PSI - The Pharmacy Regulator

Regulatory Risk Statement

2019-2021

PSI
The Pharmacy Regulator
An Rialtóir Cógaisíochta

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Introduction

Regulatory bodies, such as PSI, exist in part to identify and respond to risk within their particular domains of activity. These domains exist across a wide range of activities within modern societies to include such areas as financial regulation, utilities regulation, food safety regulation, environmental regulation, occupational safety regulation, transport regulation and health and social care regulation. Despite the differing requirements of regulation across these disparate domains, the necessity and challenge of how best to understand and define their particular risks is one which is familiar to all regulators.

This necessity and challenge is one which PSI recognises. We are committed, under our current Corporate Strategy (2018-2020) to an ongoing programme of work to ensure that the organisation develops the strategies, structures, procedures and activities that are required to ensure PSI is a highly-effective regulatory body.

Our Mission is to protect and promote the health, safety and wellbeing of patients and the public by taking timely and effective action to ensure that pharmacists in Ireland are competent and that pharmacies are operating to high standards of safety and reliability. The Regulatory Risk Statement will ensure that as a regulatory body, we have everything in place to address risks arising within our particular field of regulation.

Our Vision is that the public has access to trusted pharmacy services and that the PSI makes a clear and demonstrable contribution to the availability and quality of those services. The PSI envisages that the Regulatory Risk Statement will ensure a reduced risk of harm to the public by the effective mitigation of regulatory risk.

Our Values are set out under our current Corporate Strategy (2018-2020) and underpin how we deliver on our Mission. Our Values ensure that the Regulatory Risk Statement is fulfilled in a way which will meet the high standards expected of public bodies[1]:

- Serve the public
- Everyone Counts
- Work Together
- Lead by example
- Embrace Change

This Statement on regulatory risk is intended to set out in clear terms how we define regulatory risk in PSI. Based on this definition, a regulatory risk framework states how we identify, analyse and respond to regulatory risk across all of our areas of responsibility.

Recognising that risk is always changing and that regulators need to adapt and develop their definitions and responses over time, this Regulatory Risk Statement is intended to cover an initial three-year period, 2019 to 2021.

[1] PSI Corporate Strategy (2018-2020)

During this period, our learning in relation to regulatory risk will develop, as will our capability as an organisation to address risk and to use a range of regulatory responses.

The strategic background to regulatory risk in PSI

The core principle underpinning the management of regulatory risk within healthcare is that the regulator should focus on those risks which have the greatest potential to impact on patient safety[2]. Accordingly, risk based regulation promotes, and requires, robust governance by regulators, contributing to the efficient and effective use of regulatory resources and enabling the delivery of a response or intervention which is proportionate to the risk posed[3].

For PSI, the management of regulatory risk offers a means of prioritising attention to the most critical risks to patient safety in line with a transparent, systematic and defensible framework. This involves a process of applying a variety of regulatory instruments in a manner which is flexible and sensitive to the risks identified[4].

To date, PSI has used a mix of approaches to address regulatory risk across our various functions. Since 2007, the organisation has amassed considerable experience as to how these various approaches have worked in practice. In keeping with the overall goal of the current PSI Corporate Strategy 2018-2020, which commits PSI to "Assure trust in pharmacy through effective regulation", now is an opportune time to review how we address regulatory risk and to develop a clear strategy which addresses risk, in a coordinated way, across the **full range of our regulatory responsibilities**. In particular, this will support us in "promoting professionalism and quality in pharmacy" and in creating conditions whereby PSI is "regulating effectively for better health outcomes and patient safety.

