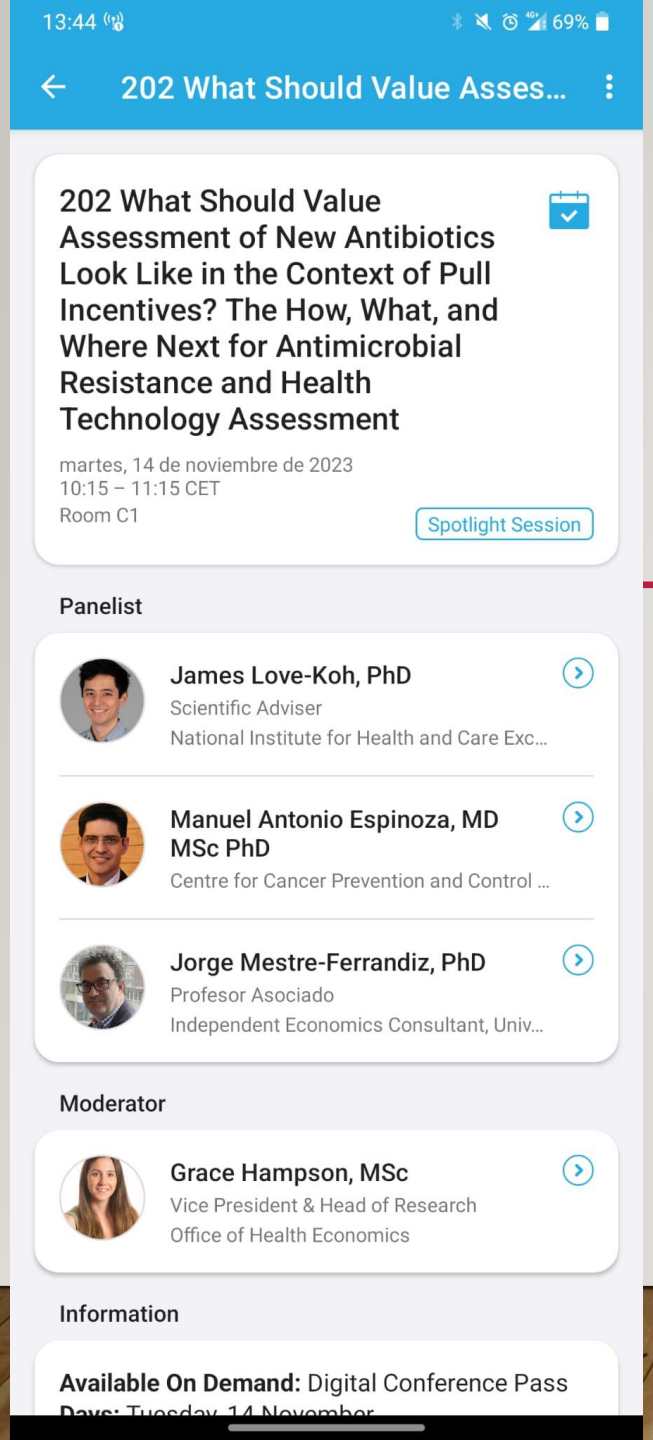

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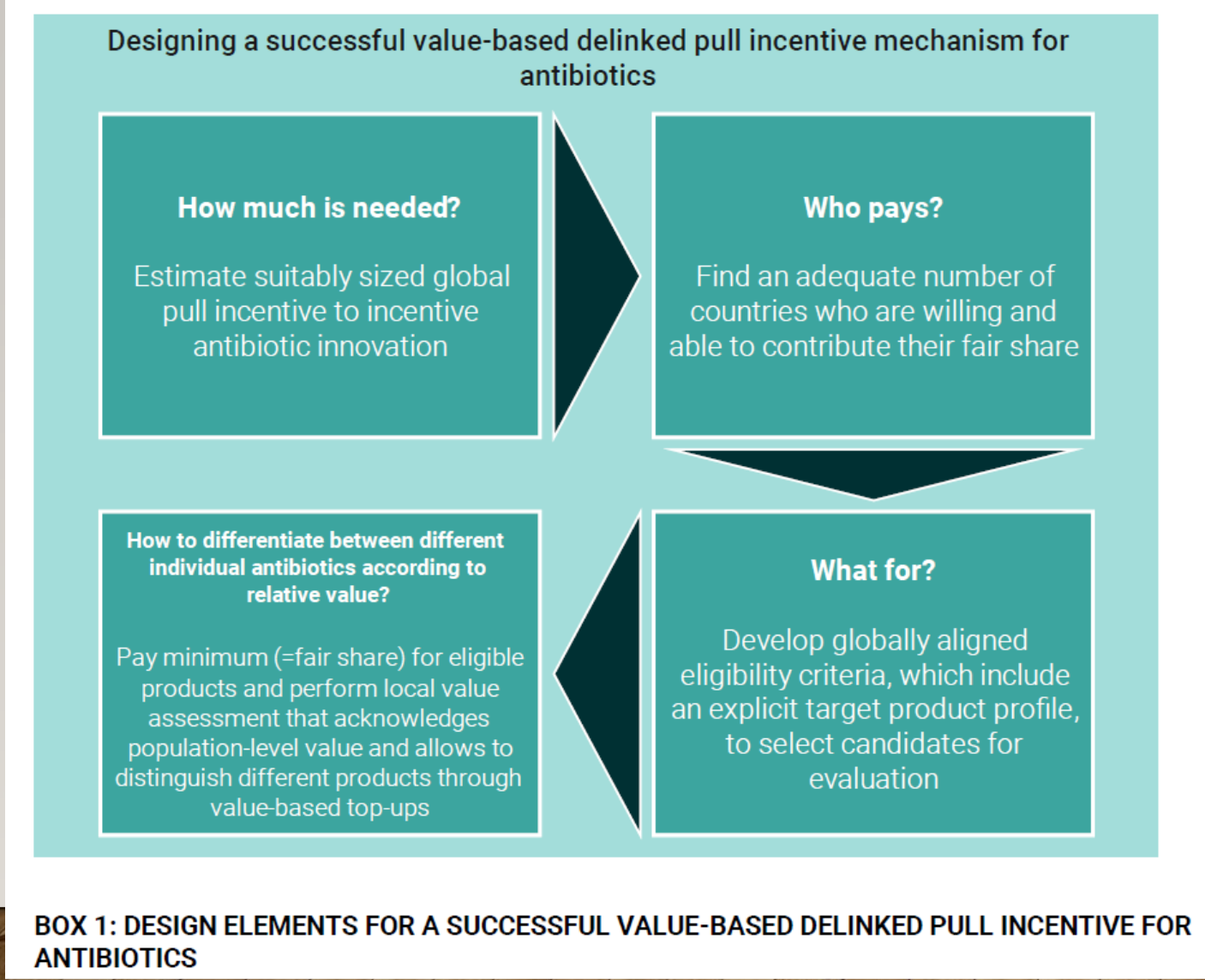
