REDUCING REGULATORY BURDEN

Evaluating Regulatory Reforms
Methodology Note

1 INTRODUCTION

Pakistan's federal Board of Investment spearheaded an ambitious regulatory reform initiative – the Pakistan Regulatory Modernisation Initiative (PMRI) - in June 2021, under which 115 reforms have been carried out so far. This methodology note is the final report that provides a framework for evaluating regulatory reforms, based on a case study of the healthcare sector reforms conducted under the PMRI.

The report is commissioned by the **Revenue Mobilisation, Investment and Trade (REMIT)** program, on request of the federal Board of Investment of the Government of Pakistan.

1.1 The REMIT Programme

The Adam Smith International (ASI) component of the Revenue Mobilisation, Investment and Trade (REMIT) is a 39-month (2021 – 2025) programme funded by the UK's Foreign, Commonwealth and Development Office (FCDO). The programme provides technical assistance (TA) to the Government of Pakistan in implementing reforms for *strengthening macroeconomic stability and improving conditions for higher and sustained growth, mutual prosperity, job creation and poverty reduction*. The programme works towards supporting the Government of Pakistan, its relevant ministries, institutions, and departments to strengthen its tax revenue mobilisation reforms/initiatives; address investment climate and business environment challenges; facilitate trade and drive competitiveness by reducing barriers to trade; and improve the macroeconomic policy and its management.

This report falls under the **Investment Climate** component of REMIT, which focuses on supporting effective regulatory reforms that will make Pakistan's investment climate and specifically business environment competitive internationally and attractive for domestic investors.

1.2 Objectives

The objectives of the assignment are to:

i. Develop a Pakistan context relevant regulatory impact evaluation methodology and undertake an ex-post impact assessment of a few substantial reform areas implemented under PRMI
ii. Assess and help develop a strategic response to enable BOI/notifying bodies to reduce the transaction costs of implementing reforms by addressing institutional inertia and resistance to reforms
iii. Work with BOI to test some of these strategies to build evidence on what can work better

1.1 Problem Identification

The research team started with understanding the types of reforms that are to be evaluated. This was done through discussions with the Board of Investment team, and a review of the reforms that have been undertaken. There are 115 reforms in all, spread across 31 sectors. They range from automation of business registration to attempts to simplify getting NOCs for imports and exports in various sectors.

The Board of Investment team noted that it had been challenging to push these reforms through the regulatory departments. The main objective of an independent evaluation was to showcase the value and contribution of the reforms, and buttress political will, public acceptance, and awareness of the reforms. This in turn, would strengthen and pave the way for future reforms.

Discussions with the BOI team and a review of the listed reforms also revealed several important features which impact the choice of methodology. First, the reforms are largely sector-specific and there are several reforms clustered in certain sectors (e.g., healthcare devices, food, and energy sector), implemented almost simultaneously. This means that it will not be possible to disentangle the sector-wide impact of one sector-specific reform from another. Secondly, there was no systematic baseline data available against which to establish a counterfactual. Thirdly, some of the reforms have been implemented very recently, which means that it would be too early to assess impact. Finally, there was a wide variation in the type of reforms: while some reforms reduce the costs and time taken of specific business transactions, others enable new types of economic activity or reduce the costs and availability of inputs to the sector.

With these features in mind, it was agreed that the research team would shortlist a cluster of sector-specific reforms and trace out their individual and economy-wide impacts. The research team shortlisted the solar panels and healthcare devices sectors, since these were the largest clusters. After discussion with the BOI team, the healthcare devices sector was selected since more time has lapsed since the reforms were notified. The reforms for this sector are listed in Table 1 below. (Further details can be seen at **Annex-I**)

Table 1 Regulatory reforms in the Healthcare Devices sector

Sr.	Regulatory Reform	Description
1.	Introduce separate regime for licensing of non-sterile Personal Protective Equipment (PPE) **(06-11-2021)**	**Before:** The manufacturers of PPEs were following a pharmaceutical regime which required them to hire pharmacists and install HVAC systems etc., causing huge financial burden. **After:** Under the new Regime, all such unnecessary requirements have been removed for PPE manufacturers.
2.	One Stop Shop for licensing of Medical Devices https://e.dra.gov.pk/login **(21-08-2021)**	**Before:** License application along with documents had to be physically submitted in DRAP's Islamabad office, causing delay and extra costs to business. **After:** The Registration process has been simplified and automated. Applicants can now submit applications online from anywhere in Pakistan.
3.	Allow approved premises to be used for additional relevant processes such as manufacturing of medical devices	**Before:** DRAP restricted utilization of approved premises for production of other relevant products due to which businesses couldn't utilize extra space in manufacturing of allied products. **After:** Now DRAP has allowed use of approved premises for additional relevant processes such as manufacturing medical devices.
4.	Eliminate requirement of hiring of a pharmacist in a factory making medical devices **(22-11-2021)**	**Before:** Medical devices manufacturing units were required to hire the services of a pharmacist. **After:** Now, requirement for hiring the services of pharmacist is no more required. Factories manufacturing medical devices now can start manufacturing without any such burden.
5.	Eliminate requirement of Drug Sale License (DSL) to obtain license for importing medical devices **(4-06-2021)**	**Before:** For import of medical devices, it was mandatory for businesses/importers to obtain a Drug Sale License without which they could not import, whereas they weren't manufacturing nor selling any drugs/medicines. **After:** The requirement of obtaining Drug Sale License has been abolished for importers of medical devices
6.	Simplification of registration process for low-risk medical devices **(6-11-2021)**	**Before:** The registration process of the Low-Risk Medical Devices was cumbersome and registration process for all the medical devices was same. **After:** With the risk categories of medical devices in place the registration process for Low-Risk Medical devices has been simplified.
7.	Eliminate need for testing/ processing of products already registered by Stringent Regulatory Authorities (SRAs) abroad **(27-04-2022)**	**Before:** It was required that DRAP will test the product and subsequently it will be registered with DRAP **After:** Now any product which is already registered with any of the Stringent Regulatory Authorities aboard may need not be registered with DRAP for import and subsequent use in the country.
8.	Enhancement in validity period of GMP certificate from 1 year to 3 years for manufacturers of medical devices	**Before:** DRAP extended the Good Manufacturing Practices (GMP) certification only for one year which required renewal on expiry and resulting compliance. **After:** To avoid recurring compliance and associated hassle the GMP certification has been extended to a period of 03 years instead of 01 year.

