Mapping of Current Obstacles for Rationalizing Use of Medicines (CORUM) in Europe: current situation and potential solutions

Mohamed Gad¹, Ahmed Salem², Wija Oortwijn³, Ruairidh Hill⁴, Brian Godman⁵,6,7,8

¹Global Health and Development Group, Imperial College, London. Email: mohamed.a.gad@hotmail.com
²Real World Evidence Solutions, IQVIA, 1930 Zaventem, Belgium. Email: ahmed.salem@iqvia.com
³Department for Health Evidence, Radboud University Medical Center, Nijmegen, The Netherlands. Email: w.oortwijn@radboudumc.nl
⁴Liverpool Reviews and Implementation Group, Whelan Building, University of Liverpool, Liverpool, UK. Email: rahill@liverpool.ac.uk
⁵Department of Laboratory Medicine, Division of Clinical Pharmacology, Karolinska Institutet, Karolinska University Hospital Huddinge, Stockholm, Sweden. Email: Brian.Godman@ki.se
⁶Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, UK. Email: Brian.Godman@strath.ac.uk
⁷Health Economics Centre, University of Liverpool Management School, Liverpool, UK. Email: Brian.Godman@liverpool.ac.uk
⁸Department of Public Health Pharmacy and Management, School of Pharmacy, Sefako Makgatho Health Sciences University, Garankuwa, South Africa

*Author for correspondence: Brian Godman, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow G4 0RE, United Kingdom. Email: brian.godman@strath.ac.uk. Telephone: 0141 548 3825. Fax: 0141 552 2562 and Division of Clinical Pharmacology, Karolinska Institute, Karolinska University Hospital Huddinge, SE-141 86, Stockholm, Sweden. Email: Brian.Godman@ki.se. Telephone + 46 8 58581068. Fax + 46 8 59581070

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ABSTRACT

Introduction: There are increasing concerns regarding the inappropriate use of medicines with expenditure continuing to grow driven by increasing sales in oncology and orphan diseases, enhanced by their emotive nature. As a result, even high income countries are struggling to fund new premium priced medicines. These concerns have resulted in initiatives to better manage the entry of new medicines and enhance the rational use of medicines (RUM). However, there is a need to ascertain the current situation. We sought to address this by developing the Current Obstacles for Rationalizing Use of Medicines in Europe (CORUM) mapping tool to qualitatively investigate the current situation and provide analysis of current views on RUM and interventions among key European payers and their advisers. The findings will be used to provide future guidance. Methodology: Descriptive study exploring and identifying perceived gaps to achieving optimal RUM. The CORUM tool was based on the WHO 12 key interventions to promote RUM. Results: 62 participants took part with most respondents believing their country could improve RUM capacity. This included educational initiatives on the use of clinical guidelines (90%) and the inclusion of problem-based pharmacotherapy in undergraduate curricula and for Continued Professional Development. Key challenges included a lack of regular updates of guidelines exacerbated by limited funding and a lack of follow-up to monitor adherence to agreed guidelines. RUM could also be enhanced by the development of regional formularies as well as implementing Drug Therapeutic Committees where these are currently limited. There also needs to be greater co-ordination between RUM and Health Technology Assessment activities, with countries learning from each other. Conclusion: There is an urgent need to improve RUM through improved educational and other activities among European countries, with countries learning from each other. This will involve addressing current challenges and we will be following this up.
1. INTRODUCTION

The World Health Organization (WHO) estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly (1, 2). This results in the waste of healthcare resources as well as leads to health hazards. The situation is even more critical in lower- and middle-income countries (LMICs) where expenditure on medicines can be up to 70% of total healthcare expenditure, much of which is out-of-pocket (2, 3). Expenditure on medicines has increased since 2015 beyond US$800 billion (€720 billion) among countries of The Organisation for Economic Co-operation (OECD) (4, 5). This is driven by increased expenditure on biological medicines, including those for cancer, as well as new medicines for patients with hepatitis C (4). Total retail pharmaceutical expenditure in Europe was more than €210 billion in 2016 (adjusting for purchasing power parities), an increase of 5% since 2010 (6). The increase was limited by strategies across Europe to enhance the prescribing of low-cost generics and biosimilars versus originators and patented products where care is not compromised (6-12).

Expenditure on cancer medicines is a concern, with global expenditure in 2017 at US$133 billion (~€117 bn) up from US$96 billion in 2009, and estimated to reach US$200 billion (~ €176 bn) by 2022 with an average growth rate of 10 to 13% per year during the coming years (13). This increase in expenditure will be driven by anticipated increases in the prices of new cancer medicines and increased incidence rates with an estimated 21.4 million new cancer cases globally per year by 2030 up from 18.1 million in 2018 (14-18). In addition, over 500 companies are actively pursuing new cancer medicines across multiple indications (19, 20), intensifying the expectations for the rising costs for oncology medicines (18, 21-23). There are similar concerns and issues with new medicines for patients with orphan diseases (20, 24, 25) where we are likely to see global spending on orphan medicines reaching US$178 billion (~€160 bn) per year by 2020 (26). This will again be enhanced by the number of medicines for orphan diseases currently available and in development, and their envisaged prices (20, 24, 27).

Overall, the costs of new medicines are a growing concern across countries driven by changing demographics, rising patient expectations, single disease treatments and the continued launch of new premium priced medicines (20, 28, 29). This is set to continue exacerbated by the number of new medicines in development as well as the emotive nature of diseases such as cancer and those for orphan diseases (20, 22, 24, 25, 29-31). We are also seeing high income countries increasingly struggling to fund new medicines, and this will continue unless actively addressed (20, 32-34). These challenges have led to the development of new models to better manage the entry of new medicines as well as initiatives to enhance the rational use of medicines (RUM). These new models include encouraging the use of biosimilars and multiple sourced products where pertinent to conserve resources alongside instigating active disinvestment processes (7, 9, 20, 29, 35, 36) as well as a growing use of managed entry agreements (MEAs). However, there are concerns with MEAs including the extent and usefulness of any clinical data collected, as well as monitoring the role and value of new medicines in routine clinical care to provide future guidance (29, 36-47).