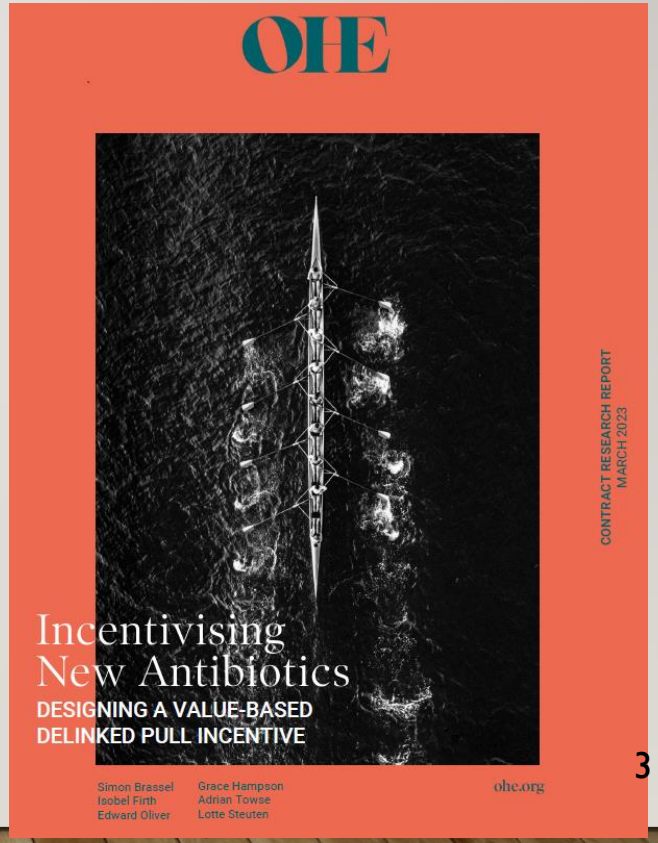
4. WHAT ARE THE NEXT STEPS FOR VALUE ASSESSMENT AND PULL INCENTIVES IN EUROPE?

- **Some context**
- At European level
- At national level

FRAMEWORK TO THINK ABOUT THE QUESTION



BOX 1: DESIGN ELEMENTS FOR A SUCCESSFUL VALUE-BASED DELINKED PULL INCENTIVE FOR ANTIBIOTICS



6 REQUIREMENTS FOR AN EFFECTIVE PULL INCENTIVE

I. needs a way to determine the **minimum size** of the global incentive that would be large enough to attract R&D investment.

II. needs a way to **share this incentive** across a reasonable group of contributo countries

III. an a **priori-defined description** of what products will be rewarded

IV. mechanism to **assess product eligibility** (i.e., whether or not it meets the a priori requirements)

V. needs an agreed mechanism to pay the reward defined through a **contracting** process

VI. should be able to **distinguish higher from lower value products** to incentive high-value innovation.

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LONG AWAITED REGULATION WITH SPECIFIC RECOMMENDATIONS FOR AMR

EUROPEAN
COMMISSION

Brussels, 26.4.2023
COM(2023) 193 final

2023/0131 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

(Text with EEA relevance)

{SEC(2023) 390 final} - {SWD(2023) 192 final} - {SWD(2023) 193 final} - {SWD(2023) 194 final}

As a key part of the EU's comprehensive response to these challenges, the Commission is proposing an ambitious revision of the EU pharmaceutical legislation to achieve five main objectives:

1. Make sure all patients across the EU have timely and equitable access to safe, effective, and affordable medicines.
2. Enhance security of supply and ensure medicines are always available to patients, regardless of where they live in the EU.
3. Offer an attractive, innovation- and competitiveness friendly environment for research, development, and production of medicines in Europe.
4. Make medicines more environmentally sustainable.
5. Address antimicrobial resistance (AMR) through a One Health approach, encompassing human health, animal health and the environment.

EUROPEAN
COMMISSION

Brussels, 26.4.2023
COM(2023) 190 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance

EUROPEAN
COMMISSION

Brussels, 26.4.2023
COM(2023) 191 final

2023/0125 (NLE)

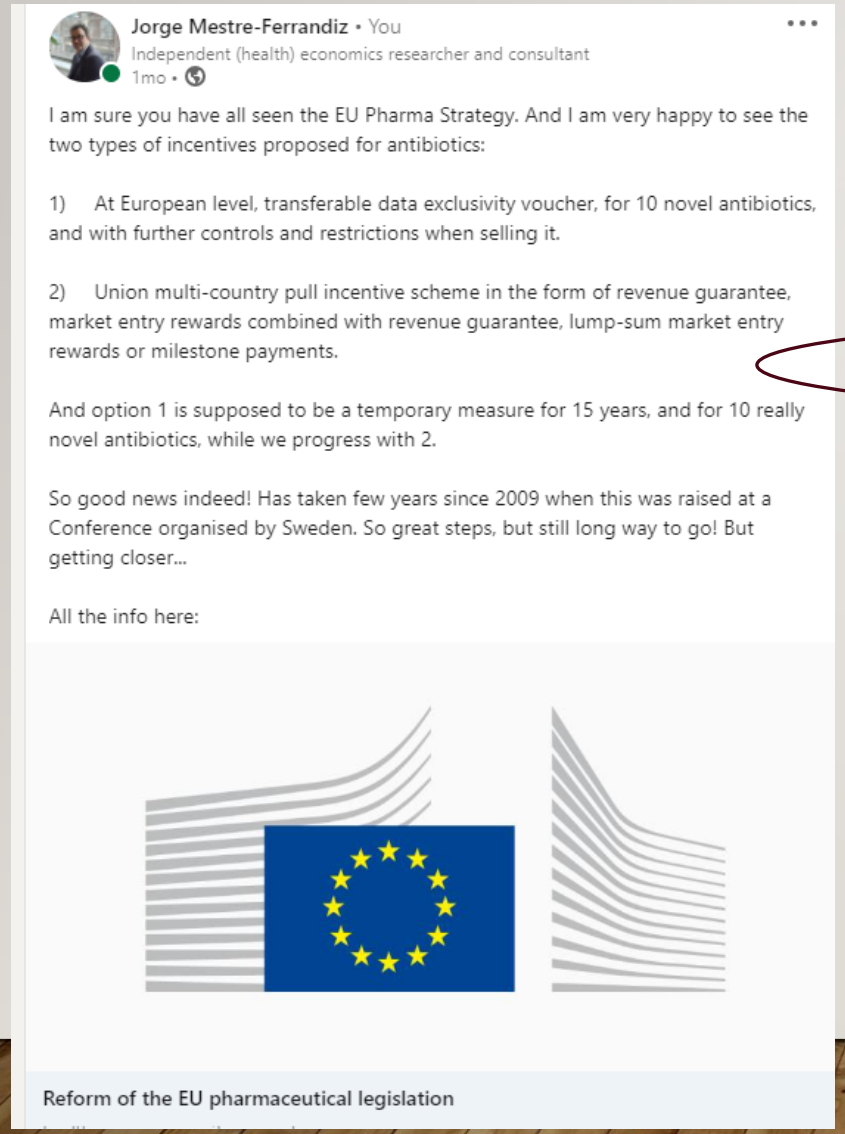
Proposal for a

COUNCIL RECOMMENDATION

on stepping up EU actions to combat antimicrobial resistance in a One Health approach

{SWD(2023) 190 final}

I WOULD ARGUE THESE ARE GOOD NEWS (NOT WITHOUT SOME 'DEBATE' ABOUT THE TRANSFERABLE VOUCHER…)



Development of, access to, and prudent use of antimicrobials

Incentives for development of and access to antimicrobials

The EU needs both push incentives (i.e. funding for antimicrobial research and innovation, primarily via research grants and partnerships) and pull incentives (both regulatory and financial) to reward successful development and secure access to effective antimicrobials. The Commission is proposing the following pull incentives:

- Temporary mechanism consisting of transferable data exclusivity vouchers, for the development of novel antimicrobials to be granted and used under strict conditions.
- Procurement mechanisms for access to new and existing antimicrobials that would guarantee revenue for antimicrobials marketing authorisation holders, regardless of sales volumes.

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{SEC(2023) 190 final} - {SWD(2023) 102 final} - {SWD(2023) 103 final} - {SWD(2023) 104 final}

CHAPTER III
INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'

Article 40

Granting the right to a transferable data exclusivity voucher

1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.

2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection for one authorised medicinal product.

3. An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:

   (a) it represents a new class of antimicrobials;

   (b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

   (c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.

   In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.

4. To be granted the voucher by the Commission, the applicant shall:

   (a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;

   (b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.

   Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.

Article 41

Transfer and use of the voucher

1. A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.

   A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection.

   A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.

2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.

3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.

4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available.

Article 42

Validity of the voucher

1. A voucher shall cease to be valid in the following cases:

   (a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product;

   (b) where it is not used within 5 years from the date it was granted.

2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.