9.	Elimination of unnecessary requirements for renewal of registration for healthcare devices	Data not available yet
10.	Allow authorized distributor to import medical devices on authorization by registration holder, in line with international practices **(27-04-2020)**	**Before:** It was not permitted to import medical devices by authorized distributors after authorization from registration holders. **After:** In line with the international best practices now authorized distributors can import medical devices.
11.	Eliminate restriction of being sole representative to import from OEM **(27-04-2020)**	**Before:** In the medical devices rules it was permitted that only a sole representative can import from original equipment manufacturers. **After:** Through an amendment the condition of sole representative has been done away with.
12.	Repealing of SRO for fixation of Minimum Export Price for Surgical Instruments. (**30-09-2021)**	**Before:** The manufacturers of surgical items could not export goods below the price fixed by the Ministry of Commerce even if it was financially feasible. **After:** This restriction has been eliminated and exporters of surgical instruments can sell goods in accordance with market conditions.

Source: BOI website https://business.gov.pk

1.3 Expected impacts

Regulatory reforms impact not just the target firms, but also the regulator and the wider economy.

For the firm, they can reduce the costs and time taken to meet compliances and receive approvals. They can also reduce uncertainty and risk, improve transparency, protect firms against rent-seeking behavior and informal payments, and improve efficiency (for example through improved access to inputs and consumer markets).

For the regulator, they can increase the efficiency with which they process applications, reducing enforcement costs and helping improve compliance rates. On the other hand, they can also reduce the leverage that regulators have to extract informal payments, and consequently lead to frictions in their acceptance and implementation of the required reforms.

For the economy, a high regulatory burden disproportionately impacts small and women-led firms, as they typically lack the information and dedicated resources to deal with regulatory frictions. Firms report staying small and/or informal to avoid this burden. Therefore, reduced regulatory burden can have the impact of leveling the playing field in favor of small and women-led firms, improving competition, formalization and business confidence, and increasing economic activity. In addition, some kinds of regulatory reform (e.g., allowing the import of a competitively priced input, easing an export restriction, creating suitable rules for venture capital firms to register in Pakistan etc.) can enable new types of economic activity that were not feasible earlier. Enabling new economic activity or reducing end prices can also

have a beneficial impact on consumers, the balance of payments, employment, diversification of the economy etc.

The magnitude of the impact varies based on:

- impact per transaction (e.g., did the firm save Rs. 2,000 or Rs. 200,000 with the reform?)
- number of firms impacted (e.g., did the reform improve the situation for just exporters within the healthcare devices sector, or all SMEs in the country?)
- frequency of transaction (e.g., was it a one-off registration transaction, or a monthly transaction for the life of the firm?)

For the health care devices sector, for example, one of the reforms targets the non-sterile Personal Protective Equipment (PPE) sector. This sector was previously burdened with unnecessary requirements to hire pharmacists, install HVAC systems etc. which were creating a financial burden, without any consequent positive impacts for consumers. The removal of this requirement is expected to have the following impacts:

- For the firm, it reduces costs of manufacturing and administrative time spent in hiring/procuring the resources and showing compliance. This can enable the firm to produce at more competitive prices and gain market share domestically and internationally
- For the regulator, it reduces monitoring resources
- For the end consumer, it reduces the costs of non-sterile PPE
- For the economy, it can lead to increases in production volume and employment, a reduction in imported PPEs and an increase in exports

This was a regular, ongoing costs (rather than a one-off), so has continued benefits.

Similarly, for the one-stop shop for licensing imported and locally manufactured medical devices, the registration process no longer requires physical visits to DRAP's Islamabad office but can be done online. The easier registration process is expected to have the following impacts:

- For the firm, it reduces the costs and time taken for registration of devices (one-off). It can also reduce rent seeking by minimizing physical interaction between firms and officials
- For the regulator, it can reduce physical paperwork and files, and ease digitization and simplification. Additionally, it reduces scope for rent-seeking
- For the end consumer, it can improve access to medical devices
- For the economy, it is likely to marginally increase imports and local manufacturing by providing a quicker, cheaper route to market

Since this is a one-off reduction in costs, the impact per firm is likely to be smaller than that for the PPE reform suggested above.

These examples illustrate the **types** of impact that would be useful to capture in the methodology. The remaining reforms for the health care devices sector fit broadly into these illustrative categories: some are one-off improvements in registration, licensing, exporting or testing procedures and others are continuous reductions in costs from the removal of unnecessary and inappropriate restrictions.

1.4 Techniques for evaluation of regulatory reforms

The identification and selection of evaluation techniques was based on a review of the existing literature on impact assessment methodologies and the international best practice, and interviews with the Regulatory Impact Assessment teams from the World Bank, Pakistan Institute of Development Economics (PIDE), and the UK Department for Business, Energy and Industrial Strategy (BEIS).

Kirkpatrick (2014) discusses several quantitative techniques for estimating the impact of regulatory reform. Many of them are based on aggregated cross-country studies that correlate economic growth of the country with indices on governance and regulatory performance. These studies are useful for establishing the impact of regulatory performance in general at the aggregate country level but are not suitable for establishing the impact of specific reforms. Also, the data of regulatory performance is index based, and is therefore limited to the extent that standardised indices truly reflect the de facto regulatory burden of firms (see Box 1).

There are also some disaggregated studies, such as Klapper and Love (2010) which use panel data to show the negative impact of enterprise set-up costs on the number of business registrations. Similarly, Gutierres and Berg (2000) explore the impact of regulatory governance in the Latin American telecommunications sector, using regression analysis to explore the determinants of number of telephone lines. The determinants include institutional indices for a sound regulatory framework (independence of regulatory body, enforcement powers, neutrality, mechanism for resolving conflict). This set of literature is more useful for us. However, it is data intensive, and requires a time-series of sector-specific data on the size of the sector e.g., production volumes, employment, turnover, which is not currently available. While this approach is unfeasible now, it would be useful to put in place mechanisms to collect the data required for future reforms.

Box 1: Using indices to measure regulatory burden

Indices such as the World Bank's Doing Business Indicators have been useful at comparing improvements in the measured indicators over time, and for benchmarking across countries. In Pakistan, the index was also useful for mobilizing efforts to reduce regulatory burden. For example, the improvement in scores was reported in the press and used politically to demonstrate progress when Pakistan was placed in the Top 20 Improvers on Doing Business 2020 (Dawn 2019). However, for the purposes of evaluation, it is important to be aware of the limitations of such indices, which provide an incomplete picture of true regulatory burden.

Firstly, the areas that are determined quantitatively as the most problematic may not be the ones that are most burdensome or obstructive to growth to firms de facto. A classic example is reduction in time taken to register for a one-off license/approval. Firms that can provide speed money or use a political connection have found an easy workaround. While there is no doubt that this is problematic from the perspective of fairness and competition, the impact on an individual firm of improving the process is likely to be small. Related to this, a one-off process might lead to an overall small impact per firm.

Secondly, the reforms might target outdated, unenforced regulations. Again, while this type of reform is important from the perspective of the regulator and might also reduce rent-seeking, if the regulation was not being enforced in the first place, it would not have a strong impact on the economy.

Thirdly, the indices focus on a narrow set of indicators, largely the administrative burden of compliance, rather than the full social costs and benefit of the regulation and its reform. Some of these fuller impacts have been discussed in Section 1.3. When there is a focus on improving the ranking on the index, it can lead the focus of reforms to those that will move the needle on the index, rather than generating the largest benefits to the economy.

An excessive focus on index-based quantification can therefore risk the credibility of a reform program, as private sector stakeholders do not see the actual benefits being touted by the published figures.

Some of the common quantitative techniques that measure regulatory burden are described below. These are useful to review as they can be used to construct a firm level pre-post comparison of regulatory burden after the reform.

1.4.1 Regulatory Impact Assessment (RIA)

The OECD Regulatory Policy Outlook, 2018 defines RIA as *"Systematic process of identification and quantification of benefits and costs likely to flow from regulatory and non-regulatory options for a policy under consideration" (OECD, 2018, p. 250).*

While definitions of RIA vary, there are several key elements (Box 2), which indicate that its intended purpose is an **ex-ante** assessment of **proposed** regulations. For this purpose, studies have found that requiring RIA for all proposed reforms reduces the number of new reforms as

civil servants become more aware of the negative consequences of poorly designed regulations. For example, Moldova experiences a 39% reduction and the Republic of Korea experienced at 25% reduction in regulatory proposals following compulsory RIA (Lemoine, 2021).

Lemoine (2021) summarises the spectrum of impacts covered by an RIA:

- Impact of the proposed regulation on the public sector (for example, administrative
- costs)
- Impact on the private sector
- Expected benefits from the regulation
- Impact on international obligations or agreements
- Impact on the environment
- Impact on competitiveness and market openness
- Impact on small- and medium-size enterprises
- Implementation of proposed regulations

Since the RIA methodology is designed and usually used for an ex-ante assessment of proposed reforms, it is not directly suitable for the objective of ex-post assessment of implemented reforms. Still, the framework is useful as it defines a set of areas that are impacted by the reforms. These can be incorporated in the proposed methodology.

Box 2: Key Elements in RIA Process

1. Defining a regulatory problem:
   This phase is the preliminary point of RIAs: identifying the regulatory or policy problem. Problems usually fall within 3 categories: market failure, regulatory inefficiencies and new policy targets or objectives.

2. Identifying different regulatory options:
   During this step, the need for regulatory intervention identified in phase 1 must be translated into concrete policy options.

3. Collecting data:
   This phase is crucial and the means to achieve it are diverse and vary greatly among countries. Relevant data for the RIA are collected from public consultations, telephone and face-to-face interviews, paper questionnaires, online surveys, focus groups, etc.

4. Assessing alternative options:
   This central phase of RIAs results in a cost-benefit analysis but can also be a cost-effectiveness analysis or a risk analysis. Options assessed must include the "no policy change" scenario.

5. Identifying preferred regulatory options:
   Once the different options have been identified and scrutinized (usually by comparing the costs and benefits), the comparison of the different options will lead to the identification of the most efficient choice.

6. Communicating results of the conducted RIA:
   Once taken into consideration by the policy makers, best practices suggest publication of the result of the RIA. This allows further exchange with stakeholders and improves the general transparency of the regulatory process.

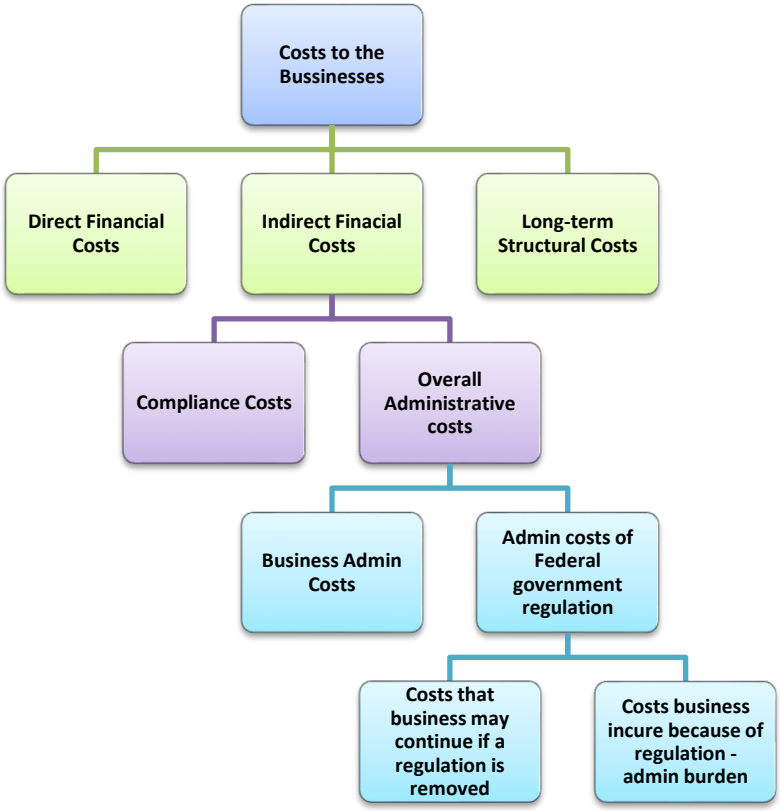
Sources: OECD. 2008. Introductory Handbook for Understanding Regulatory Impact Analysis. Paris: OECD Publishing; International Telecommunication Union (ITU). 2014. "Using Regulatory Impact Analysis to improve Decision Making in the ICT Sector." GSR14 Discussion Paper. Geneva: ITU.

1.4.2 Standard cost model

SCM is a quantitative methodology that **measures administrative burdens and all direct and indirect costs for businesses** imposed by government regulations. It can focus on a single regulation or a cluster of regulations. It can also perform a baseline measurement of all proposed regulations and the consequences of simplification proposals (ex-ante evaluation).

Compliance costs are all the costs of complying with regulation, except for direct financial costs and long-term structural consequences. Administrative costs encompass the administrative activities that the businesses will continue to conduct if the regulations were removed and include administrative burdens that companies must bear because it is a regulatory requirement. These are summarised in Figure 1.

Figure 1: Various compliance costs of regulations



Source: Adapted from Standard Cost Network (2004)

Costs to businesses also include information obligations and their components (data requirements and administrative activities) An information obligation does not necessarily mean that information must be transferred to authority but may include a duty to have information available for inspection or supply on demand. A regulation may contain many information obligations, and each information obligation may consist of one or more data requirements. Businesses conduct several specific administrative activities to provide the information for each data requirement. The SCM estimates the costs of completing each activity.

Cost parameters used to measure each administrative activity include price, time, and quantity.

- **Price:** Price consists of a tariff, wage costs, and overhead expenses for internal administrative activities or hourly costs for external service providers.
- **Time:** The amount of time required to complete the administrative activity can be quantified.
- **Quantity:** Quantity comprises the size of the population of businesses affected and the activity frequency that firms must complete each year.

Combining these elements gives the basic SCM formula:

Cost per administrative activity (or per data requirement) =
Price x Time x Quantity (population x frequency)
(Source: the SCM Manual)

SCM can help to reconstruct baseline data of administrative burdens imposed by government regulations. Once the baseline is measured, it can be used to measure impact of the simplification process (the ex-post impact of the implemented reforms quantifying the factual administrative consequences for the businesses). SCM is also useful for highlighting areas of regulations ripe for administrative-burden reductions. In addition, it incorporates both the magnitude of the impact per firm, the number of times it must be repeated, and the population of firms impacted. This gives it an edge over other methodologies such as the Doing Business index, which capture just the cost per firm per transaction.

For the purposes of this report, SCM will be useful in measuring the impact of the administrative burden of the reforms. For this, baseline data is required to establish a counterfactual, which is not available in this case. However, a second-best approach is to interview impacted firms to record their perceptions of the change in costs/time taken.

SCM cannot however capture the wider impacts of the reform, whether at the firm level, or at the regulator or economy level. Therefore, it will have to be supplemented with other methods.

1.4.3 Sludge Audit

Excessive or unjustified frictions, impediments or burdens imposed by government regulations make it difficult for businesses to operate and add to unwarranted costs. Professor Richard H. Thaler terms these as "**sludge**", aptly illustrating both the negative nature of the impediments, and the impact of slowing down activity (Thaler, 2018).

Duplicative paperwork, time consumed in travelling and seeking registrations, licenses, certificates, waiting in queues or time spent online in completing regulatory tasks or frustration or humiliations faced by individuals all constitute sludge. Behavioural biases and cognitive scarcity make sludge much more harmful than what regulatory authorities may expect. Sludge can significantly hurt small businesses and women-led enterprises disproportionately.

Behavioural science has now modified perceptions about regulations and makes a strong case for behaviourally informed initiatives under deregulation drives. Sludge Audits are used to ensure behaviourally informed regulatory reforms.

Sludge audit is an empirical approach to measure administrative burdens by quantifying various financial and psychological costs and weighing them against regulations' benefits through a careful assessment of their distributional effects. These audits can be highly quantitative, embodying an effort to calculate both costs and benefits, or more qualitative, with an effort to understand what is required to ask to assess whether existing levels of burdens are excessive or not (Sunstein, 2013). The main advantage of the sludge approach over the SCM methodology is the explicit acknowledgement and attempt to measure the psychological costs imposed by the "sludge".

Pakistan Institute of Development Economics (PIDE) is undertaking sludge audits of several selected sectors. As part of its sludge series, PIDE has so far audited processes such as obtaining trade licences, construction permits for high rise building, a new electricity connection, setting up a school or a pharmacy – to highlight the sludge involved in different activities. To assess overall administrative and monetary burdens that firms must bear in carrying out these activities and its impact on economy, PIDE has opted to quantify and compute a wide array of costs. The typical factors covered are illustrated in Figure 2.

While the incorporation of economy or regulator benefits is not included and remains a weakness as in other standardised methodologies described here, the psychological costs, hassle, exposure to rent-seeking etc. are important factors to take on board for the methodology.

Figure 2: Sludge costs of Obtaining a residential construction permit

Source: PIDE: Sludge Series, https://pide.org.pk/pdf/Sludge-Series

1.5 Proposed approach

The approaches described in Section 1.4 are suitable for exercises where standardization is a priority. For example, in the Doing Business methodology, the objective was to find comparable results for a wide range of sectors, types of firms and types of reforms and countries. Therefore, customization and economy-wide impacts were compromised for a narrow and easily quantifiable set of indicators that could be replicated at a low-cost across all the economies.

For the objectives of this exercise to evaluate BOI's reforms, a quantitative cost-time based methodology would be incomplete and unsuitable. Firstly, it would not capture the more important impacts of the diverse set of reforms that BOI has undertaken, such as enabling new types of economic activity and access to markets that some of the reforms allow. And secondly, the subset of reforms is quite small which makes a customized approach feasible. Standardization is a lower-level priority.

Therefore, the proposed approach is to set a **framework** for a systematic identification of the impacts at the first stage. At a second stage, appropriate tools and sources of information are defined. This approach combines some of the relevant features of the standardized, quantitative methods with more flexible perceptions data and expert insights drawn from interviews to capture the full range of impacts. This proposed framework is illustrated below:

Table 2 Framework for ex-post evaluation of reforms

	Indicators	Source of information
Firm level indicators	Costs of compliance	Perceptions data from interviews with firms
	Time taken to meet regulatory requirements	
	Access to inputs and markets	
	Impact on exports	
	Impact on prices, revenue and employment	Perceptions data from interviews with firms Healthcare Devices Association of Pakistan (HDAP)
Regulatory environment	Transparency and rent seeking	Perceptions data from interviews with firms
	Predictability and stability	
	Hassle/psychological costs/business confidence	
	Costs of enforcement	DRAP, PSQCA, Ministry of National Health Services Regulation & Coordination, Min of Commerce
	Compliance rates	
Economy impact	Trade (imports, exports)	ITC Trademap, Ministry of Commerce
	Growth of sector (revenue, employment, number of firms)	Healthcare Devices Association of Pakistan (HDAP)
	Reduction of consumer prices and improved access to devices	Stockists of affected products

Within this:

- For administrative burden, an SCM-based methodology will be adopted (the full SCM might not be feasible)
- For trade and sector size, where the data is available, time trends will be constructed and analyzed in conjunction with dates of implementation to see if there are any discontinuities or shifts in trends discernible that could be attributed to the reforms. In addition, a difference-in-differences exercise can be carried out for a reference sector where regulatory reforms did not take place but is impacted the same way by other shifts in the economy and health dynamics (e.g., comparing shifts in trends in the healthcare devices sector to those in the pharmaceutical sector).
- For impacts that are not readily quantifiable, for example the data on improvements in transparency and predictability, qualitative insights from the interviews with firms will be reported.

1.6 Health care devices: a case study

The Board of Investment selected the health care devices sector as the pilot sector on which to apply this methodology to evaluate the reforms. The research team then interviewed important stakeholders within the sector to understand the impacts that the reforms had had and data availability to quantify the impacts. Stakeholders were:

- The healthcare devices association
- Surgical good association
- Firms in the healthcare devices and surgical goods industries
- DRAP

The questions they were asked are appended in the annexures. This section summarizes the findings from the fieldwork for each of the reforms, first reporting the impacts reported by the stakeholders by each of the reforms we examined, followed by a discussion.

1.6.1 Impact of the selected reforms

Reform 1: Introduce a separate regime for licensing of non-sterile Personal Protective Equipment (PPE)

A large unmet demand for non-sterile PPE arose during the early days of the COVID pandemic, which the local garments manufacturers and medical devices manufacturers felt well placed to meet. However, initially non-sterile PPE was regulated under pharmaceutical regulations, such that the requirements for a DRAP manufacturing license for non-sterile PPE were the same as those for more invasive/ingested pharmaceutical products. For example, firms were required to hire a pharmacist and instal HVAC systems, just as they would have needed to if they were producing higher risk/hazard devices such as contact lens. Non-sterile PPE is non-surgical and non-invasive, and therefore a low-risk product category to which such regulations should not apply. Stakeholders noted that the issue was not the law itself,

which mirrors international laws such as those applied by US FDA, but the inappropriate implementation and interpretation of the law.

The impact of this was that without the license, firms could not qualify for government or other local procurement tenders. It was easier to export and meet international requirements, rather than to cater to the local market. For example, one of the firms interviewed noted that s/he got a US FDA approval fairly quickly, but still could not meet domestic requirements for a license. As the same time, imported products were not subjected to the same requirements, which gave an edge to imports over local manufacturing. For importing firms, once they have a generic Import Sale License, they do not need a fresh license for every other medical device. Older established firms that were already importing medical devices and/or were exporting were able to bypass these issues more successfully to export non-sterile PPE, but for newer firms that were trying to access the market opportunity, the obstacles and lack of information around them became insurmountable.

Stakeholders noted that this regulation has now been removed and has had a positive impact on production and employment in the country. In addition, they reported positive impacts on trade, both in terms of lowering imports and on expanding exports. However, there was a potential to expand these impacts further, since it took several months to get the regulations implemented as appropriate and licenses granted. Firms also point out that firms that were willing to make side payments or had contacts were able to complete the process more quickly.

Firms that were not successful and abandoned their plans due to delays felt that the lower-level staff created frictions in order to extract payments. For example, one firm explained how DRAP officials would visit their factory and communicate fresh requirements on every visit. An employee from the firm was stationed at DRAP and expected to run personal errands for DRAP staff. The process reinforced the impression that the objective of DRAP was not to facilitate the firm in obtaining a license which was their legal right, but to create conditions which generated rent seeking opportunities. Once the BOI facilitated access to the decision-making tier at DRAP, however, the process was quick and easy, and was completed in two weeks.

Reform 2: One-Stop Shop for licensing of Medical Devices

Stakeholders note that while the files can be submitted online now, the procedure and timelines for approval remain slow. They note that the only impact is that their employees do not have to go in person, and this is a one-off, small impact. The real impact would have been if this digitalisation was accompanied with improvements in back-end processing which would have reduced the time required to get the license. Some respondents claimed that the digital interface is not operational.

Reform 3: Allow approved premises to be used for other relevant processes such as manufacturing of medical devices

There was mixed feedback on this reform. Some respondents noted that the reform is operational but has had negligible impact as there is limited demand for locally manufactured medical devices. Others claimed that this was never a regulation to begin with, so the reform has made no difference.

Reform 4: Eliminate the requirement of hiring a pharmacist in a factory making medical devices

Respondents noted that this reform is operational and beneficial. Firms that were hiring pharmacists unnecessarily earlier save the salary that the pharmacist was paid every month (200,000 – 300,000/year). They also save on the hassle of hiring a pharmacist. There are no further operational or economy-wide impacts expected, as the firms were already hiring the relevant technical staff and will continue to do so. It was not a major obstacle to business, but a regular, unnecessary financial cost that has eased.

Reform 5: Online issuance of registration certificates of medical devices and NOC for export of medical devices

Stakeholders claimed that the online portal is still not functional.

Reform 6: Eliminate the requirement of Drug Sale License (DSL) to obtain license for importing medical devices

The reform was introduced last year and is effective, but since it targets imports, it not expected to have economy-wide impacts.

Reform 7: Elimination of unnecessary qualification and experience requirements for technical persons in the medical devices industry

The reform is effective and very similar to the reform for hiring pharmacist discussed in Section 1.6.4. There were unnecessary salary costs associated with the regulation. There is now a regular annual cost saving for the affected firms. Respondents did not feel that there would have been any economy wide impacts given the size of the saving.

Reform 8: Simplification of the registration process for low-risk medical devices

This reform has led to some simplification, for example by the risk category of the device. However, stakeholders noted that registration was never a requirement in the first place. Importers had to enlist their product i.e., just inform DRAP that they were importing it, not actually register it.

Reform 9: Eliminate the need for testing/ processing of products already registered by Stringent Regulatory Authorities (SRAs) abroad

The reform was initially approved in 2017. Firms were given three-year grace period and then an additional two years to complete the requisite conditions to submit details about their imported products. The period ends in December 2022. There is no counterfactual for this since there is no real change. DRAP never had any facilities or accreditation body to test medical devices so were not testing them in the first place.

Reform 10: Enhancement in the validity period of GMP certificate from 1 year to 3 years for manufacturers of medical devices

Stakeholders noted that this reform is effective, in the sense that it saves the time, cost and hassle required to renew the license every year.

Reform 11: Elimination of unnecessary requirements for renewal of registration for healthcare devices

Stakeholders noted that this reform has been completed, but it is too early to gauge impact as renewal is done after five years and none of the firms are at that stage yet.

Reform 12: Allow authorised distributor to import medical devices on authorisation by registration holder, in line with international practices

This reform allows indenting, and therefore facilitates imports. In that sense it is effective. However, since it is an import-based reform economy level impacts are not expected.

Reform 13: Eliminate the restriction of being the sole representative to import from OEM

Stakeholders felt that this reform was not effective, as they did not think it is practically possible to not be the sole representative to import from an OEM. They noted that in the last two years since this reform, there has not been a single new case of imports that utilise the relaxation issued in this reform. Therefore, it has had no impact.

Reform 14: Repealing of SRO for fixation of Minimum Export Price for Surgical Instrument

Stakeholders noted that while this reform was approved last year, it is still not effective. They claimed that DRAP uploaded the notification very recently, so it is too early to see any impacts.

1.6.2 General discussion points

Section 1.6 of this report intended to evaluate the shortlisted reforms quantitatively. However, the fieldwork revealed that it was too early to pick up the impacts of the reform, as even after they were approved there was a gap till notification and implementation. Furthermore, it appeared that there were strong communication and information gaps, which meant that some businesses (despite interviewing only those businesses that were already in liaison with and recommended by Board of Investment) were not aware of the reforms. Nevertheless, the fieldwork led to some important insights which are useful for the Board of Investment in optimizing the process and selection of the reforms and setting systems in place to support quantitative evaluation of reforms. These are summarized below.