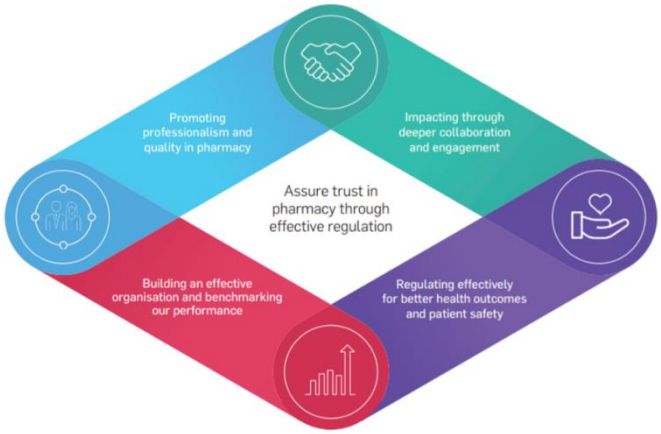

Diagram 1: PSI Corporate Strategy (2018-2020)

[2]Baldwin R and Black J (2016) Driving priorities in risk-based regulation: what's the problem? Journal of Law and Society, 43 (4). pp. 565-595.

[3] Rothstein H, Irving P, Walden T and Yearsley R (2006) The risks of risk-based regulation: Insights from the environmental policy domain. Environment International 32(8):1056-65, January 2007. Available at: https://www.researchgate.net/publication/6942588_The_risks_of_risk based_regulation_Insights_from_the_environmental_policy_domain

[4] Black J and Baldwin R (2010) Really responsive risk-based regulation. Law and Policy, 32 (2). pp. 181-213.

PSI is committed to becoming an efficient and effective risk-based regulator. The capacity and ability of the organisation to achieve this goal has been demonstrated previously, including by the roll out of successful developments such as the Core Competency Framework in 2013, the Pharmacy Assessment System in 2016/2017 and the review of the Code of Conduct in 2018/2019. These individual achievements are positive drivers for quality improvement within retail pharmacy businesses (RPBs) as well as being examples of how PSI is developing as a responsive regulatory body.

In the period 2019 to 2021, the PSI will implement further developments which, together, will provide evidence that PSI is a risk-based regulator and is committed to identifying and addressing regulatory risk. The approach to regulatory risk adopted by the PSI will cover all four of the strategic results areas as outlined in the PSI Corporate Strategy diagram (above):

- Promoting professionalism and quality in pharmacy
- Impacting through deeper collaboration and engagement
- Regulating effectively for better health outcomes and patient safety
- Building an effective organisation and benchmarking our performance

Principles of regulatory risk management in PSI

Through extensive background research into various regulatory concepts the PSI is adopting principles in relation to the management of regulatory risk, over the period 2019 to 2021. These principles are Patient Safety First[5], Necessity, Effectiveness, Proportionality, Transparency, Accountability, Consistency[6] and Agility[7].

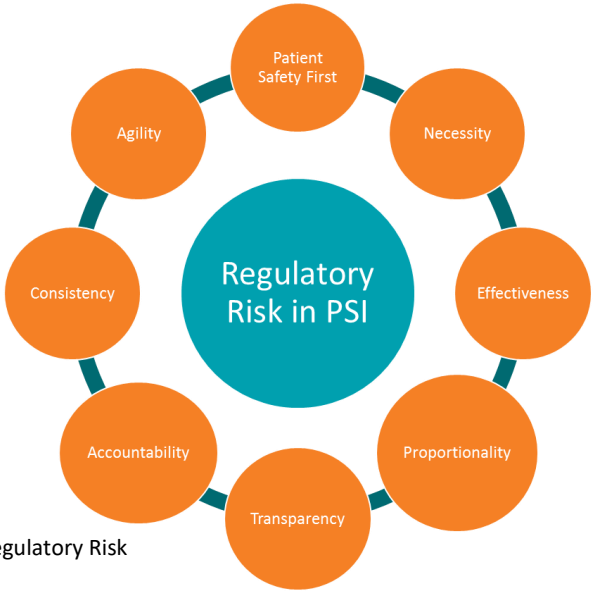

Diagram 2: Principles of Regulatory Risk Management in PSI

[5] Madden, D. (2008). Building a culture of patient safety–report of the commission on patient safety and quality assurance. *Department of Health and Children*, *3*.

