# Rational drug use. Medication management in the complex chronic patient: reconciliation, revision, deprescription and adherence

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## Summary

## Rationale

Medication is the leading cause of adverse events (AE) derived from patient healthcare, for which purpose different initiatives, proposals and programmes have been developed to increase safety in drug use.

The Institute for Safe Medication Practices estimates that 50% of medication errors and 20% of adverse drug effects could be avoided with suitable medication reconciliation, which would help to improve patient safety. Different studies have demonstrated a high incidence of medication-related problems (MRP), particularly in over-65s, which could be corrected with a systematic medication review. The review by Hajjar points to a prevalence of between 32% and 60% of patients that took a medicinal product that was not indicated, from 7% to 16% presented overlapping, and the medicinal product prescribed was not effective in 18% of the patients. The study by Barnett indicates that 31% of the patients received a potentially inappropriate medicinal product according to the Beers criteria. Moreover, it is known that therapy adherence is a problem associated with chronic medication in patients with long-term pathologies. In a literature review performed by DiMatteo, 25% of the patients did not adhere to their medication or the medical recommendations, although chronic treatments present a greater risk of non-adherence than treatments for acute pathologies.

***General objectives***

1. Improve patient safety and reduce DRP:
    a) Withdraw the medication that the patient does not need.
    b) Prescribe a drug the patient needs and which does not figure in their drug therapy record.
    c) Detect and resolve adverse drug events.
    d) Reduce hospital admissions, visits to the emergency room, medical visits caused by adverse reactions related to the patient's drug therapy.
2. Improve health outcomes and increase control of the patient's disease.
3. Improve adherence.
4. Improve healthcare quality and patient quality of life.

In order to achieve these objectives it is advisable to draw up a methodology for the optimisation of drug therapies in chronic patients by implementing interdisciplinary procedures for the medication reconciliation and review of medication and an improvement

in adherence, patient-centred and focused on their needs, and not on those of the organisation, the healthcare setting or professional groups.

This methodology has to define the minimum requirements to be applied to ensure the quality and continuity of drug therapies across the health system, in accordance with the objectives of the new model of prevention and care of chronicity of the Health Department, and which must therefore contribute to the following:

1. Fight unnecessary polypharmacy, as well as the under-treatment of health problems due to the omission of necessary medication in order to achieve better control of disease.
2. Reduce errors in medication reconciliation caused by communication problems in the transitional care and thus improve therapy safety and effectiveness.
3. Improve patient adherence by means of involvement and co-responsibility.
4. Adapt drug therapies to the specificities of each patient, taking into account comorbidity, progress of the patient's disease, life expectancy and preferences.

## Medication reconciliation

***Definition***

Medication reconciliation is a formal and protocolised process that consists of systematically comparing the patient's regular medication to the medication prescribed **after a transitional care or a transfer in the same care setting**, with a view to analysing and solving any observed discrepancies, documenting and reporting changes.

Medication reconciliation requires the following:

• A systematic and exhaustive review or validation of all of a patient's medication (taking into account both the clinical information from the records and the patient-reported information gathered during the clinical interview), with a view to ensuring that the medicinal products that have to be **added/initiated, changed or withdrawn are carefully assessed** in order to keep an **exact and updated list** of the medicinal products, **available** to the patient or their family/caregiver as well as to all the suppliers that participate in their healing.

• **All the transitions** in the healthcare continuum must be implemented (table 1).

Table 1. Transitions in the health system

| Ambulatory care | Hospital care* |
|---|---|
| • Visit to PC (FD, paediatrician)<br>• Visit to the specialised care outpatient department<br>• Recent hospital discharge<br>• Visit to PC specialists: mental health, gynaecology...<br>• Visit to private prescribing doctors<br>• Visit to the Emergency room:<br>  • Hospital<br>  • CUAP<br>  • Continuing healthcare<br>• Visit to day hospital<br>• Home visit<br>• Non-attendance based visit<br>• Admission to geriatric residences<br>• Admission to a social and health centre<br>• Pharmaceutical attention services in a community pharmacy | • Admission<br>• Internal transfers<br>• Discharge:<br>  • To home<br>  • To another centre (hospital or social and healthcare centre)<br>  • To a geriatric residence |

FD: family doctor
CUAP: primary care emergency centre

***Prioritisation should be given to the medication reconciliation on admission and on discharge** with regard to other transitional care points, since an undetected reconciliation error at patient discharge time is potentially more serious than if it occurs while the patient is in the hospital.

The objective is to ensure that the patients receive all the necessary medicinal products they were taking before, that the correct dose, route of administration, regimen and duration are described and that they are appropriate for the new prescription. Under no circumstances it is a question of assessing medical practice or of questioning individual clinical decisions, but rather of detecting and correcting possible medication errors that would have gone unnoticed.

Ideally, the **full medication list/pharmacotherapeutic list should record** prescription **medicinal products**, including hospital medication dispensed at hospital level and medication dispensed in the day hospital, medication prescribed by private health, clinical trial medication, self-medication, non-prescription medicinal products, medicinal plants and homoeopathic medicines.

