QUALITY COUNCIL® OF INDIA
QCI
Creating an Ecosystem for Quality

PADD

THIRD EDITION 2021

PADD INSIGHTS

JAN' 21 - SEP' 21

INSIDE THIS EDITION

FROM THE EDITOR'S DESK

Dear readers,

Welcome to the third edition of PADD Insights - newsletter of the Project Analysis and Documentation Division (PADD), Quality Council of India.

The novel coronavirus pandemic has spawned healthcare crises that reveal and compound deep underlying problems in the health care systems of the world. However, the pandemic has made us realize that we need to take measures that could improve our ability not only to cope up with likely future incidents but also to think about a way forward in the healthcare sector.

This edition will therefore highlight some of our initiatives in the broad theme of healthcare, the developments in PADD, milestones achieved and the interview of a person of excellence. PADD's involvement in the healthcare sector is reflected in crucial schemes such as ICMED, VCSMPP, AYUSH Mark scheme and VCS-TCHP. We are delighted to share the updates with you and present our engagement in the healthcare sector.

Motivated by the valuable guidance of the Chairman and the Secretary General, PADD has seen major updates this year. We extend our gratitude to the management and our team for their valuable guidance and support throughout this journey.

We encourage you to read more about our recent activities and our regular updates in this Newsletter. In writing this, we would like you to follow our journey on our Twitter account.

Happy reading!
Aayushi Dhawan
Reeti Mahobe

FROM THE DIRECTOR'S DESK

It is with immense pleasure that we present to you the third edition of 'PADD Insights'. At PADD, we have made steady progress in developing new initiatives and innovations for the Indian as well as International Stakeholders.

Recent events in the world have highlighted the importance of building a resilient and adaptive organization. It is a time of great uncertainty considering the pandemic situation in the world. We, at PADD, ensured that our energies are directed on high leverage tasks. PADD has been working tirelessly since the lockdown to ensure steady progress in developing new initiatives and expanding programmes even in the COVID era.

The newsletter paints a picture of the activities of the schemes and projects in PADD and focuses on the broad ranging theme of healthcare. Offering further food for thought in the healthcare domain is Mr. K. L. Sharma, former Joint Secretary, Ministry of Health and Family Welfare, who is a pioneer in this field. I would like to express my gratitude towards him for taking out his time and giving us an interview exclusively for this edition.

We are grateful to our stakeholders, our team, our colleagues from other Boards and the management team for their continuous support in all our endeavours. The team is growing stronger and working with more rigour to take PADD to greater heights, thereby building a thriving stakeholder community.

Our involvement in the healthcare domain is deep rooted through our schemes. I trust the newsletter would give an update on intervention of PADD in flagship initiatives of government such as drones, smart food, cyber security and bio-trade.

Hope it offers an enriching experience. Looking forward to continued engagement with all our stakeholders.

Warm Regards,
Dr. Manish Pande

ABOUT PROJECT ANALYSIS AND DOCUMENTATION DIVISION (PADD)

The Project Analysis and Documentation Division (PADD) of QCI handles projects which aim towards the design, development, and implementation of voluntary conformity assessment frameworks for governmental, inter-governmental, regional, and global organizations.

The Division prides itself in driving noble initiatives that have national, regional, and global relevance. QCI through this division continues to offer solutions to various Government ministries/ departments/ organizations, industrial bodies, international donor agencies, developmental organizations, and inter-governmental bodies such as the FAO of the UN, ICRISAT, ITTO, UNDP, UNCTAD, UNFSS, UNCTAD, SAARC Agriculture Centre etc.

PAD Division currently handles numerous voluntary certification schemes and projects cutting across various sectors ranging from agriculture, aviation, bio-trade, construction, cyber security, food, forestry, healthcare and traditional knowledge. Explore more about PADD **here.**

PADD

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Exclusive Interview

Sh. K.L. Sharma in conversation with Ms. Aayushi Dhawan

Sh. K.L. Sharma is a **career civil servant** who worked in the Government of India for four decades. Having been part of the Cabinet Secretariat for around 11 years, he has a ringside view of the governance in India. During the period, he worked in Cabinet Secretariat, Rashtrapati Bhawan, he coordinated all the meetings of the Union Cabinet and its Committees and remained present in them. For over a decade, he also trained the middle and senior-level government officials on writing proposals for the Cabinet and Cabinet Committee at the Lal Bahadur Shastri National Academy of Administration, Mussoorie and the Institute of Secretariat Training & Management, New Delhi.

