



## 5.3 Bibliography

In addition to the references throughout the toolkit, the following is a non-exhaustive list of resources and references that are relevant to SFMPs, organized by module.

### 5.3.1 General: Selected WHO guidance documents

- Annex 2 Good manufacturing practices for pharmaceutical products: main principles. In: Forty-eighth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2014 (<https://iris.who.int/handle/10665/112733>, accessed 26 November 2024).
- Protecting the supply chain: reports on informal markets. In: Member State survey on informal markets and literature review on informal markets. Geneva: World Health Organization; 2023.
- Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. Geneva: World Health Organization; 2021 (<https://iris.who.int/handle/10665/337551>, accessed 26 November 2024).
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- Annex 1: WHO good pharmacopoeial practices. In: Fiftieth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2016 (<https://iris.who.int/handle/10665/255338>, accessed 17 November 2024).
- Annex 4: WHO good practices for pharmaceutical quality control laboratories. In: Fifty seventh report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva: World Health Organization, 2024 (<https://www.who.int/publications/m/item/who-good-practices-for-pharmaceutical-quality-control-laboratories>, accessed 12 Dec 2024).

### 5.3.2 Module A. Background

#### WHO guidelines on use and regulation of pharmaceuticals

- A study on the public health and socioeconomic impact of substandard and falsified medical products. Geneva: World Health Organization; 2017 (<https://iris.who.int/handle/10665/331690>, accessed 26 November 2024).
- Annex 3. Model quality assurance system for procurement agencies. In: Forty-eighth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2014 (<https://iris.who.int/handle/10665/112733>, accessed 26 November 2024).
- Annex 3. Reporting form for complaints for medical devices including in vitro diagnostics. In: Report of Africa Medical Devices Forum COVID-19 Task Force. African Medical Device Forum; 2020 (<https://www.afro.who.int/publications/report-africa-medical-devices-forum-covid-19-task-force>, accessed 26 November 2024).
- Annex 5. Technical supplements to Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products. In: Forty-ninth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2011 (<https://iris.who.int/handle/10665/176954>, accessed 26 November 2024).



- Annex 5. WHO good distribution practices for pharmaceutical products. In: WHO Expert Committee on specifications for pharmaceutical preparations: forty-fourth report. Geneva: World Health Organization; 2010 (<https://iris.who.int/handle/10665/44291>, accessed 26 November 2024).
- Annex 5. Guidelines on import procedures for medical products. In: Fifty-third report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva: World Health Organization; 2019 (<https://iris.who.int/handle/10665/312316>, accessed 26 November 2024).
- Annex 8 Joint FIP/WHO Guidelines in good pharmacy practice: standards for quality of pharmacy services. In: Forty-fifth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2011 (<https://iris.who.int/handle/10665/44079>, accessed 26 November 2024).
- Annex 10. Good reliance practices in the regulation of medical products: high level principles and considerations. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fifth report. Geneva: World Health Organization; 2021 (<https://iris.who.int/handle/10665/340323>, accessed 26 November 2024).
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## 5.3.3 Module B. Prevent

### WHO documents

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- Annex 7. Good storage and distribution practices for medical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020 (<https://iris.who.int/handle/10665/331814>, accessed 26 November 2024).
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### Non-WHO guidelines

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### 5.3.4 Module C. Detect

#### WHO surveys

- Annex 5. WHO guidance on testing of “suspect” falsified medicines. In: Fifty-second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva: World Health Organization; 2018 (<https://iris.who.int/handle/10665/272452>, accessed 27 November 2024).
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### 5.3.5 Module D. Response

#### WHO surveys

- Rapid risk assessment of acute public health events. Geneva: World Health Organization; 2012 (<https://iris.who.int/handle/10665/70810>, accessed 26 November 2024).

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