Guidelines on
MEDICATION REVIEW

Committee of Experts
on Quality and Safety Standards
in Pharmaceutical Practices
and Pharmaceutical Care
(CD-P-PH/PC)

EDQM
2024

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Guidelines on

MEDICATION REVIEW

European Directorate for the Quality of Medicines & HealthCare

Publication available from: https://freepub.edqm.eu/

Editorial director: Dr P. Doerr
Page layout and cover: EDQM
Cover photo: © Adobe Stock

European Directorate for the Quality of Medicines & HealthCare (EDQM)
Council of Europe
7 allée Kastner, CS 30026
F-67081 Strasbourg
France

Internet: www.edqm.eu

FAQs & EDQM HelpDesk: www.edqm.eu/hd/

Contents

This document was prepared by a working group of experts from academia, community and hospital pharmacy and representatives of national competent authorities of the Council of Europe member states. The guidelines were discussed and reviewed by stakeholders via a consultation and were subsequently revised and approved by the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC).

The Council of Europe, the EDQM and pharmaceutical care

Council of Europe

The Council of Europe is an intergovernmental organisation with its headquarters in Strasbourg (France) [1].

It was set up in 1949, in the wake of the Second World War, to ensure the political reconstruction of Europe based on a set of fundamental values, the loss of which had brought the continent to its knees.

It comprises 46 European countries[1], representing more than 700 million citizens. Its role is to promote democracy and protect human rights and the rule of law in Europe [2, 3].

Council of Europe activities in the area of safe and appropriate use of medicines

Since its inception, the Council of Europe has been concerned with the safe and appropriate use of medicines and, at a later stage, pharmaceutical care. Committee of Ministers Resolution ResAP(94)1 on the rational use of medicines advocated measures and structures to be set up in order to make healthcare professionals and patients aware of the necessity of a new approach to the consumption of medicines [4], whereas Committee of Ministers Resolution ResAP(93)1 on the role and training of community pharmacists was inspired by the principles of patient-centred multidisciplinary pharmaceutical care and called on member states to take these principles into account when regulating the role and training of pharmacists [5].

A number of reports, recommendations and resolutions were issued in the subsequent years. These documents focused on different aspects related to pharmaceutical practice and care, including, but not limited to, the development of the function of pharmacists, management of patient safety and prevention of adverse events in healthcare, medication safety and prevention of medication errors [6, 7, 8, 9].

In 2007, the Council of Europe Committee of Ministers agreed to transfer the activities related to pharmaceutical issues from the Partial Agreement in the Social and Public Health field to the European Directorate for the Quality of Medicines & HealthCare (EDQM), as of 1 January 2008 [10].

1 Council of Europe member states: Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Republic of Moldova, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom.

European Directorate for the Quality of Medicines & HealthCare (EDQM)

The EDQM is a Directorate of the Council of Europe [11].

It traces its origins and statues to the Convention on the Elaboration of a European Pharmacopoeia (Ph. Eur.), an international treaty adopted by the Council of Europe in 1964. The 39 member states[2] and the EU that have signed the Ph. Eur. Convention are committed to achieving harmonisation of the quality of medicines throughout the European continent and beyond [11].

The EDQM protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation, consumer health protection and safe and appropriate use of medicines [12, 13].

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate committees of experts

The CD-P-PH is one of the 26 intergovernmental steering committees of the Council of Europe. It was set up by the Council of Europe Committee of Ministers and it reports directly to this latter. The core mission of the CD-P-PH is to support national competent authorities of the Council of Europe member states parties to the Ph. Eur. Convention to make the medication process safer, more responsible and accessible to all who need it [14].

Activities in the area of safe and appropriate use of medicines are overseen by the CD-P-PH and carried out by the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC). This latter is in charge of improving pharmaceutical practices and pharmaceutical care in community and hospital pharmacy settings through the development and promotion of guidance documents, standards and recommendations [15].

Pharmaceutical care

The Committee of Experts CD-P-PH/PC acknowledges that different terminologies and definitions may be used when referring to medicine-related patient care. In its activities, the CD-P-PH/PC uses the term *pharmaceutical care* and the definition developed by Hepler and Strand. According to this definition, "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." It "involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient." Pharmaceutical care plays an important role in ensuring the appropriate use of medicines and helps achieve the best possible medication outcome for the patient. Therefore, pharmaceutical care can ultimately improve quality of life and rational use of healthcare resources and reduce inequities in healthcare [16].

In March 2020, the Committee of Ministers of the Council of Europe adopted Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services [17]. The resolution provides health authorities, professional bodies and healthcare professionals across Europe with a legal basis for the implementation of a pharmaceutical care philosophy and working methods in community and

2 Ph. Eur. members: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom and the European Union.

hospital settings. The implementation of its provisions is expected to enhance patient-centred care and interprofessional collaboration, and to ensure access to safe and good quality healthcare in Europe.

Among other things, the above resolution recommends that medication reviews (MRs) be performed under the pharmaceutical care process with a view to evaluating actual and potential medicine-related problems (MRPs), to optimise medicine use, and ensure the best possible health outcomes for the patients.

In the light of the above recommendation, and taking into account that the MR process appears to have been implemented in different ways and to different degrees across the Council of Europe member states, in 2019 the Committee of Experts CD-P-PH/PC agreed to develop a guidance document to support the harmonisation of the MR process in Europe.

This guidance has been developed from this recommendation. As pharmacists are experts in medicines, MR is usually conducted by a pharmacist. Prescribers can also conduct MR and other suitably qualified healthcare professionals with training may be able to provide MR as part of a multidisciplinary team. It goes without saying that interprofessional collaboration is essential to ensure that the goals of MR are met. Therefore, the implementation of collaborative approaches with general practitioners (GPs) and other members of the care team is strongly encouraged as best practice.

Executive summary

Medication review (MR) is a structured and systematic evaluation of a patient's medicines with the aim of optimising their use and improving health outcomes. It involves the identification of actual or potential medicine-related problems (MRPs) and results in recommendations to optimise medicine use.

Guideline scope and aims

This guidance is intended for competent national authorities and policy makers, pharmacists and healthcare professionals conducting MR and for health service organisations establishing MR programmes.

The primary aims of the guidance are:

- to establish a common understanding of what MR is and how it contributes to improving the use of medicines;
- to set out the process of conducting a MR (including the identification and prioritisation of patients who would benefit from a MR, and the recommended frequency of MRs);
- to provide some insights on how to support the development of this service and to facilitate the implementation into practice at European level.

Medication review and medicine use

Demand for healthcare and for medicines is rising. The routine checks carried out by prescribers and pharmacists are no longer sufficient to ensure optimal use of medicines and patient safety.

The potential impact of poor selection and use of medicines and of adverse effects from medicines are significant and system-wide problems for the health service.

Regular MR to assess the patient's need for and experience of the medicines that they are taking, from all sources, is therefore good practice.

The integration of a MR programme into the care pathway for the patient population is recommended and is essential to enhance the safe use of medicines, especially in those with greatest need.

Medication review

Pharmacists and physicians routinely conduct MRs, but pharmacists, as experts in medicines, do so most frequently.

MRs can be conducted in all healthcare service settings, but the type of MR used must be appropriate for the patient's circumstances and clinical need, and the outcomes must be communicated to the relevant people who care for the patient.

There are three types of MR:

- a "simple MR" in which the patient's medication history (records of medicines used) is reviewed;
- an "intermediate MR" which combines several sources of information – from the patient, the medication history and possibly also some of the patient's clinical information in more complex clinical situations;
- an "advanced MR" which involves the patient and all the available medicines and clinical information. This is the most in-depth type of MR used to address the most complex and potentially serious circumstances.

Medication review process

A MR should follow a structured, standardised procedure to ensure consistency in the provision of quality patient care and should consist of the following steps.

MR consists of the identification of patients who may benefit, collection of all the relevant information, followed by medication reconciliation and then evaluation to determine and prioritise the MRPs requiring intervention and consequent recommendations. These are formulated into a pharmaceutical care plan, which should be prepared with the patient and the relevant information shared with the patient and other healthcare professionals. Implementation and follow-up should be carried out and added to the patient's MR records.

Data collection, protection and storage

A complete picture of the patient's medicine history, related clinical information and healthcare professionals who are providing care is essential to the effectiveness of MR. It is recommended that the pharmacist should be able to access, collate, comment on and share information that is pertinent in the patient's records.

All of the data generated in MR should be recorded, processed, stored and retained in accordance with international and national regulations, standards and guidance on all platforms and in all systems in all healthcare settings. This should include security features and procedures to regulate access to patient and MR data by other staff in the practice or institution in order to protect the integrity of the data and the privacy of the patient.

Education and training

Prescribers and pharmacists may need to update their knowledge prior to conducting simple MRs, but should receive comprehensive training to conduct advanced MRs.

Other healthcare professionals need education and training to conduct all of the different types of MR.

Once a suitable structured and recognised MR education programme has been established, this should be followed by periodic continuing professional development to maintain competency.

Health service context

MR should be available for an individual patient and as a health service-wide programme with the aim of improving public health.

MR should be integrated into the care pathway for the patient population.

It is the responsibility of the health service together with the stakeholders to provide the vision, leadership and (human and financial) resources to ensure that MR is developed and implemented effectively and efficiently.

MR is an important tool to optimise medicine use and should be used to its full extent to improve patient care and patient safety.

Chapter 1 – Guideline scope and aims

MR is performed in parts of Europe, with pharmacist-led MR the most prevalent and most researched method [18]. However, MR is an under-used health service intervention in Europe and needs to performed in a consistent and systematic manner to realise the benefits [19]. The potential value of MR to patients and to health services does not seem to be appreciated, and while some countries have national guidance, there is no standardised guidance at the European level available across the Council of Europe member states at present. For these reasons, in 2019 the Committee of Experts CD-P-PH/PC agreed to develop a guidance document to support the harmonisation and improvement of the MR process in Europe in different care settings and for various target patient groups.

The aims of the guideline are:

- to establish a common understanding of what MR is and how it contributes to improving the use of medicines;
- to set out the process of conducting a MR (including the identification and prioritisation of patients who would benefit from a MR, and the recommended frequency of MRs);
- to illustrate the necessity for the collection and sharing of data;
- to provide guidance concerning education and training;
- to provide insights on how to support the development of this service and to facilitate the implementation into practice at the European level;
- to provide information on existing MR programmes.

The guidelines are intended to:

- assist national competent authorities and policy makers in establishing and adapting MR as an intervention in their healthcare systems;
- support countries and health services where the application and performance of MR are considered suboptimal;
- assist pharmacists and healthcare professionals involved with medicines to ensure that MR is carried out in a consistent and systematic manner;
- assist health authorities to drive medicine optimisation, to improve patient safety and patient health outcomes, and to support efficient medicine management.

