Gesundheit Österreich Forschungs- und Planungs GmbH •••

# Assessment of Centralised Procurement of Medicines in Portugal



Summary Report

#### EMSPOS

Estrutura de Missão para a Sustentabilidade do Programa Orçamental da Saúde







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## Summary Report

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**EMSPOS** Estrutura de Missão para a Sustentabilidade do Programa Orçamental da Saúde







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This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 3.8 "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all".

### Abstract

The study assesses the performance of **centralised procurement of medicines (CPM) in Portugal** from a public health perspective and develops policy recommendations. The OECD "Methodology for Assessing Procurement Systems" (MAPS) was applied in an adapted manner. Information was retrieved from literature and procurement documents, including bids of selected procurement procedures, and from 42 interviews, thereof 37 on-site interviews with representatives of public authorities, hospitals and regional health administrations, patients and pharmaceutical industry. Input of procurement experts of five European countries, of Portuguese participants in a stake-holder workshop and of academics in a Delphi survey have contributed to quality-assurance, participation and acceptance.

The Shared Services of the Ministry of Health (SPMS) is responsible for performing centralised procurement processes, which comprise both open procedures (Aquisições centralizadas / AC) with one (or two) suppliers and the two-stage processes of framework agreements (Acordos Quadros / AQ). Legal implementation of CPM is compliant with European standards, and the Portuguese system was found to have several strengths. The latter include its contribution to lower prices (compared to individual purchases) in several (but not all) cases and thus to savings for the public sector, to improved transparency of processes and governance, to more equity in access to medicines across Portugal and to lower workload for individual procurers. However, weaknesses were also identified: lack of strategy related to CPM and a lack of clarity related to the roles and responsibilities of SPMS and further relevant public institutions and stakeholders with regard to their CPM activities; lengthy and bureaucratic processes in centralised purchases and delays in the conclusion of procedures, resulting in non-availability of centrally procured medicines at the beginning of a year, as scheduled, and possible launch of direct procurements by hospitals (parallel procedures); lack of performance indicators; SPMS communication perceived as insufficient and a low level of involvement of clinical expertise in CPM processes; an outdated list of active substances for central purchasing (last updated in 2016), no institutional coordination between the key public institutions ACSS, INFARMED and SPMS and limited knowledge of the market by SPMS.

All addressed stakeholders were, in principle, positive towards the idea of CPM in Portugal. It is advised to maintain and extend the strengths of the current CPM system while addressing identified weaknesses. The overarching **recommendation** is **to develop an updated procurement strategy** to ensure clarity on objectives, roles and responsibilities and procurement tools. Management recommendations urge for **strengthening** the following areas: the **measurement of performance**, **capacity**, **collaboration** among public authorities and with users, **stakeholder management**, the **service character** of SPMS and **procedures to prepare and conduct procurements**.

### Keywords

Public procurement, pharmaceutical, evaluation, access to medicines, processes, Portugal

# 1 Background

In Portugal, centralised procurement of medicines (CPM) is provided through centralised purchases via open procedure (Aquisições centralizadas / AC) for defined medicines and two-stage frame-work agreements (Acordos Quadros / AQ) for mainly off-patent medicines. Following an interest of public authorities for an evaluation of CPM from a health system and public health perspective, Gesundheit Österreich Forschungs- und Planungs GmbH (GÖ FP / Austrian National Public Health Institute) was commissioned to perform an **assessment of CPM in Portugal** and to **develop policy recommendations**.

## 2 Methods

The study is based on a mixed methods approach.

The assessment was guided by the **analytical framework** "Methodology for Assessing Procurement Systems" (**MAPS**) of the Organisation for Economic Co-operation and Development (OECD). The framework was adapted for the purpose of this study to account for the specificities of medicines. Information and data were collected from literature (including grey literature) and through interviews (five exploratory telephone interviews with representatives of public authorities who were members of the project's Advisory Board and 37 on-site interviews in Portugal). These 37 face-to-face **interviews** were held with a total of 52 people, representing different stakeholder groups (public authorities, hospital management, procurement and pharmacy, regional health administrations, patients and pharmaceutical industry) in eleven municipalities of all five mainland regions in January / February 2020. Procurement **documents**, including bids, of selected procurement procedures were analysed in terms of efficiency of the processes, the competitiveness and prices achieved.

