

Terms of reference for the FIP Regulators Advisory Group

1 Background

Professional organisations with regulatory functions play an important and decisive role in overseeing the profession and setting standards of practice, ethical conduct and public protection, namely by regulating workforce capacity and sustained performance and the scope of practice of pharmacists, to ensure patient safety and optimal health outcomes. Recognising the need for international collaboration and potential coordination in terms of pharmacy regulation, FIP established in 2018 a permanent advisory group for pharmacy professional regulators to advise FIP and to enable FIP to advise regulators on changing needs and emerging developments.

2 Mission

To provide a global platform for pharmacy professional regulators, for sharing best practices among peers, emerging trends and needs for the profession and associated regulations, thus contributing to protecting the public and achieving optimal health outcomes through a competent and adequately regulated pharmacy profession.

3 Objectives

The main objectives of the Advisory Group are:

- 1 To contribute to the overall mission of FIP of advancing pharmacy worldwide, by providing expertise, advice and support.
- 2 To provide a platform for pharmacy professional regulators to discuss and share challenges and best practices.
- 3 To share good practice around public protection and the roles of regulators therein.
- 4 To support the advancement of pharmacy regulation worldwide in a coordinated and collaborative manner.
- 5 To offer an advisory group to FIP members with regulatory roles and a place for organisations with regulatory roles to engage, share and advise.
- 4 To inform strategies in terms of workforce capability and competence in an international environment.
- 5 To share research in pharmacy regulatory practices worldwide and use the resulting evidence to inform policy and the activities of the Advisory Group.
- 6 To provide expertise and advice, as well as experts for FIP in the World Health Professions Alliance in matters related to pharmacy regulation. This expertise and advice can be for specific events as the need emerges, and, in particular, in the organisation of the biannual WHPA interprofessional conferences on health professions regulation.
- 7 To advise the FIP Council, Bureau and Executive Committee in matters related to
 - 7.1 professional regulation
 - 7.2 personnel (for example pharmacists, technicians, supportive staff, student interns, etc.),
 - 7.3 the practice of pharmacy inclusive of the dispensing of medicines and medical devices, and facilities (for example, pharmacies, distributors, etc. where appropriate within a particular regulatory entity's scope).
 - 7.4 Other items over time which require advice and support.

4 Remit of the Advisory Group and strategic areas of collaboration

Some of the possible areas of collaboration among Advisory Group members may include, but are not limited to:

- 1 Identifying key challenges and opportunities for pharmacy regulators at global, regional and national level, and developing tools and guidelines to address them.
- 2 Sharing and actively promoting innovative and evidence-based regulatory practices, from across the globe.
- 3 Sharing standards of practice and disciplinary options across the globe.
- 4 Sharing disciplinary data as appropriate, across the globe.
- 5 Identifying challenges and opportunities in terms of workforce capacity and mobility, in coordination with other areas and constituencies across FIP.

5 Membership of the Advisory Group

1 Definition

For the purpose of this Advisory Group, the definition of a regulatory organisation is:

"Ministries or organisations that regulate, inspect and/or accredit pharmacy practice, including education, for the protection of the public."

2 Eligibility

Membership in the Advisory Group is open to any organisation that meets the above definition.

Some organisations may combine regulatory and other functions, such as advocacy or negotiating roles. Such organisations may become members of the Advisory Group to collaborate on issues related to professional regulation.

The Advisory Group may also invite and engage with organisations that are not Member Organisations of FIP, as some of them may not be able to join because their public mandate prevents them from joining the Federation. In this regard, their involvement and engagement in the Advisory Group will be welcomed.

6 Functions of Advisory Group members

The functions accompanying the definition are intended to provide additional clarity and should be considered the inclusion criteria rather than examples. Members of the Advisory Group shall have at least one of the following functions:

- 1 Registering pharmacy professionals;
- 2 Inspecting pharmacists and/or pharmacies to ensure compliance with professional Standards/requirements;
- 3 Initiating disciplinary sanction process;
- 4 Restricting the practice of a specific individual or forbidding the practice to specific individuals;
- 5 Being in charge of the application of the Code of Ethics and other regulation related to the practice;
- 6 Setting standards for the initial education of pharmacy professionals and the assessment of pharmacy professionals.

7 Membership fees and financial contributions

- 1 FIP member organisations that are eligible to be members of the Advisory Group, are able to take part within their membership fees.
- 2 Regulatory organisations that are not member organisations of FIP but wish to participate in the meetings or activities of the Advisory Group are eligible to do so by attending the annual meeting of the Advisory Group and paying an attendance fee to FIP. This fee will not establish a membership relationship with FIP but will entitle these organisations to participate fully in the Advisory Group and its activities, including advice and expertise, as well as experts at events.

8 The meeting of the Advisory Group

- 1 Given the role and function of the Regulators Advisory Group, an annual face to face meeting is essential to provide the space for discussion and wider engagement and develop expert advice and support and outputs. An annual event for members of the Advisory Group will also allow for engagement and exchange of ideas and priorities.
- 3 This annual meeting can take place at the FIP global congress, supplemented by an event at the WHPRC biannually.

