Management of non-communicable diseases

Regulatory self-assessment and development tool for transforming pharmacy practice

2022

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Colophon

International Pharmaceutical Federation (FIP)
Andries Bickerweg 5
2517 JP The Hague
The Netherlands
www.fip.org

Authors
Ronald Guse, Chair, FIP Forum of Pharmacy Professional Regulators 2020-2022, Canada
Gonçalo Sousa Pinto, FIP Lead for Practice Development and Transformation

Editors
Al Carter, National Association of Boards of Pharmacy, USA
Carmen Catizone, National Association of Boards of Pharmacy, USA
Adele Fifield, National Association of Pharmacy Regulatory Authorities, Canada
Hélène Leblanc, French Chamber of Pharmacists, France
Luís Lourenço, International Pharmaceutical Federation, Portugal
Marie-Hélène Morzadec, French Chamber of Pharmacists, France
Ema Paulino, National Association of Pharmacies, Portugal
Anastasia Shiamptanis, National Association of Pharmacy Regulatory Authorities, Canada
Andi Shirtcliffe, Ministry of Health, New Zealand
Brett Simmonds, Pharmacy Board of Australia, Australia
Leonor Soares, Portuguese Pharmaceutical Society, Portugal
Carine Wolf-Thal, French Chamber of Pharmacists, France

Editorial support
Rúben Viegas, FIP Practice Development and Transformation Projects Coordinator

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Foreword

Welcome and thank you for accessing "Management of non-communicable diseases: Regulatory self-assessment development tool for transforming pharmacy practice". We hope that you will find this tool valuable in the development of quality and safe pharmacy practice for the betterment of patient access to pharmacists' services, and patient care.

Pharmacy practice is abundant with highly motivated, educated and trained professionals with the ability to provide patient-centred care. This is the case in countries all over the world and in all practice settings. Some countries have drafted and enacted enabling legislation to position the pharmacist to provide patient care that meets the needs of patients while safely filling-in some of the gaps that exist in most healthcare systems.

This development tool is an excellent way to assess the status of pharmacy practice regarding non-communicable diseases (NCDs). It applies in areas where pharmacists already provide additional care, but will also be an invaluable asset to those countries where pharmacists are not involved in an expanded scope of practice in NCDs.

The recent overwhelming impact on global healthcare systems during the pandemic called all healthcare professionals to practise within the full scope of practice and extent of their knowledge, skills and abilities. Pharmacists in community, hospital and long-term care were at the forefront of practicing at scope and to welcome patients to provide care in their practice sites. In any patient-centred care, collaboration is key and pharmacists are ideally situated for this, to communicate and collaborate with others on the healthcare team.

The FIP Forum of Pharmacy Professional Regulators researched pharmacy practice legislation throughout the world and has developed this tool for the betterment of patient access to safe and quality care for NCDs, as part of the resources developed under the FIP Practice Transformation Programme on NCDs. The regulators forum has the primary goal of public protection and patient safety and this development tool delivers that goal.

Thank you for being a leader in patient care and patient safety by adopting or adapting this tool to meet the needs of health care and patient care in your jurisdiction. On behalf of FIP and the forum, we welcome your thoughts and feedback and we are here to assist in any way we can.

All the very best, and stay safe!

Dominique Jordan
FIP President

Ronald Guse
Chair of the FIP Forum of Pharmacy Professional Regulators

1 Introduction

1.1 Background on non-communicable diseases

Enhancing the role of the pharmacist and primary healthcare services being available in a community pharmacy are global imperatives. The challenges of sufficient numbers and sufficiently trained healthcare providers available and accessible for the public are critical limiting factors when addressing equity in the healthcare system of all countries. Pharmacists can help in meeting these challenges through a multitude of roles. As community-based, trusted and highly accessible healthcare professionals, community pharmacists can provide a particular contribution to public health strategies, equitable health outcomes and patient safety. The FIP focus for this initiative is community pharmacy practice.

FIP's Practice Transformation Programme on Non-Communicable Diseases (NCDs) is working to fulfil its mandate of advancing the impact and visibility of pharmacists in addressing the global burden of NCDs.