Based on a **SWOT** (strengths, weaknesses, opportunities and threats) analysis, high-level policy recommendations, including proposals for specific projects for optimisation, were developed. Input of procurement experts in five European countries with a CPM system (Denmark, Cyprus, Estonia, Italy and Norway) mainly collected through telephone interviews conducted in May and June 2020 was considered.

A **stakeholder workshop** with approximately 40 participants (held virtually due to the COVID-19 pandemic) ensured validation of key findings of the assessment and draft recommendations. The recommendations were finalised upon further comments received in a two-stage **Delphi survey** with academics.

## 3 Assessment of CPM in Portugal

SPMS (Serviços Partilhados do Ministerio de Saúde / Shared services of the Ministry of Health) is commissioned by the Central Administration of the Health System (Administração central do Sistema de Saúde / ACSS) to perform CPM.

Two CPM procedures are in place:

- Aquisições centralizadas (AC): SPMS procures centrally for users such as hospitals and regional health administrations ((Administrações Regionais de Saúde / ARS) in the whole country for a period of usually one year. This is based on the needs assessment submitted by the users and their proof of availability of funds, via open procedure bids awarded to one or two suppliers (in 2020, the "winner-takes-it-all" principle was changed to a "two-winners-approach", where possible).
- » Acordos Quadros (AQ): In the framework agreements, SPMS lists qualified suitable suppliers within an acceptable price range in an e-catalogue for up to four years, and users can then make call-off orders in a second stage.

Major findings of the assessment are as follows:

- » Legislation related to CPM is compliant with international standards, and mechanisms to combat fraud and ensure good governance are in place. However, the assessment suggested that not all procurement tools (aiming to make procurement more effective) provided for in legislation appear to be (fully) utilised. Strategic guidance and prioritisation provided by pol-icy-makers to support management and operational levels was perceived to be missing.
- » For performing CPM, Portugal established a **dedicated procurement agency** (SPMS), which is an asset and key prerequisite. However, the role and the **responsibilities** of SPMS are not sufficiently clear, in particular in comparison to other public procurement entities (eSPap) and other public authorities responsible for pharmaceutical policies (INFARMED and ACSS). This lack in clarity on the roles also indicates that there is room for improvement regarding the **collaboration between the public institutions** ACSS, INFARMED and SPMS. Better coordination in this context would also be needed so that **the list of active substances** to be centrally purchased is **updated** (current list as of 2016).
- » The bids analysis identified a rather **low participation rate** in some cases. The latter suggests limited attractiveness of the Portuguese market for some suppliers. This can negatively impact competitiveness and eventually access to medicines (non-availability).

- » Overall, CPM was perceived to have contributed to more transparent processes. However, in several cases, in particular for AC, processes were considered to be lengthy and bureau-cratic. The bids analysis also identified some appeals and rejections among the selected tenders. As a result, procedures may not be concluded on time, and medicines are not available for users at the beginning of a year, as scheduled. This resulted, in several cases, in direct procurements of hospitals, thus having led to parallel procedures.
- In general, CPM, in particular the framework agreements, appear to have contributed to reduced workload for the users. However, inefficiencies in the procedures (for open procedures, in particular, with redundancies due to parallel procedures) have limited this potential.
- » High-level **data** to assess the CPM in Portugal are not readily accessible, and ACSS has not yet developed **performance indicators** to assess on a routine basis progress under CPM.
- » Although better knowledge of the market would be beneficial in some procurement procedures, no systematic market research and consultation is done by SPMS. Concerning clinical expertise, the involvement of hospital pharmacists in the development of AQ in recent times constitutes a good practice example.
- » For some centrally purchased medicines, prices have decreased compared to the earlier situation, while prices of other medicines did not change or were found to have even increased. Large hospitals would be able to achieve lower prices in direct procurement, while smaller hospitals would not have access to the same medicines without CPM. Thus, CPM contributed to improved equity in access to medicines across Portugal, possibly at the cost of higher prices in a few cases. For some medicines, particularly those under AQ (as also confirmed by selected samples of the bid analysis), significantly lower prices compared to the "base price" (estimated contract value) were achieved. This contributed to considerable savings. However, the methodology on how the savings are calculated is not transparent and provides room for improvement.
- Portuguese CPM is based on e-procurement which is considered extremely helpful and appreciated by users. However, the existence of non-interlinked platforms calls for optimisation. This adds to perceived need to improve the service character of SPMS. This includes improved communication with users and stakeholders (e.g. currently no routine meetings of SPMS with hospital pharmacists) and the need to strengthen contract management (e.g. feedback to users in case of problems in fulfilling the contract under AC, lack of AQ management in terms of constant monitoring and feedback in case of missing competition).