***Terminology and classification of discrepancies and medication reconciliation errors.***

A *discrepancy* is a difference between the medicinal products that were being taken regularly by the patient and the medicinal products in the new therapeutic plan, which is not necessarily a mistake. In fact, most discrepancies are due to the beginning of medication or to changes in the chronic treatment generated by the patient's new clinical condition, or else because of the performance of explorations and/or interventions with which the regular medication may interfere. There is a classification of discrepancies according to the analysed situation.

*Medication reconciliation errors* are the **discrepancies or differences that are not clinically justified** between the patient's regular chronic medication and the new prescription after transitional care (table 1).

We understand that **a discrepancy**:

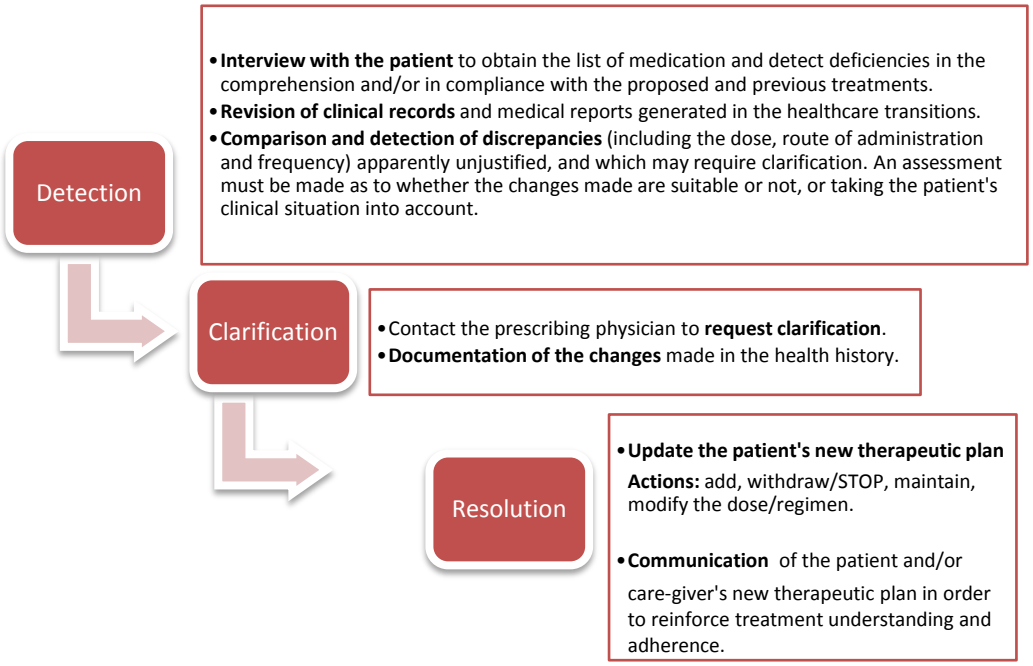
- **Is justified** when it can be accounted for by the patient's clinical situation or is justified when the doctor is consulted.
- It is a medication reconciliation error when it cannot be accounted for by the patient's clinical situation, it is not justified in the clinical course or the medical report and **is accepted as an error by the prescribing doctor after clarification has been requested**.

***Stages in the medication reconciliation process.***

Figure 1 includes the different stages of the medication reconciliation process.

The process should be initiated on the basis of the updated list of **medication** of the medicinal products the patient is actually taking **before the transitional care.** Discrepancies can be detected in the **interview with the patient**, in the visit to the healthcare professional and the different current **clinical records** (primary care active prescription records, HCCC [Shared Health History of Catalonia], health history, hospital discharge reports, specialised healthcare reports, hospital-dispensed medicinal products, community pharmacy and complementary sources).

Figure 1. Stages in the medication reconciliation process.




***Patient selection***

Medication reconciliation is applied to all the patients in all transitional care, whenever the patient changes healthcare area in the same setting. Medication reconciliation must be part of **regular clinical practice in all healthcare settings**.

## Medication review

### *Definition*

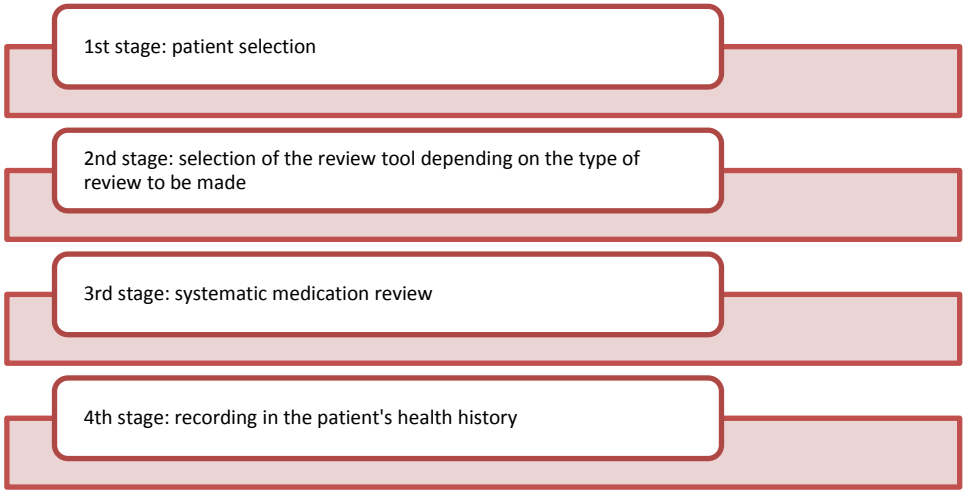
*Medication review* is defined as a **critical and structured examination of the patient's therapeutic regimen**, which must be consensus-based with the patient, with a view to optimising the impact of the medication, reducing medication-related problems, simplifying the regimen and maximising its efficiency.

