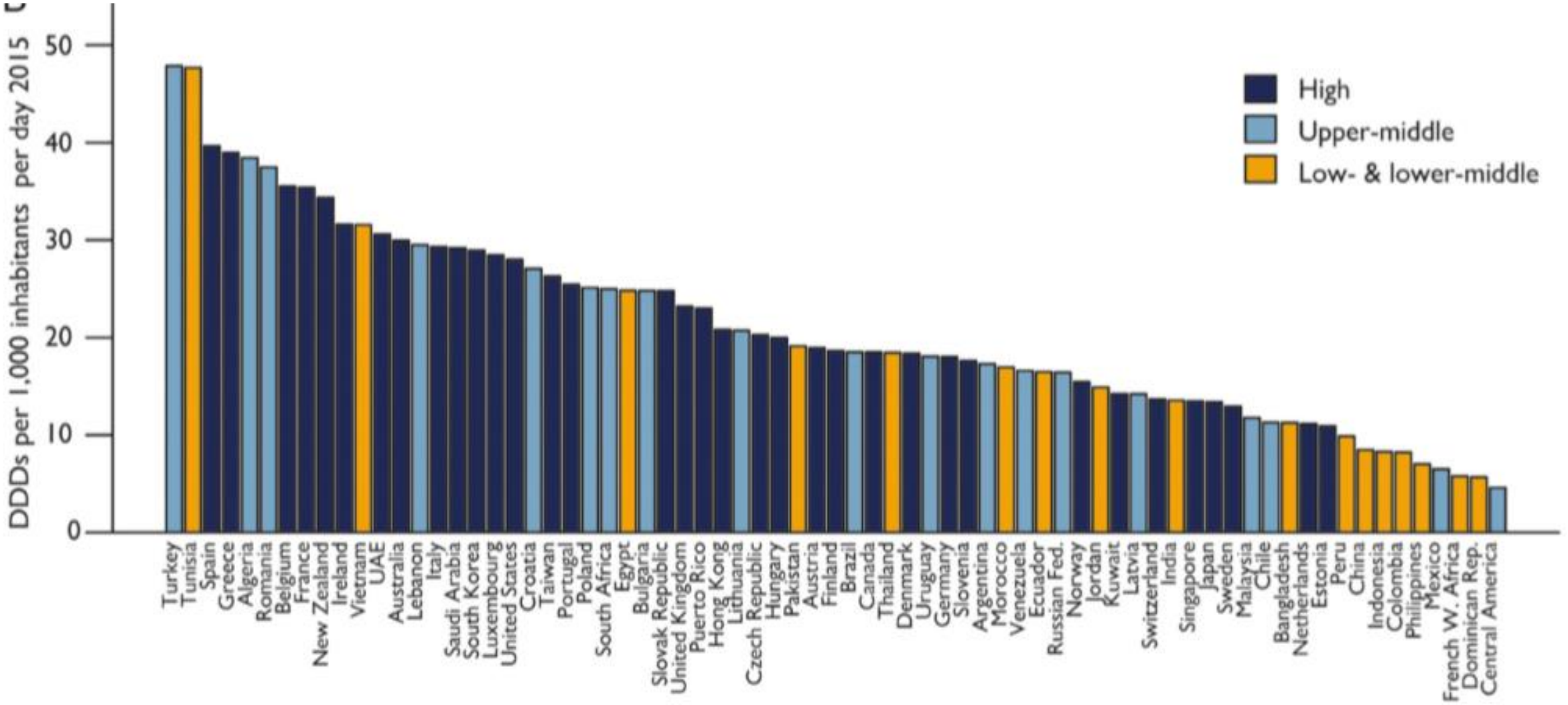