This multi-year programme will provide expertise, tools and strategic support to FIP member organisations (national pharmacists' associations and regulators) and individual members to transform pharmacy practice and provide evidence-based interventions and professional services for the prevention, early screening and management of NCDs.

The programme is designed to address the five major NCDs, namely, diabetes, mental health, chronic respiratory diseases, cancer and cardiovascular diseases. However, the drafted enabling legislation could be utilised in other areas of disease management which can be further described in the regulations. This programme aims to have a sustained and measurable impact in terms of improved patient outcomes and health systems efficiency and sustainability. While the project will have a particular focus on low-and-middle-income countries, it will encourage implementation by countries of all income levels, since the role of pharmacists in NCDs is an imperative across all countries.

The mission of the programme is:

- To assist FIP member organisations in self-assessing the needs of their country for pharmacist and pharmacy services that address NCDs and the conditions in which these services are provided;
- To support the training and education of pharmacists, transforming the way they provide NCD-related pharmacy services; and
- To support countries in the implementation of pharmacy services and programmes that can reduce the burden and impact of NCDs.

One of the dimensions that this programme will need to address is the regulatory framework for the provision of NCD-related services. In some countries, regulations may be a barrier to, for example, performing point-of-care tests for the screening and disease-state management of some NCDs. As such, it is important to assess if regulations enable or limit pharmacy professionals (pharmacists and pharmacy technicians) to provide and support such services, so that a strategy to advocate regulatory changes can be developed.

1.2 Aim of the tool

This regulatory self-assessment tool is not specific to one NCD area, but rather describes and enables pharmacists to have broad roles, for example, regulations that authorise pharmacists to perform point-of-care tests (POCTs) in pharmacies. This can then be applied to a range of POCTs, including glycaemia for diabetes screening and monitoring, but also other tests that may be used (now or in the future) in assessing cardiovascular risk or other conditions. In areas of mental health, the POCT might be replaced by an assessment of mental health status of the patient and the interpretation of the result by the pharmacist for appropriate referral.

Although the FIP focus for this initiative is community pharmacy practice and enhancing the accessibility to primary health care, the suggested legislation and regulations do not specifically describe community

pharmacy practice. This tool can also be applied to pharmacists practising in hospital, long-term care facilities and other patient-centred care settings.

In addition to POCTs, determinations of parameters such as blood pressure or body mass index, or peak expiratory volume through spirometry may also be included in the regulations to support pharmacists' role in NCD screening and referral. In some countries, these may be considered as exclusive roles of other healthcare professionals. However, pharmacists with the proper skill set can competently and safely perform these roles.

Clearly, the intent is not to set a pharmacist as a sole practitioner in the care of the patient. Instead, the pharmacist is well adept and ideally placed to enhance patient entry into a care pathway and to be an integral part of a collaborative care approach to patient care and treatment, and to intervene where high-risk patients need to be referred for observation and diagnosis. The importance and patient safety benefits of shared and accessible health care records cannot be overstated. Pharmacists providing testing, treatment and care to patients need read-and-write access to patient records.

This tool will identify two critical areas of NCD practice that pharmacists can provide, or may provide following the necessary regulatory adaptions. Those two areas are testing (ordering and interpreting) and prescribing. Pharmacists, after appropriate undergraduate training or ongoing continuing professional development, can provide this level of care, which also includes interpreting patient self-administered tests and prescribing supportive non-prescription medicines treatments or non-medicine treatments.

