

# Managing conflicts of interest

**A how-to guide for public pharmaceutical-sector committees in low- and middle-income countries**



**World Health  
Organization**



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## Contents

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Acknowledgements .....	iv
List of abbreviations .....	v
Executive summary .....	vi
1. Introduction: about this guide .....	1
2. What is a conflict of interest and why is its prevention and management important? .....	2
2.1. The need for prevention and management of conflicts of interest.....	2
2.2. Understanding conflicts of interest .....	5
Conflict of interest distinctions .....	6
2.3. Pervasiveness of conflicts of interest.....	6
3. Conflict of interest policy and practice in low- and middle-income countries.....	8
4. Strengthening policy, prevention and management of conflicts of interest .....	10
4.1. Overview .....	10
4.3. Guiding principles .....	11
A special note on transparency and conflict of interest .....	12
4.4. Policy and implementation mechanisms .....	13
Step 1: Establish a working group to plan and prioritize actions .....	13
Step 2: Review existence and adequacy of legislation, policies, rules and codes of conduct and develop/revise as needed.....	15
Step 3: Educate, provide guidance and raise awareness .....	16
Step 4: Establish oversight and enforcement mechanisms and monitor policy implementation ....	17
Step 5: Promote a culture of disclosure/ethical conduct .....	18
4.5. Processes and procedures for conflict of interest prevention and management .....	19
Step 6: Ensure definitions of conflict of interest and primary interests or obligations are included and clearly explained .....	19
Step 7: Safeguard committee independence.....	20
Step 8: Strengthen procedures for disclosure, verification and evaluation .....	21
Step 9: Identify and implement actions for preventing and managing conflicts of interest .....	25
Step 10: Monitor, enforce and provide oversight of prevention and management actions .....	29
6. Conclusion .....	31
References.....	32

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## List of abbreviations

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HITAP	Health Intervention and Technology Assessment Program [Thailand]
HTA	health technology assessment
LMICs	low- and middle-income countries
NICE	National Institute for Health and Care Excellence [United Kingdom]
WHO	World Health Organization

## Executive summary

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The Sustainable Development Goals highlight the importance of good governance for realizing development goals, including universal health coverage. Governance concerns include the effective prevention and management of conflicts of interest that may compromise the integrity of decision-making in the public pharmaceutical sector. Adverse outcomes can occur throughout the pharmaceutical system, including poor quality of care and harm to individuals, wastage of valuable health system resources, and a lack of trust in government institutions. Conflicts of interest in the public pharmaceutical sector are common in high- and low-income countries alike and are often not well understood.

There is limited information on how conflicts of interest are managed in public pharmaceutical decision-making, particularly in low- and middle-income countries (LMICs). A recent World Health Organization (WHO) 10-country study identified common gaps, including a lack of organized practices for preventing and managing conflicts of interest. This manual was developed in response to the need to improve the understanding of conflicts of interest in public pharmaceutical decision-making and the need for guidance on preventing and managing conflicts of interest as identified in the WHO study and the WHO Good Governance for Medicines programme.

The primary objective of conflict of interest policies and strategies in this context is to safeguard the integrity of decision-making in the public pharmaceutical sector. Improving conflict of interest prevention and management in public pharmaceutical decision-making committees require strategies that strengthen (1) policy and implementation mechanisms and (2) prevention and management processes and procedures. The principles of proportionality, transparency, accountability and fairness are important for conflict of interest policies and practices. Transparency in how decisions are made and specifically on how conflicts of interest are identified, prevented and managed, when possible, is particularly important for oversight, accountability and securing public trust.

Ten key steps for improving conflict of interest policy, prevention, and management in public pharmaceutical decision-making committees are identified and explained in this manual. The steps lay out how to get started with evaluating what currently exists in a country and how to build on or develop policies and processes. The steps elaborate on approaches for training, monitoring and enforcement mechanisms and activities to raise awareness and encourage compliance with policies. Finally, the steps outline processes and procedures at the committee level to identify and prevent conflicts of interest and implement responses when situations arise.

Going forward, more work will be needed to enable countries to share experiences and good practices; advance learning on specific tools and actions; and gather more evidence on what works, how and under what circumstances. This manual is a step forward in supporting countries in preventing and managing conflicts of interest in public pharmaceutical committees. The approach is practical and may be adaptable to specific contexts and can be elaborated on as more evidence is gathered.



## 1. Introduction: about this guide

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This publication aims to provide practical guidance on how to prevent and manage conflicts of interest in the public pharmaceutical system in LMICs. Cross-sectoral collaboration, including public entities and non-State actors (including civil society groups), is essential for access to safe, effective medicines of good quality in all areas of the pharmaceutical system, from research and development through regulation, policy, and procurement and supply. The goal of collaboration should be to enable substantive discourse amongst the various stakeholders who may at times have differing interests. Preventing conflicts of interest when and where possible and reducing their impact in pharmaceutical committee decision-making are important measures for safeguarding public health. This guide focuses on public pharmaceutical committees and agencies because of the potential risks posed to the health and safety of populations from conflicts of interest that compromise the integrity of these decision-making processes and the potential impact on public budgets, out-of-pocket expenditures, and public trust in the decisions made and the health system itself.

The guide is intended for policy-makers, managers, committee conveners and chairs, and those involved in oversight looking to strengthen the prevention and management of conflicts of interest in key public pharmaceutical-sector committees and agencies. It is useful for personnel and committee members involved in the selection, registration, reimbursement and procurement of medicines and may be appropriate to other committees as well. While the guide focuses on pharmaceuticals, the content may be relevant to other health products, as appropriate, including diagnostics and other medical devices. Institutional conflict of interest is outside the scope of this guide, although mention is made when relevant.

The impetus for developing this guide was a request for support from countries participating in the **WHO Good Governance for Medicines programme**. **Countries identified a need for guidance on the management of conflicts of interest.** In response, WHO convened a group of experts to review gaps and needs for support and discussed a draft background paper, *“Guidance on Developing Conflict of Interest Policies in the Pharmaceutical Sector”* prepared by Lisa Bero (1). Several workshops were held to provide training and enable countries to share experiences (2) and in 2021, a survey was conducted in 10 countries in the WHO South-East Asia Region to examine conflict of interest policies and their implementation in the public pharmaceutical sector (3,4). This manual draws on the background paper, the study findings and published sources.

The guide examines relevant definitions and the nature of conflicts of interest in the context of the public pharmaceutical sector. It explains the need for preventing and mitigating the impact of conflicts of interest in public pharmaceutical-sector committee and agency decision-making processes and outlines gaps and challenges around conflict of interest policy and practice in LMICs. The guide proposes options for guiding principles and strategies for preventing and managing conflicts of interest. It recognizes that policy and practice approaches for conflicts of interest need to be adapted for the local country situation and committee-specific decision-making processes. As such, it makes use of selected country experiences to provide managers and others with examples for improving conflict of interest management in their own settings and, given that LMICs may have resource constraints, suggests an approach to selecting strategies at least in the short term.

## 2. What is a conflict of interest and why is its prevention and management important?

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### 2.1. The need for prevention and management of conflicts of interest

The Sustainable Development Goals highlight the importance of good governance in all sectors, including health, for the achievement of development goals, including universal health coverage (5). An important component of good governance is the effective prevention and management of conflicts of interest (6). Conflicts of interest are a concern because they may improperly influence the independent judgement or actions and undermine the loyalty of an individual who is obligated to serve a party or perform a role (7,8). Conflicts of interest, particularly those arising from financial or contractual relationships between the private sector entities and committee members, have been shown to compromise the integrity of decision-making (Box 1), impacting public health and public health budgets.

#### **Box 1. Association of conflicts of interest with compromised decisions: some examples**

**Regulatory advisory committee:** A study of voting activity of the US Food and Drug Administration Center for Drug Evaluation and Research advisory committees revealed that members who were also paid board members of, or had a financial interest in, the sponsoring pharmaceutical manufacturer were more likely to vote in ways that favoured the manufacturer than those with no ties or financial links to manufacturers (9).

**National formulary:** A 2019 study in Indonesia found that among the reasons reported by physicians for prescribing medicines not listed in the Indonesian National Formulary was the lack of confidence in its development process. Concerns included lack of transparency on the selection process and specifically the use of evidence in decision-making, the selection of committee members and the perception of industry interference (10).

**Health insurance:** A comparison of the purchasing processes of Thailand's two tax-financed health insurance schemes found that the health expenditure of one was four times that of the other, even though both schemes referenced the national essential medicines list. The difference was partly ascribed to governance arrangements. The scheme with higher costs relied on the expert opinion of its own advisory committee of medical experts and lacked provisions for managing conflicts of interest in their advisory capacity, while the scheme with lower costs was informed by the health intervention and technology assessment program (HITAP) and had implemented conflict of interest identification, prevention and management provisions (11).

**Clinical practice guidelines:** A study of 95 national and international organizations found that clinical practice guidelines produced by organizations with more comprehensive conflict of interest policies requiring disclosure of direct funding sources and financial relationships were associated with fewer recommendations for and more recommendations against the use of patented medical products (12).