The medication review aims to make sure that **the drug therapy is appropriate for the complex chronic patient (CCP) over time and over the different stages of evolution of their disease.**

### *Stages in the review process:*

Figure 2 includes the different stages of the medication reconciliation process.

Figure 2. Stages in the medication review process.



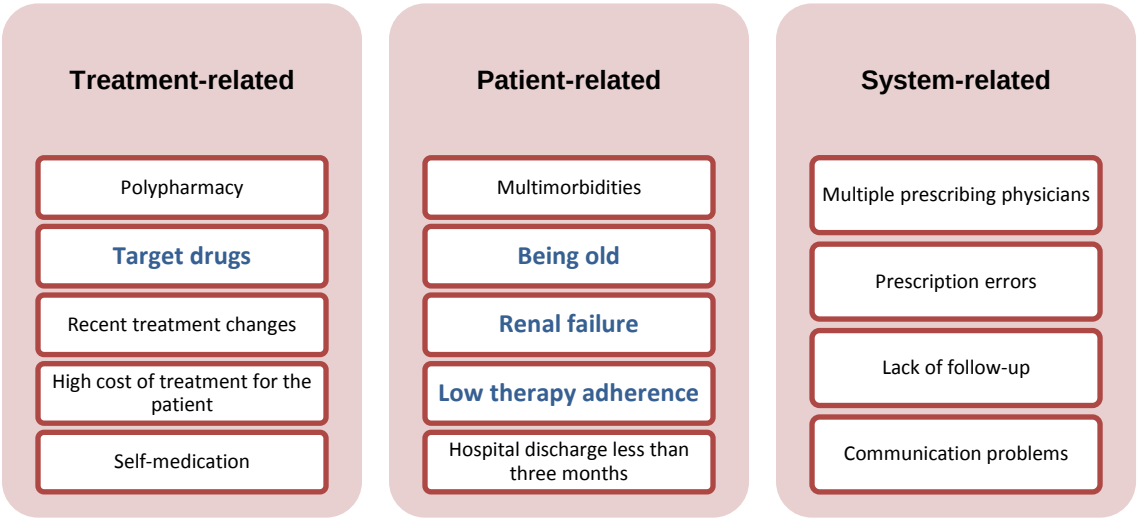

### *Patient selection*

All patients on chronic treatment should undergo a drug therapy review once a year in accordance with CatSalut Instruction 04/2012; however, the patients that benefit most from the implementation of a medication review programme are those who present the greatest risk of suffering adverse drug events (ADE), either for the type of medication they are taking, their clinical situation or patient-related characteristics or those derived from the actual health system. The greater the risk, the greater the probability of having an ADE, and consequently the benefit obtained from the medication review.

Figure 3 presents the risk factors most frequently related to an ADE and which, when they are combined, indicate a higher priority. For example, a patient that presents different risk factors such as multimorbidities, being elderly or on polypharmacy, with frequent hospital

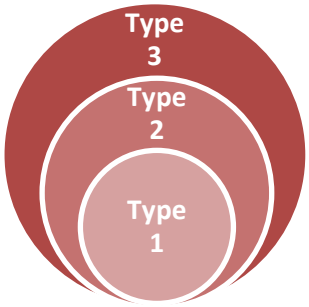
admissions, should be prioritised in a medication review programme, since they would obtain greater benefits from this process than a patient presenting fewer risk factors.

Figure 3. Risk factors most frequently related to adverse drug events




***Type of review***

The different types of review are classified taking the following criteria into account: the purpose of the review, the patient's presence at the visit, the exclusive review of the medication or whether the medication is reviewed relating it to the patient's clinical conditions or all of them together




Type 1: Review of pharmacological prescriptions

Type 2: Review of adherence and “concordance” (agreements)

Type 3: Clinical review

The **clinical review** of the medication might be addressed as a sequential model, since it comprises type 1 and type 2 reviews.

*Type 1: Review of pharmacological prescriptions*

It only evaluates the “technical” aspects of the patient's drug therapy, without taking into account other data from the health history, such as the patient's analyses or diagnostic tests. **The objective is to improve safety and efficiency.**

*What is reviewed?* Overlaps, interactions, contraindications, drugs that are not recommended in certain age groups (for example, the elderly), medicinal products that can be replaced by other more profitable alternatives, among others.

