The antibiotic Research & Development and Access chain

GLG information session on the antibacterial pipeline and access crisis, 17 May 2023

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As long as we use antibiotics, resistance will continue to emerge and we will need to develop new antibiotics.
The fragmented antibiotic Research & Development and Access chain
The antibiotic Research & Development and Access chain
Challenges to connecting the links in the chain

- Projects start without clear clinical or public health relevance
- Unresolved scientific challenges
- Lack of sustainable, long-term and targeted funding (time is spent on writing funding applications)
- Lack of experience on how to run a drug development project
- Lack of expertise on how to scale up project to proof of concept
- Lack of research coordination
- Lack of access to expert advice
- Lack of knowledge sharing (e.g., failures)

- Additional research prioritisation tools needed
- Insufficient research coordination and prioritisation by funders

- Locally diverging treatment guidelines in EU
- Use also guided by availability
- Unclear overview of needs/demand
- Lack of common lists of prioritized antibiotics
- Lack of (transnational) guidance for introducing new antibiotics

- Limited global surveillance

- Public health needs and prioritization
- Surveillance of resistance development
- Clinical needs, stewardship and use
- Procurement
- Production and supply chains
- Country registration
- Market approval

- Preclinical development
- Clinical development
- Discovery

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- High-Level Meeting on Antimicrobial Resistance 6–7 March 2023

- Preclinical development
- Clinical development
- Discovery

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- Limited global surveillance
Selected Challenges to connecting the links in the whole chain

- Projects start without clear clinical or public health relevance
- Lack of sustainable, long-term and targeted funding (time is spent on writing funding applications)
- Lack of expertise on how to scale up a project to proof of concept

Insufficient research coordination and prioritisation by funders

Unclear overview of needs/demands

- Preclinical development
- Clinical development
- Country registration
- Production and supply chains
- Procurement

Challenging recruitment of patients (time & costs)

Risk of bankruptcy despite successful approval (SMEs)

Uncertain and volume dependent revenues (at odds with stewardship efforts)

- The value of new antibiotics is not fully reflected in HTA

- Fragile supply chains with overreliance on few producers and countries
- Lack of supply chain transparency

- Short-term contracting
- Price pressure
- Fragmented and/or decentralised purchasing

- Public health needs and prioritisation

- Surveillance of resistance development

- Clinical needs, stewardship and use

- Access to new and existing antibiotics

- Market approval
Launch June
Challenges to connecting the links in the chain and suggested solutions

- Projects start without clear clinical or public health relevance
- Unresolved scientific challenges
- Lack of sustainable, long-term and targeted funding (time is spent on writing funding applications)
- Lack of experience on how to run a drug development project
- Lack of expertise on how to scale up project to proof of concept
- Lack of access to expert advice
- Lack of knowledge sharing (e.g., failures)

• Additional research prioritisation tools needed
• Insufficient research coordination and prioritisation by funders

• Strategic & EU-coordinated research prioritisation based on public health needs

• Locally diverging treatment guidelines in EU
• Use also guided by availability
• Unclear overview of needs/demand
• Lack of common lists of prioritized antibiotics
• Lack of (transnational) guidance for introducing new antibiotics

• Joint list of important antibiotics and common guidelines to increase market size
• Improve forecasting
• Improve diagnostic capacity

• Technical /regulatory support & project advice structure (e.g. HERA and/or EMA)
• Development “Cookbook”
• Targeted funding to overcome “valley of death” i.e. transfer from basic research to preclin/clinical studies (e.g. ENABLE)
• Invest in attracting young scientists to antibiotics field
• Data & experience sharing

• Early involvement of HTA agencies
• Reduce/abolish registration fees
• Mandatory registration and supply to all EU MS
• Accept old documentation for re-registration of older antibiotics
• E-labelling

• EU-common procurement principles
• Revenue guarantees contracting access
• Joint procurement
• Diversified contracting conditions beyond price, e.g. delivery security, contract duration and volume

• Pipeline coordinator (Incl. network of expertise)
• Milestone rewards

• Locally diverging treatment guidelines in EU
• Use also guided by availability
• Unclear overview of needs/demand
• Lack of common lists of prioritized antibiotics
• Lack of (transnational) guidance for introducing new antibiotics

• Limited global surveillance

• Initiate surveillance informing public health needs

• Pipeline coordinator (Incl. network of expertise)

• Difficulties in forecasting, insufficient capacity in SMEs

• Differentiated sourcing
• Increase transparency and oversight of supply chains
• Virtual stockpiling
• Strengthen production capacity in EU and globally
• Increase predictability for manufacturers

• EU-common procurement principles
• Revenue guarantees contracting access
• Joint procurement
• Diversified contracting conditions beyond price, e.g. delivery security, contract duration and volume

• Pipeline coordinator (Incl. network of expertise)
• Milestone rewards

• Short-term contracting
• Price pressure
• Rigid procurement regulation
• Fragmented and/or decentralised purchasing
• Lack of purchasing competence

• Non-profit development- and access initiative

• Incentives that delink revenue from volume & price (e.g. MER & subscription)
• Risk of bankruptcy despite successful approval (SMEs)

• Selective registration in most profitable markets
• Uncertain and volume dependent revenues (at odds with stewardship efforts)
• Lack of funding for distribution and post-approval studies
• Value of new antibiotics not fully reflected in HTA

• Risk of bankruptcy despite successful approval (SMEs)
• Challenging recruitment of patients
• Small patient groups allow only non-inferiority trials
• Lack of information on development costs
• Insufficient capacity in SMEs
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This material was developed in relation to the High-level meeting on AMR in Stockholm 6-7 March 2023.

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