Between 2014 and 2017, he worked as the **Joint Secretary in the Ministry of Health and Family Welfare**. During that period, he streamlined the processes and rationalized rules for regulation of drugs, cosmetics, medical devices and clinical trials. It was during this period that Medical Devices Rules, 2017 were notified. A strong supporter of quality, his stewardship witnessed prohibition of the irrational Fixed Dose Combinations in 2016; conduct of the largest ever drug survey 2014–16 involving over 47,000 samples; risk-based inspections of the pharmaceutical manufacturers and surprise inspection of the wholesale pharmacies in Delhi in June, 2017. He has authored a book titled "**Healing the Pharmacy of the World**". It has been published in August 2021. The book also includes a chapter on medical devices.

1. In the wake of COVID-19 pandemic, the relevance of healthcare industry and public health was felt worldwide. How do you analyze the present situation in India within the larger global perspective?

The COVID-19 pandemic induced health crisis has morphed into an economic catastrophe for all the countries. The pandemic will have serious long-term consequences with its impact likely to be even severer than the 2008 global meltdown. The scale and the ferocity of the pandemic impacted almost all sectors of the economy including the healthcare sector, education, industry, tourism, etc. in multiple ways. It has changed the healthcare landscape for good. The adverse impact of the pandemic has been felt even in countries that had done an elaborate exercise for handling epidemics. The suffering was much more in other countries.

In India, it took the entire healthcare sector and the governments, both the central and state, by surprise. The worst affected were the migrant workers who did not have any means to survive without work and they had, in view of the lockdown, no means to travel back to their native places. Given the large number of migrants, despite best efforts made by the Government, their sufferings could not be mitigated.

The second wave of the pandemic in April-May 2021 has impacted almost every family with a large number of mortalities especially in the metropolitan cities including Delhi. The scale of the pandemic forced diverting all healthcare facilities and resources for COVID-19 management. Many critical healthcare activities such as dialysis or emergent cardiac procedures, other routine healthcare activities and the elective procedures had to be put on the backburner. The result of this was that a large number of professionals, the specialists and the super specialists in diverse fields, remained idle while the patients suffered. The pandemic also created major shortages of critical components such as medicines, oxygen, intensive care facilities, ventilators and personal

protection equipment for caregivers both at home and in healthcare facilities.

It has been observed that by and large, the response to the virus has been more effective in countries with state-funded healthcare systems such as Singapore, Taiwan, New Zealand and Japan. The uniform access to testing facilities either for free or with significant state subsidy in these countries helped in better management of the crisis. Even in India, the states that have better equipped and functional public healthcare facilities performed better than the states where the healthcare facilities are mostly in the private sector.

In India, the process of vaccination is picking up slowly. Given the limited availability of vaccines and the time required for scaling up of the production of vaccines, it will take time to inoculate everyone. In the interregnum, it will be necessary to adhere to non-pharmacological interventions and there cannot be any let up in those.

2. What lessons have we learnt from the COVID-19 crisis?

The critical lessons learnt from this pandemic include that the state cannot completely recede from providing public healthcare and entrust it substantially to the private sector. It is, however, another matter that the public healthcare facilities need to be better equipped and professionally reoriented. The other equally important lesson to be learnt is that the remit of the respective governments in the Indian federation in so far as health is concerned needs to be revisited. Currently, public health falls in the domain of the states. The interference by the Centre can, therefore, be questioned legitimately. There can be no doubt that the solutions for health emergencies cannot be state specific and, in any case, most international bodies interact only with the federal government. Shifting of the public health to the Concurrent List might, in this light, appear to be in order. It will, in fact, even require intense international collaboration in view of the fact that no one is safe till everyone is safe.

An equally important lesson is that the healthcare spending has to be augmented substantially. This is necessary to make healthcare facilities resilient to handle any future health emergencies. Augmenting the research and development in healthcare related areas also needs serious attention. It needs to be remembered that nearly all the solutions deployed for managing the COVID-19 pandemic relied on the past R & D and innovations. Had the necessary investment not been made in the past, the consequences of the pandemic could have been much more devastating.

3. What do you think are the major challenges healthcare industry is facing today?

Healthcare Industry broadly comprises the healthcare providers (hospitals); the pharmaceutical industry; the medical devices industry; the diagnostic industry and the health insurance industry. At the centre of it all is the consumer. Efficient delivery of healthcare requires that all of them grow in tandem to provide maximum satisfaction to the consumer. The services should be affordable and accessible to all irrespective of their economic or social standing. Each of these five segments is today facing a crisis both in terms of constraints on demand as well as on supply side.