Overall, the Portuguese CPM system is characterised by **strengths and weaknesses**, as also summarised in the SWOT matrix (cf. Figure 1).

The findings of the gaps analysis should not convey the message that CPM in Portugal would not be functional. Identified strengths should be used, maintained and extended and opportunities be seized. In addition, good practice examples are to be disseminated across Portugal and beyond in order to allow for lessons learning.

### Figure 1: Addressing the findings of the SWOT analysis of CPM in Portugal

| maintain<br>support<br>enhance<br>extend<br>enlarge<br>disseminate<br>enforce | <ul> <li>Strengths</li> <li>Procurement legislation</li> <li>Procurement agency</li> <li>Increased transparency and<br/>improved governance</li> <li>Lower workload</li> <li>Lower prices / savings</li> <li>Fewer appeals</li> <li>e-Procurement</li> <li>Publicly accessible<br/>procurement documents</li> <li>Improvements</li> <li>Audit and control systems</li> </ul>   | <ul> <li>Weaknesses</li> <li>Bureaucratic, inefficient procedures</li> <li>Lack in strategy and prioritisation</li> <li>Lack in clarity of roles of institutions</li> <li>Overall several procurement platforms</li> <li>Limitations in communication to users, limited involvement of civil society</li> <li>Higher prices</li> <li>Limited ompetition</li> <li>Limited flexibility in technical specifications</li> <li>Lack of performance indicators</li> <li>Lack of data</li> <li>No systematic market consultation</li> </ul>   | clarify<br>change<br>abolish<br>invest<br>communicate<br>improve |
|---|--|--|--|
| seize<br>apply  | <ul> <li>Opportunities</li> <li>Positive attitude of all</li> <li>Committed staff and<br/>willingness to improve</li> <li>Willingness of stakeholders<br/>to collaborate and improve</li> <li>Involvement of users in AQ<br/>preparation as good practice</li> <li>Collaboration between<br/>hospital pharmacy and<br/>hospital procurement</li> <li>Progresses over time</li> <li>Budget increase for<br/>hospitals 2020</li> <li>Increased attractiveness of<br/>the Portuguese market due<br/>to CPM / higher volumes</li> <li>"Two-winners" approach<br/>since 2020</li> <li>Equity potential across<br/>Portugal</li> </ul> | <ul> <li>Redundancies following<br/>unclear roles</li> <li>Inefficiencies and demoti-<br/>vation due to lack of strategy</li> <li>Portuguese market gets<br/>unattractive due to low prices</li> <li>Biosimilar policy (switch only<br/>after 6 months) limits savings</li> <li>Parallel processes due to<br/>delayed procedures; resulting<br/>in redundancies, higher prices,<br/>higher workload and poorer<br/>governance</li> <li>Risk of co-financing of other<br/>SPMS areas</li> <li>Limited budgets</li> <li>Misleading price information<br/>due to confidentiality</li> <li>Lowest price as sole award<br/>criterion</li> </ul> | manage<br>avoid<br>prevent                                       |

Source and presentation: the authors

# 4 Recommendations

### 4.1 Policy recommendations to address gaps

Figure 2 summarises seven high-level recommendations that aim to contribute to improve CPM in Portugal.

The overarching recommendation is a call for strategic guidance. The **Ministry of Health and the Ministry of Finance** are urged **to develop**, if needed in consultation with other ministries (e.g. the Ministry of Economy), a **clearer and consistent procurement strategy**.

Such a procurement strategy can only be developed and implemented if there is strong **political will** to move forward and take strategic decisions, accompanied by a clear focus on a few key actions and by the political commitment to invest wherever needed and considered appropriate (financial investment, e.g. to ensure appropriate funding for hospitals, as well as appropriate staff resources at SPMS and at users' levels).