Chapter 2 – Medication review and medicine use

Physicians and pharmacists share responsibility for the use of medicines throughout the health service. They check the suitability of the medicines that they provide for patients. However, by themselves, these routine checks are no longer sufficient to detect and remedy the MRPs that occur in today's complex healthcare systems. A MR is a structured evaluation of a patient's medicines, designed to address these needs with the aim of optimising medicine use and improving health outcomes. Physicians and pharmacists have the qualifications and expertise to carry out MRs and, with training, can conduct advanced MRs.

MR is performed in primary care by community pharmacists and pharmacists who work alongside GPs/family doctors, across the hospital sector by hospital pharmacists and community pharmacists, and in residential care homes GPs/family doctors usually conduct them. In other settings, and in healthcare system MR programmes, either a pharmacist or another healthcare professional working as part of a multidisciplinary team with pharmacist input may conduct a MR, once they have received specific training. Some of the ancillary tasks that contribute to MR can be undertaken by other healthcare staff under the condition that appropriate supervision by a trained healthcare professional is in place.

This chapter establishes the context and reasons for MR and its potential for improving the use of medicines.

The need for MR

Demand for healthcare and for medicines continues to grow, driven by many factors. The complexity of treatment using medicines and the properties of the medicines themselves, as well as the multiplicity of sources from which medicines can be obtained, combine with individual patient factors to create circumstances in which there is both a loss of benefit and an increased likelihood of risk and harm. Studies estimate that up to 50 % of medicines are not taken as prescribed and that medicines are associated with 5-17 % of hospital admissions, most of which – up to 80 % – could be avoided [20]. Good quality MR is the foundation of medicine optimisation for patients, ensuring patients get the most out of their medicines while minimising risks and reducing medicine-related costs.

A patient who requires many medicines, polypharmacy – 5 or more regular medicines – is at greater risk of MRPs. Advances in pharmacotherapy mean that people with several chronic diseases are increasingly likely to be prescribed polypharmacy, often by different prescribers. Evidence-based guidance for prescribing is largely based on single diseases, which does not generally take account of multimorbidity, which is now the norm in those over 65 years of age. Consequently, patients are prescribed several medicines recommended by disease-specific guidelines by prescribers who may not be able to consult each other in a timely way and co-ordinate the patient's care. There are many patient groups for whom polypharmacy, high-risk medicines and non-adherence are particularly important, including children and older people, as well as vulnerable groups, such as those with dementia or certain disabilities.

Multimorbidity and polypharmacy are associated with an increased risk of adverse medicine events, medicine interactions, medicine errors and poor medicine adherence. In most patient populations, inappropriate polypharmacy and medicine non-adherence are two key inter-related problems and, particularly in the elderly, are associated with falls, hospitalisations and emergency admissions [21], which lead to poor health outcomes [22]. The standardisation of policies, procedures and protocols is critical to polypharmacy, and their application from the initial prescribing to addressing non-adherence is part of the MR process [23].

Adverse events are now estimated to be the 14th leading cause of morbidity and mortality in the world [24]. Most of this harm is preventable [25]. Given that medicines are the most common therapeutic intervention, the World Health Organization (WHO) believes that ensuring safe medicine use and having the processes in place to improve medication safety should be a priority in health policy [26].

Over time the patient's medical conditions and health status may change and these may have an impact on their response to their medicines. Consequently, new medicines may be needed, medicines or their doses may need to be changed and medicines may have to be stopped or deprescribed. The patient's personal and social circumstances may also change and affect their ability to manage their medicines. Changes to the dosage forms or the presentation of their medicines may be necessary to simplify and facilitate the taking of medicines regularly.

While medicines that are prescribed receive most attention in the research literature and in the public media, non-prescription medicines, medicines used off-label and unauthorised medicines can, increasingly, be obtained easily by people, sometimes with little or no consultation of a healthcare professional. These too can produce harm, either by themselves or as a result of interacting adversely with the patient's other medicines. Consequently, in order to accurately assess the medicine history of a patient, an evaluation of all potential influencing factors is required, and the use of herbal preparations, food supplements, traditional remedies and substances such as alcohol need to be taken into account. Patients are often reluctant to divulge all of the medicines and supplements that they take to their physician, but pharmacists have been shown to be capable of obtaining a complete medicine history [27, 28].

Medicine use process and MR

Physicians and pharmacists routinely conduct simple MR as part of their usual practice. Before a medicine is prescribed and before it is dispensed, a review is carried out to determine if it is appropriate for the patient. All medicines have both therapeutic and adverse effects that must be taken into account for each patient. However, the potential benefits and risks of taking a medicine depend, first of all, upon whether the need for a medicine is correctly identified and the medicine selected is the most appropriate one. Whether the patient uses the medicine as recommended, or does not take it at all, alters both the potential benefits and risks. The patient's preferences and goals for their treatment may be different from those of the healthcare professionals caring for them. It is important to understand the patient's point of view because it influences their adherence with their prescription medicines and their use of non-prescription medicines, supplements and other preparations. These factors mean that the balance of risks and benefits can vary from one patient to another and from one point in time to another for the same patient. Periodically, an extensive review of all of the factors that may affect medicine use should be conducted for each patient.

The medicine use process involves the selection, prescribing, dispensing, administering and monitoring of medicines. It is a complex cycle of care and is the responsibility of the patient, the prescriber and the pharmacist. Patients with multimorbidity receive care from both specialists and GPs. Co-ordinating the provision of these medicines and of the patient's care is a substantial challenge. MR plays a role in this. Regular review of the patient's need for, and experience of, the medicines that they are taking, from all sources, is good practice. MR is a patient-centred process that empowers and supports the patient. MR supports all those who care for patients and in this way, it also benefits the health service.

Effective and safe care with medicines can only be assured when detailed care records are shared. Continuity in the medicine use process is attained when all the steps in the use cycle relevant to the episode of care are completed and the information transferred to each of the relevant professionals. The capability to access and share information and recommendations about the patient and their medicines is crucial to MR. Discontinuity in patient care frequently results in suboptimal use of medicines and leads to significant patient harm. Therefore, to be effective, MR must be a collaborative process between the patient, pharmacist, prescribers and all of the healthcare professionals who provide care for the patient, underpinned by up-to-date, shared records. Interprofessional collaboration is essential in MR and to improving the use of medicines.

Scale and scope of MR

MR is required across the entire health service because medicine use is ubiquitous in healthcare and the associated benefits and risks must be evaluated at each step of the patient's journey. The system-wide impact of MRPs also affects the provision and sustainability of health services and MR is an essential policy response.

Most medicines are used in primary care (ambulatory care) and in this setting they are used by the greatest proportion of the population. It is clear that the number of medicines taken and the opportunity for MRPs are increasing as the treatment of more complex conditions and of multiple morbidity becomes possible in the patient's home. Addressing medicine use problems in primary care not only increases patient safety, it has the potential to significantly reduce unplanned utilisation of health services [29].

Patients who are admitted to hospital are likely to have poor health status, to have more advanced diseases and to require more medicines, including high-risk medicines, as part of their treatment. Therefore, an essential first step on admission is to reconcile the patient's medicines by establishing the best possible medication history (BPMH). If they are transferred from the care of one speciality to another while in the hospital, their medicines are reconciled again; otherwise, MRPs will accumulate, and the patient's safety will be compromised. Before the patient is discharged, medicine counselling is needed and liaison with those responsible for the patient's medicine use in primary care, or in a residential home, should occur to prevent medicine-related hospital readmission. WHO has highlighted the importance of medication harm at the transitions of care and in high-risk settings such as surgical units [30].

People living in residential care settings also need medical care and take medicines. On admission, on return from hospital visits and as their needs change, both medication reconciliation and MR should be carried out. In these settings, access to pharmacists may be limited for a number of reasons and the monitoring of patients' medicines needs conducted by non-healthcare staff may be inadequate. The population of frail elderly, cognitively impaired and intellectually disabled people in residential care is substantial, and each of these groups is particularly susceptible to poor quality use of medicines and, therefore, they require additional care and attention.

In all of the settings described above, it is apparent that several different healthcare professionals prescribe, dispense and administer medicines as part of their role in the care of the patient. All of them need to be informed about MR, to be able to contribute and to receive or at least to be able to access the records of the outcomes of the MR. Without this co-ordination and integration, appropriate action is unlikely to be taken in response to the findings of the MR. In turn, this will reduce the value of the MR and the quality of the care provided, as well as damaging the patient's perception of the health service. Shared electronic health records (eHRs) can facilitate this, but each professional has a unique perspective of the patient and of the medicines so it is important that the eHR enables write permissions as well as viewing. Similarly, patients can be empowered by having access to the records of their MR and their eHR, and their safety can be enhanced by being able to share this information with others involved in their care. It goes without

saying that the protection of the data and of the privacy and confidentiality of the patient's records is the responsibility of the health service and of those engaged by it to perform MR.

Physicians, pharmacists and patients determine the need for MR at the individual level while the health service determines need at the population level. The purpose of the MR must be clear and then the most appropriate type selected. For a patient with recently diagnosed type 2 diabetes mellitus, a MR focused on their diabetes and the medicines used to treat it using the patient's medicines records (MR type 1 or 2b) may be conducted to check that their treatment was appropriate, whereas for a similar patient whose adherence to their diabetes medicines and monitoring seemed poor, a MR in which the patient is directly involved (MR type 2a) would be more appropriate. On the other hand, the health service may prioritise certain patient groups for MR (stratified according to risk) to address a perceived public health need; for example, older patients with type 2 diabetes mellitus and coronary artery disease may be considered a priority and a guideline-based MR programme to improve their treatment and monitoring could be implemented across the health service. These system-wide programmes require careful development and implementation, including co-ordination, to realise their aims and objectives.

Each type of MR generates information and recommendations to improve patient care. This information not only has immediate value and should be part of the patient's medication history, but it should also be added to the patient's records and made available for future episodes of care. The multiplicity of siloed services and medicine records within fragmented healthcare systems creates a burden that is challenging for healthcare professionals to manage. The integration of MR programmes into the care pathway for the patient population is therefore necessary to attain all of the benefits of MR both for individual patients and for the population as a whole. The impact of the poor use of medicines and of adverse effects from medicines are significant and system-wide problems for the health service and are an avoidable burden for patients.

The potential benefits of MR

The primary goal of MR is to improve the quality, safety and appropriate use of medicines in order to enhance health outcomes.

Depending on the type of MR and the setting in which it is conducted there are several possible outcomes:

- improved patient understanding of their medicines and how to use them;
- improved shared understanding between the patient, prescriber and pharmacist about the patient's medicines and their role in the patient's treatment;
- opportunity to engage and empower the patient to take an active role in the management of their condition(s);
- reduction in unnecessary and unused medicines;
- reduction in adverse effects related to the use of medicines;
- improved adherence to medicine use;
- improved current and future management of the patient's condition(s);
- reduction in unplanned healthcare utilisation;
- improved health outcomes associated with optimal medicine use.

MR detects and addresses problems with medicines that have not been identified through routine prescription review. The emphasis on optimising medicine use leads to more appropriate medicines being used to treat the patient's condition and simultaneously to consideration of deprescribing potentially inappropriate medicines.