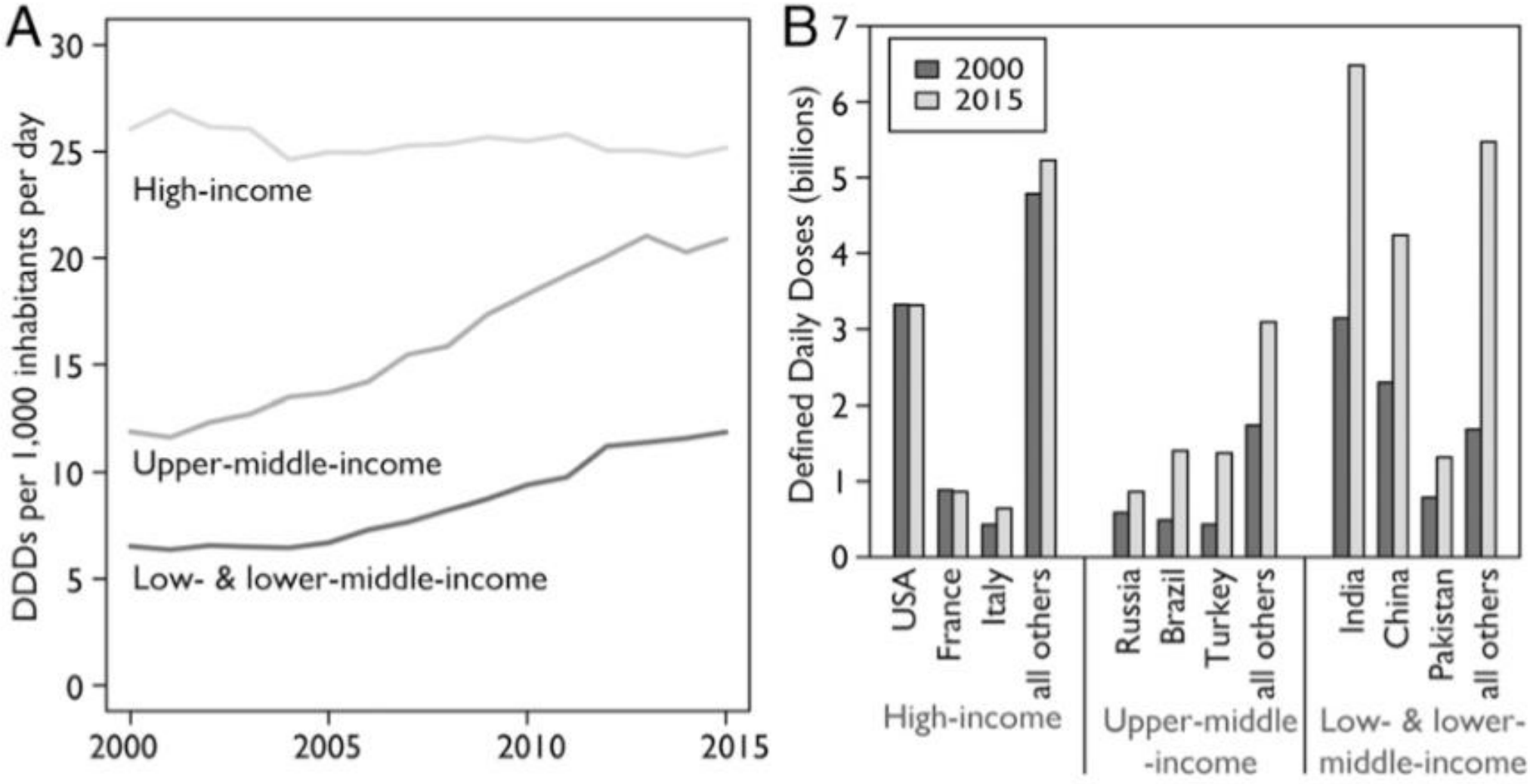


