GOOD REGULATORY PRACTICES

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Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

1 HISTORY

This is the first edition of these guidelines.

2 APPLICATION - Guideline for Regulators

This document is intended for use by the officers of DRAP and is implemented on all the regulatory procedures carried out by officers of DRAP.

3 PURPOSE

3.1 The objective of this guideline is to outline the internationally accepted principles of GRP and its application to the national rules / regulations / policies and guidelines. Intention of this policy is to describe the process, by which the DRAP will develop, amend or revise rules / regulations / policies and guidelines following the principles of GRP.

3.2 DRAP will continuously review, revise and implement rules/regulations in a transparent, non-discriminatory and a predictable manner by also involving stakeholder. Once implemented, there is a process for monitoring their impact, effectiveness and improvement whenever appropriate.

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4 INTRODUCTION

4.1 It has been recognized that development of an effective regulatory system is need of time for Drug Regulatory Authority of Pakistan (DRAP). It is expected that system strengthening will lead to healthier public health outcomes. Regulations are essential part of workforce and in-efficient regulation can be a barrier to the access of safe, effective, and quality products.

4.2 It is the responsibility of the Federal Government to regulate the safety, efficacy and quality of therapeutic products marketed in Pakistan. Under this obligation, Federal Government has promulgated DRAP Act, 2012 and Drug Act, 1976 for governing the safety, effectiveness and quality of drugs, medical devices and alternative medicines & health products available to public.

4.3 Good regulatory practices provide a mean for establishing a system of effective and practical regulations of therapeutic goods. Application of those laws for which compliance is mandatory may be supported with the instruments such as pharmacopeial monographs, international standards and regulatory guidelines for harmonization and smooth execution. In general the GRP may be described as a set of practices that are to be applied for establishment and maintenance of controls, including law, rules, regulations, policies and guidelines in order to achieve a public health policy objectives.

4.4 DRAP is continuously promulgating, reviewing, revising and implementing rules / regulations / policies / guidelines through a transparent, non-discriminatory and an established process through involvement of stakeholder. Once implemented, there is a process for monitoring their impact, effectiveness and improvement whenever appropriate.

4.5 Foundation pillar of GRP are transparency, good governance and government policy. GRP help to ensure that national regulatory system remains coherent and flexible for international harmonized regulatory practices as technology evolves. GRP also takes into accounts compliance with international treaty obligation and agreements.

5 DEFINITIONS AND ACRONYMS

Good Regulatory Practices: "These are internationally recognized processes, systems, tools and methods to improve the quality of regulations and ensure that regulatory outcomes are effective, transparent, and inclusive and sustained (World Bank, 2015)."

6 GUIDING PRINCIPLES

6.1 Legality: Regulation should have sound legal basis.

6.2 Impartiality: Regulations and regulatory decisions should be impartial, fair, transparent and avoid conflicts of interest.

6.3 Consistency: Regulation should be clear and predictable to both regulators and the regulated party. Expectation of both party should also be clear.

6.4 Proportionality: Regulation and regulatory decision should be linked to risk and should not exceed what is necessary to achieve the objective.

6.5 Flexibility: It should be prospective and allow flexibility.

6.6 Effectiveness: Effective regulations are those that achieve the intended public health goals.

6.7 Regulations achieving the intended public health goal, should be periodically assessed using performance based indicators.

6.8 Efficient: Efficient regulations are those that achieve the intended goals within defined timelines.

6.9 Clarity: Rules / regulations / policies and guidelines must be clear and be drafted in a language and form consistent with local laws.

6.10 Transparency: Process of developing rules / regulations / policies / guidelines should be clear, transparent and have proper consultation with the stakeholders and with the general public (if needed).

6.11 A policy making process within DRAP requires an examination of benefit and risk to clear severity of the problem. Policy making process involves a step by step approach in light of the information and by use GRP principles of transparency and clarity along with the due consideration of affected parties. A regulatory impact

analysis is a valuable tool for the systematic assessment of the expected outcome of any regulatory proposal.