The consequent reduction in polypharmacy and in the burden of medicine-taking will be welcomed by the patient and will benefit the health service. MR provides many opportunities to improve patient care and to maintain this effect through the active and informed participation of the patient. By doing so MR can reduce the unnecessary and avoidable burden of MRPs and the adverse health and financial impact of these problems. MR is therefore an important intervention and should be deployed nationally, to optimise the use of medicines.

Chapter 3 – Medication review

MRs can be conducted in all healthcare service settings, including residential care facilities. However, it is crucial that the type of MR used is appropriate for the patient's circumstances and clinical need, and that the outcomes are communicated to the relevant people who care for the patient. The purpose of the MR determines the breadth, depth and range of data sources required. The most comprehensive MRs require the participation of the patient. In practice, when patients are willing and able to participate, they should be consulted and should take part in the decision-making.

Pharmacists routinely review prescriptions for clinical, technical and administrative problems as part of their professional responsibilities. MR is a broader and deeper review that goes beyond the individual prescription. Consequently, MR is most commonly carried out by pharmacists when they identify a need, at the request of a patient, at the request of a prescriber or for a health service programme. Pharmacist-led MR links the detection of problems of adherence, side-effects and other MRPs to the recommendation of interventions, both for patients to implement and for other healthcare professionals, as part of a multidisciplinary approach to care [18].

Pharmacists in community and hospital practice have developed MR services based on their assessment of the need for such services. In many countries these have been recognised and remunerated by the health authorities, but in others the health service has established pharmacist-led MR to address specific needs [31].

There are several classifications of MR, but all of them describe three types: from the simple MR (usually a prescription review), through intermediate MRs (using two sources of information) and on to the advanced MR (resorting to three sources of information). One of the most comprehensive, detailed and widely used classifications is that of the Pharmaceutical Care Network Europe (PCNE) [18, 32, 33].

Type 1: Simple MR: this is a screening process that can be conducted rapidly to determine if the medicines are appropriate for the patient. A simple MR is based on the available medication history in the pharmacy. This type of review reveals medicine interactions, some side-effects, unusual dosages and some adherence problems. It is usually carried out in less complex cases when the patient is not available.

Type 2a: Intermediate MR: this type of MR can be performed when the patient can contribute and is based mainly on the medication history. It reveals medicine interactions, manifest/actual side-effects, unusual dosages, medicine-food interactions, effectiveness issues, problems with non-prescription medicines and, in particular, records the patient's experience(s) and preferences.

Type 2b: Intermediate MR: this is carried out when the patient is not available. If clinical and laboratory data are available they can be combined with the patient's medication history and medical information to give a detailed MR. It is used to detect medicine interactions, some side-effects, unusual dosages, medicine-food interactions, effectiveness issues, indications without a medicine, medicines without an indication, potentially inappropriate medicines and some adherence problems.

Type 3: Advanced MR: an advanced MR is used to assess complex cases. It is carried out with the patient using the full medication history, including non-prescription medicines and herbal, complementary and other supplements and treatments together with clinical and laboratory data. As the most in-depth type of MR, it can be used to address adherence issues as it takes account of the patient's experience(s) and preferences and because the patient is actively involved. It may also be used when the patient is not capable of full participation but has a dedicated expert carer, usually a nurse, who can provide this information. This type of MR is also sometimes referred to as a Complex MR or a Comprehensive MR, and in a modified form when one particular medical specialty is the focus, as a Specialist MR.

Chapter 4 – Medication review process

Being a structured activity, the MR process should follow a standardised procedure to ensure consistency in the provision of quality patient care. This procedure may differ in some details between countries, and even between settings (community, hospital or residential care), depending upon the organisation of the healthcare system and other aspects [34]. However, certain elements will always be included.

The following is an accepted framework:

Step 0. Prior to initiation of the MR process

Criteria to identify the need for MR

The process must have a well-defined initiation method, including any possible triggers to identify the need for MR. Typically,

- any healthcare professional involved in direct care of an individual can formally or informally refer the patient to the pharmacist;
- if a pharmacist identifies a need for a MR, as part of a periodic, opportunistic or systematic assessment of the patient and their medicines (e.g. recent discharge from acute care, higher risk of experiencing MRPs), they can start the process;
- the patients themselves or their carer (if previously authorised) can request the service;
- there are situations that may be associated with the risks posed by the medicines: the seriousness of the patient's condition, multimorbidity and polypharmacy or transitions of care may trigger the need for MR (Table 1).

Criteria for identifying priority groups

In most countries, any individual who meets the above triggers will be eligible for a MR. However, in other countries, particularly for the most advanced type 3 MR, certain predetermined criteria related to factors associated with the patient, medicine, disease, social circumstances or changes in care provision will determine the initiation of MR.

Extensive criteria have been suggested, which include patient concerns about taking medicines and difficulties in medicine adherence. Other examples are shown in Table 1. A recent scoping review provides insight into existing tools to prioritise outpatients for this pharmaceutical service [35].

Table 1 – *Examples of groups who may need an Advanced MR*

Goals of medicine therapy not reached or maintained, including suboptimal response to medicines
Chronic medical condition associated with a high risk of unplanned hospital admission (e.g. chronic obstructive pulmonary disease, heart failure, chronic pain, diabetes mellitus)
Significant changes to medicine regimen for a chronic condition, including newly prescribed medicines
High-risk medicines requiring close monitoring for adverse effects and/or efficacy (e.g. opioids, psychotropic medicines, insulin, anticoagulants, non-steroidal anti-inflammatory drugs (NSAIDs), anticholinergics)
Three or more chronic medical conditions
Polypharmacy
Recent discharge from hospital or frequent unplanned hospital admissions
Vulnerable groups at risk of harm and/or with reduced chance of benefit from medicine use (e.g. frailty, frequent falls, cognitive impairment, intellectual disability, swallowing difficulty, renal or hepatic impairment)
Difficulty understanding and following medical advice and medicine regimens

Patient involvement, shared decision-making, communication and consent

In many countries a patient medication record is created when a medication is prescribed or dispensed, but in those in which this is not the case the patient's permission will be required. These patient medication records are used in type 1 and type 2b MRs. For type 2a and type 3 the patient will be asked for additional information and possibly to give permission for data to be obtained from other health service records. Prior to the initiation of these types of MR, the patient should be duly informed about the procedures to be followed, including requirements for personal health data storing and sharing, and be totally comfortable with all conditions associated with the service. The patient's consent should be sought and recorded in a structured and consistent way in accordance with professional, health service and national privacy and data protection guidance, regulations and rules (see Chapter 5). To ensure that the MR process meets its goals, patient communication should be clear and timely and, whenever the patient is present, patient-centred care should be delivered. According to the seven-step Scottish model [36], the identification of the patient's needs and desires should initiate the process. When following this approach, the pharmacist can begin the discussion (MR type 2a or MR type 3) by assessing the patient's views, understanding, concerns, questions and problems related to their medicines and this assessment should be made repeatedly throughout the whole process. Furthermore, the patient's rights, needs, quality of life and preferences should be considered throughout the whole process and, in particular, when making clinical decisions about the management of their medicines [36, 37].

Step 1. Information gathering

The first step consists of collecting all relevant information, including the identification of missing data and definition of a process to obtain it. In some countries, there may be centrally shared health records where data linkage allows access to all relevant information. However, in most European countries, data linkage

systems are still suboptimal, and information may be dispersed and even paper based. Regardless of the context, the core information to be obtained for the MR process will vary according to the MR type, and may be grouped in five main categories:

- patient data, including socio-demographic data, socio-economic and support structures (where applicable), and lifestyle data;
- medical history, including disease conditions diagnosed and currently active, past events and family medical history;
- clinical and laboratory data, including biomarkers measured at home, in the pharmacy or elsewhere (e.g. blood pressure values), point-of-care testing (e.g. renal function), known polymorphisms or genetic variants;
- medication history, including medicines currently taken (prescription and non-prescription, herbal medicines and food supplements) and discontinued medicines (note: this includes assessment of the patient's previous experiences of lack of effectiveness or adverse drug events and information to enable evaluation of medication adherence problems);
- use of healthcare services (planned, missed and unplanned visits and check-ups).

To obtain this information, several data sources may therefore be used, namely the patient himself/herself (MR type 2a and MR type 3), prescriptions issued either on paper or electronically and eventually stored in pharmacy medication records (all types of MR), laboratory analysis results either on paper or electronically and provided by the patient or stored in the pharmacy software, (electronic) medical records or information from the prescriber and, of course, combinations of these (see Chapter 4).

Step 2. Medication reconciliation

Before performing a MR, an accurate, up-to-date medication list should be accessible to anyone providing care. This step is called medication reconciliation and is one of the first steps of MR.

Medication reconciliation may also be carried out separately from MR in hospital and at transitions of care to compare the two medication histories before and after the patient has moved from one care setting to another.

The main aims of medication reconciliation are to reduce unintentional medication discrepancies and to prevent adverse drug events and patient harm [38], to contribute to the continuity of medication treatment, and to promote effective and expeditious transmission of patient information between healthcare professionals [17]. Obtaining the BPMH is a crucial step in medication reconciliation in transitions in care, namely when a patient is admitted to and discharged from hospital, and specialised or residential care. Moments of transition of care can also happen within the same setting, including different wards in the hospital, and this often means changes in prescribers and in the medicines needed by the patients. There is a need to reconcile when multiple prescribers are caring for a patient and in ambulatory care when prescribers change. This means that the pharmacist will use at least two different sources of information (e.g. hospital record and the pre-hospitalisation medicines) to compile the most accurate list of all medicines a patient is taking, compare it with the regimen being considered for the new setting of care and identify any possible discrepancies [39]. It is important to consider that the sources of information available may have different levels of completeness (e.g. time captured, herbal medicines or non-prescription medicines included, discontinued medicines signalled), implying that when a pharmacist reconciles medication they should be fully aware of potential limitations of the data sources and, if needed, find alternative methods to obtain the missing information [40, 41].

Some examples of forms and guidance documents that may be used to support medication reconciliation have been published by various organisations [42, 43].

Step 3. Evaluation of medicines taken

The third step of the process includes a detailed evaluation of all medicines taken and identification of actual and potential MRPs. To support the evaluation of medicines, a seven-step approach has been proposed by National Health Service (NHS) Scotland [36]. While evaluations typically focus on need, effectiveness and safety, it is important that the assessment is patient-centred and it should identify what matters to them. The process of evaluation should be supported by validated and standardised tools.

There are two main types of tools that use either explicit or implicit criteria.

Explicit criteria are standardised tools that support the identification of potentially inappropriate medicines for a particular population subgroup in which the risk of using such medicines is considered to outweigh the benefit, particularly in the presence of safer options. This approach is quite practical, mostly for less experienced providers, but has the drawback of not covering all population subgroups and being most focused on the elderly. Examples of explicit criteria include the Beers criteria [44], the Screening Tool to Alert to Right Treatment (START) and Screening Tool of Older Persons' Prescriptions (STOPP) criteria [45], PRISCUS List [46], European list of Potentially Inappropriate Medications (PIM) [47] and Laroche criteria [48], to name a few. Furthermore, IT tools and clinical decision support systems have been developed to integrate explicit criteria and to flag up medicine-related risk situations in real time [49].

Implicit criteria are strongly anchored in clinical judgement and therefore are more dependent on the practitioner's experience. One of the most common lists of implicit criteria is the Medication Appropriateness Index (MAI) [50]. In this methodology, the use of MRP classifications may also be particularly useful, as it enables consideration of the necessity, effectiveness and safety of each medicine and of the medicine list. Examples of MRP classification include the PCNE-DRP classification [51], the Strand classification [52] and the derived Dader classification [53].

For the process of medicine evaluation and identification of MRPs, the need to evaluate the different types of data will vary according to the MR type (see Chapter 3). When the patient is involved (MR type 2a or type 3), the evaluation of signs and symptoms, experience of adverse drug reactions and perceived improvement of disease condition is crucial. When the patient is not present and there is access to clinical data (MR type 2b), the deviation from target values may be an indication of lack of medicine effectiveness or safety. When evaluating clinical data, for instance, the absence of bacteriuria could also suggest lack of indication for antibiotics. When there is access to the medical history and confirmed medical diagnoses, the identification of contra-indicated medicines is more reliable and so is the possibility of detecting untreated conditions. The types of MRPs that can be identified therefore depend on the types of information sources available.

Step 4. Listing problems and defining priorities for intervention

The medicine evaluation yields a list of actual or potential problems. From this list, those which are a priority for intervention should be selected. The criteria for selection are situations in which the risks outweigh the benefits, but to verify these criteria, a consultation with the patient and other healthcare professionals should be carried out with a view to achieving a shared agreement that balances clinical need, patient concerns and medicine safety.

Step 5. Pharmaceutical care plan

The pharmaceutical care plan is a document developed by the pharmacist based on the available medication information and on their knowledge and competence [17]. This plan can be supplemented and aligned with the plans of the prescriber(s) and other healthcare professionals (e.g. nurses).

Ideally, a pharmaceutical care plan should be developed (at least in MR types 2a and 3) in agreement with the patient and should include the medication plan, the selected priorities for intervention, targets to be achieved, the process to be followed for the interventions to be implemented and monitored, information about those involved in the process (e.g. patient or informal carer, prescriber, nurse and social care personnel), and the time frame for the follow-up to enable the evaluation of progress. To ensure full implementation of the plan, it should be shared with all care providers as well as with the patient. Depending on the country, legal requirements may determine that some interventions are carried out by certain healthcare professionals (e.g. in many countries a medicine change can only be made by the prescriber). Ideally, a report or letter should be provided by the pharmacist to the referring medical practitioner in a timely manner after the patient consultation. The report should be concise and include details such as date, time and place of the patient consultation; summary of the patient's medicine experience (if appropriate); summary of any assessments conducted during the consultation; details of any issues identified and resolved during the course of the consultation; issues identified to be followed up and specific recommendations, appropriately justified and referenced [54].

Step 6. Record keeping

For the continuity of care and the communication and sharing of the outcomes of MR, good record keeping is essential. The process should be documented, and the records generated should be periodically updated. Chapter 5 focuses on the aspects of data collection, documentation and storing, including data sharing and confidentiality considerations.

Step 7. Implementation and follow-up

MR can be provided as a stand-alone intervention or on a regular basis, depending on the needs of the patient and the organisation of the healthcare system. Integral to implementation is collaboration with the other healthcare professionals responsible for the care of the patient. Pharmacists should use their professional judgement to decide when to refer a patient to the prescriber, both at the time of the MR and subsequently during the follow-up.

Whenever possible, the provision of scheduled, regular MR should be preferred as there is evidence of greater benefit from such an approach [54]. When provided on an ongoing basis, a clear definition of a realistic timetable for the implementation of interventions should be part of the pharmaceutical care plan. The timing may vary according to the complexity of the interventions (e.g. interventions to be made directly with the patient or involving others), to the complexity of the healthcare system (e.g. time needed for medical appointments) and even the time needed for behaviour change interventions (e.g. treatment of alcohol use disorders). Implementation should then be evaluated and recorded in a timely manner, including the outcomes [37].

Additional considerations

Frequency of MR

In many existing MR services, annual reviews are specified, but if the patient's circumstances require it, MR can be conducted more frequently. One important reason is, for example, that the patient has recently been discharged from hospital and changes were made to their medication plan while they were hospitalised (see Step 2. Medication reconciliation). In some countries, population subgroups have been defined to justify different frequencies (e.g. complex patients with multimorbidity).

Deprescribing

The term "deprescribing" refers to a process of medicine withdrawal, supervised by a healthcare professional, with the goal of managing polypharmacy and improving outcomes [55]. This can encompass dose reduction or stopping of medicine that may be causing harm, or no longer be of benefit. Typically, deprescribing is a proactive approach. During MR, multiple MRPs can be identified that can be solved or reduced through deprescribing. Nevertheless, multiple steps may be necessary and careful monitoring is always warranted to ensure that the process is patient-centred and achieves the best possible outcomes. There are several explicit tools that may support the pharmacist in deprescribing, including criteria for potentially inappropriate medicines (see Chapter 4).

Chapter 5 – Data collection, protection and storage

Introduction

The standards that apply to data collection, use, protection and storage should be equivalent to the most recent standards applicable to the health services – for example, from the European Union [56] and the Council of Europe [57]. They should cover:

- informed consent;
- intended use;
- storage and retention;
- sharing and communication;
- protection and privacy.

This chapter sets out some specific points that apply to conducting a MR because of the need to gather, process, share, store and communicate patient-related data. It does not set out detailed requirements because these are part of public policy [56, 57]. However, it is particularly important that requirements are continuously updated as services and technology develop and that they are aligned across the different sectors of the health services. All healthcare professionals are bound to uphold these standards in their daily practice.

In this chapter, whenever reference is made to "patients", the same principle should also apply to a person authorised to act on their behalf. The holder of these data is the individual, i.e. the recipient of care, or the person acting on his/her behalf (for minors or people living with disabilities), who is entitled to determine who has access to their data, according to current European legislation [56, 57]. The data referred to are both the patient's personal data and their health-related data. The records described may be electronic or hard copy and may be stored in the practice or in another secure repository in line with the relevant regulations and practice guidance.

Need for data in MR

Patients should always be informed that a MR is required and what it entails. As described in Chapter 4, depending on the MR type, different and additional information may be needed by the service provider to complete the MR. These data are essential to ensure that a complete picture of the patient's medicine history and preferences can be compiled so that informed decisions can be made and communicated for the good of the patient.

Records of prescriptions and the medicines dispensed, together with the details of the patient and of the prescriber, are required to be made and retained by pharmacists in an appropriate format that depends

upon the setting in which the medicines are provided. However, by themselves these records will not provide enough information for MR types 2a, 2b and 3.

In their daily work with patients and other healthcare professionals, pharmacists handle, and are made aware of, both personal and health-related data – their professional code of practice protects the patient from inappropriate or unintended disclosure and this also applies to the services they offer, including MR services. MR does not add any complexity to the procedures in place that already require data access, storing and sharing and the respective regulations.

In primary care, community pharmacists keep records of the medicines dispensed for each patient. In most, but not all member states of the Council of Europe, these records are collated into a patient medication record and so provide a history of the medicines used over time. However, as prescriptions do not usually include the indication (purpose) of the medicine, the pharmacist discusses this with the patient when advising and counselling them on the use of their medicines. In some member states other relevant information is available either because the patient can provide it or because the pharmacist can access a shared patient record through the health service IT system.

In hospitals, pharmacists can usually access the relevant information, but in more complex cases the records may be held in separate systems associated with different clinical specialties.

Patient's medicine data and other relevant health data required to complete a MR are frequently retained in records held by different practices in different settings. The more complex the patient's conditions, the greater the number and diversity of these records. While many countries are working to facilitate record linkage and ease of access, progress varies in both scope and speed. The pharmacist needs to be able to access, collate and share information that is pertinent to the MR.

Informed consent

Healthcare professionals work within certain boundaries when gathering, using and sharing information about their patients. These boundaries are established by the professional bodies to which they belong, the health service and national rules and regulations relating to privacy and data protection. Nevertheless, it is essential that the application of the guidance and regulations is clear to the healthcare professional conducting MR and that the patient is fully informed about MR and what information about them and their medicines is being gathered, how it will be used and by whom.

When a patient consults a healthcare professional, they provide information about themselves (personal) and about their symptoms and previous medicine use. In doing so the patient gives a form of consent, implied consent to the use by that healthcare professional and the sharing of the information with any other healthcare professionals whose expertise is needed to provide care for the patient. Simple MR and MR type 2b use the existing records so they can be conducted in much the same way as a clinical audit – as the information provided is concerned with the care of the patient, implied consent is assumed.

The collection of information beyond that for the usual care of the patient, both from the patient themselves and from the records elsewhere in the health service to which the healthcare professional may not usually have access, may be considered as requiring explicit consent. In MR type 2a and MR type 3 the patient should give their consent and the information they provide in the consultation with the pharmacist will be recorded and will form part of the patient's medical records. The patient should be able to decide to provide differential access to the providers involved in the process. This implies that any record linkage systems in place should be clearly presented to the patient. It will also be important to explain the reasons why data sharing among different healthcare providers may be necessary and how this may contribute to improving the quality of the service provided. When MRs are being conducted it is important to ensure that any other staff working in the pharmacy, surgery, hospital or residential care service who may be involved

in delivering the MR are suitably trained. Professional bodies and representative organisations should collaborate to ensure suitable, updated practice guidance is available.

Storage and retention

As stated above, there are usually legal requirements for the recording, storage and retention of prescription data which are specific to each country and often to each service. For the MR service, additional health data must be collected, recorded and stored. These data are collected, recorded and stored for a number of reasons, some of which are complementary to each other, namely:

- providing the rationale for interventions by gathering information on baseline assessment that justifies a situation or condition that would benefit from MR, as indicated in the trigger section;
- documenting MRPs identified and interventions considered to resolve them;
- documenting shared agreement (for interventions to be made) with the patient and other healthcare providers;
- monitoring the development of these interventions and evaluating the outcomes on the patient level;
- justification for remuneration, either already agreed nationally (and requiring submission of macro information on the service delivered) or providing the basis for future negotiations on remuneration to be achieved.

When used in an aggregate manner, data may also be used to evaluate the added value of the service (including for advocacy purposes).

Interpretation of the data requires some functionality and report templates in order to:

- assess and document the BPMH, which is essential for the medication reconciliation phase (see Chapter 4);
- record demographic and socio-economic data, clinical data and biomarkers (measured in the context of self-care, at the pharmacy or in other healthcare settings) and be designed in a format that enables longitudinal tracking to capture any changes observed;
- document MRPs (preferably resorting to a predefined classification established nationally or internationally);
- establish a pharmaceutical care plan and to schedule and record follow-up assessments.

Privacy

Security features and procedures to regulate access to MR data by other staff in the practice or institution and to protect the integrity of the data and the privacy of the patient should be defined and implemented. Access may be fully restricted to certain professional categories or individuals or have different levels of access granted, according to patients' expressed preferences and compliance with national legislation and scope of practice. In a few European countries, this access is often controlled by the use of cards (with or without electronic signature included) that enable verification of the professional status of the person accessing the system and may grant differential access to information sections. Digital fingerprints or facial recognition may be other ways of ensuring that access is restricted to those authorised.

Information governance

Information governance enables organisations and individuals to make sure that the information contained in a health record is dealt with legally, securely, efficiently and effectively in order to deliver the best possible care to patients. The national legislation, guidance and approved practice for handling information and the many different legal provisions, best practices and professional codes of conduct that apply to handling personal health information will differ in their detail from one country to another. The responsibility for ensuring that staff are properly trained and implement all of these requirements appropriately in a MR service is usually assigned to one person. The roles and responsibilities of this person need to be clearly and explicitly stated so that everyone involved in a MR service, and particularly the patients, are aware of them. Effective information governance will result in improvements on a continuous basis and will raise the standard of the care being provided.

Chapter 6 – Education and training

Two of the key components of MR education and training are medicines knowledge and the related clinical knowledge, and the requirements of the healthcare system for recording and sharing the results of the MR.

MR requires an expert level of knowledge and understanding of medicines and medicine use in order to be able to exercise professional judgement. The provision of MR must be aligned with the pathway of care and must be of a level of quality consistent with the requirements for safe and effective care in the health service. Consequently, although pharmacists and physicians possess the medicines knowledge, they will require training to be able to disseminate the results of a simple MR type 1 and they may need to update their knowledge for more complex MR and, in some cases, may need additional specialist training. Other healthcare professionals will also need to complete additional medicines training in order to be able to undertake a MR training programme.

New medicines, revised clinical guidelines and alterations in the indications, cautions and provision of medicines associated with changes in licensing/authorisation are a constant feature of healthcare. All healthcare professionals need to keep up to date in order to be competent. A suitable structured and recognised education programme is required to begin to provide MR services and this should be followed by periodic continuing professional development to ensure competency. In the early stages of delivering MR, practitioners should be supported.

In order for a MR service to be effective, a suitable training programme should ensure that:

- MRs are carried out in a structured, consistent way and are of adequate quality to meet the standards set by the health service;
- the participants have a full understanding of the importance, objectives and benefits of MR;
- the participants have the necessary competences to address the patient's clinical needs;
- the participants can communicate effectively with the patient and engage them in shared decision-making;
- the participants record the MR appropriately and communicate effectively with other relevant professionals in order to co-ordinate the care that the patient receives after the review;
- participants should collaborate with all of those providing care to the patient receiving the MR in order to ensure the effectiveness of the MR and the safety of the patient;
- MRs meet the needs established by the health service for the settings and the communities it serves;
- MRs are provided in accordance with the legal and regulatory framework of the health service.

The more complex the MR, the greater the requirement for a comprehensive, structured and systematic approach to the development of the training programme. It will be necessary to ensure that adequate resources, educational and clinical expertise, work-based experiential learning opportunities and a robust

assessment strategy are all in place. Implementing and sustaining the programme requires leadership and commitment from health service managers as well as healthcare professionals. Patients and patient representatives should also be involved in the design, delivery and review of the programme, as MR is about the patient's medicines and the patient's care.

Participants who complete the programme successfully should be awarded a suitable qualification and therefore the programme should be accredited by an appropriate independent body. The qualification should be valid for a defined period (e.g. 3 to 5 years) and then a refresher course should be taken to renew the qualification for a further period.

The scope and scale of the MR service will, in turn, determine the level of sophistication, complexity and expertise needed to create, deliver and sustain certain elements of the programme; for example, the degree of interprofessional collaboration that is required to meet the service specification. Nevertheless, each of the elements described below should be considered and addressed to establish a programme of sufficient quality.

An education and training programme for MR should comprehensively address all of these topics: governance and management of the programme, MR programme design, educators, attendees, programme content and learning outcomes, teaching and assessment methods, early practice support, continuing education/ continuing professional development courses.

Two examples of the detailed content of these topics are given below.

Programme content and learning outcomes

The programme and its learning outcomes must be closely aligned to the clinical needs of the patients, the care pathways of the health service and the intended clinical outcomes of the service. It must clearly present opportunities for the participants to rehearse the tasks, develop the skills and meet the responsibilities placed upon them when carrying out MR.

The person providing the MR should have:

- adequate clinical knowledge, in particular, of the groups of patients, including those with special needs, of the pharmacotherapy, therapeutic guidelines and recommendations for the patient groups, of the settings and of the critical points in the patient's treatment when care may be improved;
- an understanding of the characteristics and purposes of the types of MR and their appropriate use in different settings;
- adequate knowledge of the laws, regulations and other requirements to conduct a MR;
- demonstrated the competencies needed to conduct a MR, e.g.
  - processes;
  - tools - both specialist decision support and specific IT applications, including those for assessment, intervention, making records and communication;
  - sources of information;
  - teamwork and collaborative practice;
- the ability to communicate with the patient and their carer or representative about the MR;
- demonstrated that they can record the outcomes of the MR and communicate and discuss them with other healthcare professionals appropriately;
- demonstrated that they can arrange a follow-up consultation as required by the MR service;
- demonstrated the knowledge, skills, attitudes and values to be able to co-operate and collaborate with other healthcare professionals in all aspects of the provision of a MR service;

- the competencies to audit and review the MRs that they have conducted in line with the relevant requirements and processes;
- an understanding of the place of the MR within the health service and of the leadership and management required to sustain the MR service.

Early practice support

It is best practice in the early stages of delivering MR for a healthcare professional to be supported by a mentor and a community of practice. The mentor should provide feedback that is objective and constructive to support the practitioner's development. It is therefore recommended that for a designated period an experienced practitioner should take on this role and, at a defined time point, the MRs completed by the practitioner should be assessed to ensure the standard and appropriateness of the work. Particular attention should be paid to interprofessional collaboration, as this is crucially important to the effectiveness of MR.

The practitioner should keep records of their development and could do so in a portfolio. This would also indicate the proficiency of the practitioner in the processes of the audit and review of MRs. A community of practice could also provide a forum for learning and sharing of experience from experts and more experienced providers. Participation in such a community should continue throughout the professional's career as a provider of MR.

Chapter 7 – Health service context

MR should be available at the individual patient level and at the population level.

- At the individual patient level, GPs and pharmacists provide MR according to the procedures and standards of professional practice. MR will contribute to the effectiveness and safety of the patient's treatment and reassure them about the quality of care they are receiving.
- At the population level, pharmacoepidemiological and public health data and research will drive the process of risk stratification and, from that, the development of tailored and targeted MR services delivered by designated teams in the health service.

The clinical importance and the scale of expenditure on medicines makes it vital for the health service to do everything possible to optimise medicine use. Health services need to take this broad approach because medicines are important in every setting and in self-care. MR is recognised as a logical and potentially very valuable intervention both for patients and for the protection of public health [58]. The health service's priority setting process, based on an assessment of clinical need, should take account of all of these aspects. Moreover, the health service should use both MR provided for individuals and for the population to help improve the co-ordination and the continuity of care. This requires careful mapping and modelling of the place of MR in existing services, and probably the reconfiguration of some services to provide MR for those most in need.

MR is a tool to improve the quality of the use of medicines and mitigate MRPs. It can be used in every healthcare setting to benefit all patient groups. It is practical and feasible to implement, and it has been shown to be effective. It can improve the continuity and overall quality of patient care and it strengthens patient safety across the health service. MR is just one of a number of measures that are needed to optimise medicine use. However, it addresses crucial problems and processes and should be used as the first step in quality improvement.

The integration of a MR programme into the care pathway for the patient population and its acceptance and appropriate use by all healthcare staff are necessary to realise all of the potential benefits of MR. Therefore, it is the responsibility of the health service to provide the vision, leadership and resources to ensure that MR is developed and implemented effectively and efficiently to enhance the safe use of medicines.

Patient consultation

As most medicines are taken by people themselves, rather than administered to them, people are the main decision-makers. Medicine-taking is not simply a physical act, because the patient has expectations and concerns both about their symptoms or condition and about their medicines. Medicine-taking triggers emotions even if they are not often expressed. Therefore, the patient consultation must be patient-centred and must enable the patient to describe and discuss what matters to them and to expect to be heard.

While patient-centred care and shared decision-making are often aspired to by health services, the patient's experiences of the consultation and of the circumstances of the consultation are frequently at odds with these aspirations. For the health service, the training of healthcare professionals and the facilitation of the consultation should be central features of any MR programme.

As described above the patient should have access to the outcome of the MR and should be made aware of who has contributed to, and who else has access to, the records of the MR. They should always be assured of the privacy and confidentiality of their data.

Stakeholder engagement

Apart from the patients and the healthcare professionals performing MR, all of those who contribute directly and indirectly to the development, implementation, integration and maintenance of MR should be considered as stakeholders; for example, other clinical professionals responsible for caring for the patient, carers and those supporting the patient, health service staff responsible for the delivery, co-ordination and management of health services. They should be consulted about the MR service and should be involved and represented in the management and governance structures and processes. They should be fully aware of the aims and objectives of the service, of its key performance data, of its quality assurance and of its impact on the health of patients and on the health service. At the national level, the professional representative bodies should be engaged by the health service to enlist their co-operation and support.

Service design

Goals and outcome measures

The patient population, the aims and objectives, and the type of MR all need to be aligned to establish a service capable of delivering high value care. The arrangements for the development and provision of the service, the recording and dissemination of outcomes and the monitoring of key performance indicators should be discussed, specified and communicated to all stakeholders from the outset.

Patients

As patients are aware that each prescription is checked before it is dispensed, they may not see the need for, and value of, a MR provided by a pharmacist. The acceptance and implementation of the recommendations of a MR depend on the patient's understanding, appreciation and acceptance of the need and potential value for them of the review. Therefore, it is crucial that the MR service is seen to be supported by the health service and that when a prescriber or another healthcare professional refers a patient for a MR, they explain these aspects and make clear their endorsement of this intervention. When it is not routinely included in the care process, patients should be able to ask for a MR service if they believe it could be beneficial for them.

MR provided by pharmacists

Where a MR service is led by pharmacists, it should be designed and developed in consultation with prescribers and other healthcare professionals as well as hospital, community and primary care pharmacists and pharmacy organisations. Recommendations from MR concerning prescribing should be communicated to the prescriber, who, having made a decision, should inform the pharmacist so that the continuity of the patient's care is maintained. All communication between the patient, pharmacist and prescriber should be comprehensive and timely. Recognition, acceptance and support for pharmacist-led MR by prescribers and others help determine the extent to which its recommendations are acted upon in routine practice. The health service should integrate pharmacist-led MR services into its medicine management strategies, for example, by facilitating the sharing of data for MR and the results and recommendations of MR.

Collaboration

MR entails collaboration between patients, pharmacists, prescribers and other healthcare professionals. A key area for attention is recommendations from MR about prescribing and deprescribing. These will be referred to the prescriber, but particular importance should be given to cases that may be difficult to implement, such as a medicine that is to be used off-label, sourcing a suitable alternative when a medicine is not available, or monitoring a patient's condition after a medicine has been deprescribed. Without these efforts, some of the potential benefits of MR will not be realised. Collaboration can be enhanced through tailored training programmes aimed at developing competencies in patient-centred and interprofessional collaborative practice in primary care, development of skill-mix policies, establishment of collaborative activities and multidisciplinary team meetings, and availability of funding and/or new payment methods focusing on co-operation between primary care professionals.

Communication between healthcare professionals

The establishment of a structured and consistent framework for communication between healthcare professionals is recommended. The following elements may help enhance effective communication between pharmacists and the other healthcare professionals delivering MR or receiving recommendations from a MR:

- education programmes: these should address the barriers that are present within healthcare settings and hamper effective communication, enhance the understanding and appreciation of professional roles and responsibilities, support professionals in placing the patient's needs at the centre of collective and interprofessional decisions;
- training to address the cultures that exist within healthcare and contribute to traditional hierarchical frameworks that limit and exclude interprofessional co-operation and collaboration;
- mutual understanding and acknowledgement of the diverse styles, expectations and educational needs of each healthcare profession;
- use of tailored means of communication or systems that are interprofessional in nature and work for all the parties involved, such as a secure health service email system;
- clear communication offering timely information and providing an adequate level of detail (to this end, the use of standardised forms may be considered);
- scheduling of regular face-to-face meetings, especially when interactions involve complex and in-depth discussions;
- implementation of a national, real-time digital health record to facilitate information exchange and sharing (with the patient's consent) [59, 60, 61, 62].

Pharmacist-prescriber collaboration

In primary care, collaboration between community pharmacists and GPs/family doctors and other prescribers is essential for the co-ordination, continuity and quality of medicine use and patient care. Examples of meetings between primary care prescribers and community pharmacists can be found in the Netherlands and in Belgium [63]. Experience from these programmes shows that it is important that the health service and the MR service facilitate and support pharmacist-prescriber collaboration, because this not only promotes an effective and efficient service [64], it also gives patients confidence in the operation of the health service.

In many countries, GPs/family doctors and pharmacists provide services to residential care facilities, often asynchronously, and good co-operation and collaboration are therefore especially important. Where a primary care pharmacist is part of a GP practice team, they can perform MR and also co-ordinate the

outcomes and follow up with community pharmacists, and liaise with community pharmacists who perform MR for patients of the practice of which they are a member.

In hospitals and specialist care facilities, co-operation and collaboration between specialists and advanced practitioners and pharmacists is necessary because of the conditions being treated, the complexity of the patients and the higher level of risk associated with some of the medicines required. The quality of the care provided depends upon the utilisation of all the expertise available and the smooth integration of the different patient care services.

Interprofessional teams

Patients with multiple morbidity will be cared for by several specialists as well as their GP and community pharmacist. MR for these patients requires the co-operation and contribution of each of these professionals to a degree that may not be obtained in routine care. While co-ordination and communication with informal, disseminated teams is challenging, if the MR service has appropriate procedures that facilitate engagement, awareness raising and training, these challenges should be overcome. The key actors in the medicine use process should have their roles clearly established and have the means for effective communication and for the sharing of relevant information. In healthcare systems where these processes are still developing, the organisation of periodic interdisciplinary meetings may assist the change in work practices. The facilitation of interprofessional working by all concerned will provide a foundation for high-quality care. It is the responsibility of every professional providing care for the patient to contribute to the MR in the best interests of the patient. Leadership and organisation within the health service and professional representative bodies will be required to support this aspect of MR.

Implementation strategy

The complexity of the needs of patients and of the health service will necessitate a comprehensive and coherent MR implementation strategy. From national to local and institutional levels, a coalition of the willing and able will have to pursue the strategy, supported by champions and management. Patients and the public should also be made aware of the development of the MR service and of its place in the policies and strategies of the health service. The education and training programme should be an integral part of the development of the service and also of its implementation. The collection and collation of data from the service will help guide its implementation, particularly in the early stages.

Guidelines and standards

Appropriate guidelines and standards for the MR service will be needed to support those providing the service. These will ensure that a consistent and high-quality service is delivered. The MR guidelines must align with other relevant health service procedures and arrangement for the provision of medicines. They must also take account of evidence-based, disease-focused guidelines and the treatment recommendations relevant to the patient population for whom the service is intended. This will require regular updating and dissemination of the MR guidelines.

Process support

The organisation and management of a MR service will require administrative and managerial support as well as facilities. IT resources and facilitated processes will need to be carefully tailored to the MR and to the needs of the health service. It should be inter-operable with other clinical support systems to facilitate access and contribution to the results of MR for all of the relevant healthcare professionals. IT support is key in enabling collaboration and the efficient operation of MR and the follow-up. Data recording, communication and reporting functions should be easy to use and intuitive, so that operation is unlikely to lead to errors and supports productivity. They must also be robust and provide adequate protection for the data of the patients and the users. The rules, regulations and standards of the health service, the healthcare

professions and the national privacy and data protection requirements should be incorporated into the process support for MR.

Support for pharmacists

In many countries barriers of different types prevent pharmacists from fully contributing their knowledge and expertise to the development and delivery of MR. Government authorities and health service bodies can remove these barriers and facilitate pharmacists providing MR in every healthcare setting.

- Legal changes to facilitate data access and professional actions: wherever necessary, legal and regulatory changes should be drawn up and put in place to enable and authorise pharmacists to access patient data and service records to carry out their professional functions within the MR service.
- Education and training: a programme of education and training should be established with a suitable governance structure and appropriate resources to provide practitioners with the competencies and proficiency to deliver and operate the MR service (see Chapter 6). The qualification should be recognised and accredited within the relevant framework of the health service and professional education sector. Continuing professional development opportunities should enable practitioners to maintain their competencies and to undertake MR in additional settings as the service develops.
- Workforce planning: deployment of pharmacists to a MR service will also require some workforce planning to ensure that other sectors and services are not compromised and to maintain the quality of the pharmacists and the services that they provide. For example, if a pharmacist is engaged solely to provide a MR service, a replacement is required, and if reorganisation of the workflow is needed to facilitate the delivery of a MR service, then some tasks may be delegated and performed under supervision by other suitably qualified staff such as pharmacy technicians.
- Resources and remuneration: providing a MR service is a complex undertaking that requires an investment of time, equipment and personnel on a continuing basis, as well as an increased responsibility. Whether the MR service is provided by health service staff or contractors, resources will be required and, in the case of contractors, they may be entitled to remuneration. Patient and health service needs will determine the eligibility criteria that will govern the conditions under which the service will be reimbursed.

Promotion of MR services to patients

Lack of awareness and understanding among patients about MR is a significant barrier to its use. For the health service to move towards medicine optimisation, it needs patients to know that MR is available, how to access it and what benefits it may provide. In some MR services, patients may request a MR while in others a MR is recommended by a prescriber or a pharmacist. In all instances, patients need to be informed about the MR service, its aims and objectives, the potential benefits and outcomes and of their entitlements and role in it. Patients should be consulted and involved in the development and monitoring of the MR service and of its effectiveness.

Service evaluation and quality assurance

At the practice level, regular audits must be carried out and at the system level, the service should be monitored on an ongoing basis. Every healthcare professional who performs MR should carry out a regular audit and use the results to improve the delivery, use and impact of the service. It is recommended that in addition to this, a comprehensive, regular and structured independent evaluation be carried out by an accredited body. This evaluation should assess the service, its performance and its impact. Quality assurance measures (e.g. national or local quality indicators) should be drawn up for these evaluations and should be transparent and accessible to all stakeholders. Patient and professional satisfaction and feedback should be elicited regularly and should form part of the quality assurance of the service.

Research

As part of the implementation strategy for the MR service, research should be conducted to evaluate the effectiveness of different types of MR in various settings, both clinically and in terms of cost. Research should be used to determine the patient groups for whom MR may be beneficial and to identify and address the barriers to the effective use of MR and its outputs. For example, in primary care, limited evidence is available often because of inadequate systems for recording and researching poor medicine use and its consequences. The balance of patient and health service benefit will require systematic and robustly designed research to establish the evidence.

Chapter 8 – Resources and examples of MR programmes

Buckley L. How to conduct a clinical review of a patient's medicines. Best practice principles and practical advice for structuring medication reviews and approaching conversations with patients. *The Pharmaceutical Journal* 2023;310: 7971. doi: 10.1211/PJ.2023.1.176888 – Available at: https://pharmaceutical-journal.com/article/ld/how-to-conduct-a-clinical-review-of-a-patients-medicines

Clinical Excellence Commission of the New South Wales Government (Australia). Guides and tools for medication reconciliation, medication review and medication safety – Available at: https://www.cec.health.nsw.gov.au/keep-patients-safe/medication-safety/cmm

Clinical Excellence Commission (Australia). Continuity of Medication Management: Medication Reconciliation (2014) – Available at: https://bit.ly/3NDITkA

International Pharmaceutical Federation (FIP). Medication review and medicines use review. A toolkit for pharmacists. A revised version of an earlier document with useful guidance, tools and reference material (2022) – Available at: https://www.fip.org/publications

International Pharmaceutical Federation (FIP). Medicines reconciliation: A toolkit for pharmacists. The Hague: International Pharmaceutical Federation (2021) – Available at: https://www.fip.org/file/4949

National Health Service (NHS). Structured medication reviews and medicines optimisation: guidance (2020) – Available at: https://www.england.nhs.uk/publication/structured-medication-reviews-and-medicines-optimisation/

Note: This document sets out guidance for primary care networks implementing the structured medication review (SMR) and medicines optimisation service. It includes the principles of undertaking a SMR and should be read alongside the Directed Enhanced Service (DES) Specification and the Network Contract DES guidance.

National Institute for Health and Care Excellence (NICE). Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes – Available at: www.nice.org.uk/guidance/ng5

NHS Cumbria Medicines Management Team. Clinical Medication Review - A Practice Guide (2013) – Available at: https://medicines.necsu.nhs.uk/necs-good-practice-guidance-and-tools-for-care-homes/

Patient-Centered Primary Care Collaborative (PCPCC) Task Force. Integrating Comprehensive Medication Management to Optimize Patient Outcomes (2012) – Available at: https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf

Pharmaceutical Care Network Europe (PCNE): several resources available at: https://www.pcne.org/

Pharmaceutical Society of Australia. Guidelines for pharmacists providing Residential Medication Management Review (RMMR) and Quality Use of Medicines (QUM) services (2017) – Available at: https://www.ppaonline.com.au/wp-content/uploads/2019/01/PSA-RMMR-and-QUM-Guidelines.pdf

Pharmaceutical Society of Australia. Guidelines for pharmacists providing MedsCheck and Diabetes MedsCheck services (2017) – Available at: https://www.ppaonline.com.au/wp-content/uploads/2019/01/PSA-MedsCheck-Guidelines.pdf

Pharmacists Manitoba and the College of Pharmacy. Manitoba Comprehensive Medication Review Toolkit (2013) – Available at: https://www.pharmacistsmb.ca/

Royal Pharmaceutical Society of Great Britain. Polypharmacy: Getting our medicines right – Available at: https://www.rpharms.com/recognition/setting-professional-standards/polypharmacy-getting-our-medicines-right

Scottish Health Service. Polypharmacy guidance (2018) – Available at: https://www.therapeutics.scot.nhs.uk/polypharmacy/

Specialist Pharmacy Service. Using tools to support medication review – Available at: https://www.sps.nhs.uk/articles/using-tools-to-support-medication-review/

Note: Specialist Pharmacy Service is part of NHS England and produces a number of guides and tools, including for medication review.

WHO Third Global Patient Safety Challenge. Details and associated publications can be found on this site: https://www.who.int/initiatives/medication-without-harm

Glossary

Accreditation: the process of reviewing an organisation's ability to meet specific standards, regulations and quality requirements. In the case of healthcare educational organisations, accreditation simply means that the institution meets the standards set forth by the industry, state and federal regulations or specific certifying boards or organisations (source: Cambridge College of Healthcare and Technology – Available at: https://bit.ly/36WZxLH).

Clinical data: clinical data consist of information ranging from determinants of health and measures of health and health status to documentation of care delivery. These data are captured for a variety of purposes and stored in numerous databases across the healthcare system (source: Institute of Medicine (US) Roundtable on Value and Science-Driven Health Care. Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good: Workshop Summary. Washington (DC): National Academies Press (US), 2010).

Communities of practice: groups of people who share a concern, a set of problems, a passion about a topic and who deepen their knowledge and expertise in that area by interacting on an ongoing basis (source: Wenger E, McDermott RA, Snyder W: Cultivating Communities of Practice. 2002, Boston, MA: Harvard Business School Press).

Deprescribing: systematic process of identifying and discontinuing medications in instances in which existing or potential harms outweigh existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values and preferences (source: Scott IA, Hilmer SN, Reeve E, *et al*. Reducing inappropriate polypharmacy: the process of deprescribing. *JAMA Intern Med* 2015;175:827-34. doi: 10.1001/jamainternmed.2015.0324).

Medicine-related problem: an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes (source: PCNE: Classification for Drug related problems V9.1. 2020).

Electronic health records: real-time, patient-centred records that provide immediate and secured health information to authorised users. Electronic health records play a vital role in universal health coverage by supporting the diagnosis and treatment of patients through provision of rapid, comprehensive and timely patient information at the point of care (source: World Health Organization. Regional Office for Europe 2016. From innovation to implementation: eHealth in the WHO European Region – Available at: https://apps.who.int/iris/handle/10665/326317).

Guideline: a non-mandatory statement or set of statements of desired good or best practice (source: A Dictionary of Dentistry (2 ed.) Robert Ireland and Chuen Albert Yeung. Oxford University Press. Published online: 2020 eISBN:9780191828621).

Implied consent: implied consent refers to when a patient passively cooperates in a process without discussion or formal consent. The principles of good communication apply in these circumstances and

health professionals need to provide the patient with enough information to understand the procedure and why it is being done (source: Kakar H, Gambhir RS, Singh S, *et al.* Informed consent: corner stone in ethical medical and dental practice. *J Family Med Prim Care* 2014;3(1):68-71. doi: 10.4103/2249-4863.130284).

Informed consent: in relation to healthcare, the process in which a healthcare provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention (source: Shah P, Thornton I, Turrin D, Hipskind JE. Informed Consent. In: StatPearls. Treasure Island (FL): StatPearls Publishing, 2022 – Available at: https://www.ncbi.nlm.nih.gov/books/NBK430827/).

Laboratory data: information that is generated from microbiological, serological, chemical, haematological, radiobioassay, cytological, immunohaematological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of a disease or assessment of a medical condition (source: Law Insider. Clinical Laboratory Medical Information Services definitions – Available at: https://bit.ly/3v1x3rZ).

Medication reconciliation: the process of comparing the medicines prescribed to a patient with all of the medicines that the patient has been taking. Medication reconciliation is done in order to avoid and/or correct medication errors (such as omissions, duplications, dosage errors or medicine interactions), to contribute to the continuity of medication treatment and to promote effective and expeditious transmission of patient information between healthcare professionals (source: Sentinel Event Alert. Using medication reconciliation to prevent errors. *Jt Comm J Qual Patient Saf* 2006;32(4):230-2).

Medication review: a structured evaluation of a patient's medicines with the aim of optimising medicine use and improving health outcomes. This entails detecting medicine-related problems and recommending interventions (source: Griese-Mammen N, Hersberger KE, Messerli M, *et al.* PCNE definition of medication review: reaching agreement. *Int J Clin Pharm* 2018;40(5):1199-208).

Mentor: a mentor's role is to teach, guide and help shape the professional growth and learning of the mentee and to serve as a positive role model (source: Harvard School of Public Health – Available at: https://bit.ly/3ulZP7A).

Pharmaceutical care: the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. It involves the process through which a pharmacist co-operates with a patient and other professionals in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient (source: Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990;47:533-43).

Pharmaceutical care plan: the pharmaceutical care plan is a written, individualised, comprehensive medication therapy plan based on clearly defined therapeutic goals. Its aim is to ensure that the medication meets the patient's needs and expectations, and that the medication contributes optimally to the effective management of the patient's condition (sources: Gold ML, Fedder DO. Developing a pharmaceutical care plan. *US Pharm* 1992;17(10):53-60 and Resolution CM/Res(2020)3).

Polypharmacy: the use of multiple medications by a patient, with 5-10 medications usually accepted as the cutoff (source: Cifu DX, Lew HL, Oh-Park M. Geriatric Rehabilitation. Elsevier 2018. 978-0-323-54454-2).

Potentially inappropriate medications: medications whose risk of adverse events exceeds their expected clinical benefit, and which can be replaced by better-tolerated alternatives (source: Laroche ML, Charmes JP, Bouthier F, *et al.* Inappropriate medications in the elderly. *Clin Pharmacol Ther* 2009;85(1):94-7).

Standard: a document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. Standards should be based on the

consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits (source: International Organization for Standardization (ISO). ISO/IEC Guide 2:2004 – Available at: https://bit.ly/3NYnu5K).

References

1. The Council of Europe – Available at: https://www.coe.int/en/web/portal/home

2. The Council of Europe, guardian of human rights. 2023 – Available at: https://edoc.coe.int/en/an-overview/6206-the-council-of-europe-guardian-of-human-rights.html

3. The Council of Europe - An overview. 2023 – Available at: https://edoc.coe.int/en/an-overview/6966-the-council-of-europe-an-overview.html

4. Committee of Ministers Resolution ResAP(94)1 on the rational use of medicines – Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168062e5ea

5. Committee of Ministers Resolution ResAP(93)1 on the role and training of community pharmacists – Available at: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168o4bc591

6. Committee of Ministers Resolution ResAP(97)2 on the development of the function of pharmacists and adaptation of their initial training – Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168o4c1619

7. Committee of Ministers Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security – Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168050af58

8. Committee of Ministers Recommendation Rec(2006)7 on management of patient safety and prevention of adverse events in health care – Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168o5ae8b5

9. Council of Europe Expert Group on Safe Medication Practices. Creation of a better medication safety culture in Europe: Building up safe medication practices. 2006 Strasbourg: Council of Europe.

10. Decision of the Committee of Ministers of 11 and 12 July 2007 (CM/Del/Dec(2007)1002/6.1) to transfer the activities related to pharmaceutical issues to the European Directorate for the Quality of Medicines and Health Care (EDQM) – Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=090000168o5d53do

11. The EDQM at a glance. 2019 – Available at: https://www.edqm.eu/documents/52006/58906/edqm-at-a-glance.pdf/503a6c26-44b9-4fc0-643d-cd772201275d?t=1623746901948

12. European Directorate for the Quality of Medicines and HealthCare – Serving public health in Europe since 1964. 2017 – Available at: https://edoc.coe.int/en/health-care/6219-brochure-the-edqm-a-leading-organisation-that-protects-public-health.html

13. The European Directorate for the Quality of Medicines & HealthCare – Link: https://www.edqm.eu/

14. European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) – Link: https://go.edqm.eu/CDPPH

15. Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) – Link: https://go.edqm.eu/PC

16. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990;47:533-43.

17. Committee of Ministers Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services – Available at: https://go.edqm.eu/ResPhCare20203

18. Griese-Mammen N, Hersberger KE, Messerli M, *et al.* PCNE definition of medication review: reaching agreement. *Int J Clin Pharm* 2018;40(5):1199-208. doi: 10.1007/s11096-018-0696-7.

19. Soares IB, Imfeld-Isenegger TL, Makovec UN, *et al.* A survey to assess the availability, implementation rate and remuneration of pharmacist-led cognitive services throughout Europe. *Res Social Adm Pharm* 2020;16(1):41-7. doi: 10.1016/j.sapharm.2019.02.002.

20. Task Force on Medicines Partnership and The National Collaborative Medicines Management Services Programme (2002) *Room for Review: A guide to medication review: the agenda for patients, practitioners and managers*. National Prescribing Centre.

21. Zaninotto P, Huang YT, Di Gessa G, *et al.* Polypharmacy is a risk factor for hospital admission due to a fall: evidence from the English Longitudinal Study of Ageing. *BMC Public Health* 2020;20:1804. doi: 10.1186/s12889-020-09920-x.

22. Mair A, Fernandez-Llimos F, SIMPATHY Consortium. Polypharmacy management programmes: the SIMPATHY Project. *Eur J Hosp Pharm* 2017;24(1):5-6. doi: 10.1136/ejhpharm-2016-001044.

23. WHO - Medication without Harm - WHO Global Patient Safety Challenge 2017 – Available at: https://www.who.int/initiatives/medication-without-harm

24. Jha AK, Larizgoitia I, Audera-Lopez C, *et al.* The global burden of unsafe medical care: analytic modelling of observational studies. *BMJ Qual Saf* 2013;22(10):809-15. doi: 10.1136/bmjqs-2012-001748.

25. Panagioti M, Khan K, Keers RN, *et al.* Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *BMJ* 2019;366:l4185. doi: 10.1136/bmj.l4185.

26. World Health Organization (WHO) - Medication Safety in Polypharmacy - Technical Report 2019 – Available at: https://www.who.int/publications/i/item/medication-safety-in-polypharmacy-technical-report

27. Mekonnen AB, McLachlan AJ, Brien JaE. Pharmacy-led medication reconciliation programmes at hospital transitions: a systematic review and meta-analysis. *J Clin Pharm Ther* 2016;41:128-44. doi: 10.1111/jcpt.12364.

28. Choi YJ, Kim H. Effect of pharmacy-led medication reconciliation in emergency departments: A systematic review and meta-analysis. *J Clin Pharm Ther* 2019;44(6):932-45. doi: 10.1111/jcpt.13019.

29. Milos Nymberg V, Lenander C, Borgström Bolmsjö B. The impact of medication reviews conducted in primary care on hospital admissions and mortality: an observational follow-up of a randomized controlled trial. *Drug Healthc Patient Saf* 2021;13:1-9. doi: 10.2147/DHPS.S283708.

30. WHO - Medication safety in high-risk situations. Technical report 2019 – Available at: https://bit.ly/3Kvk8oz

31. Imfeld-Isenegger TL, Soares IB, Makovec UN, *et al.* Community pharmacist-led medication review procedures across Europe: Characterization, implementation and remuneration. *Res Social Adm Pharm* 2020;16(8):1057-66. doi: 10.1016/j.sapharm.2019.11.002.

32. PCNE. Position paper on the PCNE definition of medication review 2016 – Available at: https://www.pcne.org/upload/files/149_Position_Paper_on_PCNE_Medication_Review_final.pdf

33. PCNE. PCNE statement on medication review 2013 – Available at: https://www.pcne.org/upload/files/150_20160504_PCNE_MedRevtypes.pdf

34. Chen T. Pharmacist-led home medicines review and residential medication management review: the Australian model. *Drugs Aging* 2016;33:199-204. doi: 10.1007/s40266-016-0357-2.

35. Sousa MDCVB, Fernandes BD, Foppa AA, *et al.* Tools to prioritize outpatients for pharmaceutical service: A scoping review. *Res Social Adm Pharm* 2020;16(12):1645-57. doi: 10.1016/j.sapharm.2020.02.010.

36. Scottish Government Polypharmacy Model of Care Group. Polypharmacy Guidance Realistic Prescribing. Scottish Government. Scotland: 3rd edition, 2018.

37. Pharmaceutical Society of Australia. Guidelines for comprehensive medication management reviews. 2020 - Available at: https://www.ppaonline.com.au/wp-content/uploads/2020/04/PSA-Guidelines-for-Comprehensive-Medication-Management-Reviews.pdf

38. Society of Hospital Medicine. Safer medication management for better transition of care. Medication reconciliation for hospitalists - Available at: https://www.hospitalmedicine.org/clinical-topics/medication-reconciliation/

39. Beuscart JB, Pelayo S, Robert L, *et al.* Medication review and reconciliation in older adults. *Eur Geriatr Med* 2021;12(3):499-507. doi: 10.1007/s41999-021-00449-9.

40. Oliveira J, Cabral AC, Lavrador M, *et al.* Contribution of different patient information sources to create the best possible medication history. *Acta Med Port* 2020;33(6):384-9. doi: 10.20344/amp.12082.

41. *No authors listed*. Using medication reconciliation to prevent errors. *Jt Comm J Qual Patient Saf* 2006;32(4):230-2. doi: 10.1016/s1553-7250(06)32030-2.

42. International Pharmaceutical Federation (FIP). Medicines reconciliation: A toolkit for pharmacists. The Hague: International Pharmaceutical Federation, 2021 – Available at: https://www.fip.org/file/4949

43. Clinical Excellence Commission (Australia). Continuity of Medication Management: Medication Reconciliation (2014) – Available at: https://bit.ly/3NDITkA

44. 2023 American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc* 2023;71(7):2052-81. doi: 10.1111/jgs.18372.

45. O'Mahony D, Cherubini A, Guiteras AR, *et al.* STOPP/START criteria for potentially inappropriate prescribing in older people: version 3. *Eur Geriatr Med* 2023;14(4):625-32. doi: 10.1007/s41999-023-00777-y.

46. Mann NK, Mathes T, Sönnichsen A, *et al.* Potentially inadequate medications in the elderly: PRISCUS 2.0. *Dtsch Arztebl Int* 2023;120(1-2):3-10. doi: 10.3238/arztebl.m2022.0377.

47. Renom-Guiteras A, Meyer G, Thürmann PA. The EU(7)-PIM list: a list of potentially inappropriate medications for older people consented by experts from seven European countries. *Eur J Clin Pharmacol* 2015;71(7):861-75. doi: 10.1007/s00228-015-1860-9.

48. Laroche ML, Charmes JP, Merle L. Potentially inappropriate medications in the elderly: a French consensus panel list. *Eur J Clin Pharmacol* 2007;63(8):725-31. doi: 10.1007/s00228-007-0324-2.

49. Meulendijk MC, Spruit MR, Drenth-van Maanen AC, *et al.* Computerized decision support improves medication review effectiveness: an experiment evaluating the STRIP assistant's usability. *Drugs Aging* 2015;32(6):495-503. doi: 10.1007/s40266-015-0270-0.

50. Hanlon JT, Schmader K, Samsa G, *et al.* A method for assessing drug therapy appropriateness. *J Clin Epidemiol* 1992;45(10):1045-51. doi: 10.1016/0895-4356(92)90144-c.

51. PCNE. Classification for Drug related problems V9.1. 2020 – Available at: https://www.pcne.org/upload/files/417_PCNE_classification_V9-1_final.pdf

52. Strand LM, Morley PC, Cipolle RJ, *et al.* Drug-related problems: their structure and function. *DICP* 1990;24:1093-97. doi: 10.1177/106002809002401114.

53. Comité de Consenso. Third Consensus of Granada on Drug Related Problems (DRP) and Negative Outcomes associated with Medication (NOM). *Ars Pharm* 2007;48(1):5-17 – Available at: https://bit.ly/34 gkPSy

54. Bunting BA, Smith BH, Sutherland SE. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. *J Am Pharm Assoc* (2003) 2008;48(1):23-31. doi: 10.1331/108658003321480713.

55. Reeve E, Gnjidic D, Long J, *et al.* A systematic review of the emerging definition of "deprescribing" with network analysis: implications for future research and clinical practice. Br *J Clin Pharmacol* 2015;80(6):1254-68. doi: 10.1111/bcp.12732.

56. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) – Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri =CELEX%3A02016R0679-20160504

57. Council of Europe. Modernised Convention for the protection of individuals with regard to the processing of personal data. Adopted at the 128th Session of the Committee of Ministers of the Council of Europe, 2018 – Available at: https://rm.coe.int/convention-108-convention-for-the-protection-of-individuals-with-regar/16808b36f1

58. Shekelle PG, Wachter RM, Pronovost PJ, *et al.* Making health care safer II: an updated critical analysis of the evidence for patient safety practices. *Evid Rep Technol Assess (Full Rep)* 2013;(211):1-945.

59. Stewart MA. Stuck in the middle: the impact of collaborative interprofessional communication on patient expectations. *Shoulder Elbow* 2018;10(1):66-72. doi: 10.1177/1758573217735325.

60. Foronda C, MacWilliams B, McArthur E. Interprofessional communication in healthcare: An integrative review. *Nurse Educ Pract* 2016;19:36-40. doi: 10.1016/j.nepr.2016.04.005.

61. Weissenborn M, Haefeli WE, Peters-Klimm F, *et al.* Interprofessional communication between community pharmacists and general practitioners: a qualitative study. *Int J Clin Pharm* 2017;39(3):495-506. doi: 10.1007/s11096-017-0450-6.

62. Sim TF, Hattingh HL, Sunderland B, *et al.* Effective communication and collaboration with health professionals: A qualitative study of primary care pharmacists in Western Australia. *PLoS One* 2020;15(6):e0234580. doi: 10.1371/journal.pone.0234580.

63. Damiaens A, Fraeyman J, Fakroune S, *et al.* General Practitioners and Community Pharmacists' Collaboration in Primary Care: Small Steps for a Major Change. *Int J Integr Care* 2021;21(2):10. doi: 10.5334/ijic.5612.

64. Kwint HF, Bermingham L, Faber A, *et al.* The relationship between the extent of collaboration of general practitioners and pharmacists and the implementation of recommendations arising from medication review: a systematic review. *Drugs Aging* 2013;30(2):91-102. doi: 10.1007/s40266-012-0048-6.

Acknowledgements

The EDQM and Medication Review Working Group wish to thank the following people for their work on the production of these guidelines:

The delegations of the member states participating in the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) for their invaluable contributions in the guideline revision process.

All the stakeholders who contributed to the Stakeholder Consultation Process.

The EDQM proofreader, Ms Louise Birrell, for her diligent proofreading of the guidelines.

List of authors

The activities related to the drafting of these guidelines were carried out with the support of the Medication Review Working Group, which was established in 2019 and consisted of the members listed below.

The Medication Review Working Group was led by Dr Sabine Thomas (2019-2021) and Prof Martin Henman (2022-2023).

The guidelines were produced under the overall co-ordination of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC), whose Secretariat is provided by the EDQM (Council of Europe).

Author names and affiliations (in alphabetical order)

Dr Filipa Alves da Costa
University of Lisbon – Portugal

Dr Anna Bryndis Blondal
University of Iceland and The Primary Health Care of the Capital Area – Iceland

Dr Zaza Chapichadze
Ministry of Labour, Health and Social Activities – Georgia

Prof Christine Fernandez
Saint Antoine Hospital Paris – France

Ms Agnieszka Galinska
Chief Pharmaceutical Inspectorate – Poland *(at the time of the drafting of the document)*

Prof Martin Henman - Project Rapporteur (2022-2023)
Trinity College Dublin – Ireland

Prof Kurt E. Hersberger
University of Basel – Switzerland

Prof Branislava Miljkovic
University of Belgrade – Serbia

Dr Silvia Ravera
EDQM Secretariat
Department of Biological Standardisation, OMCL Network and HealthCare (DBO)
EDQM, Council of Europe – France

Dr Jan Saevels
Association of Pharmacists – Belgium

Dr Sabine Thomas - Project Rapporteur (2019-2021)
Federal Office of Public Health – Switzerland *(at the time of the drafting of the document)*

Ms Berit Tonissoo
Estonian State Agency of Medicines – Estonia *(at the time of the drafting of the document)*

Medication review is a structured and systematic evaluation of a patient's medicines with the aim of optimising their use and improving health outcomes. It involves the identification of actual or potential medicine-related problems and results in recommendations to optimise medicine use.

Medication review is performed in parts of Europe but is an under-used health service intervention and needs to be performed in a consistent and systematic manner to realise the benefits. The potential value of medication review to patients and to health services does not seem to be appreciated, and while some countries have national guidance, there is no standardised guidance at the European level available across the Council of Europe member states at present.

These guidelines aim to: a) establish a common understanding of what medication review is and how it contributes to improving the use of medicines; b) set out the process of conducting a medication review ; c) illustrate the necessity for the collection and sharing of data; d) provide guidance concerning education and training; e) provide insights on how to support the development of this service and to facilitate the implementation into practice at the European level; f) provide information on existing medication review programmes.

The guidelines are intended for competent national authorities and policy makers, pharmacists and healthcare professionals conducting medication review, and for health service organisations establishing medication review programmes.

Free download at
http://freepub.edqm.eu/

ENG

www.edqm.eu

The Council of Europe is the continent's leading human rights organisation. It comprises 46 member states, including all the members of the European Union. The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe. Its mission is to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect public health.

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE