

PHARMACY BASED PANDEMIC VACCINATION PROGRAMME: REGULATORY SELF-ASSESSMENT TOOL

**INTERNATIONAL PHARMACEUTICAL FEDERATION
FORUM OF PROFESSIONAL REGULATORS**

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Pharmacy-based pandemic vaccination programme: Regulatory self-assessment tool

Background

Improving vaccination access and coverage is a global imperative and pharmacists can contribute to this goal through a multitude of roles. In addition, during a pandemic, it is crucial to identify positive cases and break transmission chains through appropriate testing strategies, to which pharmacists can greatly contribute. As community-based and highly accessible healthcare professionals, community pharmacists can provide a particular contribution to public health strategies and to bringing pandemics under control.

However, any advocacy strategy aiming to achieve an expanded role for pharmacists 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 and testing 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.

Aim of this tool

This self-assessment tool will help to identify strengths and areas for improvement in order to inform pandemic planning efforts ahead of current and future waves of COVID-19. It is an aid to help national ministries of health and regulators in assessing pandemic preparedness and the state of legislation and regulations within their countries to facilitate mass vaccination and testing and enhanced patient care through pharmacists and community pharmacies. It will help with vaccination planning and mitigate risk of future waves of COVID-19. While this tool is not exhaustive, and not yet validated, it is based on the experiences of professional regulators in countries where pharmacy-based vaccination and testing have been successfully introduced and regulated and, as such, seeks to be a supportive tool.

The checklist is based on the desired function to deploy pharmacists and pharmacies to increase access to vaccination and testing services, provide supportive care for patients with chronic medication needs, and offer treatment for minor symptoms when the patient's viral condition is considered minor.

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

This tool addresses the needed enabling legislation but only makes reference to the need for additional clarification of the limitations and parameters in the regulations. 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 and its member organisations can be a resource for the drafting and development of supportive regulations, policies, standards of care and training programmes. If a permanent change in the legislation is not possible, health ministers and regulators ought to consider developing new legislation that allows for these expanded functions of the pharmacist on an “emergency basis” to address patient care needs under a pandemic or other declared emergencies.

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 mass vaccination programme is to create the enabling legislation for pharmacy-based vaccination (PBV).

With respect to the “Factor assessment” section, legislation might not be “in place”, but might be currently drafted and proceeding through the approval process. In that case, the “Estimated time needed to implement” can be noted. The “Risk level” can be assigned depending upon whether the legislation is in place or not in place, and the estimated time needed to implement changes to legislation or regulations. “Risk level” is from the public protection perspective should the task not be completed or be delayed unduly or unnecessarily. For example, a high-risk level would be if PBV is “Not in place” and there is no current plan for development or implementation of the legislation. This would place the population at a “high risk” and would then be a priority “one”.

Supportive patient care and activities in PBV are testing, prescribing and supply chain management. In some countries where PBV programmes are already in place and pharmacists are allowed to administer vaccinations, these supportive activities will enhance patient care and access to immunisation through the PBV programme. For example, if the vaccine requires a prescription in the country, the pharmacist’s ability to prescribe would enable enhanced public access to the vaccine in this regard. In addition, the pharmacist’s ability to prescribe “continued care” prescriptions for an established chronic medicine would remove the need for the patient to see another practitioner for a “routine refill” and leaving the other practitioner to attend to more critical patient needs demanded by the pandemic.

