





Multi-Stakeholder Recommendations for Action Against Antimicrobial Resistance: a Public Consultation

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BACKGROUND AND OBJECTIVES

antimicrobial resistance (AMR) Need for
(i) Facilitating the introduction of novel antimicrobials
(ii) Responsible use of existing





antibiotics

Actions included in the proposal for the reform of the EU pharmaceutical legislation

Proposal for a

Brussels, 26.4.2023 COM(2023) 193 fin

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUL

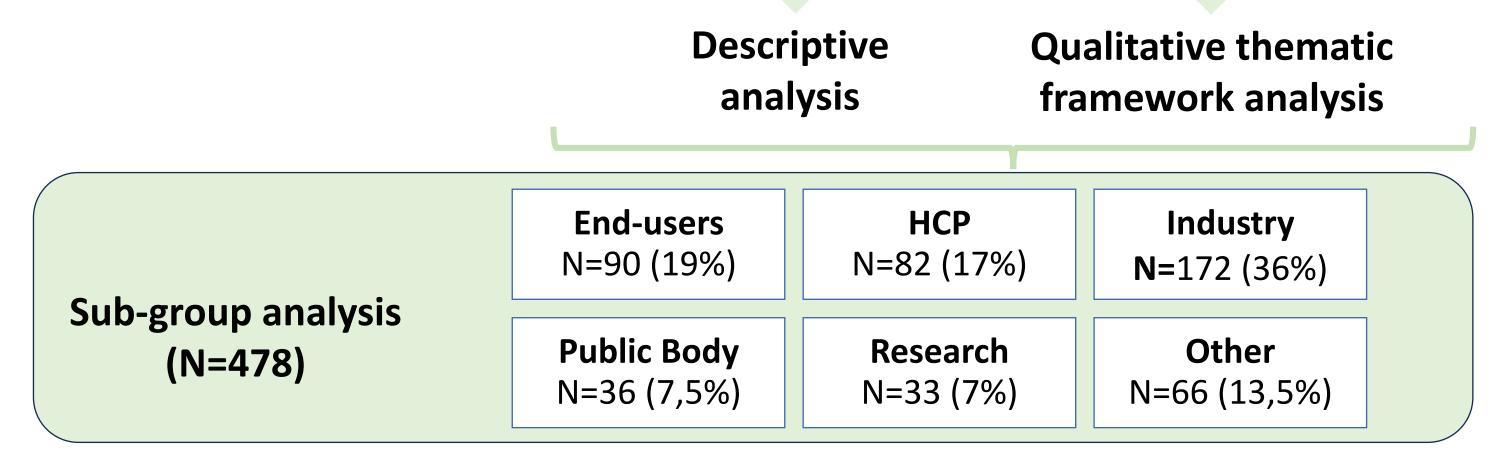
laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000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

(Text with EEA relevance)

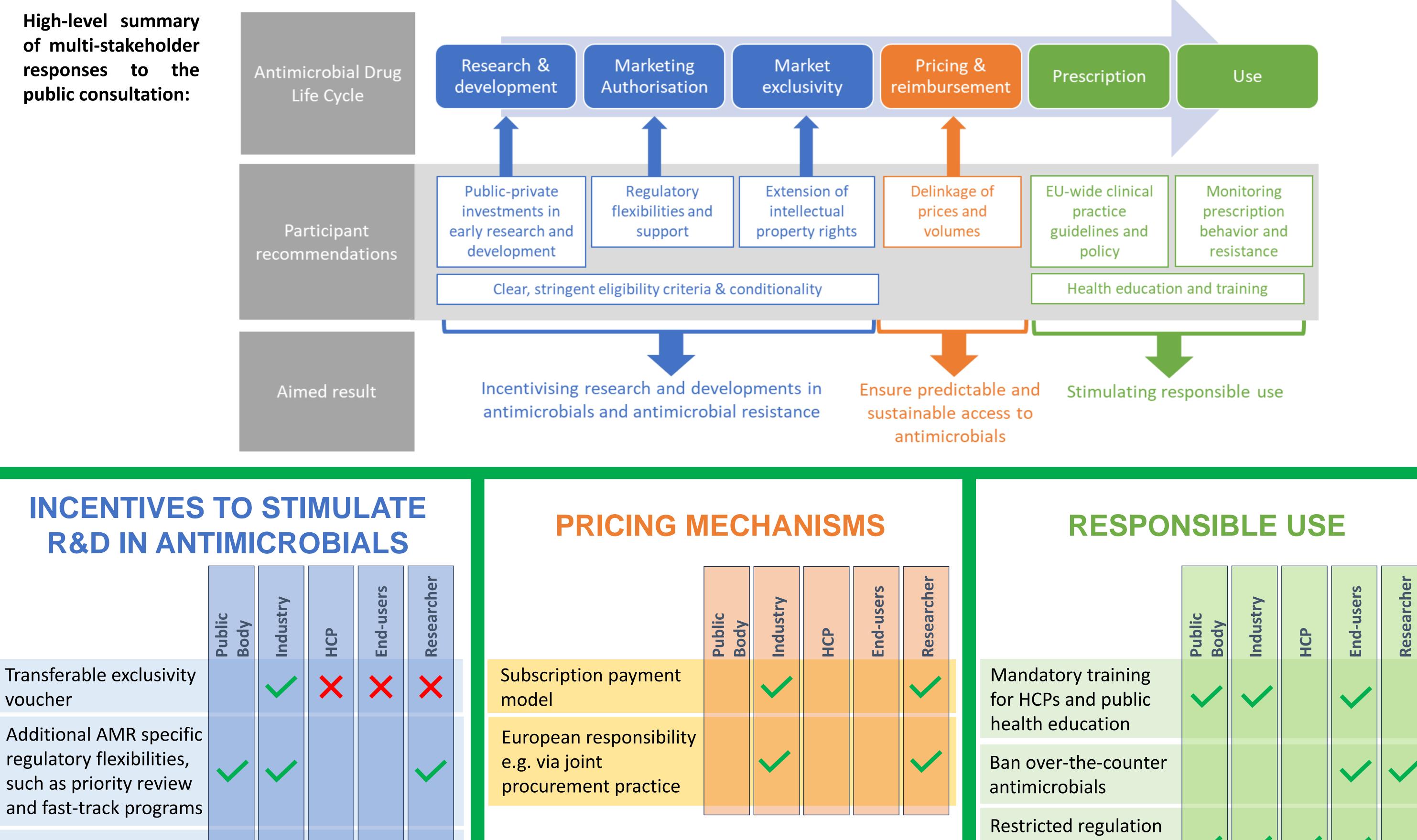
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Objectives:

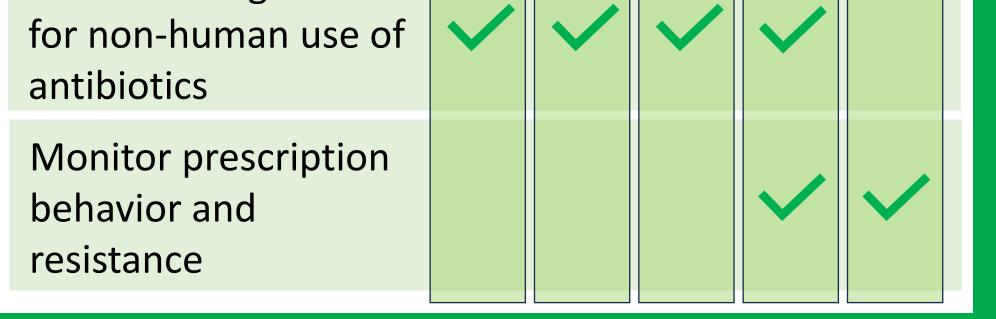
Assess stakeholder recommendations based on public consultation feedback informing the legislation



CALL FOR ACTIONS ACROSS THE MEDICINAL PRODUCT LIFE CYCLE RAISED BY STAKEHOLDERS



Decreased regulatory fees



Development of EU priority pathogen list

The proposal for the new pharmaceutical legislation receives a lot of reaction by stakeholders, this nuanced analysis of the public consultation can enhance understanding

CONCLUSION 2

Not all included actions (i.e. transferable exclusivity voucher) were supported by all stakeholder groups

3

Additional actions could be included to further enhance innovation (i.e. reduced regulatory fees, a priority pathogens list) and responsible use (i.e. more restricted regulation)

ACKNOWLEDGEMENTS

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LIST OF ABBREVIATONS

AMR: antimicrobial resistance, EU: European Union, HCP: Health care practitioner