The WHO defines RUM as “Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community” (48, 49). According to the WHO, a sound rational drug use programme in any country involves interventions on three levels. The first is on the level of healthcare authorities that includes setting strategies for monitoring the use of medicines, second is on the level of healthcare service providers, which for example includes enhancing the use of agreed clinical guidelines, and the third is on the level of medicines used by consumers, which includes raising awareness on key aspects of RUM (1). Although these strategies are operational in a number of countries, they are rarely subjected to a thorough assessment of their actual impact in practice such as encouraging the preferential use of multiple sourced medicines where pertinent without compromising care or encouraging caution for new medicines where there are concerns with patient safety (12, 28, 44, 50-55). Especially, there seems to be a gap regarding stakeholder engagement to assess the implementation of these strategies, or in gathering information about the key challenges of implementation and ways of circumventing these challenges, with a focus on variable contexts and different healthcare ecosystems.

We sought to address this gap by developing the Current Obstacles for Rationalizing Use of Medicines in Europe (CORUM) mapping tool. The objective of the CORUM tool was to qualitatively investigate the current situation and to provide an in-depth analysis of current views on RUM interventions among key
payers and their advisers among European countries in addition to the challenges encountered when attempting to implement these interventions. The findings will be used to develop strategies to enhance RUM in Europe given increasing budgetary and other concerns.

2. METHODOLOGY

2.1 General
This is a descriptive study exploring and identifying perceived gaps to achieving optimal RUM in Europe. The CORUM tool (Supplementary material) was developed by the authors based on the WHO 12 key interventions to promote RUM (Table 1) (56). For each key intervention we inquired regarding the extent to which respondents agreed to the intervention being a key intervention to promote RUM, checked for current obstacles for this intervention to be realised based on respondents’ experience in his/her own country, and asked for respondents’ views concerning possible ways to circumvent these obstacles to enhance the rational use of medicine within their own country (Appendix 1). The study also embeds considerations from common elements including cooperation between national organizations that are traditionally evident in Health Technology Assessment (HTA) frameworks widely established within member states of the European Union (EU) (57-59). HTA is the multidisciplinary process to determine the value of a health technology. The dimensions of value for a health technology may be assessed by examining intended and unintended consequences of health technologies, including the clinical, economical, ethical, social, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

We believe this combination of sources was an appropriate starting point to develop a cross-sectional survey (see section 2.3) that could be distributed across key stakeholders in Europe to gather their perception of the proposed RUM interventions.

Insert Table 1

2.2 Participants
The target audience of the tool could be categorized into two main groups. The first were the policy makers (users of evidence) who are typically the decision makers responsible for legislating and implementing frameworks for adopting and monitoring the use of medicines within their own region or country. The second group are the ‘technocrats’ (suppliers of evidence) who are often the producers of assessments of medicines or those giving recommendations that directly or indirectly influence decisions regarding RUM based on evidence-based medicine and/or HTA (60).

Sampling for the participants to be surveyed was conducted based on a purposive non-random sampling technique which is typically used for exploratory work such as this study. The participants who were approached for this initial survey were stakeholders across various realms of the healthcare community spread across different geographical locations within Europe. The participants were primarily members of Piperska Group, a non-governmental organization which the authors are also members.

The Piperska Group is a pan-European network of payers (health insurers), advisers and academics that researches and analyses key health policies and their impact with the aim of enhancing the health of populations and individual patients in a sustainable way (61). Activities include developing new models to improve the managed entry of new medicines, developing quality indicators for new medicines, assessing key issues such as MEAs, discussing minimum effectiveness levels for new cancer medicines, personalised medicine, and adaptive pathways as well as potential ways to enhance the prescribing of low cost generics and biosimilars to release resources to fund increased medicine volumes with ageing populations and new valued medicines within agreed budgets (9, 12, 20, 28, 32, 38, 57, 62-70). In addition, organising courses to improve the managed entry of new medicines and prescribing at the interface (71-73). The various activities and outputs have been achieved through cooperation and the exchange of ideas among a wide base of multi-stakeholder groups in Europe. As a result, this group helps provide European thought leadership specifically for constructing policies around enhancing RUM and related therapies.
Consequently, the Piperska group was deemed an appropriate target audience to drive this exploratory mapping study. Furthermore, we also incorporated a snowball sampling technique where existing study participants invited future participants to take part in this survey. Initially, prospective participants were approached through e-mail, inviting them to participate in the survey with the potential of forwarding the survey to known colleagues.

2.3 CORUM Mapping Survey

2.3.1 Development of the survey

The CORUM Mapping Tool is a survey of 9 structured questions where each question pertains to one of the WHO key interventions. Although the WHO proposes 12 key interventions for optimal RUM, we adapted the questions to combine one or more interventions to avoid a lengthy questionnaire. The authors established face-validity of the survey by allowing experts in the field including health authority personnel to read through the survey and share their feedback. The survey was subsequently reviewed by a psychometrician to check for common questionnaire errors. We adjusted the survey based on the received feedback and subsequently ran a pilot test on a subset of the prospective participants to enhance the robustness of the survey. The final survey is available as a supplement.

A brief introduction about the survey, its objectives, and the instructions were contained in the cover page. Each question in the survey first presented one of the key interventions and subsequently asked the participants to select a score on a 1-5 scale that best represented how strongly they agreed (score 5) or disagreed (score 1) that the particular intervention is key for RUM. A 5-point scale is standard tool for research studies such as this one (74-77). Thereafter, the participants rated their country’s performance with regards to the presented key intervention. Following this, the participants selected whether or not they believed there are current challenges to realizing the presented intervention in addition to clarifying what these challenges are. The final sub-question asked the participants to propose possible solutions to overcome perceived challenges to implementing the presented intervention.