[6] Ireland. Department of the Taoiseach. (2004). *Regulating Better: A Government White Paper Setting Out Six Principles of Better Regulation: Executive Summary*. Stationery Office.

[7] Professional Standards Authority. (2015). Right-touch Regulation Revised.

PSI's definition of regulatory risk

The PSI defines regulatory risk as:

'The risk of harm arising to the public from the actions or inactions of those we regulate'.

The PSI is responsible for the regulation of the pharmacy profession, retail pharmacy businesses and higher educational institutions. Therefore, the Regulatory Risk Statement will encompass the full spectrum of regulatory responsibilties held by the PSI. This includes but is not limited to, education and qualification recognition, registration, compliance with the PSI Code of Conduct for pharmacists and Continuing Professional Development (CPD), and any other processes which underpin the regulation of the pharmacy sector.

The definition and understanding of regulatory risk by the PSI will evolve in line with significant ongoing changes and developments within the organisation. Ultimately, and very importantly, our work on regulatory risk will help prevent harm to patients by making pharmacy a safer environment, through effective risk-based regulation of pharmacies and pharmacists.

Engagement & Communication

The PSI's contribution to public safety, health and wellbeing rely on us sharing and receiving insights and information to realise better health outcomes for the public. Therefore, in line with our current Corporate Strategy, PSI will embrace new ways of engaging and communicating internally and externally with the public, registrants and stakeholders.

Internally, appropriate resources will be allocated for both PSI staff and Council to enhance their learning and development needs, with particular emphasis on the identification, analysis and management of regulatory risk. A **risk-aware culture** will be promoted across all functions within the organisation, thus supporting the PSI to achieve its Mission, Vision and Values as set out in this Regulatory Risk Statement.

One way we plan to do this is by engaging with stakeholders, such as pharmacists, superintendent pharmacists and pharmacy owners, in the co-design of themed reviews within key areas of pharmacy practice, (e.g., controlled drugs management). The publication of new themed review overview reports will recognise, encourage, guide and support ongoing quality improvement by pharmacists and RPB's.

Furthermore, ensuring transparency, new types of pharmacy inspection reports, such as themed reviews, will be published in the future, which will acknowledge good practice and quality outcomes found during inspections conducted. The reports will also highlight those pharmacies which do not meet key requirements, pose a risk of causing harm to patient safety and which fail to discharge their duty of trust to the public. By publishing more extensive information on fieldwork results, the PSI will improve public understanding of what good pharmacy practice looks like and will increase awareness of the standards that

should be expected by all who receive care, advice and treatment in pharmacies from pharmacists.

The PSI will communicate fieldwork findings so that the public and the sector understand how the regulatory structures in place operate to help assure accountability and public trust in pharmacy.

Effective, extensive and proactive engagement and communication is a core priority for the PSI. As an organisation, we will continue to work openly and transparently, and in collaboration with the public, registrants and a wide network of stakeholders.

Commitment to the Public

The PSI is committed to evolving its stance on regulatory risk over 2019 to 2021 by exploring new ways of regulating. The PSI will embed what it has learned in the past and adopt **contemporary regulatory approaches**, which will ensure a positive impact on health outcomes and patient safety. For example, the PSI will seek substantial revisions to the scheme of regulation set out under the current Pharmacy Act. These reforms will, in due course provide the PSI with new tools and approaches to drive regulatory effectiveness and efficiency as well as providing new channels of information.

The PSI will continuously review the Regulatory Risk Statement and will adjust the Statement in line with evolving and dynamic developments within the regulated pharmacy sector. We will listen and learn from any feedback received, which will build trust, confidence and credibility in our approach to risk management. This commitment by the PSI will help ensure that the management of regulatory risk is an integral part of how we function as a regulatory body and of how we carry out our regulatory functions.

Appendix 1- Research Overview

Throughout the development of the Regulatory Risk Statement, PSI conducted research concerning risk, regulatory risk and risk based regulators. A brief overview of the research process is demonstrated below:

Diagram 3: Research Overview for Regulatory Risk Project

The Registrar of the College of Veterinarians of Ontario delivered a seminar on *'Managing Risk and Demonstrating Regulatory Effectiveness' to the PSI.* This was beneficial to the organisation for the development of the Regulatory Risk Statement.

An internal Steering Group comprising of four members of the ELT was established in order to guide and support the growth of the strategy document. The Regulatory Risk Project is overseen by the Regulatory and Professional Policy Committee (RPPC), an advisory committee to the PSI Council. The RPPC role is to advise and support the PSI Council to develop strategy and policy in relation to regulatory and professional matters.

Appendix 2- Regulatory Risk Framework

The PSI will always endeavour to prevent the risk of harm arising to the public by **assuring trust in pharmacy through effective regulation**. Despite this, there are circumstances in which regulatory risks do arise. The PSI has developed a Regulatory Risk Framework consisting of a risk management cycle underpinned by a regulatory risk cascade and a regulatory risk and response group.

The PSI defines regulatory risk as 'the risk of harm arising to the public from the actions or inactions of those we regulate'. Consequently, management of regulatory risk by the PSI will focus predominately on identifying, analysing and responding to regulatory risks which may give rise to potential harm to patients. The PSI will also monitor and evaluate any risk mitigation plans implemented. Such evaluation and monitoring will confirm that any risk mitigation responses in place adhere to the Principles of Regulatory Risk Management discussed in the Regulatory Risk Statement; Necessity, Effectiveness, Proportionality, Transparency, Accountability, Consistency, Agility and Patient Safety First. How PSI will manage regulatory risks can be seen in the Risk Management cycle:

Diagram 4: PSI Regulatory Risk Management Cycle

NOTE: The PSI Regulatory Risk Strategy will not identify or manage corporate risks to the PSI, as these are managed internally within the corporate risk register and the underlying unit risk registers. However, some regulatory risks may require escalation to the PSI corporate risk register.

Notification of Regulatory Risk

The PSI obtains and retains information concerning regulatory risk from various data sources. This data once analysed will be escalated through a risk mitigation cascade, where a proportionate response will be decided upon.

The PSI has various data sources which will be used to identify regulatory risks, some of these are demonstrated below:

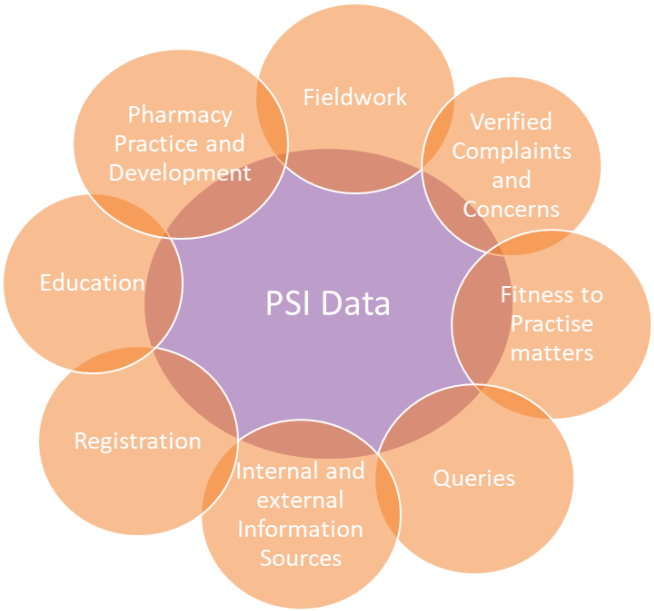

Diagram 5: PSI Data Sources

The development of a new PSI registration database will enhance and facilitate the collection of data from the sources mentioned above.

Identifying & Analysing Regulatory Risk

In order for the PSI to prioritise regulatory risk over the period 2019-2021, it will require a commitment from all functions within the organisation, to actively and consistently engage in the identification of any potential regulatory risks. Therefore, the PSI will assign resources for staff to be trained to an appropriate level, enabling the identification of any potential regulatory risks through information sources that staff may deal with on a day to day basis. The PSI has already embarked on a Business Transformation journey, which will deliver a new registration database, which will facilitate the future analysis of regulatory risks. By adopting this approach, the PSI will be able to build a culture which is risk-aware, and which is effective at building a patient safety agenda.

Regulatory risks which have been identified by the PSI will be categorised into two main types of risk:

1. Current Practice Risks

Current Practice Risks include **systemic risks** which relate to policies and procedures, and **regulatory risks** relating to pharmacists and retail pharmacy businesses (RPBs).

- Systemic Regulatory Risks
  - These risks will encompass legislation, education and registration.
- Pharmacist Regulatory Risks
  - These include pharmacist registration and qualification recognition, fitness to practice and competence.
- Retail Pharmacy Business (RPB) Regulatory Risks
  - These include registration of RPBs, governance and accountability within RPBs, compliance by RPBs with relevant regulations, standards and guidelines.

Current Practice Risks must be mitigated by the PSI in a conscientious and systemic way in order to minimise the scope for harm to occur and, hence, to protect patient safety, by building a risk aware culture and promoting a patient safety agenda.

The diagram below illustrates how current practice risks will be categorised prior to being analysed and an appropriate response being decided upon.

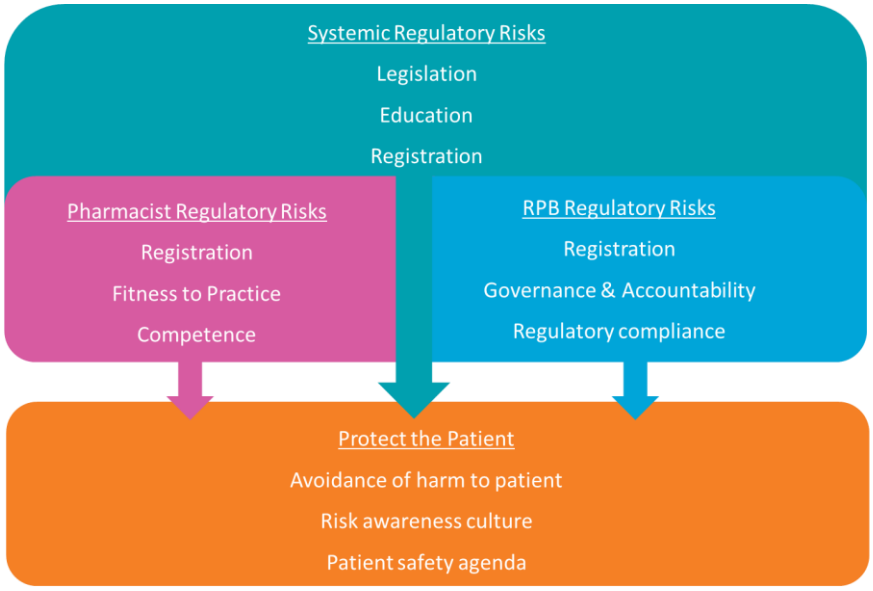

Diagram 6: Current Regulatory Practice Risks

2. Emerging Regulatory Risks[8]

Emerging risks are those which are emerging or developing within the regulatory environment, comprising of public, practice and governance risks.

[8] The College of Veterinarians of Ontario

Emerging risks can also include invisible harms. Commonly low rates of reporting or detection are associated with invisible harms, making the risk 'invisible' to the regulator as well as to other stakeholders. Additionally, the underlying scope may be uncertain, and it may be difficult for the PSI to predict the effects of any intervention[9]. Despite this, PSI must be competent in this particularly challenging area of risk management.
To identify, manage and mitigate emerging risks, PSI will proactively scan incoming information relating to regulatory risk within the pharmacy sector and thus will endeavour to safeguard the public from harm.

Regulatory Risk Assessment

In order for the PSI to protect patient safety it must ensure that both current regulatory practice risks and emerging practice risks are assessed and responded to in an effective, efficient, consistent and timely manner.