In addition to POCTs, determinations of parameters such as blood pressure or body mass index, peak expiratory volume through spirometry or any other examination may also be included in the necessary regulations to support this role in NCD screening and referral. In some countries where expanded, advanced or specialised pharmacy practice exists or can be certified, pharmacists with the appropriate training may play a broader role in the management of NCDs, such as ordering and interpreting certain clinical laboratory tests, and prescribing, deprescribing or adjusting treatments with medicines. In some countries, pharmacists may acquire the competence to provide these services as part of their foundational education and training, and there is no need for the designation or a separate register to set different levels of practice. In other countries there may be a preference to use terms like "advanced practice pharmacist", "extended practice pharmacist" or "clinical pharmacist" to describe this subset of the practitioners' register. The main goal of the programme is to develop a regulatory environment where a majority of pharmacists can safely and competently perform a range of roles as part of mainstream practice to support patient-centred screening and management of NCDs. Should an entry-to-practice educational curriculum provide the required knowledge and training for an "advanced practice pharmacist", the newly graduated could be included on the practitioners' register for this area of practice and, ultimately, that would become the overall standard of practice and would no longer be considered "advanced".

This tool does not include the ability to administer vaccines or medicines through injection. The regulatory readiness to administer medicines and vaccines via injection can be assessed using the appropriate regulatory self-assessment tool available here.

1.3 Using the tool

This tool is primarily addressed to regulators, ministries of health, policy-makers and FIP member organisations that wish to assess the regulations currently in place in their jurisdictions against these recommendations. This tool may be useful for developing strategies or enabling regulatory frameworks in countries where pharmacists have a limited role in NCD care, testing and treatment strategies. It may also be useful as a review tool in countries where pharmacists already have a role in NCD management, but wish to further expand or consolidate such roles. While this tool is not exhaustive, and not yet validated, it is based on the experiences of professional regulators in countries where patient-centred, pharmacy-based collaborative NCD treatment, care and testing have been successfully introduced and regulated.

FIP has developed a series of supportive handbooks for the Practice Transformation Programme on NCDs. This regulatory self-assessment and development tool becomes an important resource when ministries, regulators and policy-makers decide to include management of NCDs into the practice of pharmacy.

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.

2 Pharmacy-based NCD management: Regulatory self-assessment and development 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 of practice element or role, a rationale 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 Regulations for patient care testing