This can be done *without the patient being present*. Nevertheless, the changes in drug therapy that might be derived from the medication review should be conducted with the patient's participation and consent.

*Tools for performing this kind of review*. Hamdy's adapted questionnaire, lists of medicinal products that have been associated with serious adverse reactions in a given age group, particularly the elderly; the most-used lists are the Beers criteria, drawn up in the USA, the PRISCUS criteria from Germany and McLeod's criteria from Canada. These lists detail the medicinal products that should be avoided in any situation, existing therapy alternatives, doses of certain medicinal products that should not be surpassed and drugs to be avoided in certain pathologies. Another commonly used tool is the Screening Tool to Alert Doctors to Right Treatment (START), comprised of 22 prescription indicators based on evidence from certain medicinal products for frequent diseases in the elderly and the Screening Tool of Older Person’s Prescription (STOPP), a list of 65 clinically relevant criteria for inappropriate prescriptions, classified by physiological systems. The different lists and criteria expounded were used to draw up a table of inappropriate drugs for the elderly adapted to our setting.

**Ideally, clinical work stations should have assisted electronic prescription (AEP) tools with different pre-established technical criteria for safety and efficiency like the ones addressed since they would facilitate the automation of this type of review.**

*To which type of patients should this type of review be systematically applied?* To all patients on chronic treatment.

*Type 2: Review of adherence and "concordance" (agreements)*

It is used to assess adherence to the drug therapy and must be conducted in the patient's presence in the course of the visit. **The objective of this type of review is to improve therapy effectiveness.**

*Definition*. Therapy adherence is defined as the degree of correspondence between the patient's behaviour and the therapeutic recommendations agreed to with the doctor. Therapy adherence is a dynamic process of which the patient is a fundamental and active part. Following this line, in recent years a conceptual change has been advocated, based on the configuration of a health professional-patient relationship model centred on the patient's self-defined needs, in which patient values play a central role and must be explored, and their preferences for different therapy alternatives respected, if such alternatives exist. In this model, the definition of adherence is replaced by that of concordance. With this perspective, the process of prescribing and taking medication is regarded as an alliance in which patient and doctor participate to reach an agreement on the medication to be taken, when and how it is to be taken, and do so based on the knowledge and experience of the professional and of the patient's beliefs, experiences and preferences. Despite the practical difficulties of this new model, the key aspect lies in the health professional's change of role, since it switches from a paternalistic model to one of shared decision-making.

*Tools for measuring adherence*: **There is no measure of adherence with a proven validity**; for this reason different methods should be combined. Normally, the questionnaires used are those in which the patient has to provide answers, and the tablets they take are tallied. Ultimately, **the extent of disease control may be an effective measurement**.

*Strategies for improving adherence*:

Haynes established a series of interventions (presented in table 1.1) to improve adherence which have proved to be effective and have become a classic approach in this topic, laying the foundations for subsequent work.

Table 1. Effective strategies for improving adherence

| |
|---|
| Information:<br>- Simplify the regimen as far as possible.<br>- Provide the patient with clear indications on the therapeutic regimen prescribed, and if possible, deliver it to them in writing as well. |
| For chronic therapies |
| Reminders<br>- Prescribe the medication adapted to the patient's everyday activities.<br>- Remind them of the importance of adherence at every visit.<br>- Tailor visit frequency to patient needs.<br>- Phone the patient if they do not turn up for an appointment.<br>- Use ICT (text messages, etc.).<br><br>Prizes<br>- Acknowledge the effort made by the patient at each visit to improve adherence<br>- Reduce the number of visits if adherence is appropriate<br><br>Social support<br>- Engage family and friends. |

In view of the importance of adherence in the healthcare relationship and its impact on patient health, it is obvious that the results obtained with the interventions in this area are insufficient. The approach applied hitherto needs to change, and the new ideas arising from emerging theories in education for healthcare, some of which shall be briefly described herein, should be brought in.

We have to get away from the idea that a single intervention applied to improve adherence at a given moment will be effective throughout a CCP's life. In fact, adherence varies over the time that elapses after a patient begins a therapy, particularly in the case of chronic conditions; these changes may be related to the patient's state of health, but also to changes in their relationship with the doctor, satisfaction with the health services used and other aspects of their life. A good empathy-based relationship between the healthcare professional and the patient is the cornerstone of a relationship of trust that facilitates adherence to recommendations.

The tailoring of treatments is a core element of many of the strategies currently employed to improve adherence, particularly in chronic conditions, as can be deduced from the changes of state theory. In order to accomplish this tailoring, computing technology is a powerful instrument that has gained in importance in recent years. Different programs have been developed that make it possible to tailor recommendations to each person once they have completed a brief computer-based questionnaire about their disease and their relevant personal opinions regarding treatment and adherence.

Other strategies of interest are the patient decision aids, informative documents presented in paper or digital format, with the necessary objective information presented in a simple and understandable way for most patients to be able to take an informed decision, from the standpoint of their disease, in clinical situations with different therapeutic alternatives. The dissemination of these technologies opens up new perspectives for addressing interventions to improve adherence.