**Physician prescribing practices:** Two systematic reviews that studied the association between physicians' prescribing practices in the US and their interactions and financial and gift relationships with pharmaceutical companies found that physicians who accepted financial payments were more likely to prescribe the specific companies' products over alternative companies' products, have higher prescribing costs and prescribe brand name products over generics (13) and that interactions with sales representatives and receipt of gifts were associated with more prescriptions for the companies' products and more requests to add them to formularies (14).

Adverse outcomes can occur throughout the pharmaceutical system (Table 1) and include:

- **Poor quality of care and harm** to individuals—including higher mortality and morbidity—due to the lack of access to pharmaceutical products, their inappropriate use, and the use of unsafe or poor-quality products. Inappropriate medicines use can also accelerate the development of antimicrobial resistance.
- **Wastage of valuable health system resources.** Three of the 10 leading sources of health system inefficiencies identified by WHO are related to medicines—the underuse of generic medicines and inflated prices for medicines, the use of substandard or falsified medicines, and inappropriate or ineffective use of medicines (15). Conflicts of interest can contribute to all of these inefficiencies, thereby reducing the resources available for public health priorities.
- **Undermining trust** that stakeholders and the public at large have in both the institution or committee that made the decision and the decision itself (16). Conflicts of interest can threaten the legitimacy of decisions and damage the reputation and credibility of the institution, the committee and individual members. The lack of trust may cause health professionals and other stakeholders to disregard recommendations, such as those in standard treatment guidelines that are based on these decisions. It may also influence public demand for some medicines or vaccines (e.g., COVID-19 vaccines) (17).

**Table 1: Examples of conflicts of interest and adverse outcomes that can occur throughout the pharmaceutical system**

	Example of Conflict of Interest	Adverse Outcomes
<b>Marketing authorization (product registration)</b>	Regulatory official receives remuneration for a speaking engagement from a company submitting a request for marketing authorization.	Market authorization of a poor-quality, inappropriate or less cost-effective product; delays in authorizations of competitor products.
<b>Selection and reimbursement</b>	The chair of the selection committee was involved in research funded by the sponsoring company to develop the product under consideration.	Inclusion of the product on the national essential medicines or reimbursement list despite availability of lower-priced or more effective alternatives.
<b>Inspection of manufacturing facilities</b>	An inspector has a relative that consults for the pharmaceutical company they inspect.	Inspection reports minimize negative findings, allowing poor-quality products in the market.
<b>Procurement</b>	Procurement official has a spouse who owns shares in a pharmaceutical manufacturing company.	Procurement in favour of the company despite lower-priced or better-quality alternative products.
<b>Supply and distribution</b>	Official responsible for making decisions on awarding transport contracts has a relative employed by a company bidding for the contract.	Higher transport costs or supply chain disruptions due to unreliable service.
<b>Prescribing, dispensing and use</b>	The committee responsible for updating the national treatment guidelines receives sponsorship for the revision process from a pharmaceutical company that has a commercial interest in the outcomes of the decisions made.	The perception that decisions made during the drafting of guidelines are biased favourably towards the sponsoring company can impede prescribers' adherence to the treatment guidelines; inclusion of the sponsoring company's product in the guidelines can lead to patients being prescribed a less-effective or safe product.

## 2.2. Understanding conflicts of interest

Table 2 presents three definitions of conflict of interest used in law and public policy; public service; and medical research, education and practice and highlights relevant key points. A commonality to the definitions is that a conflict of interest is a situation and a risk that arises when a person has a financial or other interest that could potentially interfere with their entrusted obligation, duty or responsibility to serve a party or perform a role. In this guidance, it is referred to the obligation, duty or responsibility as a “primary interest” and the financial or other interest that conflicts as a “secondary interest”.

**Table 2: Selected definitions of conflict of interest relevant to public pharmaceutical committees**

Source	Definition	Key Points [adapted from (8, 17)]
<b>Legal definition (8 p. 6, 18 p. 163)</b>	Conflicts of interest are “situations where an individual has an obligation to serve a party or perform a role and the individual has either: 1) incentives or 2) conflicting loyalties, which encourage the individual to act in ways that breach his or her obligations”.	Derived from long-standing use in law and public policy.  Identifies two broad types of conflict of interest.
<b>Organization for Economic and Cooperative Development definition (19 p. 24, 20 p. 13)</b>	A conflict of interest “involves a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests, which could improperly influence the performance of their official duties and responsibilities”.	Derived from standard legal definitions.  Focuses on public officials and the risk to their decisions and actions as public servants.
<b>Institution of Medicine definition (21 p. 46)</b>	A conflict of interest is “a set of circumstances that creates a risk that professional judgements or actions regarding a primary interest will be unduly influenced by a secondary interest”.	Focuses on risk to professional judgement or actions of individuals in medical practice, teaching and research.  Does not mention risks due to divided loyalties.  Refers to “primary interests” in place of official obligations, duties or responsibilities.

A conflict of interest is a situation that creates a risk. It does not necessarily mean that decision-making will be improperly influenced or undermined (7). Having a conflict of interest is not the same as corrupt or improper conduct and is usually not illegitimate in itself. However, it creates an incentive and increases the risk that an individual’s judgement or action may be compromised and can provide an entry point for corruption. If a relevant secondary interest is purposefully not disclosed, this could be considered a corrupt act if laws or policies mandate disclosure.

To note, WHO's Framework of engagement with non-State actors<sup>1</sup> in paragraph 22 that "a conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of WHO's work in a given area) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (WHO's work) The existence of conflict of interest in all its forms does not as such mean that improper action has occurred, but rather the risk of such improper action occurring. Conflicts of interest are not only financial, but can take other forms as well."

### **Conflict of interest distinctions**

Direct individual conflicts of interest are those when a person may stand to gain personally if the conflict of interest is not prevented or managed. For example, if the head of the central procurement unit owns stock in a pharmaceutical company, their decisions on awarding tenders may be influenced by the potential for financial gain if medicines from that company are purchased. Alternatively, the conflict of interest may be indirect, such as when an individual's family member or close friend obtains a financial benefit from the decision (7).

Institutional conflicts of interest are those when an entity is performing two or more roles that may conflict or when the institution has financial interests that clash with its mission or obligations (7,21). An example is where a health technology assessment (HTA) entity receives funding from a pharmaceutical company to support the evaluation of a pharmaceutical product in which the company has a commercial interest.

Conflicts of interest can be difficult to recognize and assess and not all conflicts of interest have the same magnitude of risk with regards to the probability and extent to which the conflict of interest could unduly influence decision-making and compromise results. It is therefore essential to ensure that the primary interests (e.g., mission, goals, obligations, values) of the committee and its members and the secondary interests, obligations or relationships that could constitute a conflict of interest are clearly defined and understood. This will enable managers and committee chairs to make a determination about the relevance of a disclosed interest and the existence and seriousness of a conflict of interest (22).

### **2.3. Pervasiveness of conflicts of interest**

Conflicts of interest in the public pharmaceutical sector are common in high- and low-income countries alike (23) and occur throughout the pharmaceutical system. Several factors contribute to the pervasiveness of conflicts of interest in public pharmaceutical decision-making:

- Pharmaceutical systems are complex and public officials who convene or serve on committees may have frequent interactions and form relationships with private-sector and other actors (7).
- Pharmaceutical committees and agencies often rely on technical and clinical experts who are not public employees. Such experts are often in demand to serve as consultants, advisors and influential opinion leaders for pharmaceutical industry and other private actors (24). As a result, finding experts who are free of conflicts of interest can be challenging even in high-income countries. For example, an analysis of an immunization advisory group in Canada found that

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<sup>1</sup> WHO Framework of engagement with non-State actors ([http://apps.who.int/gb/ebwha/pdf\\_files/wha69/a69\\_r10-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/wha69/a69_r10-en.pdf))

only 4.7% of members were independent of industry (25). Similar hurdles may occur in countries with a limited pool of experts in some fields, such as oncology.

- Processes, such as product registration, that may involve discretionary decision-making can be particularly susceptible to conflicts of interest if there is insufficient transparency and where checks and balances are lacking (26).
- Responses to emergencies and public health crises, such as COVID-19, can require governments to make quick decisions such as on vaccination strategies and regulatory approval, and implement rapid responses that bypass usual processes and controls (17).

### 3. Conflict of interest policy and practice in low- and middle-income countries

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Information on how conflicts of interest are averted and managed in the public pharmaceutical sector, particularly in LMICs, is limited. Formal conflict of interest policies in health and pharmaceutical systems are fairly recent. Leading medical journals initiated the practice of declaring interests in the late 1980s (27). This may help explain the paucity of evidence on specific tools and actions to mitigate undue influence on decision-making in pharmaceutical and health-related committees (21).

The WHO Good Governance for Medicines programme demonstrated that strategies such as the use of declarations of interests—a necessary first step for managing conflicts of interest—can be feasibly implemented in the pharmaceutical systems of countries across income levels (28). Committees in countries around the world typically focus on disclosure of conflicts of interest. However, disclosure alone is insufficient to mitigate undue influence, and the emphasis on disclosure means that policies and strategies for prevention, management and transparency are underdeveloped (21,29).