### Reflections on possible lack of and need for a procurement strategy

**Does Portugal lack a procurement strategy? Was CPM introduced without any strategic vision?** The answers are mixed. When CPM was introduced some years ago, its purpose and vision was apparently known and shared by those who had been involved in its establishment. However, over the years, founders of the CPM may have left their position, and new people may not have learned about the rather "implicit" objectives. In particular, new situations, challenges, procurement methodologies, tools and targets have emerged (both nationally and internationally), and thus an update of strategic guidance is needed. At the time of this study (2020), according to the knowledge of the authors, **no up-to-date high-level procurement strategy** (document) was available.

*Why is there a need for a procurement strategy?* Clarity on the strategic vision of the policymakers with regard to short-term and, in particular, long-term objectives of CPM (as one mechanism in the policy framework to achieve affordable access to needed medicines at a cost that is affordable) is needed to guide those involved in procurement or other pharmaceutical policies. Those responsible for the (development of) a management plan (i.e. the procurement agency SPMS and those for the oversight (ACSS) also require this guidance. If the strategic directions are lacking, operational decisions are more difficult to take. Limited clarity can negatively impact operational work. The lack of clarity and strategy was also mentioned by some users when they commented on SPMS's work.

Figure 2: Strategy and management action to address gaps and optimise CPM in Portugal



Source and presentation: the authors based on a multi-phase recommendations development process

The procurement strategy should provide directions to, at least, the following issues:

- » Objective of CPM in the context of public health (objectives) in Portugal: Which objectives shall be primarily addressed with CPM? Savings for the public sector? If yes, at which cost? How are public health objectives and industry objectives balanced? Which role shall procurers assign to availability and affordability issues (competitiveness) in cases of conflicts between these two objectives? How is CPM, with its two types of AQ and AC, aligned with other pharmaceutical (pricing) policies (e.g. the policies with regard to the uptake of biosimilar medicines)? Which importance do policy-makers assign to policy objectives such as equity (across Portugal), good governance and transparency, and efficiency? What is the understanding of the goods purchased in CPM (e.g. medicines, or parts of medicines, being "no normal commodities" which may require specific approaches)? Do policy-makers allow, and encourage the management to develop different procurement approaches for different types of medicines (e.g. on-patent / off-patent medicines)? Which characteristics do medicines (or active substances) subject to CPM have?
- Sood governance and transparency: How transparent shall processes and outcomes be? Who shall have access to which type of information? Which audit processes shall be in place, and is there a need to strengthen governance structures? Which level of transparency (and ex-change of information) should exist between the public institutions ACSS, INFARMED and SPMS, and which (confidential) data are they supposed to share? Which documents and areas of the e-procurement system should be kept confidential?
- Roles and responsibilities: Which roles and competences are assigned to the procurement agency SPMS? This shall be clarified also in comparison to other procurement entities for the public sector (e.g. eSPap) and to other public authorities with competences for medicines (e.g. INFARMED). Which decisions are to be taken by which public entities (alone and in consultation)?
- Investments and funding: Is there a political commitment to ensure sufficient capacity (e.g. staff, appropriate professional training and experience) and funding (e.g. of the procure-ment agency, of users) in order to allow appropriate performance of CPM? Which invest-ments are policy-makers willing to take to improve the reporting system and overcome inefficiencies (e.g. improvement in the e-procurement system, new and/or optimised data-bases)?
- Collaboration and stakeholder dialogue: Which perspective do policy-makers have on the level and frequency of contacts and cooperation of SPMS with other public authorities, users and further stakeholders? Which role do policy-makers see for users (e.g. solely beneficiaries or, in addition, experts to be involved as advisors for the preparation of some procedures, establishment of advisory committees with representation of users and further stakeholders)? Which role do they see for patients and civil society related to CPM (e.g. consultation with specific patient groups before the purchase of defined medicines)?
- » Measurement of performance: In line with the overall strategic objectives that CPM should contribute to, for which domains shall the performance of SPMS and of those responsible for good performance of CPM be measured (e.g. purely monetary performance indicators such as price decreases, savings, or quality aspects, or availability, or users' satisfaction)?