9 Leadership of the Advisory Group

- 1 The Chair of the Advisory Group is elected by the members of the Advisory Group and ratified by the FIP Bureau.
- 2 The term of office for the Advisory Group Chair is of 2 years, renewable for an additional term of 2 years.
- 3 The Chair of the Advisory Group is supported by a small team of Advisory Group leads who support and guide various emerging workstreams of the Advisory Group. The Chair of the Advisory Group then advises and reports back to FIP Bureau.
- 4 The identified volunteers can change every year based on the volunteers that would present themselves at the annual event at Global Congress.
- 5 If further expertise is required for particular advice or areas of work, the groups in the Advisory Group are free to recruit expertise for that piece of work.
- 6 It is important that the working groups and advisory groups are as inclusive as possible and involve the member organisations of the Advisory Group and eligible non-member regulatory organisations, in terms of WHO regions, country income level and type of organisation (scope of regulation).
- 7 The Chair will be responsible for yearly face-to-face meetings of the Advisory Group in conjunction with the FIP World Congress or another relevant event and will receive support from FIP for the logistics of the meeting.
- 8 Between meetings of the Advisory Group at the FIP Congress, the Advisory Group Chair:
 - a. May call for virtual meetings of the Advisory Group members;
 - b. May consider and decide upon matters in accordance with the objectives listed in the Terms of Reference of the Advisory Group and all such decisions must be included in the report made annually to the members of the Advisory Group and the FIP Council; and,
 - c. Cannot usurp the authority or policy making responsibility of the Advisory Group.
 - d. Shall be responsible for the proper organisation of the activities of the Advisory Group and

- e. Shall prepare a report on their activity and the activity of the Advisory Group and make the report available to the FIP Bureau and all Advisory Group Members at meeting held during the FIP Congress.
- f. Shall develop exchange opportunities for members of the Advisory Group in-between face-to-face meetings.

10 Planned activities and outputs

- 1 Advise the FIP leadership and HQ team on key issues related to pharmacy and interprofessional regulation, and particularly in relation to FIP's collaboration with WHPA partners, including the interprofessional conferences on professional regulation organised by WHPA.
- 2 Organise a meeting at each FIP annual congress focusing on priority issues.
- 3 Produce reports, guidelines and/or other publications of relevance to the members of the Advisory Group.
- 4 Conduct surveys to FIP member organisations and all non-member organisations with regulatory roles, on issues related to its mission, objectives and remit.
- 5 Prepare, publish and disseminate reports of the survey findings;
- 6 Write articles to be published in the FIP International Pharmacy Journal (and possibly other journals) presenting the main findings and key messages.

11 Financing of the Advisory Group

The operational cost of the Advisory Group will be covered by the FIP central budget.

Annex: History and background to the FIP Forum of Pharmacy Professional Regulators

As Professor Emeritus Lloyd Sansom, AO, University of South Australia described at the FIP Congress in Glasgow, 2018:

“The pharmacy profession is one of the more regulated professions. The intent is to optimise health outcomes and to protect the population by ensuring that those practicing the profession are competent to do so within their defined scope of practice. Further, regulations may have to define the standards of practice although these are often developed by professional societies and adopted by regulators as the benchmark of standards for professional conduct.

Competence is a measure of both proven skills and proven knowledge and thus regulators must provide mechanisms for the definition, development and assessment of competencies in a given individual practitioner. This will involve the requirement to accredit educational institutions, training sites and continuing professional development programs and to provide competency assessment tools.

The recognition of pharmacists with qualifications from outside the jurisdiction of the regulator require mechanisms to ensure these persons are competent to practice in the country in which they are seeking registration as a pharmacist.

With the rapidly changing environment of health care it will be necessary to consider competencies which relate to advanced practice and whether restriction of certain professional activities to “specialists” will be needed to ensure the public is protected.

The increasing role of the pharmacist in primary care will create provide the profession with new opportunities. However, the need to ensure that the pharmacists have the skills and knowledge to perform at the required level to protect patients and to make a positive contribution to their health will be an increasing challenge to regulators.”¹

Professional organisations with regulatory functions play a decisive role in overseeing the profession and setting standards of practice, ethical conduct and public protection, namely by regulating workforce capacity and sustained performance and the scope of practice of pharmacists, to ensure patient safety and optimal health outcomes. Mandatory registration in the organisation provides an opportunity to reach out to the entire profession and to foster its cohesiveness. Such roles, however, are paired with great strategic responsibilities and tactical challenges that, despite the particularities of each country, often have common elements across the world.

Also, in an increasingly globalised world, pharmacists often practice in countries with different professional cultures and health care needs from those of the places where they received their foundational training. This may generate challenges for individual practitioners as well as the profession as a whole, but also great opportunities.

¹ Sansom, Lloyd. 2018. *Contemporary challenges facing regulators from across the globe* (Abstract). Keynote lecture at the session “Professional regulation in a global(ised) environment - challenges and opportunities”. 78th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Glasgow, Scotland, UK. 5th September 2018

With the above background in mind, FIP, in collaboration with Commander Sylvain Grenier (Canada), the National Association of Pharmacy Regulatory Authorities (NAPRA, Canada) and the National Association of Boards of Pharmacy (NABP, USA), organised a meeting at the FIP Congress in Glasgow (September 2018). For that meeting, organisations with regulatory responsibilities (both FIP members and non-members) were invited. Approximately 25 organizations attended the meeting and provided an introduction of their regulatory role.

The proposal under discussion was to establish a permanent forum for pharmacy professional regulators, where they may share their concerns and best practices among peers. There was broad support to this concept and a consensus that this forum of regulators is unique at global level, and that there is great interest in establishing it and organising collaboration and meetings on a regular basis. The FIP congress was considered a unique opportunity for this. This forum may address priority issues proposed by these member organisations themselves.

At the Glasgow meeting, it was agreed that the following organisations will serve on the steering committee until the Forum is formally established:

- Pharmacy Board of Australia
- National Association of Pharmacy Regulatory Authorities (Canada)
- French Chamber of Pharmacists
- Federal Union of German Pharmacists Associations
- Jordan Pharmacists Association
- National Association of Boards of Pharmacy (USA)

Commander Sylvain Grenier was appointed chair of the Steering Committee.

In 2023, the Bureau decided to change the name of the group was from Regulators Forum to Regulators Advisory Group.