While many public pharmaceutical committees now have policies and requirements for disclosures, gaps remain in implementing responses to such situations when they arise (3,4). Surveys indicate that gaps exist not just in LMICs. An analysis of 2011–2013 European regional pharmaceutical situation reports found that only two-thirds of 26 respondent countries had formal conflict of interest policies for pharmaceutical activities (30). Only half of the countries responding to a WHO 2015 global survey on HTA required conflict of interest disclosures for individuals developing HTA reports (31). The other countries reported not requiring such disclosures or were not aware if such a policy even existed.

Results from the use of WHO's pharmaceutical public-sector transparency assessment tool over eight years revealed that key pharmaceutical-sector committees often do not use clear criteria to guide the recruitment of their members. Results also showed that conflict of interest policies are lacking in many countries and may be poorly implemented in those that have them (32).

A recent study conducted by WHO found that public pharmaceutical-sector policies and processes in the 10 countries in the WHO South-East Asia Region surveyed generally required committee members to disclose relevant interests (3,4). However, the policies provided little detail about what should be declared, when and how often. The survey found that some countries had high levels of awareness but little evidence of organized practices around preventing and managing conflicts of interest. Others had well-established practices for identifying conflicts of interest but with the exception of a few procurement committees did little with the information. No examples were found of public availability of committee members' actual disclosures or actions taken to address conflicts of interest.

Other common gaps included the lack of:

- oversight bodies to develop conflict of interest policies and oversee and enforce their implementation;
- context-specific education and guidance on what constitutes a conflict of interest for a committee's specific decision-making processes;
- ongoing rather than one-time disclosures and consistency in disclosure processes;
- practical strategies to prevent or address conflicts of interest; and
- mechanisms for making disclosures and management strategies publicly available.



In addition to gaps, the 2021 survey identified drivers and enablers for conflict of interest policy development and implementation in the 10 South-East Asian countries. Box 2 lists some of these key facilitators.

**Box 2: Facilitators for public pharmaceutical conflict of interest policy development and implementation**

Key informants interviewed in a WHO South-East Asia Region study of conflict of interest policies and practices in 10 countries identified the following factors as important drivers and enablers for policy development and implementation (3,4):

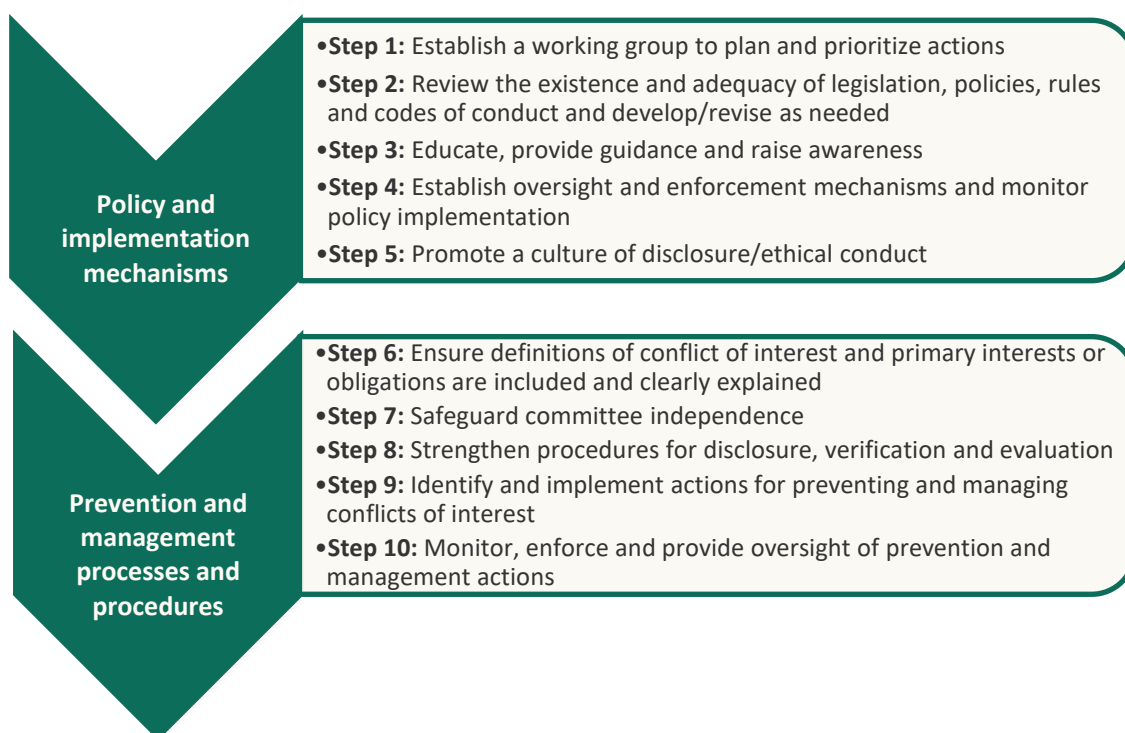
- **anticorruption and freedom of information legislation** that increased awareness of conflicts of interest and enabled nongovernmental organisations including civil society groups to access or request information about decision-making and activities of public authorities;
- **oversight bodies** such as anticorruption commissions that have drawn attention to conflicts of interest (e.g., by producing handbooks on prevention and management) and **autonomous regulators** with the power to enforce compliance to rules;
- **civil society advocacy** for greater transparency and accountability;
- **WHO initiatives and technical support to countries** through the WHO Good Governance for Medicines programme and the WHO Regulatory System Global Benchmarking Tool (33) assessments that have underlined the importance of robust conflict of interest management in the pharmaceutical sector; and
- **political scrutiny** as a result of concerns about pharmaceutical industry influence on public pharmaceutical systems (e.g., in India, a parliamentary standing committee looking into the activities of the Central Drugs Standard Control Organisation recommended that the mission of the organization be reformulated to unambiguously prioritize public health over other interests, and that this primary mission be used to guide decision-making (34).

Lessons learned from the WHO Good Governance for Medicines programme identified a need for support on preventing and managing conflicts of interest (1). The study in the South-East Asia Region also identified a need for clear guidance around how to consistently, proportionately and transparently prevent and manage conflicts of interest (3,4).

## 4. Strengthening policy, prevention and management of conflicts of interest

### 4.1. Overview

Plans for improving conflict of interest prevention and management in public pharmaceutical decision-making committees include strategies in two main areas: policy and implementation mechanisms and prevention and management processes and procedures. Fig. 1 sets out the steps to execute these strategies and the following sections explain guiding principles and describe these steps in detail.

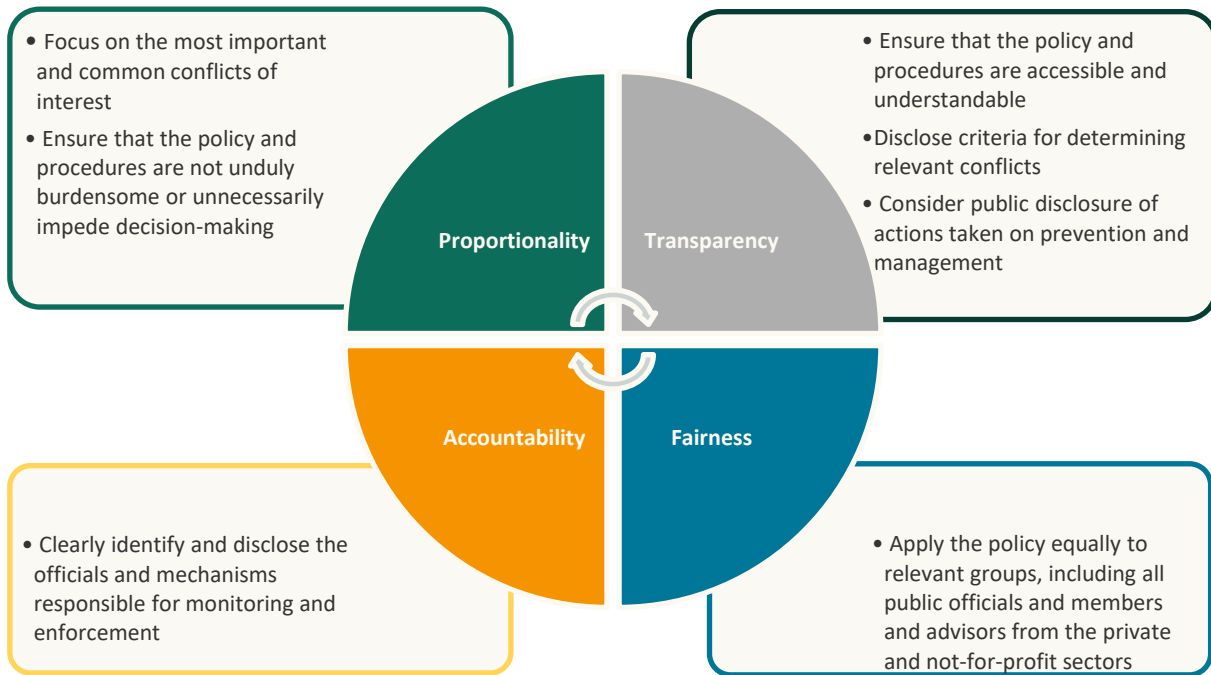


**Fig. 1. Ten steps for improving the prevention and management of conflicts of interest**

The primary objective of conflict of interest policies and strategies is to safeguard the integrity of decision-making in the public pharmaceutical sector rather than to remedy problems after they occur (21). It is important to uphold public trust in the decisions made or the institution or committee that made them. For this reason, prevention is the preferred approach for public pharmaceutical committees (23). As such, strategies such as robust and transparent procedures for selecting independent advisors and committee members, particularly committee chairs, are essential to exclude individuals with conflicts of interest from the decision-making process. However, in practice, institutions can find it challenging to muster a sizable committee of sufficient expertise with no conflicts of interest (25), and some conflicts of interest may be unavoidable. Because not all conflicts of interest can be averted, policies and strategies need to include a mix of approaches to prevent conflict of interest situations from arising, evaluate them in terms of the risk posed and manage them when they occur, and levy sanctions or redress when transgressions happen.