- Procurement tools: Procurement legislation has further developed: meanwhile European legislation provides a toolbox of procurement mechanisms (e.g. use of the "Most Economically Advantageous Tender" (MEAT) criterion, "more-than-one-winner" principle, "dynamic purchasing system" DPS, use of "mini-competitions", "molecule-based competition") which was implemented in the Portuguese procurement legislation. Which of these "new" procurement tools shall be implemented? Under which circumstances (cases of "normal risks" such as delayed procedures or new unaffordable medicines versus "exceptional risks" such as a pandemic situation) may exceptional procurement procedures be implemented (how? who decides?)?
- » Monitoring and review: In addition to the evaluation through key performance indicators (KPI), which further monitoring and reviews processes (e.g. review and update of the procurement strategy after two years) do policy-makers aim to implement in an institutionalised manner?

All further action (both management action of the procurement agency SPMS and of its supervisory body ACSS) would ideally be derived from this procurement strategy.

While awaiting specifications through a procurement strategy, the authors have identified **six areas for optimisation at management level** (thus, the responsibility of SPMS and/or ACSS). These domains are listed below (no ranking), and improvements can be achieved through dedicated projects (actions) at operational level:

- » Measurement of performance in CPM and monitoring (projects: development of key performance indicators and a review of the impact of the change from the "winner-takes-it-all" into the "two-winners" approach on the availability of medicines)
- » **Capacity** in quantitative and qualitative terms of those involved in public procurement of medicines
- » Institutionalised collaboration of public authorities (projects: establishment of an institutionalised working group of ACSS, INFARMED and SPMS, and the update of the list of active substances under CPM – an exercise to be jointly done by this working group)
- » Collaboration with users and stakeholder management (projects: SPMS to organise meetings with hospital pharmacists - in addition to existing meetings with procurement experts; systematic involvement of hospital pharmacists as "experts from the field" into the development of AC)
- » Service character of SPMS (project: optimisation of the e-procurement architecture)
- » Procedures to prepare and conduct procurement of medicines (projects: implementation of market consultation for AC; pilot project on changes in procedures such as earlier or staggered launch of the needs assessment)

Though the implementation of the above-mentioned high-level management recommendations requires guidance by a procurement strategy, action at management and even operational levels may vice versa also feed into the strategy.

While most projects relate to management recommendations, two of them address rather strategic decisions: the review of the "toolbox" of procurement mechanisms, which current procurement legislation offers, and possible selection of some tools for implementation, and the measures to enhance transparency.

### 4.2 Prioritisation and further actions

#### Next steps

It is urged to start some actions - at strategic as well as at management and operational levels as soon as possible.

#### Procurement strategy

The key action is to ensure the development (or update) of a **procurement strategy**, since further action at SPMS and other public institutions level depends on strategic guidance.

This should be started as soon as possible. If due to the current workload in the COVID-19 situation, no comprehensive procurement strategy can be produced in the coming year (2021), it is recommended to develop at least a **small-scale strategy** document. The latter should address, as much as possible, the questions listed as components of a procurement strategy. Further questions might be kept for later discussion; respective decisions could be postponed to a review process scheduled in one to three years' time.

The authors consider the development of a **basic procurement strategy within six months feasible in case of political** interest and **will** and a well-designed process.

#### Operational collaborative projects

While waiting for strategic guidance, some **projects** at operational level can be started (or continued, respectively) immediately:

- » Setting up a **working group of ACSS, INFARMED and SPMS** and ensuring a working structure that allows continuity (initiative to be taken by ACSS or SPMS)
- » Updating the list of active ingredients under CPM by this working group
- » Organisation of a meeting of SPMS with hospital pharmacists

#### As far as resources allow, SPMS should start

- » performing market consultations for all centralised purchases (AC) and
- » inviting **hospital pharmacists** to support the preparation of AQ procedures.

#### Performance indicators

Finally, another task to be started as soon as possible is the **development of key performance indicators**. This would be the responsibility of **ACSS**, which, located between the strategic level of the ministries (Ministry of Health, Ministry of Finance) and the operational level of SPMS, is responsible for overseeing the performance of SPMS and providing appropriate funding.