We used the online website checkmarket.com to build the questionnaire layout and subsequently deliver it to the participants. Checkmarket offers a user-friendly platform to creating, administering, and analysing online surveys. The survey ran for 3 months between March – June 2017 although we allowed one week prior to the “active period” where we sent the invitation e-mails to participants inviting them to take part. Weekly reminders were sent to participants requesting them to complete the survey or clarify any questions if they had any. All communications with participants were conducted through e-mail.

2.3.2 Analysis

The responses were analysed to present a frequency distribution of the answers. We typically consolidated the high-end and low-end scores in the 1-5 point scale, e.g. strongly disagree and disagree, for ease of analysis.

The same approach was followed for questions with binary answers (i.e. yes or no) and multi-select questions. Finally, the open-answers, where the participants stated possible ways to address the perceived challenges of achieving optimal rational use of medicines, were coded and analysed according to the so-called 4 E approach (Education, Economics, Engineering and Enforcement) first discussed by Wettermark et al (2009) and used extensively since then to analyse the influence of typically multiple health policy interventions to improve the quality and/or efficiency of prescribing (12, 53, 78-85).

The 4 E’s consolidate the multiple strategies that can be applied to rationalizing medicine use. Education refers to a wide range of educational activities ranging from simple distribution of printed material to more advanced strategies such as academic detailing and educational visits by trained facilitators. Academic detailing, sometimes called educational outreach visits, typically includes a visit of a trained health professional such as a physician or pharmacist to a general practitioner in their own setting on a one-on-one basis to provide information to help change behaviour (86-90). Goals can include active dissemination and discussion on agreed national or regional treatment guidelines and improving the management of targeted health conditions (89-91). Typically academic detailing is undertaken in one or more visits and often combined with other strategies to enhance its effectiveness including audits and other feedback approaches (86, 89, 92).
Engineering captures strategies that are more organizational or managerial interventions such as monitoring of prescribing against agreed targets such as the quality and outcome framework in the United Kingdom or percentage targets for prescribing in Scotland or Sweden (7, 93-95). Economics strategies typically include financial incentives or disincentives to all key stakeholder groups including physicians, pharmacists and patients, i.e. financial incentives for achieving agreed prescribing targets and writing annual reports on potential ways to improve future prescribing (93, 94, 96, 97). Finally, Enforcement strategies are those that include regulations by law such as mandatory generic substitution or mandatory prescribing restrictions (54, 78, 91, 93).

We did not seek ethical approval as this study did not involve patients. This is in line with previous studies undertaken by the co-authors in related areas including analysis of policies to enhance the rationale use of medicines as well as seeking a greater role for biosimilars and generics involving health authority personnel and their advisers (9, 12, 38, 53, 69, 70, 79, 98) as well as in line with local legislation and institutional guidelines.

3. RESULTS

3.1 Response rate
The link to the survey was eventually emailed to 235 potential respondents. Overall, 62 professionals completed the questionnaire giving a response rate of 26% which is in line with the average response rates for e-mail surveys (99).

Table 2 below shows the breakdown of respondents (n=62) by professional category and European region. The majority of the participants were from national health organisation bodies (n=20) followed by academics (n=19), while the highest portion of respondents were from Eastern Europe (n=37). There was also a high percentage of Piperska member respondents in the health insurance and national health organisation group (56%), with the least number among healthcare professionals (17%).

Insert Table 2

3.2 Capacity for Rational Use of Medicine
The majority of the respondents agreed that the presented 5 interventions are perceived as key contributors for RUM (see Figure 1). The percentage of agreement ranged from 65% (drug therapeutic committees, DTCs) to 84% (clinical guidelines).

Insert Figure 1

Respondents subsequently scored the performance of their countries in achieving the relevant key RUM interventions on a scale of 1 – 5, where 1 refers to “Poor performance” and 5 being “Strong performance”. The percentage of respondents who believed that their country performed “above average” or “strongly” ranged between 23% and 34% across all interventions (Figure 2). The remaining respondents (66% - 77%) believed that their country’s performance with achieving RUM capacity was currently poor, suboptimal, or fair.

Insert Figure 2

The majority of the respondents highlighted that there are current challenges to instigating appropriate interventions to enhance RUM (Figure 3). The percentages ranged from 66% regarding the inclusion of problem-based pharmacotherapy training to 90% with regard to the use of clinical guidelines.

Insert Figure 3

The two most selected challenges hindering the use of clinical guidelines were “lack of updated guidelines or prescribed guidance” and lack of “governmental funding” to maintaining these guidelines (Figure 4). “Lack of follow-up of adherence to formularies” was regarded as the greatest challenge to the development and use of national/regional formularies. Furthermore, 45% of the respondents selected “lack of incentives and/or time” as a limitation to establishing DTCs in districts, regions, and hospitals. Of the respondents, 39% cited “lack of time” as a challenge to including problem-based pharmacotherapy training in undergraduate courses, while 45% of the respondents believed that the
lack of government support hinders initiatives that support RUM such as education, feedback, and prescription restrictions.

Insert Figure 4

Figure 4 shows the possible solutions proposed by the respondents to overcome current challenges to promoting RUM. It appeared that most often solutions that pertain to “Education” were proposed by the respondents (46% - 53%). These include creating RUM guidelines, implementing electronic aids to support prescription writing and knowledge sharing through congresses. Initiatives that are categorized as “Engineering” approaches were the second most proposed strategies to address potential challenges, which include stronger involvement of public health authorities and national payers in promoting RUM strategies. Finally, strategies pertaining to “Economics” and “Enforcement” solutions were the least proposed by participants. Examples of these strategies are increased governmental funding for the implementation of guidelines including incentives to physicians (Economics) and payer contractual agreements with prescribers that guidance must be adhered to (Enforcement).

Insert Figure 5

3.3 Linkage Between HTA and RUM

We asked respondents what kind of body is responsible for coordinating RUM initiatives and/or policies in their countries. 56% (n=35) of total respondents stated that their country has a body that coordinates RUM initiatives and/or policies. Among these, the majority of these were governmental national units (HTA entity) within the ministry of health (MoH) (23%, Table 3). However, 23% of respondents mentioned that the HTA entity in their respective country (if this exists) is not involved in coordinating RUM activities. The other selected types of RUM-coordinating entities varied between being independent governmental agencies (13%), regulatory governmental authority (8%), or a payer agency (6%).

Insert Table 3

Of the countries in which HTA plays a role in coordinating RUM initiatives, only 27% of the respondents rated their country’s HTA entity as performing above average or strong, with 31% as fair and 42% as poor or suboptimal in helping to achieve effective RUM policy co-ordination. 77% of the respondents subsequently believed there are certain challenges to their country’s HTA entities’ contribution to effective RUM policy coordination. The top two challenges that were mentioned (Figure 6) included a “lack of political will” (48%) and “Not enough knowledge in linking RUM function within an HTA institution” (44%).

Insert Figure 6

To overcome these challenges, the respondents proposed solutions that fell under Education (39%) such as the inclusion of RUM-focused courses for undergraduate students within pharmacy and medical schools. Solutions pertaining to Engineering strategies (44%) were creating an HTA multidisciplinary independent body, while Economics (16%) highlighted the need for continuous funding to maintain RUM policies including potential incentives to physicians. No solutions were proposed under “Enforcement”.

3.4 Governance of RUM Mechanisms

The majority of respondents (79%) agreed or strongly agreed that consumer education is a key intervention to enhancing RUM. However, only 16% of the respondents rated their country’s performance to consumer education as being above average or strong to promoting RUM, with 37% scoring it as fair and 47% as poor/suboptimal.

Furthermore, 74% believed there are currently challenges to providing consumer education in the context of RUM, which need to be addressed. The greatest challenge mentioned was a “lack of innovative ways to deliver public education in a useful manner” (52%), followed by “lack of financial resources” (40%), “limited role of professional societies” (35%), and “lack of technical knowledge” (31%) (Figure 7).
Insert Figure 7

The majority of the respondents cited educational policies as a means to address the challenges that hinder effective consumer education (55%). Possible “educational” solutions that were mentioned included public campaigns via the local ministry of health in addition to increasing public understanding of medicines and their use. Engineering strategies such as further regulation on medicinal marketing was cited by 17% of respondents, and finally 23% cited financial resources as one strategy to support patient education around RUM.

3.5 Role of Pan-European Groups
The top 3 organizations that respondents are aware of in the realm of RUM were WHO Europe (85%), EuNetHTA (68%), and the Piperska group (65%) (Table), with a lower number aware of the European Association for Clinical Pharmacology and Therapeutics (EACPT – 18%).

Insert Table 4

3.6 Increasing RUM Impact

Among the respondents, 73% agreed or strongly agreed to the need for organizations that are enhancing knowledge sharing and cooperation between stakeholders across Europe with regards to RUM. However, 56% of respondents believed there are current challenges that hinder these organizations with enhancing RUM across Europe. The challenge that was mostly mentioned by respondents was “Financial support” (37%) (Figure 8). Finally, the majority of the solutions cited by respondents to address these challenges were again Educational policies (43%) such as communication of research results between these groups, followed by Engineering policies (28%) including strategic alliances among various pan-European groups (Figure 8).

Insert Figure 8

4. Discussion

The results of our study point to the use of clinical guidelines as the most important key intervention to enhance RUM (Figure 1). Whilst clinical guidelines have been instrumental in optimising care and promoting RUM across settings (100-105), there are challenges such as regularly updating the guidance or sufficient government or health authority funding for their development and active dissemination in the first place. There can also be concerns with conflicts of interest among guideline developers unless adequately addressed such as the ‘Wise List’ and guidance in Stockholm, Sweden (73, 92, 106-108). Addressing the reasons behind the lack of funding for their dissemination, including how technology can assist with their wider dissemination and usability in practice to promote RUM, should be explored further. This is particularly important in situations where physician education is principally offered via pharmaceutical companies with the potential for bias (109-114), although ethical codes of practice are increasing across countries to address such concerns (115). As a result, there might be a need in some countries to develop a better understanding of mechanisms to ensure continuous updating and dissemination of clinical guidance as well as continual professional development around clinical pharmacology and RUM. In addition, ensuring in the future that clinical guidance is readily accessible in an easy-to-find manner through Apps or other mechanisms during clinic visits and other patient interactions to improve their utility. There are concerns with RUM if clinical guidelines are not readily accessible or utilised (116-118); alternatively, where physicians are overloaded with guidelines and where they have doubts about them (119). We do know that if physicians trust key personnel involved in the development of prescribing guidance, there is a comprehensive dissemination strategy and prescribing is regularly monitored, there is high adherence to any prescribing guidance produced. This is illustrated by high adherence rates to recommended treatment guidance in Stockholm County Council in Sweden with their ‘Wise List’ of medicines and guidelines (73, 92, 120, 121).

There are concerns though that DTCs recorded the lowest percentage of being key for promoting RUM (Figure 1). The relatively high percentage of neutral responders (24%) suggests that more awareness is needed to raise the role and function of DTCs in both ambulatory and hospital care, and its link in promoting RUM, given concerns with their implementation and effectiveness especially in LMICs (122-125). According to the WHO, the goal of DTCs is to ensure access to the best possible cost effective
and high quality of care through determining what medicines will be available at what cost and how will they be used (125, 126). The important work of DTCs includes establishing documented rules and policies for all aspects of drug management including the selection of formulary list medicines and agreement regarding treatment protocols should be emphasised and reassessed for learnings. Other functions include continuing education for all key stakeholder groups, auditing and feedback, drug utilisation reviews and monitoring of adverse reactions and medication errors to promote RUM (93, 123, 125, 127). Nevertheless, it still remains unclear how DTCs with this important mandate represented by these activities failed to have a critical role in promoting RUM compared to clinical guidelines. More research is needed to uncover the reasons behind this to provide future direction given the critical role that DTCs including formularies have played with enhancing the RUM (93, 128-131), and we will be exploring this further in the future.

