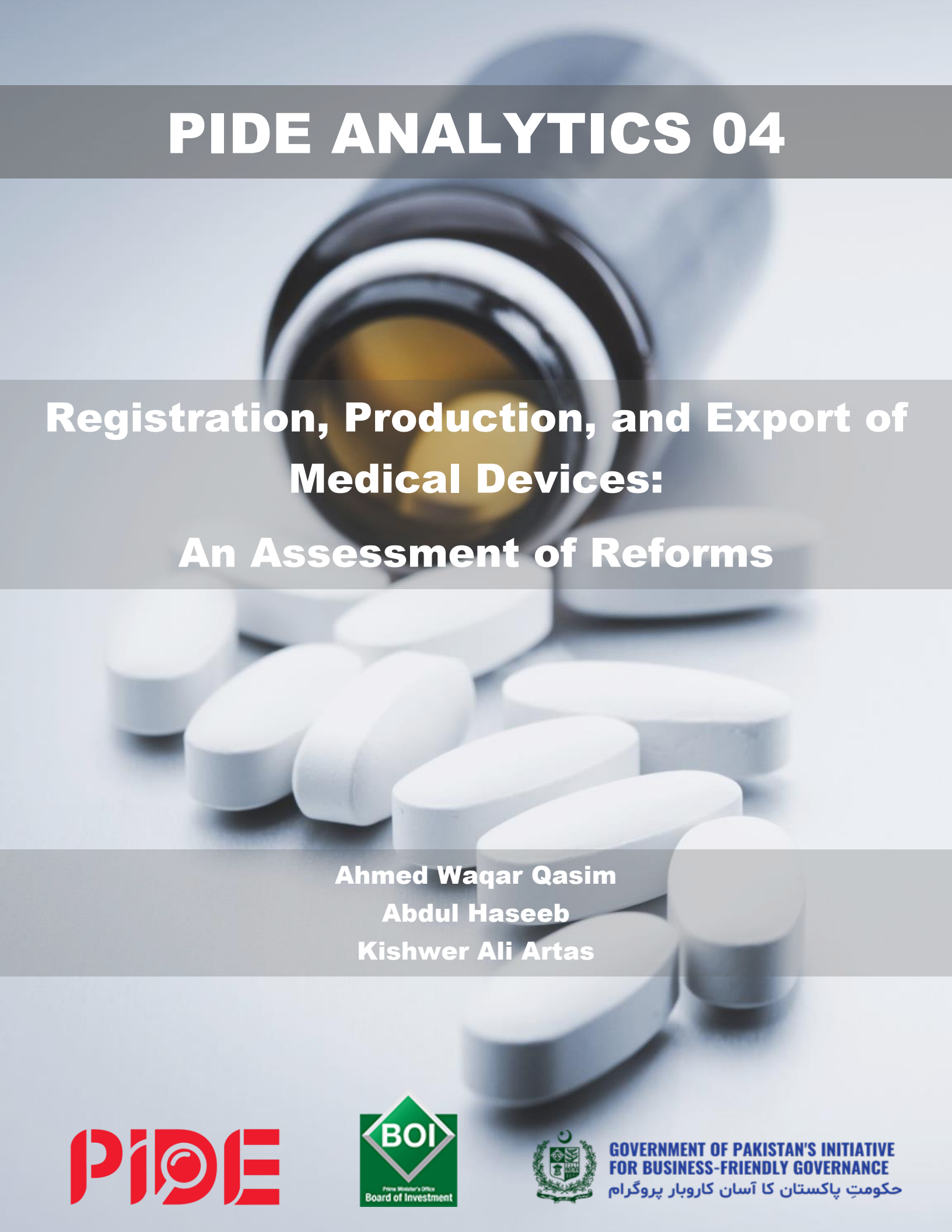

PIDE ANALYTICS 04

Registration, Production, and Export of Medical Devices:

An Assessment of Reforms

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With the growth of the healthcare market in Pakistan, the demand for medical devices is rapidly increasing. The COVID-19 pandemic has also triggered the demand for medical devices in international as well as domestic markets. Even though Pakistan has a strong link in the medical devices global value chain yet it contributes less than 0.2% to the medical devices export market.[1] To cater to the increasingdemand for medical devices during the wave COVID-19 and to transform the industry into export-oriented, the Drug Regulatory Authority of Pakistan (DRAP) took several reforms to simplify the registration and manufacturing process to facilitate the medical devices manufacturing industry and improve its export competitiveness. The objective of this report is to evaluate the impact of some of these reforms on the medical devices market in general and on the medical device manufacturers in particular. This report estimates that these reforms have saved about 6.07 billion PKR in terms of reduction in administrative burden.

Regulations governing Medical Devices manufacturing and import/ export in Pakistan

In the medical device market, key regulatoris DRAP under the Ministry of National Health Services Regulation and Coordination (MoNHSR&C). Since 2015, DRAP has also been assigned the task to regulate the registration, manufacturing, and import & export of medical devices and in-vitro diagnostic items. To regulate the market, DRAP issues licenses for the import, production, and export of medical devices based on defined categories, besides other market surveillance functions as mandated under the Medical Device Rules, 2017.

World Health Organization (WHO) definition of a medical device states that "*a medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or another similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose*". The Medical Device Rules, 2017 classify medical devices into 4 classes (A, B, C, and D) according to the risk-based classification rules.

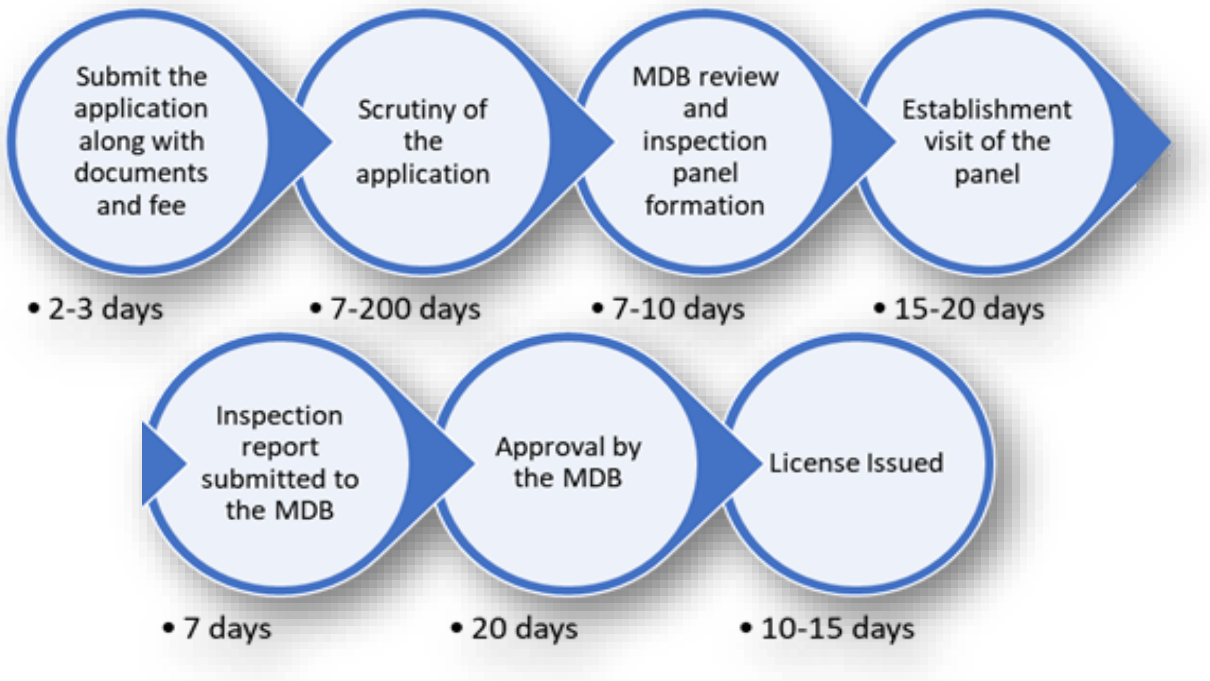
Class	level	Medical Device: Examples
A	Low hazard	Tongue depressors, Disposable masks
B	Low to moderate	Hypodermic Needles, Suction equipment
C	Moderate to high hazard	Lung ventilator, The bone fixation plate
D	High hazard	Heart valves, Implantable defibrillator

Source: WHO and DRAP

[1] Export share of Pakistan in the export of medical devices is calculated from the data (HS: 9018 to 9022) obtained from the UN Comtrade.

The body responsible for the registration, manufacturing, and import & export of medical devices under the rules is the Medical Device Board (MDB). In the case of ***manufacturing licensing***, the MBD issues two types of licenses: (i) license to manufacture and (ii) license/NOC to import/export medical devices. The steps involved in issuance of medcial devices manufacturing license and approx. time required at each step are given below:

Figure 1: **The Process of Obtaining Manufacturing License**



Note: Days required at each stage are based on the data collected from in-depth interviews of the stakeholders.

Following documents have to be provided along with the application form to obtain a manufacturing license:

Table 1

Sr.No	***Type of Document***
1	Application form
2	Drug Sale License (for importers only)
3	Appointment letter for supervising the sale, distribution, or wholesale of medical devices.
4	Proof of fee deposited (endorsed by Statistical Officer)
5	Triplicate detailed layout plan (for manufacturer only)
6	CNIC of QEC in charge, production in charge, partners, proprietors/directors.
7	Copies of Registration Certificates of Technical Persons from the concerned Council.
9	Declaration on stamp paper
10	List of medical devices to be imported (for importers only)
11	Online FBR Certification
12	4 photographs of QEC in charge, production in charge, partners, proprietors/directors
13	Undertaking on stamp paper
14	Degrees and experience certificate of QEC & production in charge
15	Certificate of license & last renewal (for renewal only)
16	USB/CD

1 Reform:

Keeping in view the importance and potential of the medical device industry, a no. of public-private dialogues were held with the sector specific association and businesses. There was a dire need to reform the licensing process, revisit the requirements and introduce automation to reduce compliance burden on the businesses in this sector. BOI proposed several reforms proposals with DRAP in line with best international practices and demand of the private sector.

In this report, we evaluated the following 7 reforms undertaken by DRAP[2]:

i. Introduction of a One-Stop-Shop for Licensing of Medical Devices (Reform ID: F009)
ii. Simplification of pre-requisites for manufacturing of Non-Sterile Personal Protective Equipment (PPEs) (Reform ID: F005)

[2] Detailed description of the reforms can be viewed at https://www.business.gov.pk

iii. Allowing approved Premises to be used for additional relevant processes (Reform ID: F069)

iv. Elimination of requirement to hire a full time Pharmacist in PPE manufacturing plant (Reform ID: F104)

v. Extension in validity period of Good Manufacturing Practices (GMP) Certificate (Reform ID: F112)

vi. Online issuance of registration certificate for Medical Devices

vii. Online issuance of NOC for export of Medical Devices

2 Impact Assessment of reforms

2.1 One-Stop-Shop for Licensing of Medical Devices

Previously, DRAP required physical submission of the license application along with the required documents. DRAP has now introduced an online system for submission of license applications (both for manufacturing and import licenses). The principal objective is to reduce administrative costs in the registration process through full automation so that the registration process boosts up in Pakistan.[3] Applicants can now submit applications online from anywhere across the globe. To evaluate the impact of this reform, we focused on the reduction of administrative burden and increase in applications.

2.1.1 Reduction in administrative burden

The automation reform has reduced administrative costs significantly. Since the administration cost includes (i) learning cost, (ii) compliance cost, and (iii) psychological cost. A substantial portion of both learning and psychological costs has been eliminated by automation. Overall the ***automation has reduced the compliance cost by more than Rs. 6.6*** million. To assess the reduction in the compliance cost, we considered

[3] There are an estimated 2 million different kinds of medical devices that are categorized into more than 7,000 generic device groups in the world market. However, DRAP was able to register around 3,200 only till 2021 (BOI-Pakistan Regulatory Modernization Initiatives).

the travelling and logistics cost, documentation cost and opportunity cost. This standard costing model is derived from PIDE Sludge Audit.