The development of the indicators should take into consideration feasibility aspects. Thus, it is advised, at least in the beginning, to **limit the number of performance indicators** (max. 10 - 12 indicators) and to ensure that overall both data collection (SPMS) and validation of the indicators are not too time- and resource-intensive. A draft of such performance indicators could be shared, before piloting, with selected stakeholders for consultation (in particular with competent minis-tries as to whether, or not, their strategic objectives have been "translated" accordingly).

| Measure   | Responsible ac-<br>tor  | Feasibility  | Time-table   |
|---|---|--|--|
| Procurement strategy  | MoH / MoF /<br>other ministries   | Depends on strong political will   | Major issues to be defined<br>within 6 months (if political<br>will)   |
| Institutionalised working<br>group of ACSS, INFARMED<br>and SPMS  | ACSS, INFARMED<br>and SPMS at op-<br>erational level<br>(ACSS or SPMS to<br>invite) | Middle – the existing high workload of<br>institutions is a limiting factor; this<br>action being mentioned in procure-<br>ment strategy would be supportive   | To be started immediately if time resources allow  |
| Updated list of active ingre-<br>dients under CPM   | SPMS, in collabo-<br>ration with ACSS<br>and INFARMED                               | Middle – the existing high workload of<br>institutions is a limiting factor; this<br>action being mentioned in procure-<br>ment strategy and the re-launch of<br>the institutional working group would<br>be a facilitating factor | 4–6 months upon start  |
| Regular meetings of SPMS with hospital pharmacists  | SPMS  | Middle   | First meeting to be organ-<br>ised within 1–2 months   |
| Systematic market consul-<br>tations for all AC (alterna-<br>tive: development of criteria<br>for which AC full market<br>consultation is required) | SPMS  | Extension of market consultation for<br>use of some AC - middle<br>Systematic market consultation for all<br>AC - low  | Systematic use: not before<br>2022 / 2023<br>Alternative approach: list of<br>criteria for mandatory use<br>of market consultation:<br>Q4/2021 |
| Involve hospital pharma-<br>cists and other experts<br>from the field, as a stand-<br>ard, in the preparation of<br>procedures                      | SPMS  | High   | To be started immediately  |
| Development and applica-<br>tion of performance indica-<br>tors   | ACSS  | Middle – high workload being a limit–<br>ing factor, whereas a procurement<br>strategy demanding indicators and a<br>focus on few high-level indicators<br>would be supportive factors   | Development in<br>Q1/Q2/2021, application of<br>a draft set for the perfor-<br>mance measurement for<br>the year 2021                          |

### Table 1:

| Top priority actions to i | improve CPM in Portugal |
|---------------------------|-------------------------|
|---------------------------|-------------------------|

Source and presentation: the authors

If developed on time, these indicators could be applied for measuring the performance in 2021.

It should be ensured that data for defined indicators are **routinely surveyed** and that they are considered and validated by ACSS. To improve transparency and accountability, it is recommended to communicate these indicators to the public, e.g. in a publication.

A mid-term review of the uptake, including challenges in the applicability, of these indicators should be planned from the beginning (e.g. after 2–3 years). This assessment should also consider the possibility to apply further indicators, which could not be included in the first set due to lack of data but for which a database will have been established in the meantime.

#### Actions for the future

Upon availability of a (draft) procurement strategy, the recommendations and derived actions are to be reviewed. Additional projects might be proposed.

Actions considered important by the authors to be performed mid-term (in 2-3 years, i.e. to be finalised by end of 2023) are the following:

- » **Evaluating the impact of the implementation of the recommendations** and adapting, based on the findings, the procurement strategy and management recommendations, if needed
- » Considering the learnings of COVID-19 pandemic management in a future evaluation
- » Defining projects to enhance transparency, including price transparency (e.g. exploring the legal feasibility of INFARMED sharing "net" price data negotiated in a managed-entry agreement with SPMS)
- » Reviewing and further developing the **methodology to calculate savings** due to CPM
- » Contributing the experiences made in Portuguese CPM to cross-country joint procurements of medicines (e.g. in the "Valletta Declaration" to which Portugal is a member, or future initiatives at EU level).

## 5 Conclusion

CPM in Portugal is, in general, well established and has contributed to positive effects, in particular with regard to good governance, reduced workload for users and more equitable access to medicines. Nonetheless, the assessment identified several areas of improvement. To support SPMS at their operational work, guidance through a high-level procurement strategy is required.

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