Furthermore, there is a clear need for clarity over the linkage between HTA and RUM. It is noted that RUM is a strategy that is applied through various structures across different tiers and levels. This assumes HTA as one corner stone structure that safe-guards RUM policies. Nevertheless, the healthcare community is yet to define the nature and depth of the relationship between the two. This may be because HTA can be linked more to reimbursement and funding decisions for new medicines across countries rather than a key role in guideline development. Similar to HTA practice, RUM policies aim to optimise treatment processes and cut waste. An example of a long-lasting research programme, funded by the Ministry of Health, and where HTA and RUM come together is the Rational Use of Pharmacotherapy of ZonMw in the Netherlands (132, 133).

Regarding the survey results, it is imperative to reflect on how RUM interventions are carried forward by different entities and bodies within the healthcare system, and how these entities translate RUM strategies into action. Equally important is the role of HTA as a function and practice, and how HTA entities establish a harmonized relationship with the remaining structures/entities that promote RUM implementation. This consequently entails more research on establishing an effective governance system across all involved entities and stakeholders to effectively incentivise and deliver RUM interventions to improve patient care. We will be following this up in the future.

Finally, it is important to emphasize that educational activities remain the most important interventions to improve RUM. Compared to engineering, economics, and enforcement, education related initiatives were perceived as the most important to address challenges hindering optimal RUM. This includes raising awareness on RUM to a wider group of stakeholders including government officials, patients, practitioners, and the public. The aim would be to focus on how best to achieve better utilisation of current interventions to enhance RUM, and how can these interventions be assessed, evaluated, and modified to appeal to different stakeholders as well as raise the level of understanding of the concept of RUM. These are projects for the future especially among Central and Eastern European countries with their increasing challenges.

We were aware of a number of limitations with this study. Firstly, the respondents taking part in the study were not representative of all key stakeholder groups. However, those taking part were actively involved in initiatives in their own countries to try and enhance RUM through different mechanisms. Secondly, some respondent groups had a high proportion of Piiperska members. Thirdly, we did not fully query all the interventions such as “avoidance of perverse financial incentives” as we believed it’s a very complex issue that is difficult to capture through one question. Lastly, the low response rate. However, we expect the impact of a higher response rate would have been limited and would not have appreciably altered the conclusions drawn as our target sample was highly specific. Consequently, those who responded are believed to be well representative of the healthcare community involved with RUM in their country to give good guidance. As a result despite these limitations, we believe the findings provide relevant insights into current RUM initiatives and challenges within Europe with the research team seeking to maximise the survey tool to obtain results that are as accurate as possible.

5. Conclusion

In conclusion, the importance of the RUM cannot be overstated given the growing pressure on healthcare resources across countries. Whilst our findings point to the importance of the key interventions surveyed, especially around clinical guideline development, the results suggest that the stakeholders are keen to develop better utilisation of these interventions, investing in their appropriate application in practice. This can be achieved most prominently by increasing educational initiatives
around RUM, and to call on creating mechanisms linking rational use of medicines with the HTA function already developed in most European countries. There is also a clear role for groups such as WHO Europe, especially in Central and Eastern European countries, EUNetHTA, Piperska, HTAi, EuroDURG and patient groups such as EUPATI to enhance RUM through their various activities and initiatives. In particular, this includes encouraging countries and stakeholders to learn from each other and to collaborate in order to improve RUM building on existing Pan-European networks. We will be following this up in the future including re-evaluating progress in this area.

6. Conflicts of interest

Ahmed Salem is employed by IQVIA. All other authors declare they have no competing interests

7. Author contributions

MG, AS and BBG developed the concept for the paper with help from WO. They subsequently coordinated the distribution of the questionnaire with the help of Jesper van den Bergh and WO. The methodology was developed by MG, with principal analysis undertaken by AS and MG with all authors contributing to the development of the paper.

8. Financial support

There was no financial support for this study

9. Acknowledgements

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Tables

Table 1: WHO's 12 Key interventions to promote rational use of medicine

1. Establishment of a multidisciplinary national body to coordinate policies on medicine use
2. Use of clinical guidelines
3. Development and use of national essential medicines list
4. Establishment of drug and therapeutics committees in districts and hospitals
5. Inclusion of problem-based pharmacotherapy training in undergraduate curricula
6. Continuing in-service medical education as a licensure requirement
7. Supervision, audit and feedback
8. Use of independent information on medicines
9. Public education about medicines
10. Avoidance of perverse financial incentives
11. Use of appropriate and enforced regulation
12. Sufficient government expenditure to ensure availability of medicines and staff.

Table 2: Survey Respondents

<table>
<thead>
<tr>
<th>Participant Category</th>
<th>CE</th>
<th>EE</th>
<th>NE</th>
<th>SE</th>
<th>TOTAL, n (%)</th>
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<td>1</td>
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<td>4 (7)</td>
</tr>
<tr>
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<td>0</td>
<td>0</td>
<td>7 (11)</td>
</tr>
<tr>
<td>National Health Organization</td>
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<td>5</td>
<td>3</td>
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<tr>
<td>Health Care Professional</td>
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<td>5</td>
<td>3</td>
<td>2</td>
<td>12 (19)</td>
</tr>
<tr>
<td>University/Academic</td>
<td>2</td>
<td>13</td>
<td>3</td>
<td>1</td>
<td>19 (31)</td>
</tr>
<tr>
<td>TOTAL, n (%)</td>
<td>7 (11)</td>
<td>37 (60)</td>
<td>12 (19)</td>
<td>6 (10)</td>
<td>62 (100)</td>
</tr>
</tbody>
</table>

CE: Central Europe; EE: Eastern Europe; NE: Northern Europe; SE: Southern Europe

Table 2: Types of HTA entities that are involved with RUM policy initiatives and/or coordination as per respondents’ answers (n=62)

<table>
<thead>
<tr>
<th>Type of HTA entity</th>
<th>Proportion of respondents, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No HTA entity involved with RUM policy coordination</td>
<td>23% (14)</td>
</tr>
<tr>
<td>Government national unit (within MoH)</td>
<td>23% (14)</td>
</tr>
<tr>
<td>Government agency (independent)</td>
<td>13% (8)</td>
</tr>
<tr>
<td>Regulatory authority national government</td>
<td>8% (5)</td>
</tr>
<tr>
<td>Funding agency (i.e. payer)</td>
<td>6% (4)</td>
</tr>
<tr>
<td>Professional society (national)</td>
<td>5% (3)</td>
</tr>
<tr>
<td>Academia</td>
<td>5% (3)</td>
</tr>
<tr>
<td>More than one entity</td>
<td>5% (3)</td>
</tr>
<tr>
<td>Network of HTA agencies (more than one country)</td>
<td>3% (2)</td>
</tr>
<tr>
<td>Healthcare provider under MoH (e.g. public hospital)</td>
<td>3% (2)</td>
</tr>
<tr>
<td>Regional drug agency</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Public insurance agency</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Professional society – international</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Network of HTA agencies (within one country)</td>
<td>2% (1)</td>
</tr>
</tbody>
</table>

HTA: health technology assessment; RUM: rational use of medicine; MoH: ministry of health
Table 4: Proportion of respondents who are aware of the different Pan-European groups advocating RUM (n=62)

<table>
<thead>
<tr>
<th>Pan-European Group</th>
<th>Proportion of respondents aware, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO Europe</td>
<td>85% (53)</td>
</tr>
<tr>
<td>EuNetHTA</td>
<td>68% (42)</td>
</tr>
<tr>
<td>Piperska group</td>
<td>65% (40)</td>
</tr>
<tr>
<td>MEDEV</td>
<td>42% (26)</td>
</tr>
<tr>
<td>HTAi</td>
<td>40% (25)</td>
</tr>
<tr>
<td>EuroDURG</td>
<td>37% (23)</td>
</tr>
<tr>
<td>PPRI</td>
<td>37% (23)</td>
</tr>
<tr>
<td>EACPT</td>
<td>18% (11)</td>
</tr>
<tr>
<td>Others</td>
<td>13% (8)</td>
</tr>
</tbody>
</table>

WHO: World Health Organization; EuNetHTA: European network for health technology assessment; MEDEV: The Medicine Evaluation Committee; HTAi: Health Technology Assessment International; EuroDURG: European Drug Utilisation Research Group; PPRI: Pharmaceutical pricing and reimbursement information initiative; EACPT: European Association for Clinical Pharmacology and Therapeutics

Figures

Figure 1: Proportion of respondents who agree/disagree that the interventions listed promote RUM (n=62)
Figure 2: Countries’ performance in achieving the distinct key interventions to promote RUM, as perceived by the respondents (n=62)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>1 (Poor)</th>
<th>2 (Suboptimal)</th>
<th>3 (Fair)</th>
<th>4 (Above average)</th>
<th>5 (Strong)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of initiatives such as education, feedback, quality targets, and</td>
<td>44%</td>
<td>34%</td>
<td>22%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prescription restrictions (in pertinent situations) to enhance RUM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion of problem-based pharmacotherapy training in undergraduate curricula</td>
<td>44%</td>
<td>31%</td>
<td>22%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>at relevant institutions, and in-service continual professional development</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Establishment of drug and therapeutics committees (DTC) in districts/regions and hospitals</td>
<td>32%</td>
<td>40%</td>
<td>34%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development and use of national or regional formularies</td>
<td>31%</td>
<td>27%</td>
<td>29%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of clinical guidelines to promote RUM</td>
<td>39%</td>
<td>27%</td>
<td>34%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 (Poor) - 2 (Suboptimal) - 3 (Fair) - 4 (Above average) - 5 (Strong)

Figure 3: Proportion of respondents perceiving that there are challenges to realizing the key interventions to promote RUM (n=62)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of initiatives such as education, feedback, quality targets, and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prescription restrictions (in pertinent situations) to enhance RUM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion of problem-based pharmacotherapy training in undergraduate curricula</td>
<td>25%</td>
<td>74%</td>
</tr>
<tr>
<td>at relevant institutions, and in-service continual professional development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Establishment of drug and therapeutics committees (DTC) in districts/regions and hospitals</td>
<td>27%</td>
<td>73%</td>
</tr>
<tr>
<td>Development and use of national or regional formularies</td>
<td>26%</td>
<td>74%</td>
</tr>
<tr>
<td>Use of clinical guidelines to promote RUM</td>
<td>10%</td>
<td>90%</td>
</tr>
</tbody>
</table>
Figure 4: Current challenges to the implementation of key interventions aimed to promote RUM (n=62)
Figure 5: Possible solutions to address identified challenges regarding the key interventions to promote RUM (n=62)

<table>
<thead>
<tr>
<th>Solution</th>
<th>Education</th>
<th>Engineering</th>
<th>Economics</th>
<th>Enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of initiatives such as education, feedback, quality targets, and prescription restrictions (in pertinent situations) to enhance RUM</td>
<td>40%</td>
<td>39%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Inclusion of problem-based pharmacotherapy training in undergraduate curricula at relevant institutions, and in-service continual professional development</td>
<td>40%</td>
<td>26%</td>
<td>15%</td>
<td>9%</td>
</tr>
<tr>
<td>Establishment of drug and therapeutics committees (DTC) in districts/regions and hospitals</td>
<td>50%</td>
<td>32%</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td>Development and use of national or regional formularies</td>
<td>53%</td>
<td>23%</td>
<td>16%</td>
<td>8%</td>
</tr>
<tr>
<td>Use of clinical guidelines to promote RUM</td>
<td>46%</td>
<td>38%</td>
<td>13%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Figure 6: Challenges hindering the countries’ HTA entities to achieving effective RUM policy coordination (n=62)

- Establishment of a HTA multidisciplinary body is costly (28%)
- Establishment of a HTA multidisciplinary body is costly (lack of financial resources) (28%)
- Other, please specify (12%)
- Not enough knowledge or linking the RUM to healthcare within an HTA institutional framework (48%)
- Lack of political will (put on the political agenda) (48%)

Figure 7: Challenges hindering achieving the key interventions to promote RUM (n=62)

- Professional societies and the medical/pharmacy/nursing associations’ role in public education is limited (32%)
- Public education is costly to carry out (lack of financial resources), especially if this needs to be continually expected (60%)
- Lack of innovative ways to deliver public education in a useful manner (11%)
- Other, please specify (11%)
- Lack of adequate research or technical knowledge strategies to educate the public about the rational use of...
Figure 8: Challenges to support local entities in enhancing RUM (n=62)
Appendix 1 - CORUM Questionnaire

* Contact Information
Please provide the details of the person integrating/completing this questionnaire:

<table>
<thead>
<tr>
<th>Job title</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization</td>
<td></td>
</tr>
<tr>
<td>City/Region</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
</tbody>
</table>

* 1 - How strongly do you agree/disagree with the following statement being a key intervention to promote the rational use of medicines (RUM): “Use of clinical guidelines to promote RUM”

<table>
<thead>
<tr>
<th>1 (Strongly Disagree)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Strongly Agree)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 1A - On a scale of 1-5, how would you rate your country’s performance in realizing/achieving the above statement

<table>
<thead>
<tr>
<th>1 (Unsatisfactory)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Optimal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 1B – Do you believe there are current limitations in achieving the above statement?

- ☐ Yes
- ☐ No
* 1C – Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): “Use of clinical guidelines to promote RUM”

- Lack of updated national guidelines/ prescribing guidance
- Lack of updated local guidelines/ prescribing guidance
- National guidelines are not mandated or encouraged for practical application
- Local guidelines are not mandated or encouraged for practical application
- Governments do not provide sufficient funds for the development, regular updating, and implementation of guidelines/ prescribing guidance (lack of resources)
- Too many national guidelines to allow for effective compliance
- No governance framework or legal backing for the use of guidelines
- Other, please specify

..........................................................

* 1D – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 1C (if pertinent to the situation in your country/ region)

1
2
3

* 2 - How strongly do you agree/disagree with the following statement being a key intervention to promote the rational use of medicines: “Development and use of national or regional formularies”

1 (Strongly Disagree)  2  3 (Neutral)  4  5 (Strongly Agree)
* 2A - On a scale of 1-5, how would you rate your country’s performance in realizing/achieving the above statement

<table>
<thead>
<tr>
<th>1 (Unsatisfactory)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Optimal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>▲</td>
<td>▲</td>
</tr>
</tbody>
</table>

* 2B – Do you believe there are current limitations in achieving the above statement?

- ☐ Yes
- ☐ No

* 2C – Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): “Development and use of national or regional formularies”

- ☐ Lack of political will
- ☐ Lack of technical expertise
- ☐ Lack of financial resources
- ☐ Opposition to medicines policies by some stakeholders
- ☐ Lack of trust in those developing the formularies
- ☐ Lack of dissemination of formularies
- ☐ Lack of follow-up of adherence to formularies
- ☐ Other, please specify

.................................

* 2D – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 2C (if pertinent to the situation in your country/region)

1
2
3
3 - How strongly do you agree/disagree with the following statement being a key intervention to promote rational use of medicines: "Establishment of drug and therapeutics committees (DTC) in districts/regions and hospitals"

<table>
<thead>
<tr>
<th>1 (Strongly Disagree)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Strongly Agree)</th>
</tr>
</thead>
</table>

3A - On a scale of 1-5, how would you rate your country’s performance in realizing/achieving the above statement

<table>
<thead>
<tr>
<th>1 (Unsatisfactory)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Optimal)</th>
</tr>
</thead>
</table>

3B – Do you believe there are current limitations in achieving the above statement?

- Yes
- No

3C – Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): 'Establishment of drug and therapeutics committees (DTC) in districts/regions and hospitals'

- Lack of incentives and/or time for members to undertake any drug and therapeutic committee activities
- Lack of financial resources
- Lack of local expertise
- Drug and therapeutic committees not seen as important
- Lack of promoting for DTCs as organizations that can promote RUM
- Limited follow-up of drug and therapeutic committees recommendations
- Other, please specify

............................................................
3D – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 3C (if pertinent to the situation in your country/region)

1
2
3

4 - How strongly do you agree/disagree with the following statement being a key intervention to promote the rational use of medicines: “Inclusion of problem-based pharmacotherapy training in undergraduate curricula at relevant institutions, and in-service continual professional development”

1 (Strongly Disagree) 2 3 (Neutral) 4 5 (Strongly Agree)

4A - On a scale of 1-5, how would you rate your country’s performance in realizing/achieving the above statement

1 (Unsatisfactory) 2 3 (Neutral) 4 5 (Optimal)

4B – Do you believe there are current limitations in achieving the above statement?

 Yes
 No
**4C –** Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): “Inclusion of problem-based pharmacotherapy training in undergraduate curricula at relevant institutions, and in-service continual professional development”

- Training programs are costly to carry out (lack of financial resources)
- Lack of incentives to encourage dedication to the education and training programmes by students (not a mandate for licensure)
- Lack of adequate research or technical knowledge to generate education and training programs on RUM.
- Lack of trained personnel to conduct pharmacotherapy training courses such as clinical pharmacologists and clinical pharmacists
- Lack of time for pharmacotherapy courses built into physician training programmes
- Other, please specify

............................................................

**4D –** Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 4C (if pertinent to the situation in your country/region)

1  
2  
3

**5 -** How strongly do you agree/disagree with the following statement being a key intervention to promote the rational use of medicines: 'Use of initiatives such as education, feedback, quality targets, and prescription restrictions (in pertinent situations) to enhance the rational use of medicines.'

1 (Strongly Disagree)  
2  
3 (Neutral)  
4  
5 (Strongly Agree)
* 5A - On a scale of 1-5, how would you rate your country's performance in realizing/achieving the above statement

<table>
<thead>
<tr>
<th></th>
<th>1 (Unsatisfactory)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Optimal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td></td>
<td>☐</td>
<td></td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

* 5B – Do you believe there are current limitations in achieving the above statement?

☐ Yes
☐ No

* 5C – Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): 'Use of initiatives such as education, feedback, quality targets, and prescription restrictions (in pertinent situations) to enhance the rational use of medicines.'

☐ Reaching a consensus (between organizations) on the appropriate initiatives to enhance RUM is difficult
☐ Lack of political will and support to instigate the initiatives or other measures to enhance RUM
☐ Lack of financial resources to fully implement programs to enhance RUM
☐ Other, please specify

............................................................

* 5D – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 5C (if pertinent to the situation in your country/region)

1
2
3

............................................................

............................................................

............................................................
* 6 - Does your country have a different bodies (multi-national, national, regional) that instigate and/or coordinate RUM initiatives and policies?

- Yes
- No

* 6A - What organizations are responsible for RUM policy implementation and coordination in your country (national or regional) – please list key organisations?


* 6B - Please select the current type of HTA entities (unit, department, institution, organization, authority, network) in your country (national or regional) that are involved with RUM policy initiatives and/or coordination:

- Academia, University
- Funding Agency (i.e. payer)
- Government Agency (independent)
- Government National Unit (within MoH)
- Healthcare provider under MoH (e.g. public hospital)
- Healthcare provider private (e.g. private hospital)
- Network of HTA agencies – National/ Global (more than one country)
- Network of HTA Agencies – Regional (within one region)
- Pharmaceutical Industry (private)
- NGO (e.g. Fund/Foundations)
- Professional Society - National
- Professional Society – International
- Regulatory Authority National Government
- Private Insurance Agency
- Public Insurance Agency
- Other, please specify
  ............................................................
- No HTA entity involved with RUM policy coordination
* 6C - On a scale of 1-5, how would you rate your country’s performance in realizing/achieving effective RUM policy coordination?

<table>
<thead>
<tr>
<th>1 (Unsatisfactory)</th>
<th>2</th>
<th>3 (Neutral)</th>
<th>4</th>
<th>5 (Optimal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

* 6D – Do you believe there are current limitations in achieving the above statement?

- Yes
- No

* 6E – Please state the current limitations you believe are hindering achieving effective RUM policy coordination (you may select multiple answers):

- Establishment of a HTA multidisciplinary body is costly (lack of financial resources)
- Not enough knowledge on linking the RUM function within an HTA institution framework
- Lack of political will (not on the political agenda)
- Other, please specify
  ..............................................................................

* 6F – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 6E (if pertinent to the situation in your country/region)

1
2
3
* 7 - How strongly do you agree/disagree with the following statement being a key intervention to promote more rational use of medicines: ‘Consumer education about the use of medicines is essential to enhance their rational use, e.g. for infections and AMR’

1 (Strongly Disagree)  
2  
3 (Neutral)  
4  
5 (Strongly Agree)  

* 7A - On a scale of 1-5, how would you rate your country’s performance in realizing/achieving the above statement

1 (Unsatisfactory)  
2  
3 (Neutral)  
4  
5 (Optimal)  

* 7B – Do you believe there are current limitations in achieving the above statement?

☐ Yes
☐ No

* 7C – Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): ‘Consumer education about the use of medicines is essential to enhance their rational use, e.g. for infections and AMR’

☐ Professional societies and the medical/pharmacy/nursing associations’ role in public education is limited.

☐ Public education is costly to carry out (lack of financial resources), especially if this needs to be continually repeated (e.g. antibiotics for viral infections)

☐ Lack of adequate research or technical knowledge strategies to educate the public about the rational use of medicines

☐ Lack of innovative ways to deliver public education in a useful manner

☐ Other, please specify
........................................................................................................
* 7D – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 7C (if pertinent to the situation in your country/region)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

* 8 - Which of the following pan-European groups involved in advocating appropriate and efficient prescribing have you heard of?

- ☐ Piperska group
- ☐ WHO Europe
- ☐ EuNetHTA
- ☐ PPRI
- ☐ MEDEV
- ☐ HTAi
- ☐ EACPT
- ☐ EuroDURG
- ☐ Other, please specify

............................................................

* 8A - Do you believe the Piperska Group plays a role in enhancing RUM?

- ☐ Yes
- ☐ No
8B - What role should the Piperska Group play in enhancing RUM?

- Developing new concepts to enhance the rational use of new and existing medicines
- Providing governments and health authorities with expert opinions and information based on research from countries
- Reviewing concepts submitted by government and health authorities
- Other, please specify

9 - How strongly do you agree/disagree with the following statement being a key intervention to promote more rational use of medicines: 'There is a need for organizations like the Piperska Group to enhance the rational use of medicines across Europe by information sharing and cooperation’

1 (Strongly Disagree) | 2 | 3 (Neutral) | 4 | 5 (Strongly Agree)

- [ ]

9A – Do you believe there are current limitations in achieving the above statement?

- Yes
- No

9B – Please state the current limitations you believe are hindering achieving this statement from the previous question (you may select multiple answers): 'There is a need for organizations like the Piperska Group to enhance the rational use of medicines by information sharing and cooperation’

- An organization like the Piperska Group would not contribute to the RUM due to limited influence on the way countries currently enhance the rational use of medicine
- There is no need for an organization like the Piperska Group because there is already similar organization in place, e.g. EuNetHTA, PPRI and MEDEV (please expand in 'other')
- Financial support is needed for an organization like the Piperska Group to generate policies and visibility in order to enhance the rational use of medicines within countries
- Other, please specify

...........................................................
* 9C – Please suggest a maximum of 3 potential ways to overcome the limitations you have mentioned or selected in Question 9B (if pertinent to the situation in your country/region)

1

2

3

Additional comments: