Cross-programmatic consultation on the role of primary care in the responsible use of medicines and the reduction of antimicrobial resistance

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1. Introduction

The rise in antimicrobial resistance (AMR) is a growing global public health concern impacting on morbidity, mortality, and costs [1,2], and threatening achievement of the Sustainable Development Goals (SDGs) [3]. The momentum to address AMR continues following the adoption of the World Health Organization (WHO) Global Action Plan (GAP) on AMR in 2015 [4], its inclusion in the agenda of the United Nations General Assembly in 2016 [5], annual reinforcement of the AMR messages during World Antibiotic Awareness Week [6], supported by comprehensive AMR action plans [7,8].

A key recommendation of the WHO GAP to optimize the use of antimicrobial agents is that the ‘distribution, prescription, and dispensing of antimicrobials is carried out by accredited health professionals under statutory body supervision or other suitably trained person authorized in accordance with national legislation.’ In many settings, legislation requiring prescription-only access to antibiotics exists but is not enforced, allowing over-the-counter (OTC) purchase of antibiotics in pharmacies without prescription, encouraging self-medication without formal diagnosis, and facilitating accumulation of ‘leftover’ antibiotics that may be used to treat future illnesses. Prescription-only access to antibiotics also requires a well-functioning primary health care (PHC) able to respond to patients’ needs, with strong prevention programmes, competent health workforce and involvement of people to ensure access but not excess use of antibiotics.

2. Objectives and rationale

The consultation brought together participants from 16 countries of central Asia, Caucasus, eastern Europe and India (Azerbaijan, Armenia, Belarus, Bosnia and Herzegovina, Georgia, Kazakhstan, Kyrgyz, Montenegro, Russian Federation, Serbia, Tajikistan, Turkey, Ukraine, Uzbekistan) and expert speakers from western Europe and India around the agenda of responsible use of antibiotics and the role of PHC in tackling AMR. Participants were nominees of the Ministries of Health and were AMR and AMC national focal points, policy-makers and clinical leaders in the areas of antimicrobial use, PHC and medication safety. Specifically, the meeting discussed country experiences in enforcing legislation for prescription-only access to antibiotics; strategies to strengthen PHC, improving the competencies of practitioners using evidence-based clinical protocols; and understanding the patients’ perspective to be included in the design of services.

3. Setting the scene

While there are few reliable data, OTC supply of antibiotics without prescription is common in the participating countries [9–11]. Although there is a strict delineation between those pharmaceuticals that are available OTC and those that are available only on prescription in former Soviet Union countries, in practice this distinction has mostly been strictly enforced only for narcotics, psychotropic medicines and their precursors [9]. Respondents to a WHO Europe online survey (unpublished) reported a legislative
framework governing the marketing authorization of antimicrobial agents, their distribution, assessing the quality of products in circulation, as well as their prescription and dispensing and that these regulations were variably but mostly enforced. Kotoji Iwamoto (WHO Europe) summarized the most commonly nominated priority actions for improving the appropriate use of antibiotics from the survey respondents: (i) enforcing and improving legislation on the prescribing and dispensing of antibiotics (ii) educating health professionals (iii) improving public awareness on rational use of antibiotics and (iv) implementing standard clinical protocols.

Tom Jacobs (WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht University) reviewed the literature on the impact of activities undertaken to enforce laws on prescription-only access to antibiotics in low and middle-income countries. Multi-faceted interventions supported by retention of prescriptions and regular inspections of pharmacies were most likely to be useful. Potential unintended effects of law enforcement included pharmacies hiring general practitioners to conduct consultations and provide prescriptions, greater sales of other OTC medications including non-steroidal anti-inflammatory agents (NSAIDs) that have risks for some patients and shifts to sales of different classes of antibiotic than those targeted in the interventions.

Albert Figueras (Catalan Institute of Pharmacology, Spain) presented results from a study using mystery shoppers and four clinical scenarios showing it was easier to obtain an antibiotic in Spain without prescription in 2014 than in 2008 and that the quality of care offered by pharmacists was sometimes suboptimal. He reminded that regulation alone was insufficient and that it was important to recognize the factors influencing behaviors around the purchase and use of antibiotics.

4. Country experiences

Presentations from Armenia, Turkey, Belarus, Georgia, and Serbia described a range of activities undertaken to enforce and monitor existing legislation for prescription-only access for antibiotics. Interventions included engagement of health professionals in the design of a prescription form and training in its use (Georgia), applying a limited list of antibiotics that could be purchased OTC without a prescription to be phased out over time (Belarus), and implementing international nonproprietary name (INN) prescribing and generic substitution (Armenia). Serbia and Turkey described monitoring activities for antibiotic consumption. Most legislation included penalties for pharmacists for antibiotic supply without prescription, although these were variably applied and inspection capacity often quite limited. Typically, enforcement efforts provoked negative responses from stakeholders, adverse media publicity and complaints to ministries of Health, often resulting in delays or transition periods for implementation of changes. Consumers resented that convenient access to antibiotics in pharmacies was being lost, doctors complained about the additional time and costs associated with providing prescriptions, pharmacists and wholesalers feared loss of revenue and risks of unwanted, expired stocks. The presentations underscored the importance of considering the perspectives of all stakeholders in enforcing prescription-only access to antibiotics to ensure there is access to antibiotics when needed but restrictions to limit excess and inappropriate use.

5. Primary health care and AMR

As most antibiotic use occurs in the community, outside hospitals, PHC is critical to support prescription-only access to antibiotics. In many of the participating countries, the organization of services and allocation of resources prioritize secondary and tertiary care. In addition, PHC faces challenges attracting and retaining staff and with the perceived lower status of primary care practitioners. Patients’ trust in general practitioners and perceptions of the quality of primary care are often low.

Anjana Sankhil (Center for Disease Dynamics, Economics & Policy [CDDEP], India) illustrated how patients choose their health services based on knowledge of the health facility and its services, facility location and accessibility, perceptions of quality of care based on previous experiences and costs. Long waiting times, lack of diagnostic tools or referral to private providers, and poor doctor–patient relationships contribute to patient dissatisfaction, encourage self-medication and purchase of antibiotics OTC. The reasons for self-medication also include previous positive experience in the use of antibiotics, and the time saved by not having to get a prescription. Use of leftover antibiotics is common.

Jyoti Joshi (CDDEP, India) described the role of PHC in the AMR agenda, extending well beyond providing prescriptions for antibiotics. As the most common first contact between health services and the public, PHC workforce have an important role in raising awareness and educating patients and empowering people to take actions to reduce the irrational use of antibiotics. PHC can set an example for community hygiene, for promoting prevention and control of infections, and for increasing immunization in order to reduce infection spread and disease transmission and thereby reduced need for antibiotics. PHC workforce needs training in AMR and good prescribing practices along with access to reliable, independent and updated information on local patterns of antimicrobial consumption and resistance to guide practice. The WHO Access, Watch and Reserve classification of antibiotics provides a useful tool for promoting judicious use of existing antibiotics. High levels of use of Watch (first- and second-choice agents for a limited number of indications) and Reserve (last resort) agents may be an indicator of inappropriate prescribing practices. Evidence-based clinical protocols for common conditions can be converted into simple algorithms facilitating their use in PHC.

Using the example of the high incidence of rheumatic fever in some parts of eastern Europe, Lars Blad (STRAMA, Sweden) reminded about the need of caution in implementing prescription-only access for antibiotics since access to needed antibiotics needs to be ensured. He questioned whether PHC was ready and able to manage the gate-keeping role with all patients who previously purchased antibiotics directly from the pharmacy. If not, then the optimal solution was to strengthen PHC, ensure equitable access to services for the whole population and equip practitioners with evidence-based clinical protocols before banning OTC sales of antibiotics. Ruta Radzviciene-Jurgute (General practitioner, Lithuania) noted that PHC practitioners have high responsibility for maintaining a rational antibiotic policy through good clinical governance, accessible diagnostic tools including...
point-of-care testing, education of and good communication with patients, peer-to-peer support, continuing medical education and monitoring of practitioners’ performance in antibiotic use.

6. Conclusions

Enforcement of prescription-only policies for antibiotics presents many challenges and it is difficult when there has been longstanding OTC practice. There are inevitable trade-offs between ensuring access to needed antibiotics and restrictions to limit excessive or inappropriate use. Regulation and penalties contribute but will not ensure enforcement. Behavioral changes of public, patients, practitioners and pharmacists for using and accessing antibiotics should be anticipated to put in place effective enforcement mechanisms. Education of the general public is a critical element to decrease the demand for antibiotics without prescription and reduce pressures on health professionals to provide prescriptions. The perspectives of all stakeholders including the public, doctors, nurses, pharmacists, and the pharmaceutical industry should be considered as part of developing a comprehensive implementation strategy.

PHC remains an important source in the prescription of antibiotics. It has, therefore, a pivotal role in the AMR agenda. Increasing trust and utilization of PHC services requires a competent health workforce, evidence-based clinical protocols as well as rapid diagnostics at the point of care and quality medicines. Monitoring the patterns of use of antibiotics underpins effective stewardship efforts. The PHC gatekeeping function for the access and use of antibiotics should be supported by policies and simple tools to assist providers in responsible antibiotic prescribing and use.

Country-based discussions and presentations on the final day of the meeting identified priority next steps to advance the agendas of responsible use of antibiotics and PHC in their own settings.

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