

# Pharmacy-led vaccination services

## Regulatory self-assessment and implementation tool

2023



FIP Development Goals



# Colophon

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# 1 Introduction

## 1.1 Background

Improving vaccination access and coverage is a global imperative and the pharmacy workforce can contribute to this goal through a multitude of roles. The community pharmacy workforce is a community-based and highly accessible healthcare profession and can provide a clear and tangible contribution to public health strategies, illness prevention programmes, epidemic and pandemic management and overall population health through vaccination services.

However, any advocacy strategy to achieve an expanded role for the pharmacy workforce in these areas at country level needs to be grounded in an in-depth understanding of the needs at country level, with regard to vaccination services. An awareness of the requirements, resources (workforce, infrastructure, financial, etc), support systems, stakeholders and various other elements need to be considered in order to design a successful and meaningful strategy.

## 1.2 The aim of the tool

This self-assessment tool will help to identify strengths and areas for improvement in order to inform vaccination policy and planning efforts. It is an aid to help national ministries of health, regulators and national pharmacy organisations in assessing overall vaccination programmes and the state of legislation and regulations within their countries to facilitate vaccination and enhanced patient care through the pharmacy workforce and community pharmacies. The tool will help with vaccination planning and the utilisation of the pharmacy workforce in primary healthcare and community-based vaccination programmes.

While this tool is not exhaustive in content and has yet to be validated, it is based on the experiences of professional regulators in countries where pharmacy-led vaccination has been successfully introduced and regulated. The checklist is based on the objective to deploy the pharmacy workforce and utilise pharmacies to increase access to vaccination services.

This tool is primarily addressed to regulators and policy-makers to support them in developing strategies or enabling regulatory frameworks in countries where pharmacists and the pharmacy workforce have a limited role in vaccination strategies. It may also be useful as a review tool in countries where the pharmacy workforce already provides vaccine-related care but wishes to further expand or consolidate such roles.

This tool addresses the enabling legislation that is needed and makes reference to additional clarification of the limitations and parameters in the current regulations for future learning. Typically, new or changing legislation can be slow and difficult to draft and enact, but regulations can be made through a simpler and more agile process. Implementation might further require clarifying policies or standards which become the real “how to” guide for healthcare professionals from a public protection perspective.

FIP, its Professional Regulators Advisory Group and its member organisations are a resource for the drafting and development of supportive regulations, policies, standards of care and training programmes. Clearly, the desired goal is to create legislative change to establish enhanced patient care and patient access to vaccinations through pharmacy practice.

## 1.3 Using the tool

Some of the changes may be challenging to introduce in some countries because of the infrastructure and technology required. The first priority for an effective and safe vaccination programme is to create the enabling legislation for pharmacy-led vaccination.

With respect to the section “Are these regulations in place in your jurisdiction?”, legislation might not be “in place”, but might currently be drafted and proceeding through the approval process.

In some countries where pharmacy-led programmes are already in place and pharmacists are allowed to administer vaccines, the pharmacist's ability to prescribe, supply and administer vaccines would enable enhanced public access to vaccines.

## 2 Pharmacy-led vaccination services: Regulatory self-assessment and implementation tool

The tables below list and describe the elements of practice or roles by pharmacists that may require specific regulations. This list can be used to assess gaps in regulations or the language of existing regulations. For each practice element or role, a description and proposed language for regulations are provided. The proposed language can facilitate the development or update of regulations but should be adapted as appropriate to each local context. The last two columns can be used to identify gaps and assign priorities to the different elements of practice and their regulation.

### 2.1 Vaccination

| Objective   | Description and proposed language for legislative/regulatory requirements  | Are these regulations in place in your jurisdiction?   | Priority given to this category + Comments  |
|---|--|--|---|
| There is enabling legislation to allow pharmacists to be vaccinators.   | <i>A pharmacist who meets the required qualifications may, subject to any restrictions or conditions set out in the regulations or regulatory framework and in the course of the practice of pharmacy, engage in the act of administering medicines or vaccines that are designated in the regulations.</i>  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |
| There are comprehensive and clear regulations describing the conditions under which pharmacists can be vaccinators. | <i>A pharmacist may administer vaccines through intradermal, subcutaneous, intramuscular injection or other routes only if he or she holds a current certification to do so. A pharmacist may administer a vaccine that is prescribed by an authorised practitioner to a person or may administer a vaccine without a prescription to a person as part of a vaccination programme.</i> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |

| Objective   | Description and proposed language for legislative/regulatory requirements  | Are these regulations in place in your jurisdiction?   | Priority given to this category + Comments  |
|---|--|--|---|
| Education and training programmes are available and required for pharmacists to be vaccinators.   | <i>A pharmacist must be certified/authorised to administer a vaccine by injection or other routes through successfully completing the required education and training requirements approved by the regulator. Certification can occur during the undergraduate programme or through accredited continuing education.</i> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |
| There is a centralised vaccination reporting database system in place and/or patient personal vaccination booklet system.   | <i>A pharmacist who plans to administer a vaccine to a patient must check with the patients' vaccination data to confirm it is clinically appropriate to administer and, once the vaccination is completed, report the details of the administration to the patient vaccination record.</i>                              | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |
| Pharmacists may administer vaccines offsite from the pharmacy to reach homebound patients, those living in remote and underserved areas and in other community locations such as care or nursing homes, workplaces, schools, etc. | <i>Pharmacists certified in administration may administer vaccines outside the pharmacy in compliance with all the requirements of vaccine storage and administration and be prepared to readily address emergency patient response situations and monitor patients after administration.</i>                            | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |

| Objective   | Description and proposed language for legislative/regulatory requirements  | Are these regulations in place in your jurisdiction?  | Priority given to this category + Comments  |
|---|--|---|---|
| <p>Pharmacists must have an understanding of the risk, safety, value and impact of vaccination and act as educators of the public regarding vaccination programmes.</p> | <p><i>Pharmacists must be knowledgeable in the value and impact of vaccination programmes on population health and provide factual information to the public in support of the science of vaccines and vaccination programmes.</i></p> | <p> <input type="checkbox"/> Yes<br/> <input type="checkbox"/> No<br/> <input type="checkbox"/> Yes, but need updating<br/> <input type="checkbox"/> No, but the regulatory environment is sufficiently enabling                 </p> | <p> <input type="checkbox"/> 1 (top priority)<br/> <input type="checkbox"/> 2<br/> <input type="checkbox"/> 3<br/> <input type="checkbox"/> 4<br/> <input type="checkbox"/> 5 (lowest)                 </p> <p>Comments:<br/>Click or tap here to enter text.</p> |
| <p>Pharmacy personnel qualified by suitable training should be able to administer vaccines.</p>   | <p><i>Pharmacy personnel trained and certified to administer vaccines may do so in the pharmacy or at external locations as permitted in the regulations.</i></p>  | <p> <input type="checkbox"/> Yes<br/> <input type="checkbox"/> No<br/> <input type="checkbox"/> Yes, but need updating<br/> <input type="checkbox"/> No, but the regulatory environment is sufficiently enabling                 </p> | <p> <input type="checkbox"/> 1 (top priority)<br/> <input type="checkbox"/> 2<br/> <input type="checkbox"/> 3<br/> <input type="checkbox"/> 4<br/> <input type="checkbox"/> 5 (lowest)                 </p> <p>Comments:<br/>Click or tap here to enter text.</p> |

## 2.2 Vaccine prescribing

| Objective   | Description and proposed language for legislative/regulatory requirements   | Are these regulations in place in your jurisdiction?  | Priority given to this category + Comments  |
|---|---|---|---|
| <p>There is enabling legislation to allow pharmacists to prescribe vaccines or to be able to supply and administer vaccines without a prescription.</p> | <p><i>A pharmacist who meets the required qualifications may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of prescribing/administering vaccines that are designated in the regulations.</i></p> | <p> <input type="checkbox"/> Yes<br/> <input type="checkbox"/> No<br/> <input type="checkbox"/> Yes, but need updating<br/> <input type="checkbox"/> No, but the regulatory environment is sufficiently enabling         </p> | <p> <input type="checkbox"/> 1 (top priority)<br/> <input type="checkbox"/> 2<br/> <input type="checkbox"/> 3<br/> <input type="checkbox"/> 4<br/> <input type="checkbox"/> 5 (lowest)         </p> <p>Comments:<br/>Click or tap here to enter text.</p> |

## 2.3 Vaccine supply chain management

| Objective   | Description and proposed language for legislative/regulatory requirements  | Are these regulations in place in your jurisdiction?   | Priority given to this category + Comments  |
|---|--|--|---|
| There is legislation requiring the registration and licensure of manufacturers and wholesale pharmaceutical distributors (for vaccine distribution to community settings and/or healthcare providers in licensed facilities). | <i>Any person or business engaged in the distribution of medicines and vaccines to licensed facilities or healthcare professionals for the purpose of administration to a member of the public must be licensed and comply with all applicable statutes and regulations and specifically those requiring tracking, storage, transport and cold-chain requirements.</i>                             | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |
| Legislation prohibits unsafe return and redistribution activities.  | <i>Licensed pharmaceutical and vaccine distributors cannot accept for redistribution any medicine or vaccine from a licensed facility or healthcare professional unless the distributor originally supplied that exact vaccine, as confirmed through lot number and expiry date, to the facility or healthcare professional and can be assured the quality of the vaccine has been maintained.</i> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |
| Legislation requires integrity of the vaccine to be distributed.  | <i>Licensed pharmaceutical and vaccine distributors must ensure vaccines are obtained from legitimate sources and are required to keep accurate records of acquisitions and visually examine vaccines for the possibility of being falsified vaccines or having been subject to improper storage or damage.</i>  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Yes, but need updating<br><input type="checkbox"/> No, but the regulatory environment is sufficiently enabling | <input type="checkbox"/> 1 (top priority)<br><input type="checkbox"/> 2<br><input type="checkbox"/> 3<br><input type="checkbox"/> 4<br><input type="checkbox"/> 5 (lowest)<br><br>Comments:<br>Click or tap here to enter text. |

## 2.4 Additional notes

### **Additional notes**

*For objectives identified as a priority, use this section to indicate priority sequencing and implementation requirements*

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