Fig. 1. Global antibiotic consumption by country: 2000–2015. (*A*) Change in the national antibiotic consumption rate between 2000 and 2015 in DDDs per

Antimicrobial consumption in LMICs is rapidly converging to rates similar to HICs



Projections of global antibiotic consumption in 2030, assuming no policy changes, were up to 200% higher than in 2015

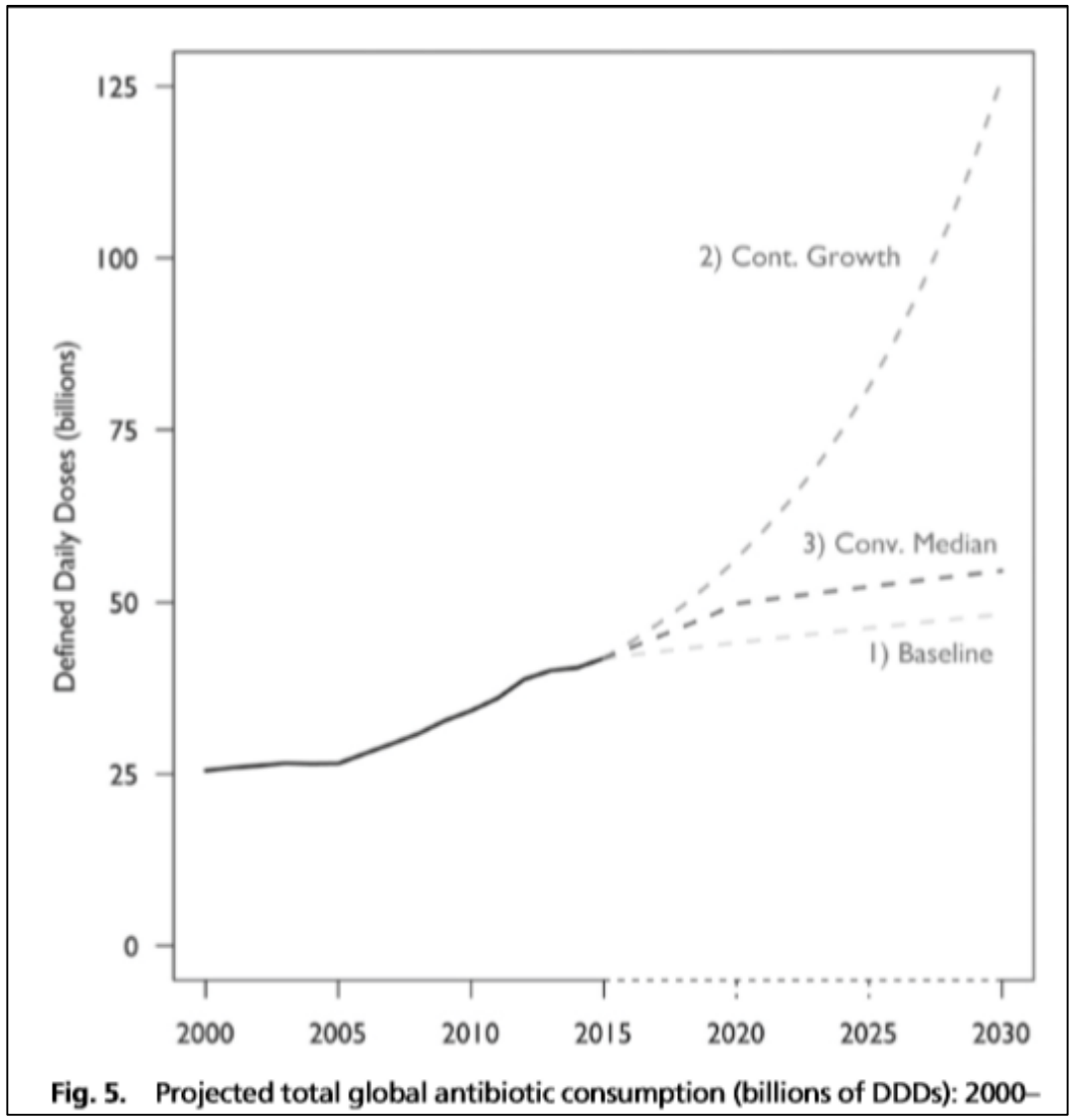


Fig. 5. Projected total global antibiotic consumption (billions of DDDs): 2000–

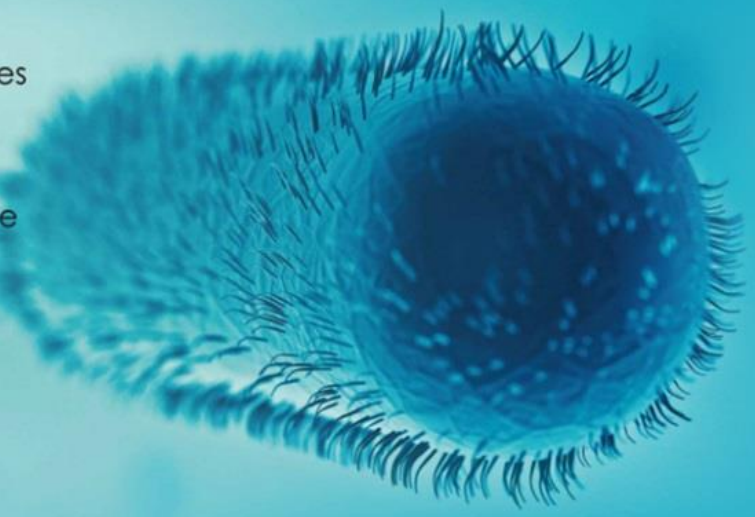
- With antibiotic consumption increasing worldwide, the challenge posed by antibiotic resistance is likely to get worse.
- As with climate change, there may be an unknown tipping point, and this could herald a future without effective antibiotics.
- Even in the absence of tipping points, the decline of antibiotic effectiveness represents a major threat to human health.
- **Radical rethinking of policies to reduce consumption is necessary, including major investments in improved hygiene, sanitation, vaccination, and access to diagnostic tools both to prevent unnecessary antibiotic use and to decrease the burden of infectious disease.**
- Immediate strategies are necessary to reduce mortality among the millions of people who die from resistant infections annually.
- While more study is needed to understand the risks of radical reductions in consumption,

We need an One World vision and strategy

AMR determinants go far beyond antimicrobial consumption

The causes of the fast increasing global resistome and the resulting AMR crisis:

