



MEDICAL DEVICES & THE DIAGNOSTIC INDUSTRY OF PAKISTAN



Supported by:


Messages

Asim Rauf
Chief Executive Officer, DRAP

TECHNOLOGICAL advancements have facilitated mankind particularly in healthcare where average life expectancy of nations has improved due to timely prevention, diagnosis, management, and treatment of various ailments.

Apart from access to essential medicines, various instruments, apparatus, implementation, machines and software, implants and reagents exposed to human body fluids have a pivotal role in delivery of healthcare system. It essentially means that a need arises to evaluate safety and efficacy of devices intended to be used for medical purposes in humans. Therefore, these medical devices have been brought under the ambit of regulation globally due to their potential impact on human health, directly or indirectly.

The need to regulate medical devices was felt in 2012. Resultantly, under DRAP Act, 2012, the mandate was awarded to Drug Regulatory Authority of Pakistan to regulate medical devices. The complex nature of classification of devices coupled with lacking awareness of manufacturers with international best practices proved to be the greatest impediment in the enforcement of regulations. However, due diligence was given in framing and phase-wise implementation of Medical Device Rules, 2017 by DRAP. The time for exemption of various classes of medical devices was given to prevent shortage of medical devices as well as to facilitate stakeholders and it proved efficient. Currently, DRAP has enlisted a considerable number of establishments and registered medical devices for local manufacture and import to cater to the need of our country.

Medical devices are manufactured through complex processes and require evaluation at various levels even after their availability in the market. Such wide scope of the regulation is itself a humongous task to perform. DRAP is working to enhance its capacity in terms of relevant trained human resources, robust enforcement mechanisms such as cardiac-stent registry, integrated management systems for track and trace of medical devices in supply chain. Strengthening the local establishments of medical devices manufacturers to international standards for the purpose of meeting the domestic requirement as well as taking advantage of the export potential remains one of our top priorities. ■



Masood Ahmed
Chairman, HDAP

IT gives me immense pleasure and satisfaction that a special supplement on medical devices and diagnostic industry in Pakistan is being published by DAWN to enhance the knowledge and awareness about the industry.

Without any doubt medical devices and diagnostic industry is one of the most critical component of the healthcare system as no medical treatment or therapy is possible without using at least one medical device or diagnostic product.

The industry is hugely diversified. From a daily home use thermometer to a highly advanced and sophisticated CT scanner, everything falls under medical devices which are hundreds and thousands in number.

Today's era of innovation is also benefiting the medical devices industry as it is enhancing faster than ever before. We need to ensure that we are ready to adopt these changes so that the benefits of latest advancements of the world could reach the patients of Pakistan in shortest possible time.

Pakistan medical devices and diagnostic industry is represented through Healthcare Devices Association of Pakistan (HDAP) which is a collective voice of all industry stakeholders for resolution of critical issues and enhancement of business environment for better patient care.

At HDAP, our mission is to promote public health and improve patient care through the advocacy of innovative, research-driven advancements in medical device and diagnostic technologies.

It is critical to understand that patient-care is the ultimate responsibility of all the stakeholders of medical industry and not just healthcare professionals or regulators. We believe and understand our role is critical and we ensure all possible efforts are made to ensure best possible patient care.

I would encourage all medical devices and diagnostics industry stakeholders including manufacturers, importers, distributors, service providers, healthcare institutions and healthcare professionals to become a part of HDAP and contribute towards shaping the healthcare environment for improved patient care. ■



HDAP helps the members with resolving their issues



The Executive Committee of the Healthcare Devices Association of Pakistan (HDAP). (Left to right) Abdul Rasheed Chohan, Member, Executive Committee, M. Abid Maniar, Vice-Chairman, Muhammad Younus Billoo, Ex Vice-Chairman, Masood Ahmed, Chairman, Dr. Zaffar Hashmi, Ex Senior Vice-Chairman, Shakeel Ahmed Shaikh, Ex Chairman and Adnan A. Siddiqui, Communication Lead.

By Humayoun Ahmed Khan

The following excerpts are taken from an interview with the Executive Committee of Healthcare Devices Association of Pakistan (HDAP).

When was the HDAP formed?

The association was formed in 2015 as need for a common platform was felt since long with the objective to act as collective voice for all the stakeholders of the society. During that time the Government was also gearing to regulate the industry therefore there was a need to ensure industry concerns were collectively compiled and communicated to the regulators.

Why is there a need for HDAP in the first place?

Medical devices and diagnostic

industry is fairly fragmented with thousands of stakeholders, and there was no platform for these businesses to represent. Therefore, there was a need to create a platform which could safeguard and serve the interests of the stakeholders, unite them on a single platform and make their voices heard at all levels.

What are the benefits of becoming a member of HDAP?

- Well, there are several benefits of becoming a member of the association including:
- Information — HDAP is a source of real time critical information for its members.
 - Resolution — HDAP gathers critical issues faced by its members and attempts to resolve those through collective efforts.
 - Training — HDAP imparts training

programmes to upgrade member's knowledge and expertise of effective business management.

What was your reaction when you saw the initial draft of the medical device rules?

When we saw the first draft of the rules for medical devices, we realised that they were crafted while keeping the foreign rules in mind. Needless to say, the conditions were not conducive for such rules in our country. We didn't have the required documentation and weren't ready for them to be implemented straightaway.

So, you opposed the rules?

Look, one has to consider the fact that the regulatory rules for the medical devices are still in preliminary

Continued on Page 4



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Message



Prof. Dr. Farhan Essa Abdullah Ph.D
CEO and MD
Dr. Essa Laboratory & Diagnostic Centre
Dr. Essa Dental services

I would like to congratulate DAWN for highlighting Pakistan's medical devices and diagnostic industry by publishing a special supplement on it. It is a very significant industry because no treatment can be performed without diagnosis. Dengue, Chikungunya, Typhoid and Malaria are widely spread in Pakistan these days. While Chikungunya and Dengue are viruses, Typhoid is a bacteria and Malaria is a parasite. Their symptoms are similar but without diagnosis, treatments cannot be done.