The PSI will establish a **risk mitigation cascade** (see diagram 7), which will provide an internal infrastructure to identify, analyse, assess and mitigate regulatory risk, with a proportionate response or action. This will help ensure that the appropriate organisational infrastructure is in place, allowing risks to be prioritised at a point which is proportionate to the level of potential harm which may arise, thus facilitating a suitable action or response to be taken by the PSI.

Regulatory Risk Analysis and Response Group

A **Regulatory Risk Analysis and Response Group** (reporting to the Executive Leadership Team) will be formed, and the Group will be responsible for analysing and assessing current practice regulatory risks, which have been identified, and deciding on effective, proportionate and consistent responses. This will be done in conjunction with the risk management cycle, as demonstrated in diagram 4.

The Group will assess the scale of identified risks and an appropriate response will be identified to mitigate the risk to an acceptable level or as low as reasonably practical (ALARP[10]). Utilising the ALARP principle will enable the PSI to respond to identified risks proportionately. Risks may not be eliminated in their entirety, but the risk of harm arising from them will be minimised to a tolerable level.

Emerging risks will be identified through the risk mitigation cascade, by the Regulatory Risk Analysis and Response Group. The Group will scan for, identify and analyse any new and emerging risks within the PSI's regulatory remit. By taking a holistic view of risk and, hence,

[9] Sparrow M. (2008) The Character of Harms: Operational Challenges in Control, Cambridge University Press, Cambridge.

[10] Available at: http://www.hse.gov.uk/risk/theory/alarpglance.htm

detecting any developing or emerging concerns at this early stage, this structure will allow PSI to be agile in its responses and to adopt a proactive approach in mitigating these regulatory risks before patient safety is compromised.

Terms of Reference for the Regulatory Risk Analysis and Response Group will be created and this will determine the function and scope of the Group. In order to facilitate the Group having an appropriate level of expertise in risk management, the PSI will allocate resources for training and support in this area, allowing Group members to fulfil their roles effectively.

When the Group is in operation, it will design a risk analysis tool, ensuring that all regulatory risks brought to their attention are identified, managed and responded to consistently across the organisation. The development of a risk analysis tool will include:

- Establishing the context in which the regulatory risk management process will take place[11]
- Defining the criteria against which risks will be evaluated
- Implementing an analysis structure/ procedure

The flow of regulatory risk data through the organisation can be seen in the following diagram, from the initial data source to the Executive Leadership Team (ELT) and PSI Council. In terms of overall governance within PSI, the Council will be briefed on significant emerging regulatory risks, and proposed responses, by the Registrar on a regular basis, both directly and via the Regulatory and Professional Policy Committee of Council.