Hospitals do not have adequate and qualified human resources and very often they also lack the required equipment and other facilities. The public sector hospitals and other health facilities also lack human resources on account of issues relating to complexities of recruitment of human resources and procurement related processes. The machinery and equipment in most of the governmental facilities is outdated.

Sufficient investment is not happening in the development of new products especially in new blockbuster drugs including biologicals and state-of the-art devices and equipment due to freezing of the investment. The severe decline in publicly funded R & D has slowed down the innovation. The lack of funding for developing new technologies and translating them to deliverables that are useful for addressing health concerns and to replace the previous technologies that have reached their peak is a serious concern.

Access to medical devices and diagnostic facilities still remains confined to select few on account of the digital divide and the high prices of medicines and medical devices. The high out of pocket expenses force the patients with limited incomes to forego the treatment options and instead use the money for meeting day to day needs. There is a need for lowering the cost of medical products and the Indian industry is ideally suited for

filling up the vacuum with plenty of human resources. Currently, there are also concerns on account of the lax, inefficient and ambiguous government regulations that fail to imbibe confidence in the safety and efficacy of medical products.

While the health insurance sector has not developed in many countries, it has been misused in others. Access to safe, efficacious and quality essential healthcare is, in the process, denied. This impedes the realization of the highest attainable standard of health, a basic human right. On a larger note, this makes out a strong case for strengthening social security to take care of the most vulnerable sections of society.

4. Drastic surge in the usage of medical devices has been witnessed during the pandemic. This includes use of such devices even at household level. What do you think are the key concerns of the Indian medical devices industry and possible solutions?

The pandemic has upset the existing healthcare delivery protocols and procedures. It has led to the increasing use of digital technologies for delivery of healthcare. The use of medical devices has become commonplace with a number of households going in for user-friendly medical devices that do not require any specific skill-sets to operate or interpret the results. Those devices either on their own or in conjunction with smart phones provide the answers to many health concerns.

Indian medical device industry has a number of concerns. Inverted duty structure in respect of many segments has the effect of giving preference to imported medical devices by making imports cheaper than manufacturing in India. This limits the scope for local value addition. The ecosystem for fast paced growth of the medical devices industry is missing. Addressing this and launch of a well-calibrated scheme for stepping up domestic production of medical devices for catering to the domestic market and also for global market are the need of the hour. The current PLI scheme will need to be made more attractive and its scale enhanced manifold to compensate for the cost disadvantage that India has as of now in manufacturing medical devices.

There is also a need for shoring up the domestic demand for medical devices. Lack of comprehensive laws and lax regulatory procedure, poor mechanisms for IP protection dissuade the global medical devices players in India.

The absence of a proper certification agency also reduces both the marketability of medical devices within the country and export opportunities as many countries require a certificate or license from the country of origin. Currently, the indigenous manufacturers need to obtain FDA or CE certification to cater to the market in India and other parts of the world. The approval process for such certification, besides being a costly affair, takes a lot of time.

Another area of concern is that a major challenge for players in most segments/sub-segments is that a large part of the component supply chain is imported. The scope for 'local innovation' has been limited. India still lags behind most countries in terms of ease of doing business. The requirement of multiple agency approvals also results in delays. The cost of financing for setting up manufacturing facilities in India is still high.

5. When it comes to medical devices, how can standards help in addressing the issues of quality and safety?

The measurement of quality without specifying standards is not possible and standards are meaningless without the authority to enforce them. Standards provide a handy tool with which an independent judgment regarding the quality of medical products can be made. The standards form the basis for gauging the quality, safety and efficiency of medical devices. These need to be continuously revised to factor in developments in science and medical practices.

The product and process standards in respect of medical devices constitute the most critical element for safeguarding the interests of patients. These ensure the availability of medical devices that conform to the pre-defined specifications. The standards go a long way in harmonizing the specifications globally and facilitating international trade in such products. Harmonized standards can form the basis for driving economies of scale. It also facilitates harnessing the potential of India by leveraging comparative cost advantage and the demographic dividend.

The defects in medical devices or their non-conformance with the specified standards can expose patients to serious risks including injury, sickness and death. This is particularly true for devices such as infusion pumps,

pacemakers and many more. The product conformity in the design, development and manufacture of medical devices is, therefore, one of the most important considerations. Deviations from expectations and claims could threaten patients' health and increase his pain, discomfort and suffering. A structured and controlled way of designing, producing and distributing medical devices ensures that the products are safe and free from unacceptable risks.

The development and the use of standards is vital to ensuring the safety and efficacy of medical devices and consumers. Regulatory agencies and standards setting organizations need to collaborate with each other for laying down the standards for medical devices and their enforcement. The standards should include development of performance characteristics, characterization and testing methodologies, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labelling, etc. The feasibility of establishing synergy between the CDSCO, QCI and BIS for standard setting and conformance with such standards needs to be explored.