1) Overpopulation, enhanced global migration and global misuse of antibiotics by laymen and professionals
2) Excessive use of antibiotics in animals (food, pets, aquatic)
3) Inadequate hygiene standards in health care, agriculture, food industries and stock farming, etc.
4) Senseless cost reduction or ignoring necessary investigations in health care (e.g. hospitals)
5) Increased number of class 3 medical devices - potential risk of foreign material-associated infections
6) Grossly negligent not to continue research and development of new antibiotics
7) Lacking knowledge about AMR mechanisms, particularly in context of FBR-associated colonization, biofilm formation and infection
8) Missing or delayed translation and implementation of alternative, complementary drug-free antimicrobial strategies



AMR: Antimicrobial crisis, particularly antibiotic crisis
FBR: Foreign body reaction

https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2018-trends-2010-2018-tenth-esvac-report_en.pdf

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sales of veterinary antimicrobial agents in 31 European countries in 2018

Trends from 2010 to 2018
Tenth ESVAC report

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

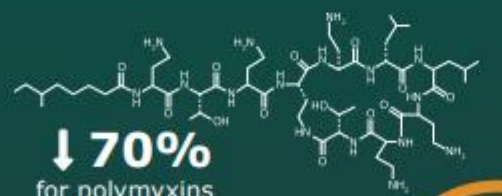
Responsible use of antibiotics protects animals and people

Europe is on the right track to fight antibiotic resistance...

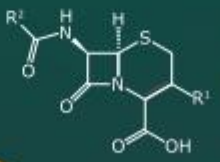
2011-2018
Sales of antibiotics for veterinary use are declining

↓ 34%
overall sales in 25 of the 31 countries in the ESVAC network

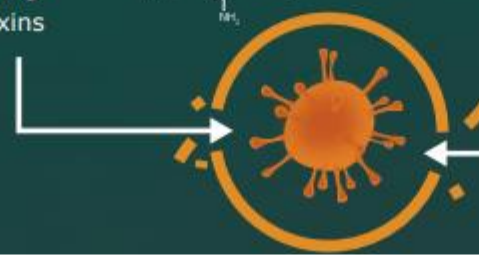
↓ -50%
in some countries



↓ 70%
for polymyxins

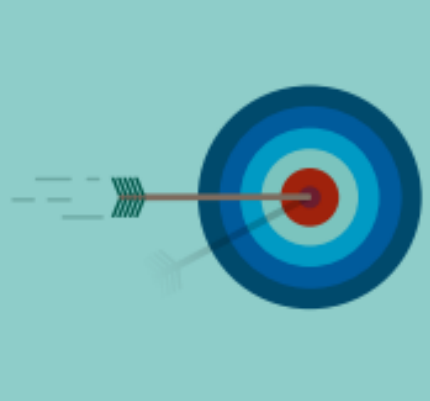


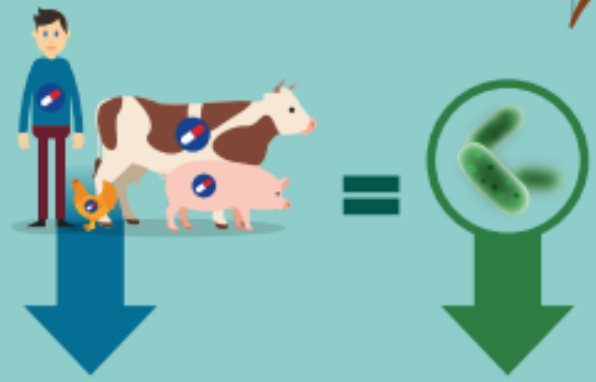
↓ 24%
for 3rd- and 4th-generation cephalosporins



...but more needs to be done

50% decrease in some countries indicates the **huge potential** for reducing the use of antibiotics in animals in other countries





Less antibiotics in animals and humans = **lower risk** of bacteria becoming resistant

Antibiotic resistance can spread from animals to people and viceversa

When antibiotics no longer work, people and animals' lives are at risk

- Previous reports of food products from animal origin,
- Lettuce is a vegetable that is commonly consumed fresh and not subjected to any cooking process
- Detection of a mobile colistin resistance gene in a raw vegetable reinforces the widespread distribution of mcr-1, and the need to promote a global and concerted strategy to contain the spread of this resistance mechanism.

Microorganisms 2020, 8, 429;
doi:10.3390/microorganisms8030429

microorganisms

MDPI

Brief Report

Plasmid-Mediated Colistin Resistance (*mcr-1*) in *Escherichia coli* from Non-Imported Fresh Vegetables for Human Consumption in Portugal

Vera Manageiro [1,2,†], Daniela Jones-Dias [1,2,†], Eugénia Ferreira [1] and Manuela Caniça [1,*]

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We need an One Health vision and strategy

One Health Global Efforts

- the 2016 United Nations Political Declaration on AMR
- the 2015 WHO Global Action Plan on AMR, which was subsequently adopted by the World Animal Health Organisation (OIE) and the Food and Agriculture Organization (FAO).
- AMR has also been addressed in the G7 and G20 forums.

- European Council conclusions of 17 June 2016 call for a new and comprehensive EU action plan on AMR based on the One Health approach. This new action plan builds on the 2011 action plan, its evaluation, the feedback on the roadmap and an open public consultation.

http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-antimicrobial-resistance

Homologo
3/10/2019
Nuno Lacasta
Presidente

Homologo
3/10/2019
Fernando Bernardo
Diretor Geral

Aprovo/Homologo
3/10/2019
Graça Freitas
Diretora-Geral da Saúde

PLANO NACIONAL DE COMBATE À RESISTÊNCIA AOS ANTIMICROBIANOS 2019-2023

2019

"UMA SÓ SAÚDE"

Precisamos de um orgão de governação interinstitucional para a implementação do Plano

Principais mensagens

- Antibiotic consumption is considered the main force driving the increase in AMR

- AMR determinants go far beyond antimicrobial consumption
- They include socioeconomic and human health organizational factors

- Our vision and strategy must be:
  - One Society and health policy based
  - One World
  - One Health

We have a Plan, we need to review it, expand it and create a Governance Alliance