*Tool for systematising the type 2 review*. It is an algorithm that makes it easier to apply the recommendations described above for improving adherence to healthcare practice; it also serves to systematise the information received by the patient about their medication, detect obstacles to adherence and propose the most appropriate intervention. *To which type of patients should the type 2 review be systematically applied?*

*a*) Patients with unsuitable disease control or else abrupt changes in their disease's evolution or who do not respond to therapy.

*b*) Patients with therapies that cause frequent adverse effects that worsen their quality of life and patients in whom no therapy-related frequent adverse effect presents.

*c*) Patients on polypharmacy, particularly the elderly.

*d*) Patients with complex and long-term treatments and/or taking medicinal products that are complex to administer and which require periodical training in the technique.

*Type 3: Clinical review*

This third strategy is the most global one, since it integrates the previous two and deals with medication safety in greater depth. **The objective is to improve, in combined fashion, the appropriateness of treatment, safety and effectiveness.**

*Definition*. The medication clinical review is the process in which the doctor, during the patient's visit, assesses the therapeutical efficacy of each medicinal product and relates it to the evolution of the pathologies they are being treated for, as well as the prevention and resolution of DRP, treatment adherence and the patient's knowledge of their drug therapy and pathologies.

The aim is to decide whether it is necessary to add, withdraw or continue with any of the medicinal products of the patient's medication, and assess the therapy's benefits and risks.

*What is reviewed*. The **indication** of the medication with regard to the patient's pathologies; the **appropriateness** of each one of the medicinal products taken for the age and/or clinical conditions, such as renal or hepatic failure, as well as the appropriateness of the dose, regimen and duration; the **effectiveness** of the therapy in relation to the therapeutic objective addressed is also assessed, as are aspects related to the **safety** of the medicinal products to avoid DRP and accomplish treatment **adherence**.

To perform this type of review, it is indispensable to refer to the patient's health history and have them present to assess adherence and agree to the changes in their therapy with them.

*To which type of patients should the type of review 3 be systematically applied*?

Priority is given to patients that present one or more of the risk factors indicated in figure 3.

*Methodology for performing the clinical review*

The steps for the systematic performance of the clinical review are detailed below. Figure 4. Clinical review

**1st step.** Hierarchise diseases, taking into account the criterion of the professional and the patient.

**2nd step.** Associate the medicinal products to the pathologies presented by the patient.

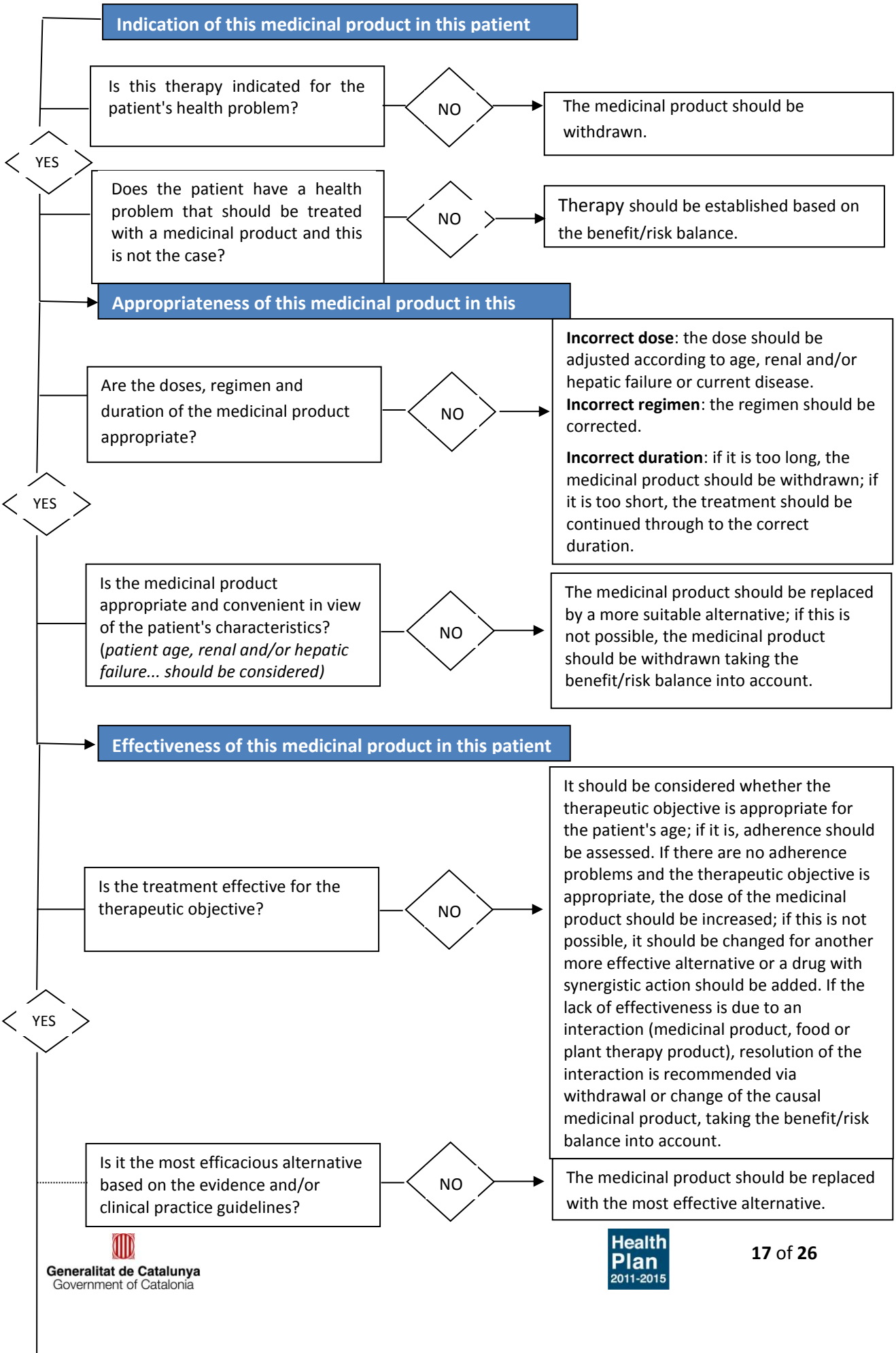
**3rd step.** Establish the therapeutic objective for each treatment, taking into account the patient's age and clinical situation.