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
1. All pharmacists performing and interpreting point-of-care tests (POCTs) and supporting patient self-administered tests	There is enabling legislation to allow all pharmacists to distribute, perform, instruct, interpret and act upon the results of POCTs and patient self-administered tests for NCDs. .	*Subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy with respect to point-of-care tests for health screening and diagnostic information, a pharmacist may engage in the acts of:* *(a) performing tests for patient assessment and medication management;* *(b) distributing and instructing on the use of tests;* *(c) ordering and receiving reports of tests, and, if needed, interpreting the results; and* *d) informing patients of test results.*	This section will provide the ability to perform, and interpret the results of non-restricted point of sale (publicly available) screening and diagnostic tests to the patient, and communicating results to the patient and the healthcare team as appropriate. The level of this participation in testing will depend upon the area of practice and competencies of the individual pharmacist. The role of the pharmacist becomes critical in population screening and supporting diagnostic activities, as part of a public health strategy. The section would also support pharmacists and pharmacy	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
			technicians explaining the proper use of patient self-administered tests and interpreting their results.		
2. Performing, ordering, receiving and interpreting results of tests to monitor medicinal management and patient care.	There is enabling legislation and regulations to allow all pharmacists to order, receive reports, interpret results and provide results of tests pertinent to medicines and treatment prescribed for a patient under their care.	*A pharmacist may perform, order and receive the results of tests specified in a schedule to this regulation in relation to a medicine prescribed to a patient, when the purpose of doing so is to monitor the patient's medicinal therapy regimen to ensure that it is safe and optimal.* *The tests included in the schedule to this section, and consistent with the scope of practice of the pharmacist, are performed, ordered and interpreted to monitor the care being provided by the healthcare team and must meet the needs of the patient.*	All pharmacists are able to order restricted (not publicly available) tests that will help determine if the proper dosage is being prescribed and the result of the medicinal therapy is consistent with the treatment goal and patient safety. Pharmacists with the appropriate knowledge and competence may be able to order a wider range of tests listed in the schedule in order to properly assess the needs of the patient and monitor the care being provided. These tests are pertinent to the prescribed medicine and treatment goal for the patient and may be more complex and advanced.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
3. Informing the patient and the prescriber of the need for ordering a test	Legislation must require patient-centred care at all times when ordering tests.	*Before ordering a test, a pharmacist must:* *(a) give the patient clear information about the reason for ordering the test to allow the patient to make an informed decision about whether to have the test;* *(b) if the medicine in relation to which the test was ordered was dispensed pursuant to a prescription, notify the practitioner who last prescribed the medicine of the test to be ordered and the reason for doing so; and* *(c) make the appropriate notation in the patient record indicating that the test was ordered.*	It is important at all times to inform the patient about the care they are receiving and this is critically important for tests that are being ordered on behalf of the patient. Test ordering must be prudent and have a definable need. Once the results are known, they need to be shared with the patient and other healthcare professionals involved with the care, and recorded. The pharmacist must also be competent to make a recommendation regarding any change in patient care in response to the results.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
4. Receiving and interpreting test results and acting upon the findings for optimal patient care.	Legislation must require patient-centred care at all times when receiving test results.	*Upon receiving the test results in relation to a medicine prescribed to a patient, the pharmacist must:* *(a) promptly inform the practitioner who originally prescribed the medicine that caused the need for the test of the results and include recommendations about patient care and any dosage adjustment;* *b) following the completion of (a), share the test results and recommendations with the patient; and* *c) ensure the test results, recommendations and end result of the recommendations are recorded in a database accessible to others providing care to the patient.*	With the authority of test ordering comes the responsibility of making a recommendation when the results are known. It is important that the pharmacist is required to make a treatment recommendation based upon the results and inform the practitioner and the patient of the results and recommendations.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
5. Ensuring competence to perform tests.	Education and training programmes are required in the legislation, or regulations, and are required for all pharmacists performing tests.	*A pharmacist must be competent to perform, order and interpret the results of non-restricted point-of-sale tests through successfully completing the education and training requirements approved by the regulator. Certification can occur during the entry-to-practice educational programme or through accredited continuing professional development education.* *Additional education and training that are part of a certification programme may be required for pharmacists to perform, order and interpret more complex or advanced care tests, included in the schedule to this section, and act upon the results.*	It is important that the competence of the pharmacist to perform, order, interpret and act upon the results of tests is regulated through the requirement of education and training programmes. There may be two educational certification programmes: one that is limited to non-restricted point of sale (publicly available) screening and diagnostic tests that can occur in a community care pharmacy and another that extends the basic knowledge to more complex and specialised practice setting.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