### 4.3. Guiding principles

Fig. 2 sets out general principles—proportionality, transparency, accountability and fairness—that can be used to guide the development, implementation and evaluation of conflict of interest policies and practices for public pharmaceutical committees (21). Other principles may include serving the public interest, promoting individual responsibility and creating an organizational culture intolerant of conflicts of interest (19, 20). Each of these principles have roots in legal protections of the right to health and other related rights.



**Fig. 2. General principles to guide the development, implementation and evaluation of conflict of interest policies for public pharmaceutical committees (21)**

## A special note on transparency and conflict of interest

Promoting transparency in how decisions are made in public pharmaceutical systems and specifically on how conflicts of interest are identified, prevented and managed is essential for oversight, accountability, and gaining or maintaining trust in the decisions made and the institution or committee that made them. Governments need to make decisions about what information related to conflicts of interest will be made publicly available and what will be provided on request based on the committee and country-specific context and as per transparency requirements in the country's legal framework.

The minimum information that should be made publicly available includes:

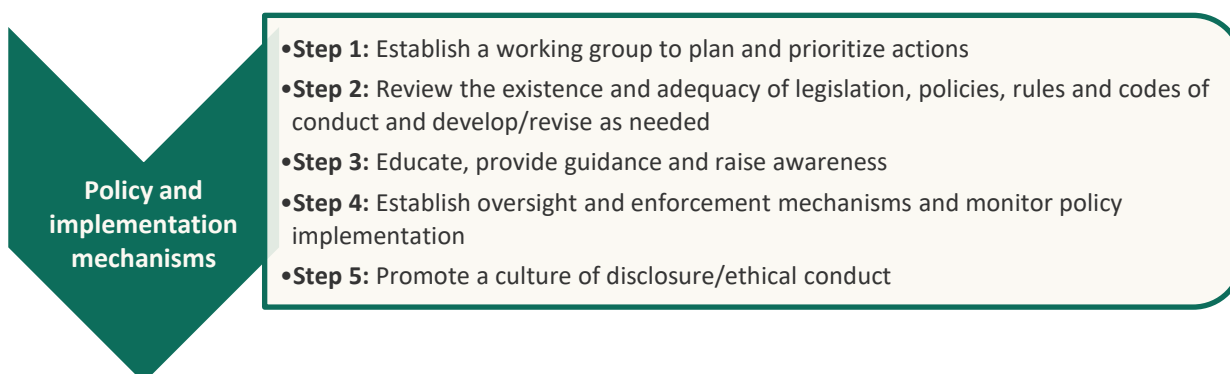
- the conflict of interest policy;
- information on the policy development process, including persons involved and the reasoning that informed the provisions included in the policy;
- information on the committee procedures, including:
  - procedures and criteria used for appointing members;
  - processes for disclosing, preventing and managing conflicts of interest; and
  - committee procedures and any criteria used for decision-making;
- procedures for submitting a complaint and the corresponding response;
- information on how complaints or breaches were responded to; and
- all funding received by the institution or committee from pharmaceutical companies or other private entities.

Some countries or committees may choose not to make names of members or their declarations of conflicts of interest public due to concerns about privacy or to protect committee members from media attention and lobbying, although some question whether these worries are sufficient to warrant secrecy (3). In such situations, the committee could disclose an anonymised report on the number of declarations collected, number of conflicts of interest identified and how they were managed. It should also include anonymised information on how conflicts of interest were addressed in selection procedures for committee chairs and members.

An annual summary report that is made public can further enhance transparency. Such a report can include summaries of the conflicts of interest identified, the percentage of committee members who declared different types of conflicts (low risk to high risk), and general statements about how the conflicts were managed (without revealing details that would identify individuals). If a committee has taken no actions to manage conflicts of interest other than recording them, this can serve as an alert that the system may not be working as intended. Some information, such as individual data on disclosures, the reasoning that underpinned the determination of the level of risk, the reasoning behind the response to the declared interests, and the actions taken, can be made available on request to a watchdog organization or for a performance audit to allow for greater scrutiny. Together with the annual summary report, this can promote accountability of the committee.

Increased transparency about financial and gift relationships will help in identifying conflicts of interest and contribute to better prevention and management. One example of such an effort is the anticorruption and transparency initiative ACTUE Colombia which is assisting the Colombian government to design and implement a platform for registering the transfer of payments and other items of value from pharmaceutical companies and trade associations to health professionals engaged in research, insurance or education (35).

## 4.4. Policy and implementation mechanisms



Effective prevention and management of conflicts of interest is founded on policy and legal frameworks—domestic, regional and international. Countries may already have pieces of the enabling policy and legal framework in place, and some of the supporting implementation mechanisms may already exist and function to varying degrees. Setting up a working group to assess the current situation and develop a plan can be a useful starting point for improving the prevention and management of conflicts of interest. Policies and legislation need to be accompanied by educational and training activities for managers, monitoring and enforcement mechanisms, and activities to raise awareness. Also important are measures to encourage compliance with the policy and to make it part of the institution’s culture.

### Step 1: Establish a working group to plan and prioritize actions

#### The working group

As a first step, countries can set up a working group to assess what exists, identify gaps and strengths to build upon, share findings to raise awareness, and develop a plan that prioritizes actions and identifies resource needs. Some countries may already have a group that focuses on strengthening governance in pharmaceutical or health systems that could take on this task, such as a task force set up under a good governance for medicines programme (36). Ideally, the group should be impartial and have no connections to the committee. Where this is not feasible, one option is to make the work of the committee public and to allow opportunities for interested stakeholders to submit comments. Another option is to have a multistakeholder group, such as those set up under the Medicines Transparency Alliance (37).

The working group can begin by establishing connections with a national unit or officer charged with oversight—for example, the government’s ethics office, anticorruption commission or compliance officer—to identify legislation and policies relevant to managing conflicts of interest. The group can also meet with other agencies and committees to learn about their policies, procedures, experiences and lessons learned. Opportunities for leveraging what already exists, such as training initiatives and monitoring and oversight mechanisms, can also be discussed. The working group can share findings and work with managers, committee chairs and other key stakeholders to develop a plan that tackles the most critical gaps and weaknesses first. The plan should allow for phased implementation and prioritize the pharmaceutical processes, decisions and actions that have a greater risk of conflict of interest situations arising or causing harm. Resources may need to be identified to support implementation of the policy.

## Prioritization

Identifying and prioritizing the public pharmaceutical-sector functions and decision points where conflict of interest situations most often arise or that are most vulnerable to undue influence or greater harms is an important starting point to improving conflict of interest prevention and management (38).

### **Box 3. Identifying public pharmaceutical functions and decision points at high risk of conflict of interest situations arising and potential harms: initial areas of focus (26,39,40)**

- **Registration:** committees that make decisions on the registration of pharmaceutical products and experts or groups that advise them;
- **Price control:** committees that regulate the pricing of pharmaceutical products;
- **Licensing:** committees that make decisions on licensing or accrediting manufacturers, wholesalers and other pharmaceutical premises and the inspection activities that inform them;
- **Selection:** essential medicines list, formulary and standard treatment guideline committees; HTA advisory and decision-making committees; and
- **Procurement:** committees responsible for developing specifications and evaluating and awarding tenders.

High-risk areas depend on the local situation and context. However, some are common across countries, particularly those that rely on discretionary decision-making (26). Public procurement, selection decisions and awarding of licenses are among the general governmental processes identified as at high risk for conflict of interest situations arising and potential influence and harms (38). Box 3 suggests some initial functions and decision points to focus on.

A risk review may be helpful to identify the most at-risk functions and decision points to focus on. The review may also help to ascertain the types of conflict of interest that are relevant and most important given the country context (Box 4). For example, some countries may have little pharmaceutical industry presence, and conflicts of interest that arise out of financial or other relationships with such companies may be of less concern than conflicts

### **Box 4. Approaches for reviewing risk for conflicts of interest (41)**

- Consult staff, committee members and external contacts;
- Review records, complaints and whistle-blower reports to identify areas where conflicts are most likely to arise;
- Review media coverage of conflict of interest issues;
- Examine the institution's relationships with external entities to identify institutional conflicts of interest;
- Repeat periodically as the local situation changes; and
- Consult conflict of interest policies of other committees working under similar circumstances as they can provide useful insights.

that arise from the interests of close relations in the outcomes of processes such as licensing or inspection of private pharmacies (3,4). In countries where the government's priorities include expanding the domestic manufacturing or export capacity, the potential impact on the impartiality of registration or procurement decisions may be an important concern. Given the evidence that suggests that financial and gift relationships are linked to compromised decisions and negative outcomes in pharmaceutical systems (Box 1), financial conflicts of interest are generally considered to be the most important and should be given careful attention.

## Step 2: Review existence and adequacy of legislation, policies, rules and codes of conduct and develop/revise as needed

### Review legislation, policies, rules and codes of conduct

A country may have laws, regulations, policy documents, administrative rules and legislative instruments that pertain to the prevention and management of conflict of interest. A mapping exercise should be undertaken to identify the relevant national policies and legislation and regional and international treaties. The conflict of interest policies of other institutions or committees operating under similar legislative frameworks or contexts can be useful in identifying issues that need to be considered when developing a new policy or updating/elaborating on an existing one. Importantly, it can also help to avoid inconsistencies in the way conflict of interest situations are handled within the same administration.

Instruments should be identified and the completeness of the policy or legislation reviewed. Table 3 lists common components of a conflict of interest policy. Instruments to review include:

- medicines/pharmaceutical laws, rules and regulations;
- public procurement laws, rules, and codes of conduct or ethics;
- freedom of information, anticorruption and whistle-blower protection laws and regulations;
- public employment laws, administrative rules and codes that set standards to govern the conduct of public officials and individuals from the private sector that advise them (e.g., gifts, secondary employment);
- national medicines/pharmaceutical policy;
- conflict of interest policies, handbooks, guidance and procedures; and
- institutional-level policy documents for managing conflicts of interest and governing the conduct of employees working in ministries concerned with pharmaceuticals and other health technologies.

In addition to policy and legal instruments, the review should include checking on the presence and functionality of various bodies responsible for administration, monitoring, oversight and enforcement, such as internal committees or independent civil society groups. The review should also include any requirements for transparency, including maintaining a registry of interests, accountability mechanisms and protection of whistle-blowers (see Guiding Principles Fig. 2 and Section 4.2 A special note on transparency and conflict of interest).

### **If policy or legislation does not exist or is inadequate, it should be developed or revised as needed**

Conflict of interest policies should be comprehensive, proportionate, accessible to individuals and institutions that may be affected by them, and equally applicable to all individuals within an institution or a committee regardless of seniority. There should also be periodic external reviews (e.g., every five years) to ensure that the policies are focused on the most important areas of risks in the decision-making processes they apply to. The supporting legislative and policy framework should emphasize preventive policies and procedures rather than relying on corrective and punitive responses alone. Also important are provisions for disciplinary measures and actions such as prosecution when breaches occur. Policy and legislation should adhere to overarching principles (Fig. 2). Once developed, the conflict of interest policy should be formally adopted as per relevant country procedures.

**Table 3. Common components of a conflict of interest policy (A) and additional components for committee terms of reference or procedures (B)**

**A: Common components of a national/institutional conflict of interest policy**

- Objective of the policy, guiding principles and values, including a commitment to transparency
- Scope of the policy and who it applies to
- Definition of conflict of interest and the primary interest or obligation
- Requirements for disclosure
- Guidelines on sponsorship of institutional or committee activities
- Procedures for record keeping and making declarations public
- Validity period and frequency for reviewing the policy
- References to relevant legislation, policies and guidance
- Provisions for oversight and enforcement and legal sanctions and procedures for appealing decisions
- Reference to government commitments (e.g., good governance, transparency, serving the public interest, preserving the integrity of decision-making)

**B: Additional components for committee terms of reference, procedures or committee-specific policy**

- Process and criteria for selecting and appointing chairs, committee members and advisors, including disqualifying interests and relationships
- Disclosure procedure and frequency
- Process for evaluating the existence, extent and severity of conflicts of interest
- Parameters concerning the value; time frame (e.g., previous five years); and nature of relationships that require disclosure and/or action and extension of requirements to a committee member's family
- Procedures for preventing and managing conflicts of interest, including descriptions of prohibited relationships and activities, and for self-recusal and other management strategies
- Procedures for reporting and dealing with complaints or breaches, including description of the consequences for not disclosing a conflict of interest

### **Step 3: Educate, provide guidance and raise awareness**

Guidance and procedures should provide practical examples and concrete steps to support the implementation of the policy. Mechanisms that support implementation of the policy will require an ongoing commitment to provide adequate resources to enable them to function effectively. These mechanisms should include systems for educating committee members and expert advisors who need to follow the policy and officials who will implement it and strategies for communicating the policy to employees, advisors and interested stakeholders (7,19).

#### **Education, advice and guidance**

Committee members and experts who advise the government on pharmaceutical policies and practices need to have a clear and shared understanding of what constitutes a conflict of interest in their specific decision-making processes and for their particular role (3,4). Countries need to assign responsibilities and resources to educate committee members and expert advisors and the officials responsible for executing the policy.



Training should coincide with the release of a new or updated conflict of interest policy; be conducted at regular intervals for new staff and newly appointed committee members and advisors; and incorporated into other relevant trainings (e.g., good procurement practices). Requiring employees and experts to complete the training annually can also be considered. eLearning courses may be useful in this regard (42).

Individuals who are required to declare conflicts of interest may need advice on whether their specific situation constitutes a conflict of interest and possible actions. Written guidance about managing conflicts of interest for staff with specific roles, such as the committee chair, or for staff involved in decision-making at high risk of undue influence can be useful (41). It may be helpful to assign a responsible officer to provide confidential advice to individuals on whether their personal circumstances meet the requirements for disclosure.

### **Communication and raising awareness**

Information on the existence of the policy and its key provisions can be disseminated through an official release of the policy and channels such as websites, emails, bulletins and briefings. This will ensure that senior managers, public officials and experts are aware of their responsibilities under the policy and alert them to any revisions. Information about the policy should also be shared more widely, such as with the pharmaceutical industry so it is aware of how the policy may affect interactions with institutions and experts. This can also help raise awareness among citizens and civil society groups that play a public watchdog role. A periodic evaluation is useful for determining whether the communication activities have been effective.

### **Step 4: Establish oversight and enforcement mechanisms and monitor policy implementation**

Periodic monitoring is required to ensure that the policy remains relevant and that its implementation is effective, proportionate, fair, transparent and accountable (19,20,21). Also important is the monitoring of conflict of interest management plans and actions; this is discussed in Step 10: Monitor, enforce and provide oversight of management actions.

### **Establish monitoring, oversight, and enforcement mechanisms**

Mechanisms need to be identified and responsibilities and resources assigned for reviewing, evaluating and managing disclosed interests and enforcing rules and sanctions. It is crucial that those tasked with monitoring and oversight are independent and have the authority to enact enforcement mechanisms. Complaint or whistle-blower mechanisms should also be established, along with appropriate protections. Studies show that organizational climate, leadership and whistle-blower protection have an influence on whether people choose to raise concerns and the impact of doing so (43). Consequences such as fines, disciplinary actions or restrictions on future engagement should be defined for both public officials and individuals not employed in the public sector who fail to declare secondary interests or report false information. Lastly, there should be a means through which both public officials and the public can challenge and rescind governmental decisions when the actors involved in the decision-making process fail to comply with conflict of interest rules (7,44).

### **Monitoring the implementation of conflict of interest policies**

The policy should be reviewed periodically, preferably by individuals who are independent of the committee, to ensure that it is focused on the most important and common conflicts of interest, usually

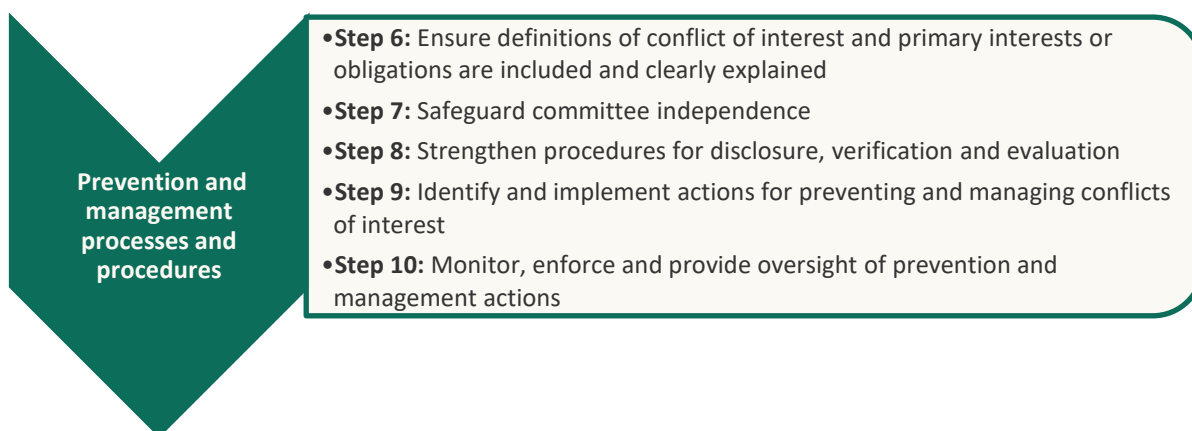
financial, and is not unduly burdensome to implement or comply with. Implementation considerations include checking that the mechanisms needed to support policy implementation, including training, reporting, monitoring and oversight, are in place and functioning effectively and that the policy is being implemented fairly, transparently and consistently. Committees should be required to produce an annual report that summarizes interests declared and prevention and management actions taken for review (see Section 4.2 A special note on transparency and conflict of interest). As mentioned earlier, if the committee has management actions other than recording the interests to report, this can signal that further enquiry is needed to check that the policy is being implemented as intended. Also important is verifying that strategies and actions for managing conflicts of interest are proportionate and do not hinder the performance of the committee.

Evaluations by countries and committees of what works in their settings and under what circumstances can provide important learning to inform their decisions and optimize strategies for preventing and managing conflicts of interest in the future.

### **Step 5: Promote a culture of disclosure/ethical conduct**

While not a substitute for legal and administrative rules, codes of conduct or ethics can help to promote compliance to conflict of interest policies and create an institutional culture that promotes such values (7). National or institutional codes of conduct often set rules for activities and financial ties, including with the private pharmaceutical sector, that are restricted or prohibited before, during and after employment in the public sector. Open discussions with committee members on preventive and mitigation measures to safeguard the integrity of decision-making, encouraging members to disclose and discuss conflicting interests, and involving them in a review of the institutions or committee's conflict of interest policy and practice can promote a culture of disclosure (19).

## 4.5. Processes and procedures for conflict of interest prevention and management



Once policies and legislation are in place, processes and procedures are needed for effective implementation. These should include definitions of conflicts of interest and the primary interest or obligation and provide clear explanations for the specific committee process. They also need to outline practical approaches for safeguarding a committee’s independence and impartiality; disclosing interests; identifying, preventing and managing situations of concern; and monitoring and addressing breaches.

### **Step 6: Ensure definitions of conflict of interest and primary interests or obligations are included and clearly explained**

General guidance on conflicts of interest can be too generic to be useful at the committee level (3,4). In addition to providing the definition of a conflict of interest—using the legal definition if already codified in applicable texts—institutional and committee policies and procedures should include an explicit explanation of what constitutes a conflict of interest within the committee’s specific decision-making context to promote a common understanding among policy-makers, managers, committee members and advisors. Additionally, policies and procedures should clearly identify situations and activities that can potentially interfere with the institution or committee’s primary goal or objective and provide specific examples of interests that may be problematic (19,20). A risk review may be helpful to identify the specific types of conflict of interest that are relevant and most important for the specific committee or decision-making context (Box 4).

A clear statement of the committee’s primary interests (mission, goals, obligations or values) should be provided so that members and advisors have a shared understanding of what is expected of them (3,4,22). This statement is important because pharmaceutical committee members may include diverse stakeholders such as civil servants; health professionals; and occasionally representatives of consumer, professional or trade associations who may have various roles and interests. Some examples of primary interest statements are provided in Box 5.

### Box 5. Country examples: primary interests

Bangladesh Public Procurement Rules (45) “... achieving economy, efficiency, transparency, fairness and equal treatment of tenders or proposals”

Thailand Health Intervention and Technology Assessment Program (46) “... to efficiently distribute and allocate the limited resource to fulfil its public objectives”

## Step 7: Safeguard committee independence

Public pharmaceutical committee decision-making should be independent and impartial, and members should be selected based on documented criteria. Such criteria may relate to technical expertise, knowledge or skills, or representation of a particular group or constituency. The committee should have clearly defined terms of reference that set out the purpose and primary interest of the committee, its authority, membership, and roles and responsibilities (47). Examples of selected actions to safeguard the committee’s independence are outlined in Table 4, and Box 6 provides a country example.

**Table 4: Examples of selected actions to safeguard a committee’s independence**

Do not allow the appointment of pharmaceutical industry representatives as members of committees that make decisions on the registration, selection, pricing and procurement of pharmaceutical products and licensing of pharmaceutical manufacturers (27,48). Industry viewpoints can be solicited through other mechanisms such as stakeholder consultation.

Prohibit industry observers during certain situations where they might gain commercial advantage (e.g., setting prices, making decisions on reimbursement).

Require that proposed members complete a detailed written declaration of relevant interests prior to their appointment; periodically, usually annually, thereafter; and in some cases prior to or at every meeting (see Step 8).

Ensure that the chair and co-chairs are independent and free of conflicts of interest.

In line with administrative rules, public officials should eliminate the conflict of interest prior to their appointment (e.g., by divesting themselves of financial ties or severing relationships with the private entity) (7).

Exclude individuals with a serious conflict of interest (e.g., those with a direct financial interest in the outcomes of the decision-making).

Restrict participation of members with conflicts of interest in decision-making and, depending on seriousness, in discussions on topics in which they have a declared interest (21,27) (see Step 9).

If members with conflicts of interest are permitted to participate in decision-making and/or discussions, ensure that they make up the minority of the committee (21,48).

Ensure that committee terms of reference; rules or policy on conflicts of interest; criteria for member selection; and, where appropriate, member names and any declared conflicts of interest are publicly available. Where member names are not published, provide summaries of any declared conflicts of interest and plans for managing them (see Section 4.2 A special note on transparency and conflict of interest).

Restrict or preferably do not accept direct funding from pharmaceutical companies for committee processes, such as selection of essential medicines (21,48).

If members of the public and representatives of civil society organizations and patient groups are to serve on the committee, both they and their organizations should be free of conflicts of interest.

**Box 6. Country example: Sri Lanka’s National Medicines Regulatory Agency (49)**

Sri Lanka’s National Medicines Regulatory Agency Act requires that the Minister ensure that prospective committee members do not have “financial or other conflict of interest in the affairs of the Authority” prior to appointment and then periodically thereafter.

The Act states that financial or other interests that pose conflicts of interest disqualify an individual from committee membership. Disqualifying interests include employment by the pharmaceutical industry in the three years prior to their appointment to the committee.

Box 7 sets out practice points included in WHO’s guidance on the selection of essential medicines at the country level that are relevant to preventing and managing conflicts of interest for selection committees.

**Box 7. Practice points related to conflicts of interest identified in the WHO guidance on the selection of essential medicines at the country level (27).**

- The committee responsible for the selection of medicines for inclusion in the national essential medicines or reimbursement list should be “independent and trustworthy” and selected “on the basis of their technical expertise, critical appraisal skills and ability to evaluate complex clinical data from trials and other data sources”.
- Members should be required to complete a declaration of interests and disclose any circumstances that could give rise to a conflict of interest with respect to their role and unduly influence their participation (1) in detail and in writing on initial appointment and thereafter annually; (2) in writing prior to each meeting, specific to the meeting agenda; and (3) verbally at the start of each meeting on any situations that have arisen since the last written declaration.
- The involvement of pharmaceutical industry representatives as members and even as observers in cases where the committee is responsible for setting prices or making decisions on reimbursement is not recommended.
- Identified conflicts should be proactively and transparently managed. Governments or institutions should establish a system for assessing and managing conflicts of interest.
- Depending on the seriousness of the conflict of interest, individuals may be excluded from the committee or be prevented (or recuse themselves) from participating in discussions and decision-making on relevant topics. Minor conflicts may be managed by allowing members to participate in discussions and excluding them from decision-making or the formulation of recommendations on relevant topics.

**Step 8: Strengthen procedures for disclosure, verification and evaluation**

Effective prevention and management of conflicts of interest relies on processes that require individuals to submit declarations of interests and procedures to identify whether any conflicts exist and the seriousness of the risks they pose. The outcomes of these procedures in turn inform the development of plans for eliminating or managing the identified conflicts of interest. Some key considerations related to establishing or strengthening these mechanisms and procedures are outlined below.

## Disclosure of interests

The disclosure of relevant interests and obligations is a common requirement in public pharmaceutical committees and an important step in identifying and developing responses to conflicts of interest. As mentioned earlier, disclosures alone are not sufficient to ensure that decision-making is protected from undue influence. The sections below explain who should disclose interests, the frequency and types of interests to disclose, and how to store the declaration forms.

**Individuals who should disclose interests.** Governments and institutions, such as academic institutions that convene public pharmaceutical committees on behalf of the government, should require that all individuals involved in decision-making or the development of recommendations for the government submit declarations of interests (7). In the interest of fairness, the policy should be applied equally to all individuals involved in the activity, whether public employees or from the not-for profit or for-profit private sectors.

Depending on the committee or activity, these individuals may include:

- people involved in making decisions or recommendations to the government
- committee members
- public-sector employees
- expert advisors
- peer reviewers
- consultants
- members of the secretariat
- members of the public and representatives of civil society organizations and patient groups.

**Frequency of declarations.** Detailed, written declarations should be submitted at the start of appointment and then regularly, usually annually, for activities that occur continuously, such as procurement, or when there is a significant change in the person's work responsibilities, activities or interests. For activities that occur periodically, such as registration advisory group meetings, written disclosures should be obtained prior to every meeting or event (7,27). Many committees include the disclosure of new or agenda-specific interests as a standing item on the agenda. This good practice can promote discussions on interests that can present a conflict and encourage a culture of disclosure (19,20,48).

**Interests that should be declared.** Box 8 provides examples of interests that may constitute a conflict of interest in public pharmaceutical decision-making.

**Box 8. Examples of interests that may constitute a conflict of interest in public pharmaceutical decision-making (7,48).**

- Any money received, including specific amounts related to employment, consulting, speaking fees, panel membership, research grants or contracts. This includes payments received from for-profit companies and not-for-profit organizations.
- Payments from companies: honoraria; travel; hospitality (hotel accommodation, meals, tickets to an event); equity (shares issued by the company); other payments (payment for enrolling patients in clinical trials, research grants).
- Gifts (monetary and non-monetary) and loans.
- Sponsorship of publications and software.
- Patents, licenses, royalties and shares.
- Directorship, board memberships, appointments and leadership positions (paid or unpaid).
- Members may represent or have roles in organizations with financial links or affiliations with industry groups that stand to benefit directly or indirectly from or be affected by decisions or recommendations (e.g., advocacy organizations that receive funding from the pharmaceutical industry). All grants and other financial relationships should be declared even if not directly related to the work that an individual member is doing.
- Family or personal relationships with those who may have the above interests.

**Declaration forms.** Individuals should be required to submit declarations using a standard form. The WHO Declaration of interests for WHO experts could be used as an example of what should be included in the standard form (50). The form should provide a structured list of possible interests with checkboxes and space to enter details regarding each interest. The declaration should state the name of the entity that the individual has a relationship or interest with, the value of any payment or interest, and reasons for any payments or nature of the interest. Committees may also want to consider monetary thresholds for disclosure as appropriate to local context, although there is evidence that even small gifts and financial ties may influence decision-making (51,52). The form should include the timeframe for reporting each type of interest (e.g., current or within the last five years). There should also be an open-ended option to disclose any interests not covered by the form.

**Storage of declarations.** Declaration forms should be stored securely in line with data protection and privacy laws. Some countries have created online forms to submit declarations of interest. This may allow the data to be more easily reviewed (e.g., previous declarations, beneficial ownership records); filtered; searched for queries and reporting; and compared to other databases.

**Verification and evaluation of disclosed interests**

**Designated reviewer(s).** An independent person or preferably an independent group should review the declaration forms to assess whether the disclosed interests could compromise the integrity, independence or trust in decision-making or the development of recommendations. The individual who reported the interest should not be involved in the review as it is not uncommon to miss the relevance of one's own interest.

The designated person may be a compliance officer, an official from the legal office within the Ministry or government, or an official from the government's ethics office or anticorruption commission (7). In

some cases, the country or institution may establish a small group or a multidisciplinary committee that includes independent experts from different disciplines, such as content area experts, legal expertise to review contracts, and representation from civil society for transparency and external inputs (20). Designated reviewers may need training to effectively evaluate whether a conflict exists and its significance.

**Verification and review procedures.** The terms of reference for the designated reviewer(s) should be established in advance so that all disclosures are reviewed in a consistent fashion. Staggered rotation of members can also help to maintain consistency in the review process over time.

In high-risk situations, disclosures may be checked for completeness by conducting internet searches or comparing the disclosure form with information on previously declared interests on file (38) (Box 9). Searchable registries of committee member interests and databases that track payments from the pharmaceutical industry to health professionals and their trade associations can also be useful in this regard.

**Evaluation of disclosed interests.** The evaluation is a two-part process that involves (1) identifying whether a disclosed interest constitutes a conflict of interest and (2) determining the significance or risk of any identified conflicts.

To ascertain whether a conflict of interest exists, the reviewer(s) should look at the individual's role in the decision-making process, the kinds of decisions and activities that the individual can potentially influence, and the extent to which they can influence them. Committee chairs have a greater role in decision-making, and therefore their disclosed interests need to be closely examined. Next, the reviewer(s) should examine the declaration to identify any financial interests of the individual or their families or unremunerated activities that create a risk that the individual will either not fulfil their primary duties or obligations or could favour their secondary interests over their primary obligation.

To determine the seriousness of an identified conflict of interest, reviewer(s) will need to assess (1) the probability and extent to which the conflict of interest could unduly influence decision-making and (2) the degree of harm that could result in both the immediate and long term (19).

Determinations of the likelihood of undue influence may include consideration of:

- The length or type of involvement with industry. For example, a long-term consulting agreement may present a higher risk than a single industry-sponsored training.

#### **Box 9. Country example: Bhutan Procurement Rules and Regulations (53)**

Bhutan's 2019 Procurement Rules and Regulations specify that the procuring agency must ensure that members appointed to the tender committee do not have a conflict of interest with any of the participating bidders.

Each member of the committee is required to make a written declaration at each meeting to acknowledge and sign that they understand the "commercial-in-confidence" nature of the proceedings; are "in no way linked, associated or involved with any of the bidders whose bids are under consideration"; will maintain strict confidentiality of information related to evaluation of bids; adhere to the conditions of the integrity pact; are aware of the responsibilities of the committee and the ethics of procurement; and will declare any conflicts of interest.

To verify this statement, the Rules state that the procuring agency "shall maintain lists of spouse and dependents (father, mother, brother, sister, and own children) of their employees engaged in formal and informal business to verify conflicts of interest during the procurement process".



- The role played by the individual. The role may be so important that all conflicts of interest must be avoided (e.g., the chair of a public pharmaceutical committee).
- The threat to the independence of the decision-making process.

The assessment of the degree of potential harm should consider the risks posed to the health and safety of populations; the potential impact on public budgets, out-of-pocket expenditures, and public trust; and the accountability measures in place that would lower the level of potential harm.

### **Step 9: Identify and implement actions for preventing and managing conflicts of interest**

If the assessment of the disclosed interest is deemed not to pose a concern, no further action may be needed except to note the decision. If a disclosed interest is assessed to be a risk, public pharmaceutical committees will generally need to use a combination of strategies to prevent and manage the conflict of interest. The choice of strategy will depend on the importance of the conflict of interest and the context in which it occurs. Approaches include:

- preventing the conflict of interest from arising by prohibiting certain interests, relationships or activities; and
- managing and/or mitigating the conflict of interest.

Table 5 lists some of the possible prevention and management options. Table 6 provides some examples of possible actions organized by level of risk. Box 10 has examples of strategies set out in country policies.

Each disclosure form that is reviewed should be marked with the determination reached (final status or outcome). If the review found no conflicts of interest, this should be noted, along with any efforts to verify the data such as through comparisons with other databases. Where a conflict is identified, the review should note the seriousness of risk; verification steps taken; the decision and arrangements made for managing the conflict of interest; and the reasoning behind the decisions made. The record should be updated with steps taken to implement the selected management strategy. A database can be used to record the decisions made about each disclosure and the actions taken. The record should include decisions on no further action in the case where a disclosed interest is assessed to not pose a concern.

**Table 5. Options for preventing and managing conflicts of interest (7,21,38,41).**

	Possible management options	Comments
<p><b>Prevent conflict of interest situations from arising</b></p>	<p><b>Prohibit.</b> Make the absence of conflicts of interest a criterion for selecting committee members (see Step 7).</p>	<p>May be challenging to implement in countries or areas where health professionals advise and consult widely for pharmaceutical companies; some conflicts of interest may be unavoidable and will need to be managed.</p>
	<p><b>Prohibit.</b> Ban public employees from accepting gifts, having certain or in some circumstances any financial interests, or engaging in remunerated outside employment with individuals or companies related to the employees' duties.</p>	<p>Drawback is that current civil service rules may allow gifts of small value (it is good to be consistent with other laws/rules in place).</p>
	<p><b>Prohibit.</b> Do not allow pharmaceutical industry representatives to serve as committee members for activities such as medicines selection; prohibit industry observers in situations where they may gain an unfair commercial advantage.</p>	
	<p><b>Prohibit.</b> Do not accept direct funding from pharmaceutical companies to support committee processes (e.g., product selection) or inputs from the sponsoring organization.</p>	<p>These measures are crucial where a conflict of interest is serious or high risk.</p>
<p><b>Manage the conflict of interest</b></p>	<p><b>Divest.</b> The individual can divest their financial interests with the private entity or place stocks or other investments in a blind trust.</p>	
	<p><b>Resign.</b> The individual can resign from the industry board, end employment or sever other relationships with the private entity.</p>	<p>May be appropriate for ongoing situations where the conflict of interest is more serious or high risk or where the type of role played by the individual requires that all conflicts be avoided.</p>
	<p><b>Recuse.</b> Recuse the individual from <u>all</u> discussions, decisions and activities regarding the pharmaceutical products made by or in competition with the company that produces the conflict.</p>	<p>Complete recusal may be appropriate if the conflict of interest does not occur often but can be unworkable if it is a frequent occurrence.</p>
	<p><b>Resign or Remove.</b> Public employees may resign from their public-sector job, terminate their involvement in the committee or be reassigned to different work</p>	<p>May be most suitable for ongoing serious conflicts of interest and if there are no other workable options.</p>