7 REGULATORY IMPACT ANALYSIS (RIA) PROCESS

7.1 A policy-making process within a health regulatory context should involve an examination of benefit and risk so that the severity of the issue is clear. Policy making is an iterative process where the GRP principle of transparency and consultation is needed. The process also requires a regulatory impact analysis as described in the following figure.

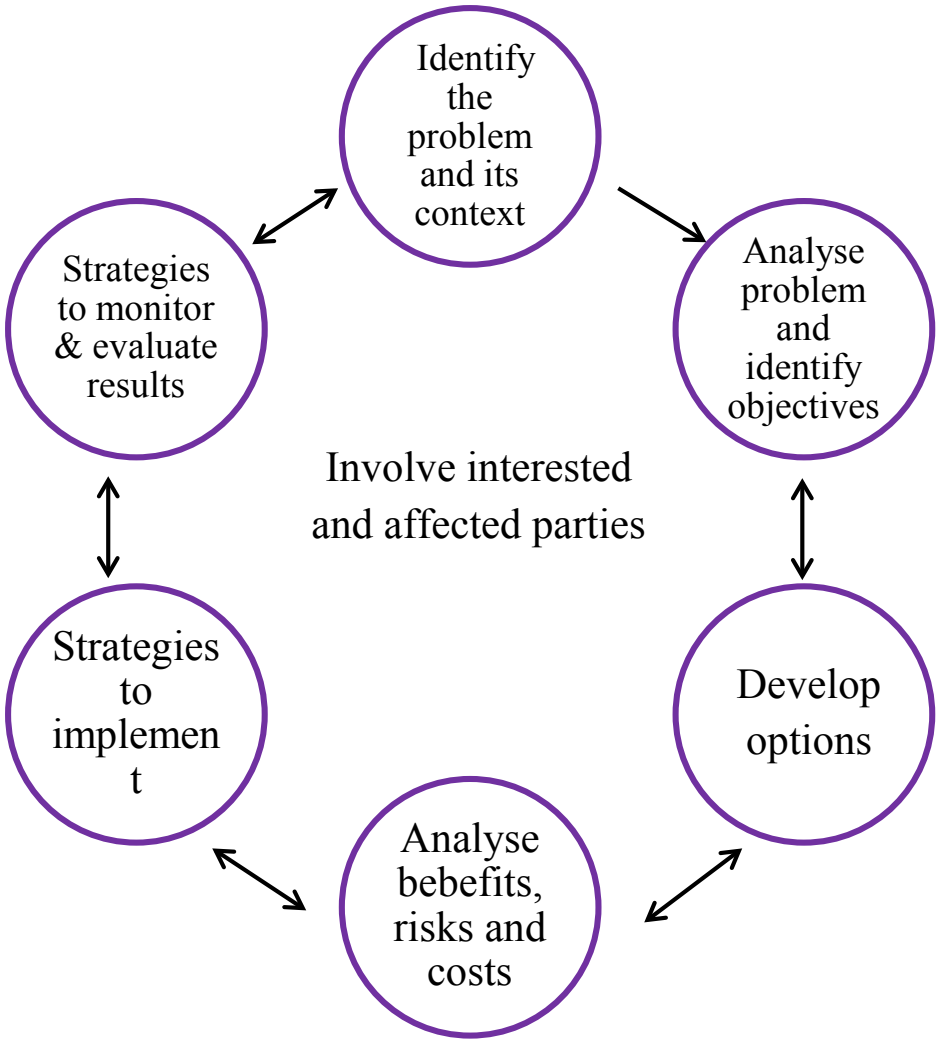


Figure 01: Regulatory impact analysis (RIA) process

7.2 The regulatory impact analysis process will demonstrate the advantages and disadvantages of option so to resolve the problem. For instance, an option may be judged as risky if compliance is expected to be low. Impact of regulation is often judged in terms of its cost to the regulated industry. However, the analysis should not overlook the cost and other impacts on the regulator, the public health sector or the consumer. The RIA process also includes consideration of all concerns on implementation and monitoring the effectiveness of the proposed regulation following implementation.

8 MONITORING AND EVALUATION

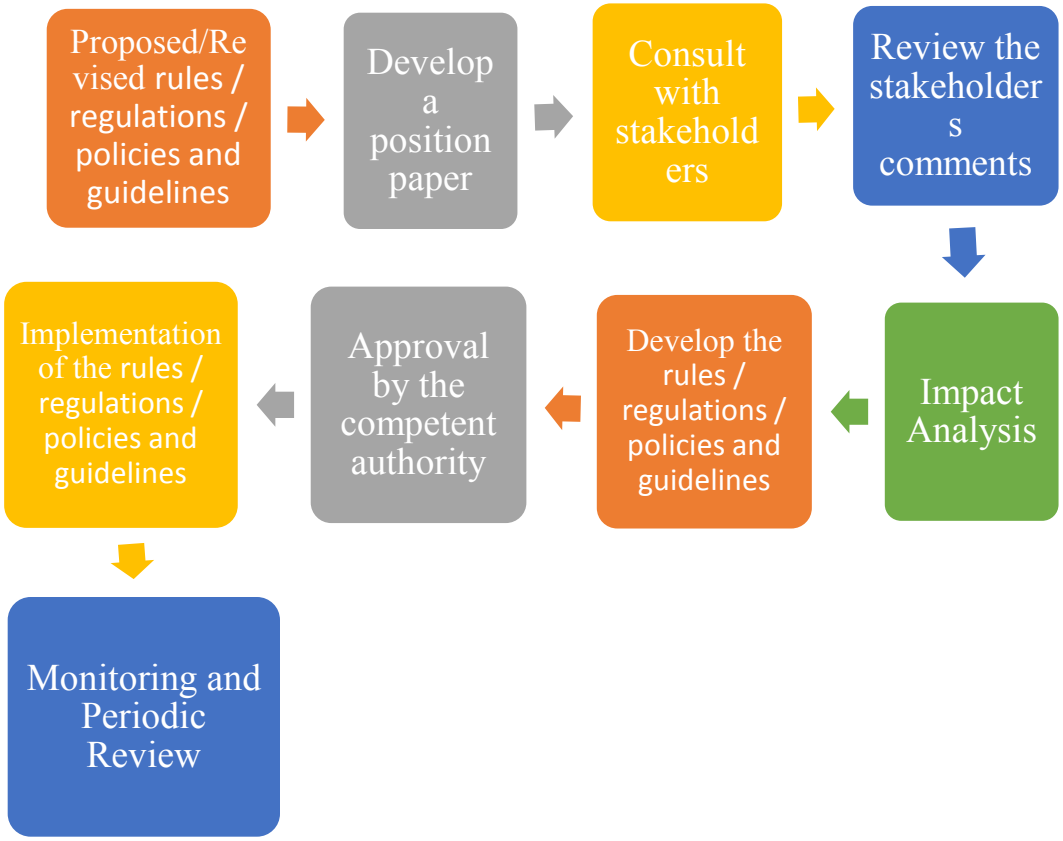
8.1 The RIA process can evaluate the potential impact of proposed rules / regulations / policies and guidelines before these are selected and implemented. In addition to the monitoring and evaluation plan there should be also be a periodic review.

9 RESPOSIBILITIES

9.1 It is the responsibility of all members of the DRAP to follow the policy and uphold the guiding principles.

10 PROCESS MAPPING

10.1 Process mapping is explained in the following figure.



9. REFERENCES

9.1. DRAP Act 2012 Section 7 (d), (r) and (w)

9.2. Established procedure under QMSC/SOP/QT/007 and QMSC/SOP/TP/010