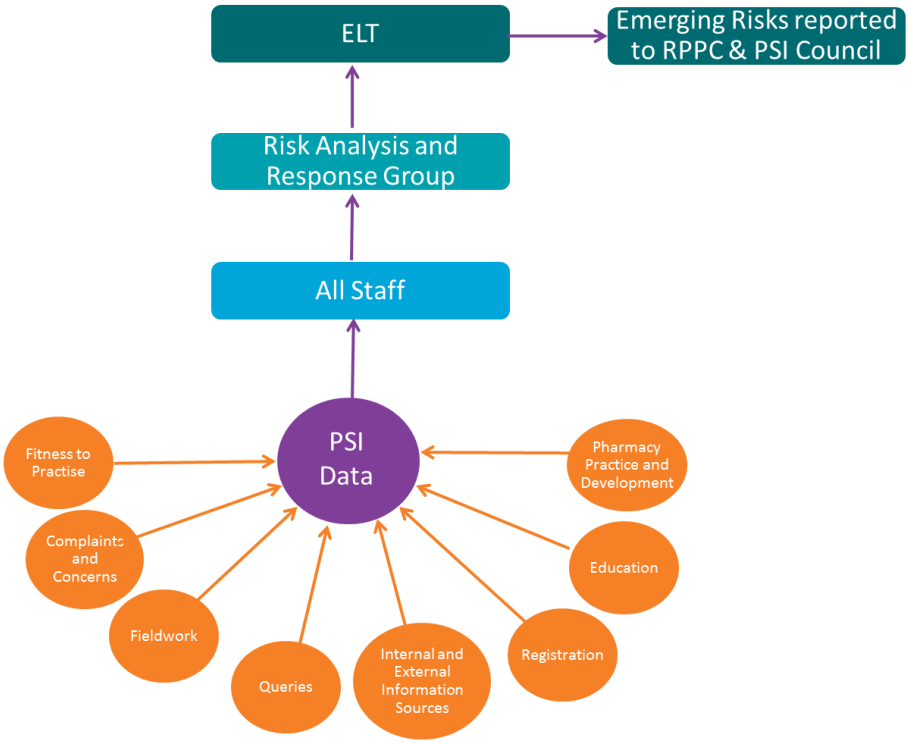

Diagram 7: PSI Regulatory Risk

[11] https://www.hse.ie/eng/about/qavd/riskmanagement/risk-assessmentin-the-hse-information-handbook.pdf

Following the escalation of regulatory risks to the Risk Analysis and Response Group, the ELT will be informed of both emerging risks and practice risks which are deemed a critical risk to patient safety.

Regulatory Risk Mitigation Response

Various regulatory tools and approaches will be utilised by the PSI to ensure that the responses to regulatory risks are agile, necessary, effective, proportionate, transparent, and consistent and put patient safety first. Approaches which will be considered when determining a response to regulatory risks include:

- Responsive Regulation Pyramid

When deciding upon a suitable regulatory response the PSI will reflect upon Ayers and Braithwaite's[12] enforcement pyramid. Regulatory responses begin at the base of the pyramid and escalate in response to an increase in risk of harm to patients. However, if there is a potentially catastrophic risk to patient safety, it may not be feasible for the PSI to work through the various layers of an enforcement pyramid, and the most appropriate response may be to resort to a higher level of enforcement.

Taking the Ayers and Braithwaite model into consideration, the organisation aims to develop a unique PSI responsive regulation pyramid as the Regulatory Risk Statement progresses over the next three years.

- Engagement and Communication

The PSI will deepen its engagement and communication with other healthcare regulators as well as with other relevant public bodies and stakeholders. These collaborations will ensure that the regulatory responses used by the PSI to mitigate regulatory risk are **evidence-based** and **effective**, ensuring that risks are addressed holistically and systemically. The PSI will be transparent with registrants and pharmacy owners surrounding regulatory risks identified and will communicate with the profession on actions that the organisation has taken to mitigate risk and protect patient safety.

[12] Ayres, Ian & Braithwaite, John, 1995. "Responsive Regulation: Transcending the Deregulation Debate," OUP Catalogue, Oxford University Press

Monitor and Evaluate Regulatory Risk Response

The Risk Analysis and Response Group will continually review and evaluate its work on regulatory risk, in an ongoing cyclical process linked to the corporate planning cycle. A **'Use and Learn'** phase will be adhered to, in relation to the identification and management of regulatory risks processed by the PSI. This process will be evaluated using the RADAR[13] framework which is an integral part of the EFQM Excellence Model.

By continually monitoring and evaluating risk mitigation plans, the Risk Analysis and Response Group will verify if the response utilised adhered to the 8 principles the PSI has chosen as the building blocks of its regulatory risk strategy, and ultimately mitigated the risk of harm to as low as reasonably practicable.

The 'Use and Learn' phase will support the PSI's ambition to embrace change and continuously improve as an innovative regulator in the domain of regulatory risk.

The PSI will monitor and review the effectiveness of all stages within the risk mitigation process. This will be done by the Regulatory Risk Analysis and Response Group. The Group will document each stage of the process to ensure that evidenced-based decisions are recorded. This evidence will facilitate the development of continual improvement and learning about the management of regulatory risk by the PSI.

[13] Available at: https://www.efqm.org/index.php/knowledge-base/what-is-radar-and-where-can-i-find-more-information-about-it/