Complianse Cost:

Travelling and logistics cost: Previously, applicants across Pakistan had to travel to Islamabad to apply for a manufacturing license . Estimations show that average cost of travelling for submission of an application is around Rs. 13,433.[4] It is assumed that an applicant visiting from outside Islamabad incurred Rs. 10,000 as the logistic cost during three days of the application submission process along with Rs. 6,000 in local travelling costs. Since the average annual number of manufacturing license applications received by DRAP is around 132, therefore, more than Rs. 3.8 million have been saved because of automation that could have been incurred by the industry.

Documentation cost: Previously the application required more than 9 types of documents to be attached. The number of pages per application was around 340, including two stamp papers, 4 photographs, and one USB. By assuming Rs. 5 for copying charges and Rs. 250 for stamp papers, the documentation cost stood at Rs. 3,560 approx for each application. Hence we can assume that around Rs. 0.5 million worth of documentation cost has been eliminated through automation.

Opportunity cost: The physical submission of the application also involved opportunity cost since the time spent on the process could have been invested in alternative economic activity. To capture this cost, we assumed that management of the establishment invests around 5 days in document preparation and submission of the application. Assuming the monthly remuneration of a manager Rs. 150,000, the opportunity cost stands at around Rs. 28,846 for each establishment. This translates into Rs. 3.8 million opportunity costs that the industry used to pay in case of physical submission of the application.

However, after the automation, we assume that the days require for document preparation and submission are reduced to just 2 days. This reduction in days also reduces the opportunity costs by 60% - Rs. 17,308 for each applicant and Rs. 2.3 million at the aggregate level.

[4] The average traveling cost was calculated by considering the travel cost from Lahore, Karachi, Peshawar, and Quetta to Islamabad. For example, the travel cost from Karachi to Islamabad is Rs. 13,433, which is the average travel cost through different means – for instance, by bus Rs. 9,000, by air Rs. 23,000, and personal vehicle Rs. 25,000.

2.1.2 Increase in the number of applications

The data provided by the DRAP indicates that the number of manufacturing license applications has increased by 46% after introduction of reform. Previously, the average monthly number of manufacturing licenses received by DRAP was 11; now, after the implementation of automation, it has increased to 16.

2.2 Simplification of Manufacturing-related Requirements of Non-Sterile Personal Protective Equipment

Companies involved in manufacturing of Personal Protective Equipment (PPEs), which include headgear, gloves, facemasks, scrubs, gowns, aprons, pants, and tops, had to follow strict regime applicable to pharmaceutical industry.The manufacturers were required to hire a permanent pharmacist and to install a Heating, Ventilation, and Air-Conditioning (HVAC) system in the establishment. Compliance with such requirements involved huge recurring financial as well as administrative costs whereas they were not required for manufacturing of PPEs.

The importance of PPE kits has never been felt more crucial than during the current COVID-19 pandemic. Responding to the demand of private sector advocated by BOI, DRAP has notified a separate regime for non-sterile PPE manufacturing in July 2021. The unwarranted requirements of hiring a pharmacist and installing an HVAC system have been eliminated for PPE manufacturers. This provided an opportunity for the textile industry to participate in PPEs manufacturing. Besides other benefits, the reform would enable the industry to **reduce the cost of production by more than Rs. 478.2 million and to substitute the import of PPEs**.

2.2.1 Affordable PPEs

The entry of new manufacturers made it possible to supply PPEs in the domestic market at affordable rates, for instance, the price of an imported N95 mask was around Rs. 2,900 while domestically produced N95 masks cost only Rs. 70 at the start of the Pandemic.[5]

2.2.2 New Entries in Manufacturing

There is a significant increase in PPE manufacturers after the implementation of the reform. The data provided by DRAP shows that only 15 PPE manufacturers were

[5] See: https://www.usp.org/global-public-health/promoting-quality-of-medicines/pakistan-begins-to-manufacture-export-quality-assured-ppe s

operating in the domestic market before the implementation of the reform. Now the listed PPE manufacturers in a business directory are more than 60.[6] These manufacturers are also exporting their products in the international market.

2.2.3 Reduction in Fixed Cost

Elimination of the requirement for HVAC system installation has reduced fixed costs by approx. Rs. 7 million for each establishment and saved more than Rs. 435 million at the industry level, (*assumed that the total PPE manufacturers are 60 only*).[7]

2.2.4 Reduction in Operating Cost

The reform has also reduced operational costs: (i) by saving energy expenditures on the HVAC system, and (ii) by reducing the employee related expenditures. The reduction in wage bills is because the establishment is no more required to hire a pharmacist to supervise PPE manufacturing. The average annual salary bill of a pharmacist is around Rs. 720,000, which implies that the industry would save around Rs. 43.2 million per annum due to this reform.[8]

2.3 Permission to use Approved Premises for Additional Relevant Processes

Regulations require at least 4 Kanal area for setting up a pharmaceutical unit. Previously,regulatory regime did not allow the manufacturers of the pharmaceutical drugs to use the premises for additional activities whether they were relevant or not. Therefore, the businesses had to establish another facility to undertake relevant processes such as manufacturing medical devices even though it may have unutilized land out of 4 Kanals that is dedicated to drug manufacturing. In September 2021, DRAP introduced a reform in this regard and has allowed drug manufacturers to use the approved premises for additional relevant processes such as manufacturing medical devices.

2.3.1 New Entries in Medical Device Manufacturing

The reform has opened the opportunity for drug manufacturers with valid Drug Manufacturing licenses (DML) to participate in medical device manufacturing. Therefore,

[6] For details see: https://pakbiz.com/Safety-Products_SID186.html
[7] Our survey shows that the system capacity required for 1 Kanal establishment (which is the minimum land requirement) is 14 tons. The HVAC system of this capacity costs around Rs. 7 million.
[8] The average monthly salary of a pharmacist is Rs. 60,000, and we again assumed that there are 60 manufacturers of PPE.

650 drug manufacturing establishments that have registered with DRAP have been provided an opportunity to manufacture medical devices.

2.3.2 Reduction in the fixed cost

Since the manufacturer does not have to establish a separate facility to manufacture a medical device in the drug manufacturing facility. Therefore, the investment in land is no more required. Assuming that the area required to establish a medical device manufacturing facility is 2 Kanal, real estate prices in the industrial area of Islamabad show that this would cost more than Rs. 7 million.[9] Now if we further assume that all 650 drug manufacturers also start medical device manufacturing. Then the reform **reduced fixed costs by Rs. 4.5 billion** at the aggregate level.

2.4 Elimination of Requirement of hiring a Pharmacist for medical device manufacturers

After the elimination of the requirement of hiring a pharmacist for PPEs manufacturers, DRAP extended this benefit to all medical device manufacturers in November, 2021. The underlying rationale for implementing this reform is that the manufacturing of medical devices is not the same as manufacturing drugs. Therefore, establishments manufacturing medical devices can operate without the supervision of a pharmacist.

2.4.1 Reduction in Operating Cost

As discussed in the above reform, the elimination of hiring a pharmacist has reduced the average annual wage bill of an establishment by Rs. 720,000. At the aggregate level, this **reform saved around Rs. 692.6 million** keeping in view that there are 962 medical device manufacturers in Pakistan.[10]

2.5 Extension of Validity Period of Good Manufacturing Practice (GMP) Certificate

The validity of the GMP certificate issued by DRAP was 1 year and establishments were required to renew it on yearly basis by submitting a no. of documents and processing fee. Private sector was of the view that obtaining renewal is a burden on them and not in line with international best practices. The certificate's validity period has been extended to 3 years under this reform

[9] The data in industrial plot prices obtained from zameen.com
[10] https://www.zoominfo.com/companies-search/location-pakistan-industry-medical-devices-equipment

following international best practices. This reform has reduced the recurring administrative burden faced by healthcare businesses **by around Rs. 1.3 million**.

2.5.1 Reduction in Administrative Cost

Travelling and logistics cost: As calculated above the average cost related to logistics and travelling is Rs. 29,433 which an establishment has to bear during the renewal of the certificate. Since there were 15 establishments listed within DRAP, the reduction in travelling and logistic costs observed due to this reform is around Rs. 441,495.

Reduction in GMP certificate renewal cost: The renewal fee for the GMP certificate is Rs. 25,000. Now the manufacturers do not have to pay this fee annually. This also translates into an annual aggregate saving of around Rs. 375,000.

Documentation Cost: Previously a no. of documents were required to be submitted alongwith renewal application.As estimated above, the average cost of documentation for a single manufacturer is Rs. 3,560, which also translates into Rs. 53,400 at the aggregate level.

Opportunity Cost: The opportunity cost stands around Rs. 28,846 for each establishment as shown above. This translates into saving Rs. 432,690 opportunity costs that the industry was born.

2.6 Online Issuance of Registration Certificate for Medical Devices

DRAP has also automated issuance of registration certificates for medical devices and licenses. Medical device manufacturers can apply for registration from anywhere in Pakistan without visiting the DRAP office physically. Therefore, the establishments are spared visiting twice to get a registration certificate for the medical devices.

2.6.1 Reduction in Administrative Burden

Automation has reduced the administrative burden (learning cost, compliance cost, and psychological cost) significantly. The calculations made in the “one-stop-shop for licensing of medical devices” case are also applicable here. These calculations show that an establishment could save around Rs. 50,301 due to automation. At the aggregate level,

this translates into the **reduction of administrative burden equivalent to Rs. 48.3 million**.[11]

2.7 Online Issuance of No Objection Certificate (NOC) for Export of Medical Devices

The process of issuing NOC for the export of medical devices has been automated by DRAP . The manufacturers who participated in the survey, have acknowledged and appreciated the implementation of this reform, and remarked it as the right step towards the promotion of exports of medical devices.

2.7.1 Reduction in the administrative burden

As discussed above in detail that the administrative burden of applying physically at the DRAP office is around Rs. 50,301 for an establishment. Automation has enabled the manufacturers to save this administrative cost along with other hassles. The data obtained from DRAP indicate that during the fiscal year 2020-21 around 7,048 NOCs were issued to medical device manufacturers. By assuming an equal number of NOCs would have been issued after the implementation of this reform, the industry would have realized a **reduction in administrative burden by Rs. 354.5 million.**

2.7.2 Observations

- Manufacturers highlighted that the **processing mechanism within DRAP** is the main cause of delay in approvals. Although automation has reduced some parts of the administrative burden, however, the bulk of the administrative burden remains intact unless the application processing mechanism within DRAP is further improved.
- Currently, there is no option for **online fee submission**. A challan will be generated by the system once the application is submitted through automation which is then paid over the counter in a bank. Introduction of an online fee payment mechanism would help to reduce the administrative burden at this step.
- Some manufacturers have also pointed out the need for **a track and trace system of the applications** so that status of the application can be observed.

[11] Since there are 962 medical device manufacturers currently operating in the market. For details see: https://www.zoominfo.com/companies-search/location-pakistan-industry-medical-devices-equipment

- The issues **in import clearance** have also been highlighted by some manufacturers. Currently, DRAP provides 3 days grace period for the clearance of consignment, however, the customs department takes around 15 to 20 days to process and clear the consignment. Therefore, the manufacturer has to pay the charges for the delay, which are around Rs. 50,000 per consignment. Since the delay in clearance is due to sluggish administrative procedures but not because of the fault on the manufacturer's end, therefore, charging the manufacturer seems unfair and needs the attention of the concerned authorities.