Pandemic preparation: Pharmacy-based vaccination, testing and prescribing — Assessment and planning

Category	Factors	Legislative/regulatory requirements	Factor assessment				Priority *
			In place	Not in place	Estimated time needed to implement changes	Risk level (high to low) if not implemented	
Vaccination	There is enabling legislation to allow pharmacists to be vaccinators during a pandemic.	<i>A pharmacist who meets the qualifications set out in the regulations 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 administering medicines or vaccines that are designated in the regulations.</i>					
	There is 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 an approved immunisation programme.</i>					
	Education and training programmes are available and required for pharmacists to be vaccinators.	<i>A pharmacist must be certified / recognised to administer a vaccine by injection 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>					
	There is a centralised vaccination reporting database system in place	<i>A pharmacist who plans to administer a vaccine to a patient must check with the centralised vaccination patient data to confirm the vaccination has not already</i>					

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	and/or patient personal vaccination booklet system.	<i>taken place and, once the vaccination is completed, report the details of the administration to the patient vaccination database.</i>					
	Pharmacists may administer vaccines offsite from the pharmacy, to reach homebound patients and those living in remote and underserved areas, in other community locations such as care or nursing homes, workplaces, schools, etc.	<i>Pharmacists certified in administration may administer vaccines outside the community pharmacy as long as they are following all the requirements of vaccine storage and administration and do so safely to readily address emergency patient response situations and monitor patients after administration.</i>					
	Pharmacists must have an understanding of the risk when a pandemic is declared and act as educators of the public regarding the value of mass vaccination programmes during times of pandemic.	<i>Pharmacists must be knowledgeable in the value and impact of mass vaccination programmes on population health and provide factual information to the public in support of the science of vaccines and mass vaccination programmes.</i>					
	There is enabling legislation to allow trained personnel (e.g., nurse technicians, pharmacy technicians) to be vaccinators during a pandemic.	<i>Personnel qualified by suitable training should be able to administer vaccines — freeing up nurses and medical doctors to treat COVID patients.</i>					

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Testing	There is enabling legislation to allow pharmacists to perform virus screening tests and provide test results during a pandemic.	<i>A pharmacist who meets the qualifications set out in the regulations 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: (a) performing point-of-care screening tests of appropriately regulated quality to support the diagnosis of disease cases in the community; (b) interpreting patient-administered automated tests that are designated in the regulations; (c) ordering and receiving reports of screening and diagnostic tests that are designated in the regulations.</i>					
	Education and training programmes are available and required for pharmacists to perform tests related to the pandemic.	<i>A pharmacist must be certified to perform tests through successfully completing the education and training requirements approved by the professional regulator. Certification can occur during the undergraduate programme or through accredited continuing education.</i>					
	There is a centralised testing reporting database system in place.	<i>A pharmacist who administers a test to a patient must check with the centralised patient data to confirm the last time a test was performed and the result and, once the test is completed, report the details of the test into the centralised patient database.</i>					

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	Mitigate the community-transmission risk through testing services provided to patients and staff and enhance their understanding of containment responsibilities and activities.	<i>Pharmacists must be knowledgeable in the value and impact of testing services as it relates to pandemic containment and key activities to decrease the spread of the virus and provide the information to patients and pharmacy staff.</i>					
Prescribing	There is enabling legislation to allow pharmacists to prescribe vaccinations during a pandemic.	<i>A pharmacist who meets the qualifications set out in the regulations 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 vaccines that are designated in the regulations.</i>					
	There is enabling legislation to allow pharmacists to prescribe continuing chronic medicines during a pandemic.	<i>In order to continue patients on current chronic medication that was previously prescribed, a pharmacist who meets the qualifications set out in the regulations 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 drugs that are designated in the regulations.</i>					

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	There is enabling legislation to allow pharmacists to prescribe treatment for minor symptoms of patients with the pandemic virus.	<i>In order to meet the needs of patients with a pandemic virus, a pharmacist who meets the qualifications set out in the regulations 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 medicines, as designated in the regulations, for symptomatic treatment of the minor symptoms associated with the viral conditions up to a point when referral to another healthcare professional or hospital admission is warranted.</i>					
Supply chain management	There is legislation requiring the registration and licensure of manufacturers and wholesale pharmaceutical distributors (for vaccine distribution to retail 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.</i>					
	Legislation prohibits risky return and redistribution activities.	<i>Licensed pharmaceutical 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>					

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	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>					
*Additional notes							

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