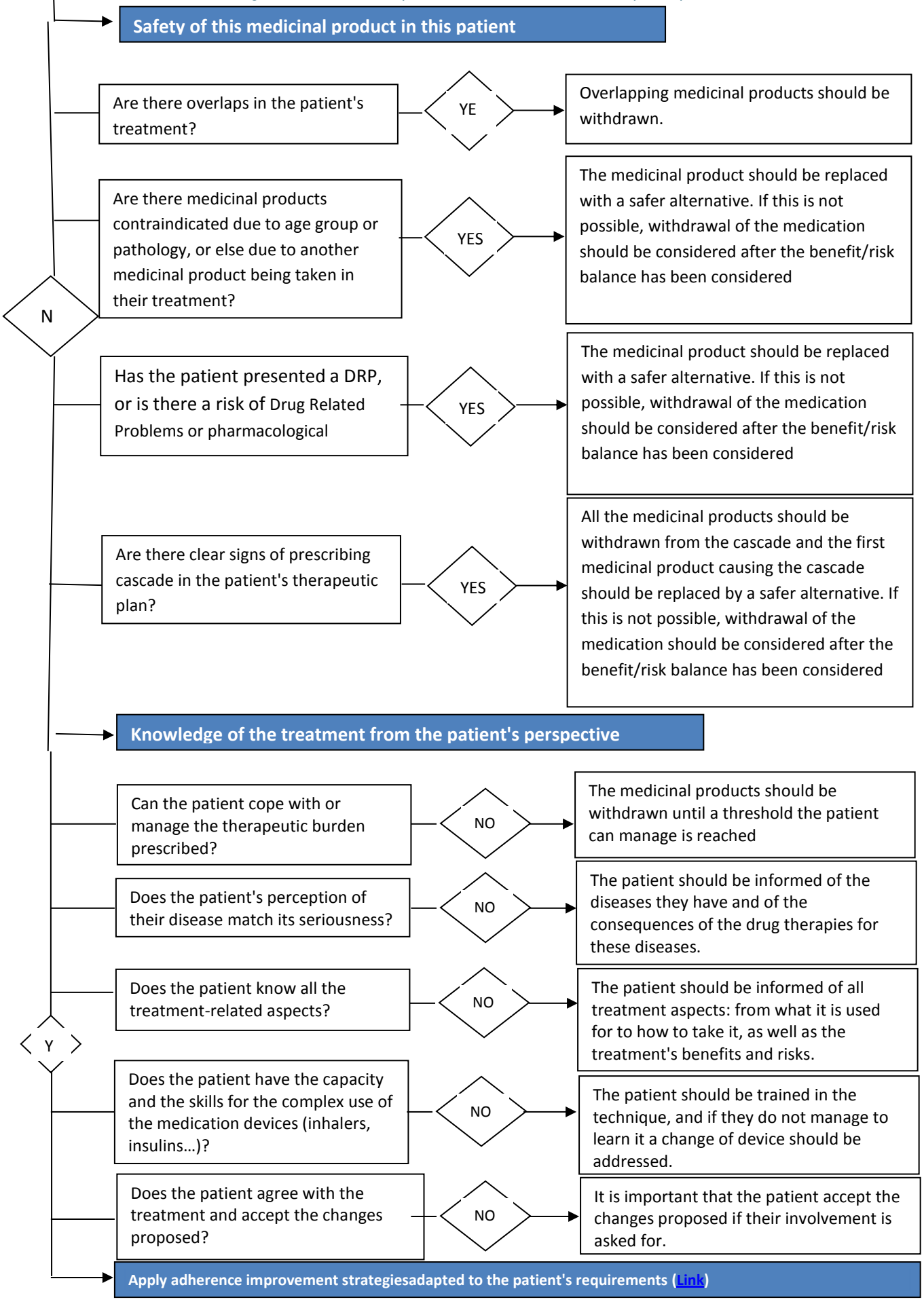
**4th step.** Apply the clinical review medication algorithm (figure 5) to assess indication, appropriateness, effectiveness, safety, cost and treatment compliance or adherence.