1. Some reforms led to small or one-off cost savings, for example increase in validity of licenses and digital submission of applications. While these had some impact on the firm's profit margin in the immediate term, these were more procedural in nature and therefore unlikely to have substantial firm or economy level impacts on their own. When combined as a holistic package of reforms, however, these can make it easier and less expensive to operate as a business, and therefore more attractive for investors.
2. DRAP came into being in 2012, and stakeholders felt that the policies that were first initiated in 2015 were inappropriate in the first place. Businesses made concerted efforts to ensure that the policies were removed or modified **before** they came into implementation. Most of the reforms in the list refer to these policies.
    a. From the perspective of evaluation, this means that there is no real change to evaluate as the policies were reformed before being implemented
    b. The process of contesting the policies and having them changed took a few years of extensive lobbying and efforts from BOI and the associations. If meaningful stakeholder consultation had taken place when the policies were being formulated, there would have been substantial time and effort saved for all parties involved
    c. The policies are in line with international organizations, but without suitably skilled staff and facilities to implement them i.e., they have been copied from other non-comparable contexts without customization. This results in inappropriate interpretation of the policies (for example in the case of PPE described above), or it being physically impossible to complete a specified requirement (for example getting local accreditation where there is no accreditation body or testing facilities to get it from).
    d. Firms feel that lack of knowledge and risk aversion leads regulators to err on the side of over-regulation
3. Stakeholders supported the role of BOI in the process of ensuring business friendly regulations, as the regulators only have a public health/safety etc. mandate without an eye to growing the economy, and consequently without sensitivity to costs imposed on firms. Firms agreed that suitable regulations are critical to ensure human health,

and professed eagerness to comply to these, as they help ensure credibility and safety. However, they contested the inappropriate regulations that contribute nothing to human safety, environmental protection etc. but add unnecessary to costs. Having unrelated qualification/experience requirements for staff or requiring HVAC or separate facilities for low-risk devices were examples of this. They felt that BOI could support liaison between businesses and regulators, and generate research on what is a suitable way that the same regulatory outcomes can be achieved at a lower cost (for example by benchmarking with other countries). While BOI has played this role in the Asaan Karobar initiative, this has had low visibility. Stakeholders felt that they were battling it out on their own with the regulators and Ministry of Commerce and were not aware of any role played by BOI. Therefore, it is recommended that BOI strengthen communications around its activities, involving and informing business at each stage, and making research publicly available.

4. Many of the reforms/changes recommended by businesses are time sensitive. This is exemplified by opportunities that arose during COVID, where unnecessary requirements meant the opportunities to grow and export were missed. For reforms such as these, especially pertaining to exports, there should be a "fast-lane". These are critical given the importance of realizing the exports for Pakistan's national economy.
5. Some processes fail to show real impacts as only part of a process was reformed. For example, front-end digitization which was not accompanied by back-end improvements to expedite processing and therefore there was not much real change
6. For evaluation, and for a better understanding of the sector in general, more regularly collected data is required. This is even more important when initiating reforms for the sector as they allow researchers to develop a baseline against which to measure impacts.
    a. Associations and regulatory bodies can collect this data on number of firms, employment, products, location, exports etc.
    b. DRAP should collect data on the applications received, nature of application, along with dates received and dates by which the process was completed

- Stakeholders also presented useful suggestions on improving the culture of regulatory bodies which tends towards over-regulation and high-handedness at substantial costs to firms. Firms noted that when regulators engage in high visibility raid-and-seal missions, they demonstrate that they are working. However, there are no repercussions of having sealed a factory incorrectly, which results in one or more days of lost work for the factory. Firms suggested penalties for officers that take such actions without evidence or verification, and a compliant portal in which firms can give feedback on such acts for the regulator to take action against such officers. In addition, there should be real time monitoring and accountability for the speed at which applications are handled. Currently, regulators come up with fresh questions/requirements towards the end of the processing time, which firms feel is a way of buying more time to not process the application.

2. Annex 1: List of reforms selected by the Board of Investment for Evaluation

1	Introduce separate regime for licensing of non-sterile Personal Protective Equipment (PPE)	Requirements for Manufacturing of Non-Sterile PPEs Simplied. **Before:** The manufacturers of PPEs were following a pharmaceutical regime which required them to hire pharmacists and install HVAC systems etc., causing huge financial burden. **After:** Under the new Regime, all such unnecessary requirements have been removed for PPE manufacturers.	Drug Regulatory Authority of Pakistan (DRAP)	Medical Devices Manufacturing	29/07/2021	PPE Manufacturers
2	One Stop Shop for licensing of Medical Devices https://e.dra.gov.pk/login	Process of Registration for Getting License for Import and Manufacturing of Medical Devices, from DRAP has been Fully Automated **Before:** License application along with documents had to be physically submitted in DRAP's Islamabad office, causing delay and extra costs to business. **After**: The Registration process has been simplified and automated. Applicants can now submit applications online from anywhere in Pakistan.	Drug Regulatory Authority of Pakistan (DRAP)	Manufacturing (Medical Devices) / Importers	21/08/2021	250+ Importers/Manufacturers registered with HDAP, whereas almost 1000+ are categorized as informal Importers/ Manufacturers
3	Allow approved premises to be used for additional relevant processes such as manufacturing of medical devices	DRAP has allowed use of Approved Premises for Additional relevant Processes such as Manufacturing Medical Devices **Before:** DRAP restricted utilization of approved premises for production of other relevant products due to which businesses couldn't utilize extra space in manufacturing of allied products. **After:** Now DRAP has allowed use of approved premises for additional relevant processes such as manufacturing medical devices	Drug Regulatory Authority of Pakistan (DRAP)	Manufacturing (Medical Devices)	**29/07/2021**	Drug Manufacturing License Holders Medical Devices Manufacturers
4	Eliminate requirement of hiring of a pharmacist in a factory making medical devices	**Before:** Medical devices manufacturing units were required to hire the services of a pharmacist. **After**: Now, requirement for hiring the services of pharmacist is no more required. Factories manufacturing medical devices now can start manufacturing without any such burden.	Ministry of National Health Services Regulation and Coordination (MoNHSR&C) / Drug Regulatory Authority of Pakistan (DRAP)	Healthcare	**22/11/2021**	All Businesses in Healthcare Industry
5	Eliminate requirement of Drug Sale License (DSL) to obtain license for importing medical devices	**Before:** For import of medical devices, it was mandatory for businesses/importers to obtain a Drug Sale License without which they could not import, whereas they weren't not manufacturing nor selling any drugs/medicines. **After:** The requirement of obtaining Drug Sale License has been abolished for importers of medical devices	Drug Regulatory Authority of Pakistan (DRAP)	Healthcare	**04/06/2021**	All Healthcare Businesses

6	Simplification of registration process for low-risk medical devices	**Before:** The registration process of the Low Risk Medical Devices was cumbersome and registration process for all the medical devices was same. **After:** With the risk categories of medical devices in place the registration process for Low-Risk Medical devices has been simplified.	PSQCA, Drug Regulatory Authority of Pakistan (DRAP)	Healthcare Sector	**06/11/2021**	All Healthcare Businesses
7	Eliminate need for testing/ processing of products already registered by Stringent Regulatory Authorities (SRAs) abroad	**Before:** It was required that DRAP will test the product and subsequently it will be registered with DRAP **After**: Now any product which is already registered with any of the Stringent Regulatory Authorities aboard may need not be registered with DRAP for import and subsequent use in the country.	Drug Regulatory Authority of Pakistan (DRAP)	Healthcare	**27/04/2022**	All healthcare businesses
8	Enhancement in validity period of GMP certificate from 1 year to 3 years for manufacturers of medical devices	**Before:** DRAP extended the Good Manufacturing Practices (GMP) certification only for one year which required renewal on expiry and resulting compliance. **After:** To avoid recurring compliance and associated hassle the GMP certification has been extended to a period of 03 years instead of 01 year.	Drug Regulatory Authority of Pakistan (DRAP)	Healthcare	Not Available	All healthcare businesses
9	Elimination of unnecessary requirements for renewal of registration for healthcare devices					
10	Allow authorized distributor to import medical devices on authorization by registration holder, in line with international practices	**Before**: It was not permitted to import medical devices by authorized distributors after authorization from registration holders. **After:** In line with the international best practices now authorized distributors can import medical devices from	Drug Regulatory Authority of Pakistan (DRAP)	Healthcare	**27/04/2022**	All Healthcare Businesses
11	Eliminate restriction of being sole representative to import from OEM	**Before**: In the medical devices rules it was permitted that only a sole representative can import from original equipment manufacturers. **After:** Through an amendment the condition of sole representative has been done away with.	Drug Regulatory Authority of Pakistan (DRAP)	Healthcare	**27/04/2022**	All Healthcare Businesses
12	Repealing of SRO for fixation of Minimum Export Price for Surgical Instruments	**Before:** The manufacturers of surgical items could not export goods below the price fixed by the Ministry of Commerce even if it was financially feasible. **After:** This restriction has been eliminated and exporters of surgical instruments can sell goods in accordance with market conditions.	Ministry of Commerce	Manufacturing (Surgical)	**30/09/2021**	Export Oriented Businesses (Surgical Sector)

3 Annex 2 Brief and questions for firms and associations

The Adam Smith International (ASI) component of the Revenue Mobilisation, Investment and Trade (REMIT) is a 39-month (2021 – 2025) programme funded by the UK's Foreign, Commonwealth and Development Office (FCDO). The programme provides technical assistance (TA) to the Government of Pakistan in implementing reforms for strengthening macroeconomic stability and improving conditions for higher and sustained growth. The Investment Climate component of REMIT focuses on supporting effective regulatory reforms that will make Pakistan's investment climate competitive internationally and attractive for domestic investors.

The ASI research team is undertaking **an ex-post evaluation of the impact of regulatory reforms in the medical devices industry**. Three types of impacts will be explored:

- Impacts on the firm (reduced costs, access to inputs, markets, growth etc.),
- Impacts on the regulatory environment (transparency, stability, compliance rates, costs of enforcement etc.)
- Impacts on the economy

In addition, the process of regulatory reform is being studied from the perspective of making it easier, smoother and quicker for the regulator to manage change related to the reform.

We are seeking out information from firms on the impact of the reforms on their firm specifically, and on the sector in general.

- Have there been changes in the costs of compliance or time taken for compliance following the reforms?
- Has access to inputs of markets improved?
- Has there been an impact on exports? Prices? Revenue? Employment?
- Have there been changes in transparency or rent seeking attitudes with respect to interactions with the relevant regulatory authorities? Any changes in the predictability and stability of the regulatory environment, or in the hassle/psychological costs of dealing with regulatory authorities?
- Has the size of the market changed? (Increase in number of firms or increase in investment of existing firms)
- Have access to and prices of the relevant medical devices improved in the economy?

We will also be looking for feedback on how the process can be improved to ensure that all stakeholders are better aligned to the objectives of supporting compliance on necessary regulations at the lowest possible cost to businesses.

2 Annex 3 Brief and questions for DRAP

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- Impacts on the economy

In addition, the process of regulatory reform is being studied from the perspective of making it easier, smoother and quicker for the regulator to manage change related to the reform.

We have reviewed the estimates produced by Pakistan Institute of Development Economics on the impacts of the reforms. We would like to schedule a meeting with DRAP to discuss only those aspects that haven't already been shared with PIDE. These are the impacts the reforms have had on:

- workload and costs **for the regulator**
- compliance rates
- relationship between the regulator and the private sector
- relationship between the regulator and BOI

We will also be looking for feedback on how the process can be improved to ensure that all stakeholders are better aligned to the objectives of supporting compliance on necessary regulations at the lowest possible cost to businesses.

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