3. Without prejudice to patent rights, or supplementary protection certificates[34], if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a

4. WHAT ARE THE NEXT STEPS FOR VALUE ASSESSMENT AND PULL INCENTIVES IN EUROPE?

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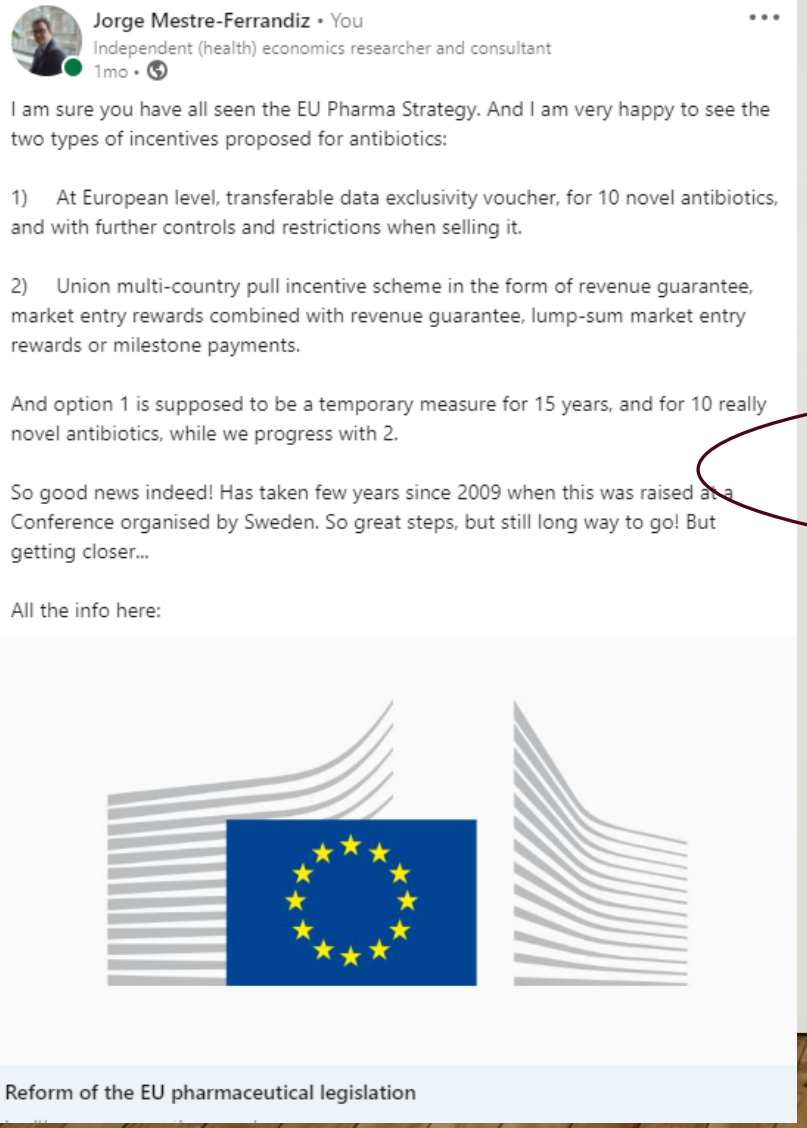
VARIOUS POSSIBILITIES



Jorge Mestre-Ferrandiz • You
Independent (health) economics researcher and consultant
1mo •

I am sure you have all seen the EU Pharma Strategy. And I am very happy to see the two types of incentives proposed for antibiotics:

1) At European level, transferable data exclusivity voucher, for 10 novel antibiotics, and with further controls and restrictions when selling it.

2) Union multi-country pull incentive scheme in the form of revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards or milestone payments.

And option 1 is supposed to be a temporary measure for 15 years, and for 10 really novel antibiotics, while we progress with 2.

So good news indeed! Has taken few years since 2009 when this was raised at a Conference organised by Sweden. So great steps, but still long way to go! But getting closer...

All the info here:

Reform of the EU pharmaceutical legislation

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Incentives for development of and access to antimicrobials

The EU needs both push incentives (i.e. funding for antimicrobial research and innovation, primarily via research grants and partnerships) and pull incentives (both regulatory and financial) to reward successful development and secure access to effective antimicrobials. The Commission is proposing the following pull incentives:

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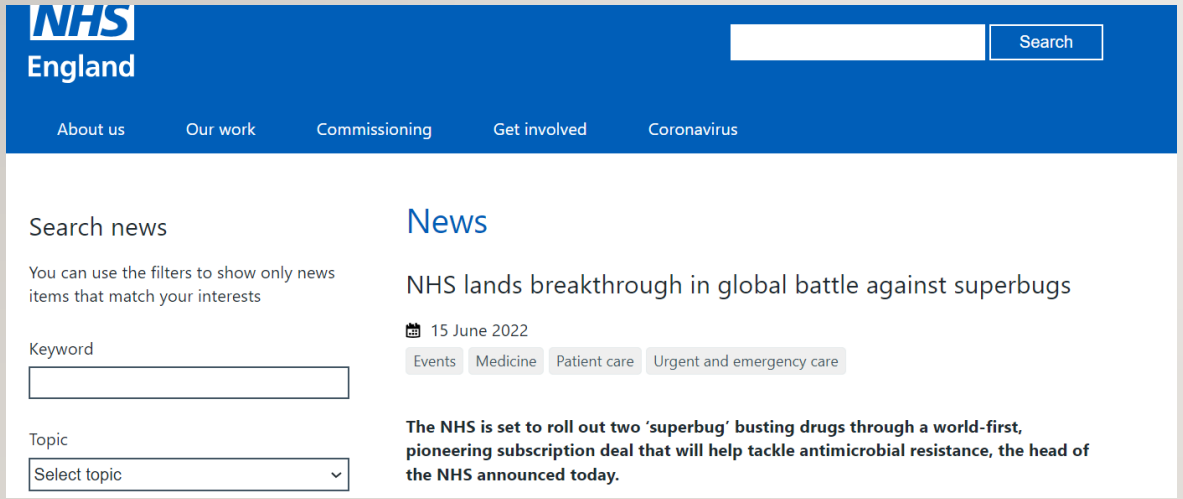
- Procurement mechanisms for access to new and existing antimicrobials that would guarantee revenue for antimicrobials marketing authorisation holders, regardless of sales volumes.

shortages.

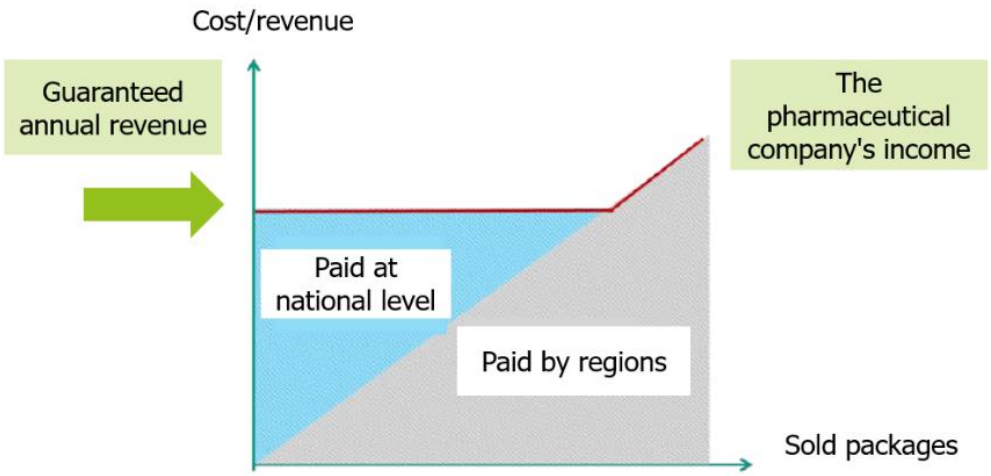
29. Contribute to the design and governance of a Union multi-country pull incentive scheme in order to improve innovation, development and access to antimicrobials. Such scheme could take the form of revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards or milestone payments. It should be implemented in a complementary manner to the regulatory framework applicable to medicinal products for human use.

IN PRACTICE, SO FAR, AND BROADLY SPEAKING, 2 MODELS USED IN EUROPE

- Existing vs pipeline products



The 2-page FAQ document (see links above) provides this really helpful figure. The key concept is that **Sweden is promising to pay at a national level the difference between actual regional sales and the guaranteed revenue**. If more units are needed (inflection point of the red line shows this), the company's income goes up:



…AND WE CAN ALSO HAVE TWEAKS TO THE SYSTEM

- HTA
- P&R
- Exclusions from DRGs
- …

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