*Tools for systematising the type 3 review*. There are different tools for performing this type of review, including Assessing Care of Vulnerable Elderly (ACOVE), an instrument for the elderly; the NO TEARS Tool, which indicates the evaluated dimensions of medication based on scientific evidence, and the Screening Tool for Medication Review, for patients on polypharmacy.

Finally, there is one instrument that has been validated in our setting, the Medication Appropriateness Index (MAI), which presents problems of feasibility for use in primary care due to the complexity of its application and the exhaustiveness of the items it measures. There is detailed description in the book published by the Spanish Society of Primary Care Pharmacists (SEFAP), which has designed an algorithm that reviews the five items (indication, appropriateness, effectiveness, safety and adherence) described above and which are easy to apply in our setting (figure 5).

**Figure 5. ALGORITHM FOR MEDICATION CLINICAL REVIEW IN THE COMPLEX CHRONIC PATIENT**




Safety of this medicinal product in this patient
Are there overlaps in the patient's treatment?
YE
Overlapping medicinal products should be withdrawn.
Are there medicinal products contraindicated due to age group or pathology, or else due to another medicinal product being taken in their treatment?
YES
The medicinal product should be replaced with a safer alternative. If this is not possible, withdrawal of the medication should be considered after the benefit/risk balance has been considered
N
Has the patient presented a DRP, or is there a risk of Drug Related Problems or pharmacological
YES
The medicinal product should be replaced with a safer alternative. If this is not possible, withdrawal of the medication should be considered after the benefit/risk balance has been considered
Are there clear signs of prescribing cascade in the patient's therapeutic plan?
YES
All the medicinal products should be withdrawn from the cascade and the first medicinal product causing the cascade should be replaced by a safer alternative. If this is not possible, withdrawal of the medication should be considered after the benefit/risk balance has been considered
Knowledge of the treatment from the patient's perspective
Can the patient cope with or manage the therapeutic burden prescribed?
NO
The medicinal products should be withdrawn until a threshold the patient can manage is reached
Does the patient's perception of their disease match its seriousness?
NO
The patient should be informed of the diseases they have and of the consequences of the drug therapies for these diseases.
Does the patient know all the treatment-related aspects?
NO
The patient should be informed of all treatment aspects: from what it is used for to how to take it, as well as the treatment's benefits and risks.
Y
Does the patient have the capacity and the skills for the complex use of the medication devices (inhalers, insulins…)?
NO
The patient should be trained in the technique, and if they do not manage to learn it a change of device should be addressed.
Does the patient agree with the treatment and accept the changes proposed?
NO
It is important that the patient accept the changes proposed if their involvement is asked for.
Apply adherence improvement strategiesadapted to the patient's requirements (Link)

## *Deprescription*

### *Definition*

It is a planned and standardised withdrawal of chronic medication, widely recommended in the elderly. In the absence of studies and guidelines focused specifically on medication withdrawal, deprescription should be based on the epidemiology of the prescription-related problems (for example medication that is not recommended in the elderly or those with a high risk profile, which should be a priority withdrawal objective), it should be tailored and driven by common sense.

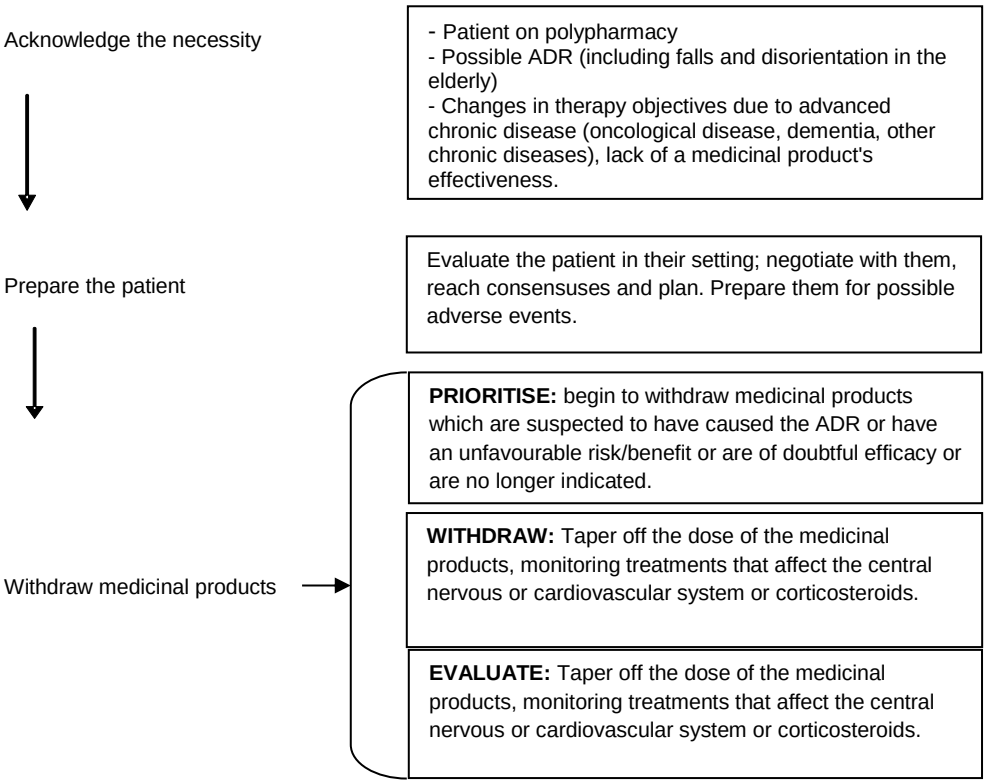
### *Situations that favour deprescription*

There are situations in which a review of the medications should be considered with the specific objective of withdrawing medicinal products. These cases are described below:

1. **Lack of treatment effectiveness**, for any of the following reasons:
    - The medicinal product is not indicated.
    - Lack of evidence on benefits in general or in the population of the elderly.
    - Existence of recommendations against the use of the medicinal product in the elderly or in people with specific health problems.
2. **People on polypharmacy**. Different studies indicate that it is possible to implement medication withdrawal strategies in the elderly taking polypharmacy which not only do not lead to a deterioration in the patient's diseases or the reappearance of symptoms, but can also improve the patient's cognitive condition, reduce the risk of falls and improve their quality of life.
3. **Adverse drug reactions (ADR)**. Frequent adverse reactions in the elderly with potentially serious consequences are included. For a long time, many of these events were regarded, as “normally related to aging”, such as falls, disorientation and cognitive impairment or behavioural disorders, for example agitation. According to some authors, “each symptom in the elderly should be regarded as an ADR until proven otherwise”.
4. **Changes in therapeutic objectives**, particularly in the event of a chronic advanced disease, including oncological diseases or advanced dementia. As the disease progresses and it becomes clearer that prevention or healing are not realistic objectives, a tailored approach, consensus-based with the patient and more geared towards symptom control, might be the most suitable one. This change of approach should be accompanied by a medication review, and any medicinal products that no longer fulfil the objectives should be withdrawn.

Usually, one objective may be comfort and symptom control (pain, anxiety, breathlessness, etc.), although other situations may also involve the desire or the need to maintain the capacity to interact with the environment or resolve certain family situations or practical questions. Similarly, it should be borne in mind that some medicinal products (for example, statins, antihypertensives or bisphosphonates) may have a preventive objective that is not appropriate for the situation, or need a long time, possibly even longer than the person's life expectancy, to be effective. The effects of other medicinal products may be impacted by organic changes associated with the disease (changes in the body composition in a situation of cachexia, or hepatic and renal disorders, for example), which might lead to an increase in the risk of adverse reactions.

***Deprescription stages***



***How should medication withdrawal be approached?***

When the deprescription process is slow, only one medication at a time is withdrawn, under medical supervision, and the dose is reduced progressively, if necessary, to ensure that withdrawal-related adverse clinical reactions are minimised.

Nevertheless, the possible appearance of the following events must be borne in mind:

- Withdrawal syndromes. This occurs above all in medication that acts upon the central nervous system, such as benzodiazepines, antidepressants, levodopa, β-blockers or corticosteroids.
- Rebound effect. Some examples are tachycardia induced by the withdrawal of β-blockers, acid hypersecretion caused by the withdrawal of proton pump inhibitors and insomnia from withdrawal of hypnotics.
- Unmasking interactions. For example, the withdrawal of omeprazole may make it necessary to modify the oral anticoagulant regimens that were previously stable as omeprazole can modify anticoagulant metabolism.
- Reappearance of the underlying disease: original symptom or risk factor. It is an apparently infrequent phenomenon, but it has to be taken into account.

If withdrawal symptoms emerge or underlying diseases reappear, treatment should be reinitiated at the initial doses and a new withdrawal attempt made at a slower pace. In these cases, information on the possible adverse reactions caused by withdrawal and the recommendations for managing them may be useful.

## Strategy for the implementation of a medication review, reconciliation and adherence programme

We do not have an ideal model of medication **review, reconciliation and adherence** programmes, hence it is necessary to adapt certain processes to each setting, taking into account, among other things, the available information resources and systems.

The core points are as follows:

- Form a multidisciplinary team and involve the entire organisation.
- Protocolise the reconciliation, review, deprescription and **adherence processes by *assigning functions, responsibilities*** and avoiding overlapping tasks, and maintain this over time.
- Define an action plan that envisages objectives, pilot project, phases, timeline, sources of information, patient screening and monitoring of the programme.
- Support from information and clinical management systems: electronic prescription modules for the prevention of DRP and for the systematic review of medicinal products.
- Training and dissemination plan for professionals.
- Train patients and involve them actively in their therapy.
- Have multidisciplinary committees between healthcare areas: standardise processes.
- Facilitate a single medication registry (Shared Health History of Catalonia, HCCC): have a single registry updated in real time.

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