Possible management options	Comments
<p>duties so they do not work on activities that can be influenced by their private interests.</p>	
<p><b>Divest.</b> Sever the institution’s financial ties to the individual or organization that creates the conflict of interest.</p>	
<p><b>Mitigate the conflict of interest</b> <b>Disclose.</b> Publicly disclose or formally register the conflict of interest to promote transparency.</p>	<p>Does not alone prevent individuals from acting based on the conflict of interest.</p>
<p><b>Divest.</b> The individual or institution can reduce their financial interests with the entity that creates the conflict of interest below a certain threshold.</p>	<p>Even small gifts and financial ties can generate good will, which may influence decision-making (51,52).</p>
<p><b>Recuse.</b> Limit the individual’s involvement by recusing them from voting; decision-making; and, in certain circumstances, discussions regarding the pharmaceutical products made by or in competition with the company that produces the conflict.</p>	<p>May be appropriate where the pool of experts without conflicts is small and if they are determined to present a low risk. However, the individual with conflicts of interest may still be able to influence other voting members/decision-makers.</p>
<p><b>Restrict.</b> Minimize the influence of individuals with conflicts of interest by ensuring they are the minority on the committee and appointing an independent chair (see Step 7).</p>	<p>May be appropriate where the pool of experts without conflicts is small and if they are determined to present a low risk. However, the individual with conflicts of interest may still be able to influence other voting members/decision-makers.</p>
<p><b>Restrict.</b> Limit the individual’s access to information that may be used to benefit their secondary interests.</p>	<p>Recusal/reassignment to new duties may not eliminate the conflict if the individual still has access to information that can benefit their personal interests.</p>
<p><b>Monitor.</b> Appoint an independent individual or oversight committee to monitor and oversee the individual’s activities.</p>	<p>Can be resource intensive so may be most useful if the participation of the individual is essential and the conflict cannot be eliminated.</p> <p>Not suitable if the conflict is serious and ongoing.</p>

**Table 6: Examples of conflict of interest prevention and management actions by level of risk.**

Level of risk	Examples of possible options	Illustrative scenarios of a conflict of interest and a possible action	
High risk	<p><b>Prohibit or Remove.</b> Prohibit the individual’s involvement in the activity.</p> <p><b>Divest and/or Resign.</b> Eliminate the conflict of interest by severing financial ties and relationships and/or ending employment with the private entity.</p>	<p>Member of essential medicines selection committee is a long-term consultant to the pharmaceutical industry.</p>	<p><i>Remove.</i> Remove the member from the committee.</p>
Moderate risk	<p><b>Recuse.</b> Recuse the individual from certain parts of the process.</p> <p><b>Restrict.</b> Ensure individuals with conflicts are a minority on the committee and increase civil society participation.</p> <p><b>Disclose.</b> Document the process and publicly disclose conflicts of interest.</p>	<p>Member of selection committee has a spouse who is an employee of a pharmaceutical company.</p>	<p><i>Recuse.</i> Include in discussion but exclude from voting.</p>
Low risk	<p><b>Record.</b> Record the conflict of interest.</p> <p><b>Disclose.</b> Document the process and publicly disclose conflicts of interest.</p>	<p>More than 3 years ago, a member of selection committee attended a training course sponsored by the pharmaceutical industry.</p>	<p><i>Disclose.</i> Publicly disclose the conflict of interest.</p>

#### **Box 10. Country examples of conflict of interest prevention and management strategies**

**Bangladesh's** Public Procurement Rules prohibit the offer of gifts; hospitality; honours; offers of foreign travel or reward; and encouragement to engage in trade, employment or other transactions to those involved in the procurement process (45).

Employees and independent researchers with **Thailand's** HITAP are prohibited from receiving benefits such as research grants, sponsorship to attend conferences and training courses, or other direct and indirect benefits from private, for-profit companies or health-related agencies. Staff must complete a disclosure of all interests annually. Depending on the nature of the conflict of interest disclosed, the individual may be precluded from undertaking particular types of work (54).

**The Philippines'** conflict of interest policy requires individuals involved in any medicines-related decision-making or policy-formulation entity such as the Drugs and Therapeutics Committee to declare all conflicts of interest arising from relationships with pharmaceutical companies. The Department of Health's management options may include assigning staff to nonconflicting duties, excluding them from the policy development or evaluation process, or requiring them to sever their relationships (55).

The policies of the **Maldives** Food and Drug Authority; **Nepal** Bid and Tender Evaluation Committees; and **Sri Lanka** National Medicines Regulatory Authority, National Advisory Committee, and Medicines Evaluation Committee all specify recusal from deliberations, meetings or procurement proceedings as the key strategy for managing conflicts of interest (3,4,56). Under Sri Lanka's policy, subject matter experts with conflicts of interest can provide testimony but are unable to vote (49).

#### **Step 10: Monitor, enforce and provide oversight of prevention and management actions**

Once the appropriate strategies have been identified for preventing or managing the conflict of interest, the next step is to monitor compliance with the management plan and decide on and implement actions for noncompliance. Responsibilities should not be assigned or fall to the committee chair by default, as this can be burdensome and challenging for the chair especially if they have personal or working relationships with other members.

The conflict of interest policy should identify the individual(s) or preferably the unit(s) that will be responsible for monitoring and enforcing the implementation of specific management plans. If possible, these responsibilities should be delegated to an independent individual or unit such as the individual(s) or committee designated to review and evaluate declarations of interests, a manager from another department, the ombudsman, or another oversight committee, particularly for ongoing functions and activities.

#### **Monitoring conflict of interest management plans**

It is important to regularly monitor and review the plan identified for managing a specific conflict of interest to ensure that planned actions have been taken and determine whether the situation that gave rise to the conflict of interest has changed or resolved. The plan may need to be adjusted to take account of such changes and modified if it is proving to be unworkable for the individual, committee or institution. It is also important to consider whether any additional actions are needed to mitigate the conflict of interest itself or to address perceptions that it is not being properly managed (41).

## Enforcement of conflict of interest policies

There must be consequences when public officials fail to conform to conflict of interest policies. A range of proportionate disciplinary measures and sanctions should be established for public officials who do not declare their financial interests, report false information or fail to address a conflict of interest. These may include negative employment evaluations, restrictions on promotions, removal from public employment or office, monetary fines, and criminal penalties (7,38).

Corrective actions, such as training or counselling for the individual concerned or addressing underlying issues such as vulnerabilities in procedures, are also important to prevent future breaches (38).

The UK National Institute for Health and Care Excellence (NICE) policy on declaring and managing interests for NICE advisory committees identifies several actions pertaining to breaches (Box 11).

### Box 11. NICE, United Kingdom: dealing with breaches (57)

The NICE policy on declaring and managing interests for its advisory committees sets out several actions concerning breaches, including:

- Staff, committee participants and other stakeholders are encouraged to speak up about actual or suspected breaches and to report them to committee chairs or a senior NICE member.
- The most serious cases of deliberate failures to disclose an interest may be treated as misconduct and referred to the relevant professional body.
- Reports on conflict of interest breaches, lessons learned and actions taken are made publicly available.

### Box 12. Public procurement and contracting: examples of sanctions for companies (38)

Depending on the legal context, sanctions in cases where contract are awarded in conflict of interest situations may include:

- nullifying the contract and/or instituting a process to recover funds paid by the public sector to the entity;
- fines for the company; and
- debarment for companies and/or individuals.

There should also be consequences (e.g., fines, disciplinary action, restrictions on future engagement) for individuals not employed by the public sector who violate conflict of interest rules when serving on government commissions or advisory boards. Redress measures may also include reversing the decision made, cancellation of contracts, and exclusion of entities that benefited from breaches from future contracts (19, 37) (Box 12).

## 6. Conclusion

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Public-sector pharmaceutical committees and agencies are tasked with making decisions that have major implications for public health and the stewardship of public resources. Robust policies and sound, practical strategies for preventing and managing conflicts of interest are essential to ensure that decision-makers can make independent and evidence-based pharmaceutical policy and operational decisions and avoid undesirable outcomes. We hope the guidance provided in this manual will help to maintain productive collaboration with private-sector stakeholders while ensuring the independence and integrity of decision-making on public pharmaceutical committees to protect the public's health.

Future areas of work should enable countries to share experiences and good practices and advance learning on specific tools and actions that can prevent or mitigate the impact of conflicts of interest in public pharmaceutical policy and decision-making in LMICs. These might include establishing an international database of conflict of interest policies and tools and setting up mechanisms for cross-country collaboration. Sharing lessons learned on approaches for adapting and applying generic guidance and tools to specific country and committee contexts would also be useful. Areas of further study could include how to provide a safer environment for whistle-blowers who want to report important conflict of interest risks and how to effectively implement legislation that protects them; identifying metrics and approaches for evaluating the results of conflict of interest policies and strategies; and investigating what works, how and under what circumstances.

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