2.2 Regulations for medicines-related roles: treatment initiation, adjustment or continuation

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
1. Ensuring continuity of established care for NCDs and other chronic care,	There is enabling legislation for all pharmacists to provide critical patient-centred care through continued care prescription.	*Any pharmacist may prescribe and dispense a continued care prescription permitting additional medicine to be provided for the patient, as originally authorised by a prescribing practitioner, if:* *(a) the patient has a continuing need or chronic condition;* *(b) the patient's history with the prescribed medicine has not changed;* *(c) the patient advises that they have not recently experienced any adverse reactions to the medicine that would indicate that the treatment should be discontinued;* *(d) the continued care prescription and medicine are issued in compliance with proper patient care and any additional requirements described in the regulations; and* *(e) a record was made of the prescribing and the continued care prescription and the prescribing practitioner who originally authorised the medicine has been informed by the pharmacist of the prescribing event.*	This section addresses the need for all pharmacists to be able to provide needed care to their patients by issuing a continued care prescription and additional medicine supply for patients when the original prescription has expired or the prescribing practitioner has not provided additional prescribing in a timely manner. This ability would support patient-centred NCD care.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
2. Prescribing or modifying the prescription of medicines and medical devices for the treatment or management of NCDs by pharmacists with the appropriate training.	There is enabling legislation to allow pharmacists with the appropriate knowledge and certified competence to prescribe medicines classified as "prescription only" (including adjusting the prescribed treatment) and to prescribe medical devices.	*A pharmacist who meets the qualifications set out in the regulations may, subject to any restrictions or conditions set out in the regulations, engage in any of the following practices in the course of practising pharmacy:* *(a) prescribing medicines that are designated in the regulations for the purpose of this clause; and* *(b) prescribing medical devices that are designated in the regulations for the purpose of this clause.*	Pharmacists with appropriate knowledge and certification are able to competently perform the function of assessing a patient and prescribing medicines (including discontinuing or altering dosages) and devices needed to treat the patient. Additional education and training and certification programmes are necessary to ensure proper patient care and patient safety. These programmes could also be part of an-entry-to practise curriculum. The authority to prescribe medical devices would be important for treatment of diseases such as diabetes.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
3. Ensuring and certifying the competence of pharmacists who have additional prescribing authority beyond continued care prescriptions.	Legislation and regulations are needed to describe the education and training requirements for pharmacists to be certified to provide a level of care that includes prescribing of medicines and devices within their knowledge, skills and abilities.	*A pharmacist must be certified through successfully completing the education and training requirements set by the regulator in order to:* *(a) assess the medicine treatment and care of the patient;* *(b) prescribe medicines, including discontinuing medicines and altering doses, and;* *(c) prescribe medical devices.*	All pharmacists will have a basic knowledge of patient assessment, examination and disease symptoms, but prescribing medicines (including discontinuing or altering dosages) or medical devices for NCDs may require additional knowledge and training in these competencies. Certification may result from postgraduate training programmes or during an entry-to-practise curriculum.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
4. Defining the list of health conditions that pharmacists can treat through prescribing practices.	There are comprehensive and clear regulations describing the disease conditions for which pharmacists with the required certification can prescribe medicines and medical devices.	*Pharmacists may prescribe medicines and medical devices for the purpose of treating a disease, medical condition or ailment listed in the regulations, and for complications that arise from the disease, condition or ailment.*	Rather than listing specific medicines, the schedule within the regulations describes the disease conditions that can be treated with the category of medicines approved in each jurisdiction for the appropriate indications. An example of medicine classifications for disease treatment can be seen at the Anatomical Therapeutic Chemical (ATC) Classification System. If the specific medicines were to be listed, the regulations would need to be amended as new medicines became available or treatment standards changed. By referring to the approved category of medicines for the appropriate indications, the regulations would not need to be amended.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Objective	Description	Proposed language for legislative/regulatory requirements	Rationale	Are these regulations in place in your jurisdiction?	Priority given to this category + Comments
5. Defining the conditions and requirements for pharmacists to prescribe.	Additional regulations are needed to cover areas of practice requirements, assessment, record keeping and access to records.	*A pharmacist with the appropriate knowledge and certified competence may only prescribe when the following conditions are met:* *(a) an assessment was done of whether the medicine will be safe and effective in treating the needs of the patient, including:* *(i) the patient's symptoms, the patient's medical history or pertinent medical information,* *(ii) the patient's allergies,* *(iii) other medicines the patient may be taking, and* *(iv) any other inquiries reasonably necessary in the circumstances; and* *(b) an assessment of the patient occurs in person or, if the assessment is not possible in person, it was done in compliance with the standards for virtual care.* *A record must be created by the pharmacist indicating the details of the assessment and treatment decisions including treatment goal or clinical indication.* *Where patient care records are permitted to be shared with other healthcare professionals providing care to the same patient, the records for the prescribing event must be entered into a common patient record.*	As with all good patient-centred prescribing events, a proper assessment of patient needs must be done and records must be kept. Pharmacists need access to the patient's medical history and chart notes, and must also be able to input their clinical intervention, assessment, and prescribing into the same database and record.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficiently enabling	☐ 1 (top priority) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (lowest Comments: Click or tap here to enter text.

Additional notes *For objectives identified as a priority, use this section to indicate priority sequencing and implementation requirements*
Click or tap here to enter text.

International
Pharmaceutical
Federation

Fédération
Internationale
Pharmaceutique

Andries Bickerweg 5
2517 JP The Hague
The Netherlands
-
T +31 (0)70 302 19 70
F +31 (0)70 302 19 99
fip@fip.org
-
www.fip.org