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Title: Exploring the case for a standardised physical appearance of oral generic antibiotics: a summary of expert roundtable meetings

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Background

Previous research in LMICs revealed a wide variety of names and appearances of oral antibiotics leading to potential misidentification and confusion. This is particularly alarming considering the rise of AMR. The aim of this study was to conduct roundtable discussions with a wide range of international experts on the idea of using the appearance of oral medicines to improve their identification by consumers and healthcare professionals. This study was conducted as part of the ABACUS II project, a collaboration between 3 LMICs in Africa (Mozambique, Ghana, South-Africa), 3 LMICS in Asia

(Bangladesh, Vietnam, Thailand) and two European countries (the Netherlands, United Kingdom) (www.abacus-project.org).

Methods

Participants included pharmacists, policy-makers, regulators, public health experts, prescribers, nurses and representatives of the pharmaceutical industry. Five online roundtables meetings with 52 experts were conducted. An overview of the participants' expertise, geographical spread and focus of discussions is shown in Table 1. The meetings were held between October 2020 and April 2021 and lasted between 90 and 120 minutes. Participants were recruited within the international network of the researchers and by snowballing. Discussions were guided by questions shared with the participants prior to the meetings to allow for preparation. Thematic summary reports were drafted after each meeting and participants were given the opportunity to review them.

Results

A summary of the discussed potential impact of a system to facilitate recognition of antibiotics and foreseen facilitators and barriers are summarised in Table 2. While discussions mainly focussed on LMICs it was recognised that the issue of (mis)identification of antibiotics was also a problem in HICs (e.g, older adult care, primary care). Several approaches were suggested for a future labelling/identification system (Table 2).

Conclusions

The roundtable discussions yielded a plethora of insights on the topic of antibiotic (mis)identification. Being able to distinguish antibiotics from other commonly sold medicines, such as painkillers, was recognised as an important global public health objective. Ultimately, the results of the roundtable reports and additional stakeholder consultations can guide the development of a labelling system to improve the identification of antibiotics and their use.

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Table 1: Roundtable meeting participants on a standardised physical appearance of oral generic antibiotics.

Participant's expertise	**Number of participants**	**Scope**
Public health experts and regulators	10	Global, Europe, United-States
Prescribers, pharmacists and nurses	9	Global, Europe, United-States
Pharmaceutical industry	11	Global
Public health and regulators	10	Africa
Public health and regulators	12	Asia

Table 2: Summary of the five roundtable discussions on a standardised physical appearance of oral generic antibiotics.

Potential impact	Potential barriers	Potential facilitators	Suggested approaches
• addressing the rise of AMR globally	• data on the burden of the antibiotic (mis)identification issue are scattered across different fields in the scientific literature (e.g., medication safety, AMR, medicine dispensing practices, medicine quality)	• the 'right financial incentives' for the manufacturers in place to support a transition to the new proposed labelling/identification system	• improved labelling or identification feature should go paired with other patient education measures (so it should not be a standalone strategy)
• contribute to patient education on responsible antibiotic use, patient empowerment and participation in treatment decisions. Also optimise impact of existing responsible antibiotic use campaigns including communities with lower literacy rates (e.g., symbol, colour, shape)	• costs of implementing a change to appearance of pills or packaging of antibiotics – especially for generic manufacturers. Even a slight increase in costs could potentially negatively affect antibiotic cost and hence access	• lessons learned from labelling initiatives in the medical field (eye drops colour code in the US, Red Line campaign for prescription medicines in India) and in other fields (forest stewardship symbol, tobacco and alcohol industries)	• align labelling/ identification system with ongoing AMR awareness messaging and the WHO AWaRe classification
• reduce self-medication with antibiotics	• need for consensus between the many manufacturers and regulators on the exclusive use of any physical feature	• early involvement of regulators and pharmaceutical industry for support and input	• start small (e.g., a prioritisation of most commonly used antibiotics or new

	(e.g., colour, shape, imprint, symbol or any combination of those)		antibiotics, first target the packaging and gradually move to the individual pills)
• improve awareness about antibiotics among health care workers	• Chemistry, Manufacturing and Controls (CMC) aspects to consider in relation to stability and packaging of the medicines	• global regulatory harmonisation	• include some simple responsible messaging to the labelling/identification system
• reduce medication errors (look alike medicines, sound alike medicines)	• the use of colours could be a potential source of confusion (colour-blind people)	• support from laws and regulations and robust policies reinforcement	• combining any physical feature with a QR code providing details and information on the manufacturing process (to hinder falsification)
• improved communication between physicians and patients and guidance of treatment decisions (e.g., identify previous antibiotic treatments)	• many cultural and socio-economic factors influence antibiotic consumption behaviours and thus improved ability to recognize and identify antibiotics could also lead to increase in demand and consumption.	• AMR recognised as a global public health priority	• consider applicability of the labelling/ identification system for antibiotics and antibiotics containing feed used for animals
• facilitate identification of falsified antibiotics	• misuse of physical feature by criminal organisations (falsified/counterfeit medicines)	• learn from COVID-19 pandemic	• collaboration with ongoing developments,

	communications and campaigns (mask icon)	for instance, track and trace barcode in Africa