6. The Quality Council of India (QCI) launched the ICMeD Plus scheme. How do you think this will contribute to India's Atmanirbhar Bharat and shape the future of industry?

ICMED and ICMED PLUS are voluntary certification scheme that are designed to support the regulators with functional quality assurance and product certification system. These schemes subsume both ISO 13485:2016 as well as Schedule 5 of the Medical Device Rules, 2017 along with the additional regulatory requirements and horizontal standards such as ISO 14971 on Risk management and Essential Principles of Patient Safety.

Pending complete regulation of medical devices by CDSCO, ICMED 13485 Plus provides a mechanism for the Indian industry to demonstrate compliance with a number of product standards - ASTM or EN or ISO or IEC. It also prepares the Indian industry to enter the global market. Many regulatory bodies ask for reduced regulatory oversight from those who have voluntary certification. USA, Health Canada, Brazil, Australia, Japan and even WHO waive of the on-site factory audit of manufacturers who are certified voluntarily. Eventually in India also we will need to develop the non-governmental structures to fill the regulatory gaps.

It needs to be recognized that in case of international certification, the genuineness and authenticity of the Certificates cannot be verified easily. The necessary wherewithal to track and trace the origin of the certificates issued is not widely available. This makes it difficult for consumers to distinguish between brands of Medical Devices that are safe and efficient or are lacking in quality vis-à-vis the prescribed specifications and standards. An ICMED plus certification can help them to make an informed choice.

Manufacturers with CE mark or USFDA approval have easier access in Indian market. An Indian manufacturer selling products in India has no mechanism to demonstrate conformance to standards. ICMED schemes will bridge the vacuum. Indian authorities should not push the domestic manufacturers to shell out a lot of money for acquiring CE or USFDA certification.

7. Medical Devices form a crucial aspect of healthcare industry. In view of the increasing importance of healthcare industry, what are your suggestions for improving the Indian policy framework concerning medical devices?

The new developments in the field of medical science have facilitated precision in the delivery of healthcare. Be it the prevention, diagnosis, treatment, cure or management of diseases, the scientific developments have made the tasks simpler and results more predictable. However, a bad quality medical product can cause unprecedented harm not only to the individual patient but also to the public at large.

Despite the often-touted scientific and engineering prowess of the country and the demographic dividend, close to 80-85% of medical devices required in India still continue to be imported. The very high level of dependence on the imported medical devices entails an annual outgo of around Rs 45,000/- crore. This is bound to increase further with the growth of the demand due to increase in population; higher disease burden; ageing of population and the improvement in the standard of living.

In the emerging geo-strategic environment, the Indian industry and government have to take the initiative to scale up the indigenous manufacturing. India has the requisite potential and it could propel its medical device industry on a high-growth trajectory with a compound annual growth rate (CAGR)

of around 23% for the next eight to ten years. Rather than being the net importer of medical devices, India has the potential to cater to the global market. Leveraging Indian entrepreneurship, provision of a nurturing ecosystem, adherence to quality standards, collaboration with international players and economies of scale can help India become the global manufacturing hub for medical devices. This will need recalibrating India's strategy. Achieving it will help generate employment, increase GDP and enhance the accessibility of medical devices across the globe. Incrementalism or inward-looking attitude on the other hand would only thwart the mission.

Successful transition of the Indian industry to a world-class medical devices manufacturing hub will, besides intent, require a robust regulatory structure, consistency in policies especially for incentivising manufacturing and research & development, handholding of industry and rendering assistance for managing crisis and improved information dissemination. With right incentives, it is possible to even push the industry to perform beyond its potential.

Admittedly, there is a need for focusing on innovation. This will entail accelerating the approvals by making the regulatory pathways and processes shorter through a single window clearance mechanism and protection of intellectual property rights; incentivizing R&D through schemes such as restructured PLI, risk sharing and tax exemption; and collaboration between the public and private players to gainfully utilize the spare facility wherever it exists.

The current PLI schemes will need to be restructured to better sub-serve the objectives of making India globally competitive; attracting investment; ensuring efficiencies; and driving innovations in the cutting-edge technologies. A PLI scheme could also be introduced for augmenting research and developmental activities by the private sector. It will be necessary to ensure continuity of the schemes over a longer period of time with such modifications as may be necessary to attract quality investors/manufacturers.