Also, I would like to inform people that there is no radiation in Ultrasound and MRI. Therefore, the importance of diagnostic industry is critical for a better treatment.

We are proud to introduce five branches of Dr. Essa Dental Services in Karachi, one of the first chains of dental clinics in Pakistan.

We are proud of the fact that all diagnostic facilities that are present internationally are available in Dr. Essa Laboratory & Diagnostic Centre. We are ISO: 9001: 2015 Quality Management Certified Organisation offering a number of services through our Departments of Radiology, Microbiology, Immunology & Serology, Histopathology, Molecular Pathology, Clinical Biochemistry and Haematology.

At Dr. Essa Laboratory & Diagnostic Centre, we have a strong corporate responsibility department and have expertise in pre-employment and health screenings. We also conduct medical seminars and educational/awareness sessions regularly. ■



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tries and are clinically validated and approved based on latest quality standards.

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We prioritise a strategy of sharp focus on cost minimising, on flexibility & on efficiency to deliver what our customer needs thus furthering our share in the market. Through our commitment to advancement in product portfolio, we are providing innovative solutions which meet the needs of our customer to ensure that we are recognised as a leader in our field of preventive hygiene and disinfection technologies, thereby delivering considerable value to our customers. We are passionate about providing them with solutions and a level of service that exceeds their expectation.

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the task of closing the hygiene gap; disinfectant, biocide, skin care products, sterilisation quality assurance indicators, surgical instrument cleaning & care, protective barrier

Uniprom Healthcare's strong and recognisable brands are synonymous with quality and efficacy.

system, laundry detergents, infection control products form the main focus of the range of products that we provide to our valued customers. Our services are not just confined to patients and hospitals rather we offer products to pharmaceuticals, food industries and HORECA as well. Because hygiene should not be just the practice of hospitals, in fact, we better start this from our surroundings to prevent the outbreak of infection in society.

Above all, we will continue to place our customers at the heart of everything we do, ensuring that collectively, we drive sustainable healthcare products availability and solution across the country. That makes Uniprom Healthcare your trusted partner in infection control and prevention. ■

Fresenius Medical Care providing reliable care for patients with renal diseases

FRESENIUS Medical Care is the world's leading provider of dialysis products and services. We are serving in 150 countries around the globe with 42 production sites and more than 112,000 employees.

We care for people with chronic kidney failure of whom around 3.4 million worldwide depend on dialysis treatment.



By Javaid Nasir Qureshi
Managing Director, Fresenius Medical Care

Our vision

At Fresenius Medical Care, we have the vision to create a future worth living, for patients, worldwide every day. We work towards this vision in various ways — by developing technologies, exploring innovative therapies and providing reliable care for our patients, even in extreme situations.

What we do

We care for over 330,000 patients

healthcare products and services as well as various dialysis treatment options for both in-center and home dialysis that are individually tailored to our patient's needs.

Our therapeutic area and product range

We provide support to renal care community in four therapeutic areas: Chronic Hemodialysis, Acute Kidney Injury, Home Hemodialysis and Therapeutic Plasma Apheresis. Our comprehensive product range includes Dialysis Machines, Disposables like Dialyzers, Blood tubing lines, Fistula Needles, and Consumables like Bicarbonates, Citrosteryl, Puristeryl and ClearSurf.

We also provide the solutions for intensive care patients with acute kidney injury i.e. CRRT machines, CRRT Filters and MultiBic CRRT solutions. ■

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Roche Pakistan providing a comprehensive range of diagnostic solutions



By Dr. Qadeer Raza
Country Manager,
Pakistan & Afghanistan
Roche Pakistan Limited
(Diagnostics)

THE huge potential of diagnostics in the fight against diseases and in creating better health outcomes is often overlooked or may not be fully understood. In vitro diagnostics testing has long been a silent champion of healthcare that accounts for two per cent of worldwide healthcare spending but influences up to 70 per cent of clinical decision-making. As a healthcare pioneer with a proud history of delivering life-changing and life-saving innovations, at Roche we push boundaries and challenge the status quo to redefine what is possible.

As market leaders in the diagnostics industry, at Roche we are committed to elevating the standard of care for patients across Pakistan by bringing value across the entire healthcare continuum through innovation in testing efficiency and medical value.

Our comprehensive diagnostics portfolio caters to the diverse needs of those at the frontline of providing care — from the largest hospitals, leading commercial laboratories, established research institutions to small physician clinics and even the most remote healthcare centres.

Did you know?

- Diagnostics accounts for two percent of worldwide healthcare spending but influences up to 70% of clinical decision-making
- Diagnostics is an enabler:
 - Physicians need diagnostics to enable them provide the best treatment for their patients
 - Governments need diagnostics to help save healthcare costs
 - Pharmaceuticals need diagnostics to help them focus medicines to the right patient group
- Across the globe, Roche Diagnostics instruments are used to conduct more than 15 billion tests every year
- In Pakistan, Roche Diagnostics is a market leader providing the industry’s most comprehensive range of diagnostic solutions with a broad test menu and array of automated equipment

Harnessing the true power and value of diagnostics

Good health begins with good information. In vitro diagnostic tests on a small sample of blood, urine, or tissue provide doctors with the critical information they need to treat illnesses. The power of diagnostics, therefore, is huge and it plays a pivotal role across the entire healthcare spectrum.

Additionally, with the right information in hand, diagnostics also has a role to play in reducing the economic burden both on the patient along with the hospital. This is because once the disease is accurately diagnosed, the clinician is in a better position to treat the patient and also efficiently utilise the hospital resources to save costs (e.g., hospital beds) — particularly in the Emergency Room and Intensive Care Unit.

The unfortunate fact, however, is that despite the critical role of diagnostics, laboratories are not given their due importance in hospitals even though they have a key role to play across the patient’s journey to wellbeing. As pioneers in the field of diagnostics, at Roche we are committed to giving laboratories the tools to empower them and enable them to address the challenges by advancing laboratory standards and making testing simpler, more cost-efficient and more insightful. This in turn is what will benefit the patients, who are at the heart of everything we do at Roche.

Enabling the right diagnosis for the right patient

We know that the right diagnosis is essential in the quest for new treatments — and potential cures — for the world’s prominent health

issues. We believe that timely and quality diagnostics is what enables clinicians to make the right diagnosis and find the right treatment for the right patient at the right time.

With physicians seeking tools that can improve decision-making; hospitals and laboratories looking for faster, more accurate solutions to ease the patient load; and governments adjusting their delivery models to reduce healthcare costs and maximise resources, diagnostics can play a crucial role in addressing the current challenges we are facing in Pakistan.

Keeping the above in mind, lasting innovation is our biggest contribution to society and so we continue to develop innovations that address unmet needs in critical areas such as cervical cancer, cardiovascular disease and HIV, to name a few. We proudly bring to the market

advanced and integrated solutions in diagnostic testing, laboratory efficiency and decision support because we strongly believe that early detection and screening via diagnostic tools can tremendously improve patient outcomes.

The role of modern diagnostics

Modern diagnostics have a key role to play as part of early interventions, reducing costs by diminishing subsequent health problems and hospitalisation and avoiding unnecessary treatment. Moreover, the future of sustainable healthcare depends on diagnostics. As a socially responsible organisation, we believe that improving access to quality and timely diagnostics solutions is a shared responsibility.

Therefore, we work with various stakeholders across the healthcare spectrum, including the government and public authorities, non-governmental organisations, patient organisations and other pharmaceutical and diagnostics companies, on a wide range of initiatives to help patients live longer, better lives.

Catering to the rising expectations of patients, laboratories and clinicians

Today, patient expectations are on the rise — not only for faster testing and diagnosis at lower costs, but also for the prevention and treatment solutions that are personalised to their needs. Many people today are thriving years after being diagnosed with some of the world’s biggest killers, such as heart disease and cancer, as well as infectious diseases like HIV and hepatitis.

Much of that progress has been supported through diagnostic innovations, which enhance the doctor’s ability to act on the right information at the right time, giving patients the chance to live longer, better lives.

In this regard, laboratories and clinicians are expected to manage an increasingly high number of patient samples and deliver results more efficiently, while improving patient outcomes.

As the world-leading in vitro diagnostics provider, our testing portfolio is the industry’s most comprehensive and we continue to expand our offerings to benefit customers and patients.

In summary, we focus on today and look beyond tomorrow to tackle the world’s most formidable healthcare challenges. ■

The dynamic medical devices and diagnostic industry of Pakistan

MEDICAL devices and diagnostic industry saves and improves lives by helping healthcare professionals diagnose diseases and provides effective treatment options for patients and the healthcare system.

Scope of medical devices and diagnostic industry is hugely wide and covers all medical specialties. From basic healthcare services to advanced medical treatments, medical device and diagnostic industry contributes in every area to benefit better patient outcome.

Pakistan medical devices and diagnostic industry, which includes medical devices, diagnostics and medical imaging equipment, comprises of importers, suppliers, distributors and manufacturers of various forms of medical devices from emerging Pakistani companies to global corporations.

The product range of medical devices and diagnostic industry is equally diverse and includes disease screening technologies, therapies, equipment and supplies from simple products like bandages, tapes and syringes to heavily complex capital equipment like MRI scanners and ICU ventilators and highly researched and developed products like implantable devices.

The industry is dynamic and with continuous innovation resulting short life cycles of many products. Several medical devices undergo constant development based on feedback from medical practitioners and advances in other sciences relevant to medical technology.

There are a range of business types that make up the medical devices and diagnostic industry in Pakistan.

- Importer of medical devices and diagnostic as subsidiary of multinational company**
An importer of medical devices and diagnostic where the Pakistani company is a subsidiary of the same multinational company. Usually, most of the products sold will be from the parent company.
 - Third party importer of medical devices and diagnostic**
An importer of medical devices and diagnostic that is not a subsidiary of a multinational company but a local company. Usually such local companies are importer of several multinational companies.
 - Supplier/distributor of medical devices and diagnostic manufactured**
A supplier/distributor of medical devices and diagnostic who procures products from importer or third party importer of medical devices and diagnostics in Pakistan
 - Manufacturer of medical devices and diagnostics**
A manufacturer of medical devices and diagnostics in Pakistan which can either be a locally owned company or a subsidiary of a multinational company. ■
- Courtesy: HDAP

HDAP and Mecomed meet in Dubai

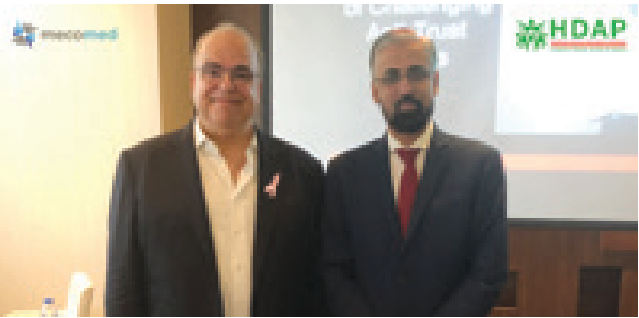
MECOMED is the medical devices’ imaging and diagnostics trade association which serves as the voice of international medical technology manufacturers across the Middle East and Africa.

Masood Ahmed Chairman, HDAP was invited by Mecomed to attend

the leadership seminar during their Annual General Body meeting in Dubai. Mr. Masood also represented HDAP in a meeting with Mecomed Chairman Mr. Rami Rajab.

Mecomed Chairman appreciated the efforts of HDAP in Pakistan. Mr. Rajab suggested that both organisations should work together and organ-

ise interactive trainings and seminars to educate the healthcare professionals and the industry personnel in the area of regulatory affairs. They also exchanged ideas about ways to increase the cooperation among the two associations in order to benefit from each other’s resources and expertise in various sectors. ■



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Enabling clinicians to make the right diagnosis, for the right patient, at the right time

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Roche, as the **world-leading in vitro diagnostics provider**, offers a broad range of laboratory solutions & tests that generate a wealth of diagnostic data to allow clinicians to provide patients with holistic, reliable and precise diagnosis, as well as prevention and treatment solutions - at a much faster pace.

Siemens Healthineers drives Breast Cancer awareness campaign in Pakistan

WITH October recognized as the breast cancer awareness month globally, Siemens Healthineers in Pakistan collaborated with several hospitals and training centers across the country to raise awareness of the disease through a series of workshops.

The workshops, open to the public, were conducted by well-known doctors with the aim to raise awareness of how yearly mammograms and early diagnosis can save lives. Addressing one of the workshops, Mr. Khurram Jameel, Managing Director and CEO, Siemens Healthineers Pakistan said, "We are working together with leading hospitals and clinicians to help raise awareness of Breast Cancer in Pakistan."

With the technologies present today, we can drastically reduce the progression of the disease, given women take the responsibility



of getting themselves checked annually. These workshops demonstrate our commitment to society and our resolve to help the women in Pakistan fight this deadly disease through early detection and timely treatment".

In Asia, Pakistan has the highest rate of breast cancer incidence, with 1 in every 9 Pakistani women developing the disease at some stage of life. It is the second leading cause of death amongst women. An estimated 83,000 cases are being annually reported in the country, and over 40,000 deaths are caused by it.

The workshops and awareness sessions led by Dr. Raima Kaleemi, Consultant Radiologist at JPMC Hospital and Dr. Fauzia Qureshi, Senior

General Physician at Service Hospital, presented an overview on facts and figures, risks and causes for the prevalence of the disease. Other workshops took place at the female Police Training Center Karachi and Service Hospital in Lahore, where doctors from the radiology department were further updated of the latest equipment and practices available in the field.

Dr. Raima Kaleemi commented, "Health needs attention and general awareness can go a long way. As a doctor we encourage people to be more self-aware, to learn and understand possible avenues and potential risks. With breast cancer, regular checkups for early detection is key."

Siemens Healthineers empowers healthcare providers on their journey towards expanding precision medicine, transforming care delivery, improving patient experience and digitalizing healthcare. Helping oncologists to make informed decisions, Siemens Healthineers offers a range of medical imaging and laboratory diagnostics equipment for women's health needs, covering areas of Mammography, Ultrasound, MRI and CT scanners. ■

What is a medical device?

A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related material:

a) Intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support, of the anatomy or of a physiological process.
- Support or sustaining life.
- Control of conception.
- Disinfection of medical devices.
- Providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body; and

b) Which does not achieve its primary intended action in or on the human body by pharmaceutical, immunological or metabolic means, but which may be assisted in its intended function by such means. ■

HDAP helps the members with resolving their issues

Continued from Page 1

stages all around the globe. No such thing existed 4-5 years ago in any part of the world. Compare the medical devices industry with the pharmaceutical industry, which is not only well developed but also well regulated for the last 70 years. So, it's safe to say that the world is going through a transitory phase at the moment, especially Europe, where there is chaos owing to the new set of rules for medical devices, which will be introduced next year.

So, to answer your question, no, we didn't oppose the rules. In fact, we supported the initiative of the government since the very first day. But, at the same time, we requested them to make the rules more conducive so that all the companies, even the small ones that are playing an important role, could comply with the rules. We understand that it's a life-saving business and it should be under the ambit of regulation.

Is everyone complying with the rules?

Not every company is on the same level which makes the process of compliance a bit difficult. We, at HDAP, want to make sure that all the companies and all the medical devices are registered in due time.

How do you address the reservations of those companies that are reluctant to join HDAP?

The participation in any association is voluntary. We can't compel anyone to join us. There were lots of "ifs and buts" when we started our journey. But, as we marched forward, people saw that we were the ones who were representing them. A lot of parallel associations were, in fact, are still being created but none has been as successful as HDAP which remains the only registered body and Drug Regulatory Authority of Pakistan (DRAP) recognised association. Currently, we have over 214 companies on-board.

Nearly, all the big names have joined us but our aim is to take on-board everyone including the companies that are being operated at very small scale.

Please talk about the role of medical devices in treating a patient?

It would not be wrong to say that the role of the medical devices is so significant that no medical treatment is possible without using at least one medical device. To put it into perspective, take the example of a man rushed to a hospital where he needs to be given an injection. Now, mind you, an injection is a medicine whereas a syringe is not. Because of the unavailability of a syringe, a medical device, the said person may end up losing his life.

Unlike the pharmaceutical, the number of medical devices runs in hundreds of thousands. Everything from a tongue depressor, a walking stick or a hospital bed to a thermometer, all the way up to a heart-lung machine, is a medical device. A medical device could range in pricing



HDAP committed to work closely with DRAP for the implementation of policies. Masood Ahmed, Chairman Healthcare Devices Association of Pakistan (HDAP) with Asim Rauf, CEO, Drug Regulatory Authority of Pakistan (DRAP) and Dr. Ghazanfar Ali Khan, Additional Director-DRAP.

from Rs.2 to Rs. 2 crores depending on the device you are talking about. We think that only the medicines cure us but don't pay attention to the devices we use.

Please discuss the challenges faced by the medical industry. What needs to be done to ensure that it's a win-win situation for both the government and the industry?

Documentation remains the biggest challenge of the medical device industry. Unfortunately, it's expensive and a time consuming process. It takes almost three months to get a single paper attested from the Pakistan Embassy in a foreign land. And unlike the pharmaceutical where there are lots of local manufacturers, the medical devices are imported 95-99% of the time. We do not make medical devices in Pakistan. Only less than 5% of syringes are locally produced here.

We are completely dependent on the West for documentation. Like we have stated before, we have always been ready to comply with the rules since Day 1. But, the timeline for implementation of the rules is unrealistic. By mid of January 2020, four

months from now on, every medical device will go under registration and it will be illegal to sell anything. And from what we understand, only a handful of devices have been registered as of now.

And since, there are millions of medical devices, it is practically impossible to get them all registered in such a short time. The deadline for 75% of the medical devices has already passed whereas the deadline for the remaining 25% is approaching quickly. So, we would like to request the Ministry to start with basic registration and give us the letter on the basis of whatever documents we have to enable us to comply with the requirements.

If you were to give us a number of the registered medical devices, what would it be?

We cannot pin-point the exact number, but, perhaps around 750, making it less than two per cent of the total number of medical devices.

Did you arrange any sessions for the members with DRAP to educate them about the rules?

Yes, we did multiple sessions! And,

those sessions also helped the Ministry to understand what the issues are.

So, it's a two-way process and they have acknowledged that they are learning from us and we are learning from them.

How do you see the move of banning the imports of syringes? And while it is projected to increase the prices of locally made syringes by at least four times, do you think we have the capacity to meet the requirement thereby increasing the foothold?

The government has a reason for doing so. Unfortunately, the illegal practice of reusing the syringes still prevails in our country.

It leads to the spread of HIV and Hepatitis. The intention of the government is right and should not be questioned, but the solution proposed by the government to bring only auto-destruct syringes does not seem practical.

Our main concern is that there are not as much syringes available that are needed in Pakistan. Auto-destruct syringes aren't used in West or, for that matter, anywhere in the world since reusing the syringes is not an issue anywhere else.

And frankly, we don't think we have the capacity to meet the requirements. In fact, even if we try, it will be a disaster because you cannot run a clinic or a hospital without syringes. Actions with good intentions won't necessarily yield fruitful results.

As far as the local competition is concerned, it will grow but we will have to give it time.

The outbreaks of dengue fever have been wreaking havoc all across the country. What would you like to suggest to the government to ensure the healthcare issues are effectively dealt with?

Dengue is a vector-borne disease. The outbreaks occur during a specific season. It is common knowledge that the dengue mosquito, born in sweet water, needs particular conditions to grow that are available to it after the monsoon season. The only way that this issue can be effectively dealt with is to limit the growth of this mosquito. As long as we keep the environment clean, there will be less outbreaks of dengue.

The government has also been unable to deal with the ongoing epidemic because of simple supply-demand issue. The units that are needed to run the dengue fever tests are imported and are in much less numbers than we need at the moment.

HDAP has ensured the availability of the diagnostic devices at good prices. Our stakeholders met the requirements of both the private and the public hospitals. What we would like from the government and the regulators is to plan accordingly when the information regarding such epidemics is available to them in advance.

There is a perception that state-of-the-art treatment is available to only the rich stratum of the society. Is the HDAP doing anything to counter that narrative?

In our opinion, there are public hospitals which provide state-of-the-art treatment but they are less in numbers to cater the needs of our huge population.

There are hospitals in every province where you get complete and quality treatment for free. So, it would be wrong to say that state-of-the-art treatment is not available at public hospitals. Our public hospitals, however, are overburdened because we never catered to the needs of the increasing population. That is where the problem lies which is primarily because our healthcare spending is too low.

Do you have any suggestion for the government with regards to the budget allocation for healthcare?

Pakistan needs to invest more in its healthcare. The World Health Organisation states that the developing countries should spend 6.5% of their total GDP on the healthcare. The United States of America spends eight per cent of its total budget on its healthcare. Compare it with ours and you'll see that we spend only less than one per cent of our budget on the healthcare. And the money that's provided to the healthcare sector should be spent wisely to save and improve quality of lives. The government should also encourage the public-private partnership.

How helpful is the Medical Device Division of the DRAP? How long does it usually take for a device to get assessed and registered before it's made available in the market?

They have got a lot of workload to deal with and though they are doing their best but because they are overburdened at the moment, the registration process is relatively slow. They need more resources to help them work even faster. Because product/device registration process is effectively initiated only this year, therefore, it is difficult to mention average time of registration at the moment. ■

HEALTHCARE DEVICES ASSOCIATION OF PAKISTAN

Shaping the industry, keeping the patient first

HDAP advocates for the highest ethical standards, timely patient access to safe and effective products, and economic & regulatory policies that reward value creation and ensure overall growth of Pakistan medical devices & diagnostic industry.

HDAP is collective voice of all industry stakeholders be it manufacturers, importers, distributors, service providers, healthcare institutions or professionals.

HDAP members yield multiple benefits including:

- Information – HDAP is a source of real time critical information for its members.
- Resolution – HDAP gathers critical issues faced by its members and attempts to resolve those through collective efforts
- Training & Development – HDAP imparts training programs to upgrade member's knowledge & expertise of effective business management

Become part of the leading voice of Medical Devices and Diagnostics Industry of Pakistan

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Allmed Solutions

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Prestige Medical Care Pakistan (Pvt) Ltd.

Health Tec

Hooora Pharma (Pvt.) Ltd.

Hospicare Systems

Johnson & Johnson Pakistan (Pvt.) Ltd.

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Meximp Technologies

Mustaj Adnan & Sons

Muslim Medical Services

Muslim Trading Agencies

Pakistan Microbiological Associates

Pharm (Pvt) Ltd.

Popular International (Pvt) Ltd.

Roche Pakistan Limited

Shamir Trading Company (Pvt.) Ltd.

Sina Medical Stores

Sina Bio-Diagnostics & Pharmaceuticals

Technology Labs (Pvt.) Ltd.

The Searle Company Limited

Tri Tech International

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The Global Language of Business

Are you ready for UDI?

GS1 has been designated as issuing entity for Unique Device Identification (UDI) by the European Commission (Brussels, 7 June 2019)

GS1, the leading global supply chain standards organization, has been designated by the European Commission as issuing entity for Unique Device Identifiers (UDIs). GS1 global standards meet the EU Commission's criteria for the issuance of UDIs, supporting the EU regulators in ensuring a successful implementation of the UDI system as defined by the EU Medical Device Regulation and In-Vitro Diagnostics Medical Devices Regulation (EU Regulations), and enabling manufacturers to comply with these requirements.

The UDI system intends to provide a globally harmonised framework for identification of medical devices to enhance quality of care, patient safety and business processes.

"The GS1 global system of standards is the most widely implemented in the world and is used by all stakeholders in healthcare supply chains. The GS1 identifiers are fundamental to enable an efficient and effective identification of medical devices from product conception through every step of the supply chain lifecycle. Strengthening patient safety is central to GS1's mission in healthcare and GS1 is committed to support the EU Commission, manufacturers and other stakeholders worldwide in implementing the new EU UDI system," said Miguel Lopez, President and CEO of GS1, which has headquarters in Brussels, Belgium.

Since 2013, GS1 is accredited as UDI issuing agency in the U.S.A. and other regulators are also planning to allow the use of GS1 standards as the basis of their national UDI system.

According to EU Regulations, the UDI number is applied to the medical device label, its packaging, and/or the device itself. Required product data must be submitted to EUDAMED (European Database on Medical Devices). In addition, a new identifier was introduced by the EU Regulations: the Basic UDI-DL. GS1 has developed a new key (i.e. Global Model Number-GMN) to support the implementation of this requirement. By using GS1 global standards, Healthcare manufacturers in Europe and around the world are enabled to create and maintain compliant UDIs.

For more information, visit the GS1 UDI resource Web page: <http://www.gs1.org/healthcare/udi>

SMS focusses on the provision of modern solutions to the healthcare industry

SMS is one of the pioneer companies in the field of medical devices, having variety of solutions for the hospitals, laboratories, blood-banks, research institutes, industries and healthcare service providers, from a basic test of blood grouping to advanced, state-of-the-art modalities for in-vitro diagnostics, automated robotic solutions for bio-banking and many more.

SMS has always kept its focus on provision of modern solutions to the industry with premium quality services at affordable prices. Apart from diagnostics, SMS also possesses a wide range of surgical and disposable medical devices such as surgical sutures, syringes (all types) etc. from renowned companies around the globe with assurance of globally accepted credentials such as FDA approved, CE marked and WHO approval/prequalified.

Currently, SMS is marketing the medical devices from BioRad Laboratories (USA), DiaSorin (Italy), Awareness Technology Inc (USA), Elitech, Alifax (Italy), Tecan Group (Switzerland), Trinity Biotech, Demetech (USA), Telic (Spain), Wuxi Yushou (China) and many leading companies from around the world.

Sind Medical Stores was established in 1958 initially starting off as a manufacturing concern — Standard Laboratories — further expansion of the production facilities saw the manufacturing for Rona Laboratories SA., later entering into the business of importing medical products at the same time from Brovon Laboratories and B. Siegfried. Successful manufacturing and distribution experience led to further expansion of the organisation.

Today, SMS is Pakistan's leading marketing, distribution and healthcare service company with pan Pakistan offices.

SMS acts as an interface between the high-tech innovative product development companies and the marketplace. It has an enviable reputation for building excellent brands and securing their distribution for the healthcare market of Pakistan. SMS has the proven capability of further raising the profile of the brands with the end-users through its professional approach and marketing expertise.

Biological Division of SMS is the leading supplier of life saving vaccines and biological products in Pakistan. The Diagnostic Division of SMS has installed more than 1500 diagnostic equipment in all major hospitals, blood-banks and private laboratories all over Pakistan. A professionally trained engineering team takes care of the after-sales services. The company's Industrial Division works with country's vast industrial segment from pharmaceutical, biotechnology, food & agriculture, poultry & dairy, chemicals and polymers, by offering them solutions in respect of healthcare, infection control, research and development, environment protection and sustainability of critical resources, such as potable water.

SMS is an ISO certified company having all its systems and protocols in place according to the industry and regulatory requirements. We possess state-of-the-art cold storage capacity, validated by Ministry of Health Pakistan, which enables SMS to maintain large inventories of life saving vaccines, diagnostic kits and reagents. The refrigerated trucks, which are capable of maintaining temperature even up to -20°C, help us maintain the cold chain during transits.

In a nutshell, SMS is a complete desirable package for both manufacturers and customers having quality products, complete market coverage, best handling of the products according to its recommendation and requirements and efficient after-sales services. ■

Hospicare Systems is offering high quality products at competitive prices

Hospicare Systems is ISO 9001:2015, ISO 13485:2016, MDR-2017 compliant company serving from 2003 in the healthcare industry as medical device and diagnostic importers along with its sister-concern "Muslim Trading Agency (MTA)" which was established in 1971.

From general medical devices like glucometers to high efficient medical devices like patient monitors, ventilators and lab diagnostic reagents and equipments, we deal in all kinds of medical equipment.

Our CEO, Mr. Masood Ahmed, is highly qualified and a technical entrepreneur. He is an engineering graduate with more than 18 years of sales and marketing experience who started the company from the scratch in year 2003 and established a well-reputed distribution setup in Pakistan's diagnostic, clinical and pharmaceutical market.

He has travelled around the globe and has in-depth understanding of Pakistan's medical industry. Mr. Masood Ahmed is now benefiting the industry as HDAP's chairman.

Our mission is to consistently provide the customers with the finest products on competitive prices backed by unmatched customer services. We continuously strive to be the best company to ensure our customers that they can rely on our products to ultimately improve the lives of the patients they serve.

At Hospicare Systems, our commitment is to provide the customers with high quality, cost-effective products that are in compliance with standards and regulatory requirements in an atmosphere that maintains and continuously improves quality management system effectiveness, and promotes customer satisfaction.

Our areas of expertise lies in various fields including: hospitals (ICU, CCU, NICU, operation theatres and blood-bank setups), laboratories (microbiology, biochemistry, molecular pathology, histopathology, cytogenetics, hematology and research laboratories) and pharmaceuticals (pharmacies, pharmaceutical industries and pharmaceutical laboratories).



Team Hs, MTA and MMS at Health Asia 2019, Karachi.

- Our services include sales i.e. product knowledge, prospecting, searching for new customers and the approach, understanding the customer's need, servicing i.e. proper service provisions, on-time delivery, customer satisfaction, clear communication skills, knowledge of the product, ability to use, positive language, time management skills and marketing i.e. price, product, promotion, and place, market creation, new product launch, business development, social networking, online marketing, advertisements, sell to customer needs, ask, listen, and act, exhibitions, trainings.
- Our service providers i.e. our engineers, technicians, application specialists and sales team have received many national and international trainings for their respective products. Our sales and service team have been trained globally by our respective principals.
- Our team is always available for customer support and they help out with the queries of our customers very efficiently.
- Our groups of companies are authorised distributors of following renowned healthcare brands in Pakistan.
- Randox — Bio-chemistry analysers, Bio-chip array analyzer, third party reagents and online software.
 - Binder — Ovens, Safety cabinets, Incubators, etc.
 - Abbott Molecular — Real Time PCRm24sp/m2000sp, FISH, HLA.
 - Aesku Diagnostic — Fully Automated ANA Processor and kits, Blot and ELISA products
 - Grifols — GRIFOLS Procleix Panther System for NAT Testing (HIV1, HIV2, HBV and HCV)
 - Haier — Refrigerators, Freezers, Water Baths, Laminar Flow and Safety Cabinets.
 - Motic — Microscope with Camera
 - Dirui — Automatic Urinalysis System (FUS-200/H-800)
 - RR mechatronics — Westergreen Gold Standard ESR Analyzers
 - Beurer — Medical, beauty, therapy, baby care, sports, etc.
 - Capecod — The Fungitell® kit
 - Genesis — Blood Bag Shaker, Sealer, Stripper & Plasma Extractor Instruments.
 - Medtronic — Ventilator (Puritan Bennett), Ventilators Newport, INVOS, Pulse Oximeters. ■

B. Braun protecting and improving lives

B. Braun is a leading manufacturer of medical technology and pharmaceutical products worldwide. The company employs 64,000 people in 64 countries. Our goal is the continuous care and improvement of people's health. The B. Braun product range comprises of 5,000 products, 95% of which are manufactured in-house in our 112 factories, focussing on 18 therapy fields and includes company-owned dialysis centres, as well as services and consulting for optimising hospital processes to prepare the patients and their families for at-home care.

In Pakistan, B. Braun is one of the largest and well-reputed companies dealing in medical devices. The medical devices sector includes both medical devices (such as X-Ray equipment, ultrasound machines, reagent and test-kits, stents and balloons) and medical equipment (surgical equipment e.g. scalpels, blood-pressure monitors, and other items like disposable gloves and masks) and is considered a high-value industry. The sector is seeing an ongoing growth despite the unfavourable economic conditions, partly because, its products are life essentials for the aging population.

In Pakistan, this area has been particularly challenging due to the fact that no law governed the medical devices until the Medical Device Rules were implemented. But change can be a painful and gruelling process and so the medical device industry has really suffered as a result.

According to Business Monitor International, the medical devices market in Pakistan is worth \$457.1mn and projected to increase to \$537.5mn by 2020, an increase by 6.2 per cent. The healthcare services and medical devices are in high demand in Pakistan, especially in the growing private healthcare market.

The healthcare providers include government, NGOs, and the private sector. Private hospitals and clinics are also expanding rapidly, especially in cities, catering to a rapidly growing middle class.

Whereas the future of medical devices is bright in Pakistan, the regulations need to support this growing sector. In the current economic challenges, we, as a company, strive to practice the utmost compliance and ethical standards.

At B. Braun, globally, the vision is to protect and improve the health of people around the world and, at the core of it all, that is what we strive to achieve. ■

Critical care division's participation in different exhibitions.

A group of people standing in front of a Medtronic exhibition booth at a trade show.



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Hoora Pharma — one of the best IVD companies in Pakistan



Signing ceremony between Hoora Pharma and Siemens Heathineers to introduce the new technology in IVD in Pakistan and Afghanistan.

HOORA Pharma, a growing enterprise, progressed exponentially during the last 12 years to become one of the leading in vitro diagnostic medical device (IVD) companies in Pakistan. Hoora Pharma started its operation in 2001 on a small scale, representing Dade Behring, a US-based company promoting Fully Automated Clinical Chemistry Analyzer, and BioMerieux, a France-based chemical company, with office in Karachi and limited workforce including sales and service staff. Hoora Pharma achieved a significant breakthrough with installation of Total Lab Automation

project in Aga Khan University Hospital, Karachi, which was the first in South Asia. This reference generated queries by leading institutions to automate their laboratory practices. Shaukat Khanum Hospital and Research Centre, Lahore, followed the suit and decided to install Lab Automation Project in the hospital. AKUH and SKMTH initiated more references and A.F Institute of Pathology Rawalpindi opted for Total Lab Automation. Hoora Pharma represented international companies in Pakistan without compromising on the quality of products and ethical standards which are implemented in all areas of company operations.



Upcoming Hi-Tech pharmaceuticals plant “Pinnacle Biotech”.

Hoora Pharma is an ISO and GDPMD certified company and follows strict compliances instituted by Siemens and other international companies. Hoora Pharma is also registered with DRAP and now all medical devices are being licensed with DRAP for the protection and safety of people.

Supply Chain
Hoora Pharma (Pvt.) Ltd. is a certified company and implementing GDPMD procedures. It has the largest warehouse within premises, walk-in cold storage, complete supply chain tracking system, cold chain tracking by data logger and fully trained and competent warehouse staff. ■

Siemens

SIEMENS, a leading imaging instrument German company, decided to diversify its product portfolio to IVD Diagnostic range worldwide and work through business partners in South Asia and Middle East. Siemens, in order to enter into IVD Diagnostic, purchased three Diagnostic companies internationally. These three companies were established operating entities. Hoora Pharma was chosen to be appointed as Siemens approved partners for Pakistan and later the territory was extended to Afghanistan.



An overview of Pakistan’s medical devices and diagnostic industry

By Adnan A. Siddiqui

PAKISTAN medical devices and diagnostic industry is estimated to worth approx \$600mn in 2017. The industry is primarily import driven as over 90% medical devices and diagnostic products consumed in Pakistan are imported from various parts of the world. Pakistan is known for export of fine quality surgical instruments from Sialkot which contributes significantly in the country’s GDP. There are very few MD&D multinationals operating within Pakistan whereas most of the MNCs are represented through various importers/distributors. The medical devices and diagnostic industry is in process of recently implemented regulation by government through Medical Device Rules, 2017 as the government aims to regulate all MD&D products in the next couple of years.

Diversification
The medical devices and diagnostic industry can be defined in one word — diversity. Just like each human being is different, almost in a similar way, the medical devices industry and products are diversified. The medical device industry has invented and developed uncountable amounts of medical devices, which are used daily for uncountable types of medical treatments and therapies. Medical devices are available in a wide range of sizes or are size adaptable to match with most patients’ needs and anatomical differences. Nevertheless, there is still enough room for patient-specific medical devices. Especially in cases, where anatomical situation has to be addressed most adequately (e.g., specific dental implants), an individualised device has to be taken into account. Formerly, individual medical devices could be understood as the need of manually performed labour. The medical device industry is estimated at US\$150bn worldwide as medical devices have now become indispensable tools in modern clinical practice. MD&D industry is represented through ‘Healthcare Devices Association of Pakistan’(HDAP) which is a very active association of medical devices & diagnostic industry stakeholders in Pakistan.

Healthcare infrastructure
Pakistan healthcare infrastructure is a combination of government and private facilities spread over urban and rural areas, however, major facilities are primarily located in urban localities only. Pakistan has 36 government teaching institutions/hospitals whereas the healthcare is further supported by 34 private teaching institutions/hospitals. In addition to these teaching hospitals, the government has over 1200 hospitals, 5518 Basic Health Units (BHUs) and 683 Rural Health Centres (RHCs). The total availability of beds in these facilities is over 120,000. The government’s healthcare spending is less than 1% of its GDP, which is way below the WHO benchmark of at least 6 per cent of the GDP required to provide basic and life saving services. Currently Pakistan’s per capita health spending is US\$36.2 which is significantly lower than the WHO’S low income countries benchmark of US\$86. The impact of low spending on healthcare is clearly reflected by the size of medical devices and diagnostic industry for a country of 200mn plus population.

- Vital stats**
- Population of Pakistan – 207,774,520
 - Registered doctors – 195,896
 - Registered dentists – 18,333
 - Registered nurses – 99,228
 - One doctor for 997 patients
 - One dentist for 10,658 patients
 - One hospital bed for 1,584 patients. ■

Author bio
Adnan A. Siddiqui is a business graduate who spent his whole life in medical devices and diagnostic industry working for blue chip companies. He has worked closely with industry leaders of Pakistan, Asia Pacific and Middle East. He is now managing his own medical devices business while advocating and contributing towards shaping the healthcare environment of Pakistan.



Hoora Pharma is a prominent partner of globally renowned companies of State-Of-The-Art equipment catering to the requirements of Health care Sector for diagnostic needs.

We take pride in our 15 years of impressive portfolio of having successfully completed projects, thus making important and vital contribution in the development of health care Sector by providing Diagnostic Solutions that improve outcomes and reduce costs.

We know that healthcare is rapidly changing, and we understand the challenges and pressures that come along with it – Including the need for continuous clinical functions, and financial efficiencies.

We pledge to use our resources & expertise to improve lives of people of Pakistan through our contribution & experience in social sectors such as Health care. Therefore, continue to help build a strong & resilient Pakistan for our coming Generations.



At Siemens Healthineers, we are passionate about enabling healthcare providers worldwide to deliver high-quality patient care, and to do so affordably.

As a leading global healthcare company, we at Siemens Healthineers continuously develop our portfolio further, from medical imaging and laboratory diagnostics, to adding managed services, consulting, and healthcare IT services – as well as further technologies for therapeutic and molecular diagnostics.