India will do better with 'One nation, one law and one regulator for medical products,' rather than three dozen-plus drug regulators. The governments will need to take serious steps both for augmenting the quality of medical products for which strengthening of regulatory structures will be necessary and offer financial, fiscal and other support for attracting the industry and enabling them to relocate to India. The burden of the National Regulator also needs to be reduced by setting up robust national certifying bodies to take up the work of certifying conformance.

The approval process for new medical products should be automated to the extent feasible by leveraging technology. Appropriate schemes should be drawn up for incentivizing integrity programs for ensuring compliances.

All possible support needs to be provided to the industry for migrating to best-quality manufacturing of medical products at the lowest cost.

Theme for the Edition
HEALTHCARE

Healthcare sector is amongst the most prominent domains as it touches the lives of every individual. The significance was even more palpable owing to Covid-19 pandemic. Varied dimensions within the healthcare sector from medical professionals, paramedical staff, public health functionaries, medical devices, pharmaceuticals, medical research, epidemiology, different schools of medicines and so forth hold their relevance in contributing to humanity as a whole.

While Sustainable Development Goal #3 is directly aligned to the 'Healthcare Sector', many other SDGs are also impacted with interventions in the healthcare sector. UN Secretary General Antonio Guterres has underlined the urgent need for the countries to increase investment in healthcare initiatives.

The healthcare budget in India saw a whopping increase of 137% to over Rs. 2.23 lakh crores for the financial year 2021-22. Moving forward, India has been one of the biggest vaccine manufacturers worldwide besides in the overall pharma industry. Thus overall, India has been making strides in terms of not just healthcare coverage, expenditure but also production and medical supplies domestically and across the globe.

India remains committed to ensuring quality healthcare services through a host of government schemes, new infrastructure, upgradation of existing infrastructure, investments in healthcare technology, research, telemedicine, and medical supplies.

QCI also has been at the forefront in providing services to the healthcare sector in terms of accreditation provided by NABH, NABCB and NABL and ensuring quality service delivery.

ROLE OF PADD IN HEALTHCARE INITIATIVES

Pandemic has highlighted the importance of building resilient, responsive and quality healthcare services both in terms of supplies as well as schools of medicine. PADD has also come up with a unique blend of schemes in the sector which cater to quality and process driven production of medical devices, AYUSH products and personnel certification of traditional community healthcare practitioners.

Through PADD's upgraded **ICMED Scheme**, it aims to integrate the Quality Management System components and product related quality validation processes through technical file review, witness testing of products with reference to the defined product standards and specifications. This is the first scheme around the world in which quality management systems along with product certification standards are integrated with regulatory requirements. This scheme comes with an objective to provide an end-to-end quality assurance scheme for the medical devices sector in India.

Voluntary Certification Scheme for Medicinal Plant Produce (VCSMPP) was formulated by QCI at the behest of NMPB, M/o AYUSH for introducing quality and traceability in the medicinal plants trade. Medicinal plants, being the raw material for AYUSH medicines, account for around 90% of AYUSH formulations which practically implies that the sustainability of the AYUSH traditional medicinal system is based on the degree of care with which medicinal plants are handled. It is designed to introduce Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) in India's medicinal plants sector and enhance confidence in produce quality among the buyers and consumers.

In coordination with the **Ministry of AYUSH**, QCI runs a voluntary product certification scheme with two levels namely, AYUSH Standard Mark and AYUSH Premium Mark. The former one, that is, AYUSH standard mark is based on compliance to the domestic regulatory requirements. The latter one, that is, AYUSH Premium mark is based on GMP requirements based on WHO Guidelines and product requirements with flexibility to certify against any overseas regulation.

PADD runs a **Voluntary Certification Scheme for Traditional Community Healthcare Providers** by employing the best practices and adopting/adapting standards and certification systems to ensure consistency and defining a mechanism to continuously monitor the activities. The Scheme also covers training to persons practising in the field of Traditional Community Healthcare Providers to upgrade them to the prescribed requirements if gaps in their knowledge and skills are found. Besides following an integrated approach, the **National Interpretation Guidelines (NIG) on GLOBALG.A.P.** prepared by PADD also has components on occupational health & safety. Similar components were considered during the **SDG Impact Study report** of TRINITEA standard and VRIKSH standard.

FEATURE OF THE EDITION

Joanna Kane-Potaka

About the author:

Joanna is Australian and began her career as an agricultural economist, later moving into market research in the agribusiness area. Since then, she has worked in a wide variety of other marketing-related areas including strategic marketing, communications, fundraising, knowledge management, and uptake of scientific research. She has worked for government, private industry and with non-profit organizations. As part of this she has lived and worked in Australia, Sri Lanka, Italy, Malaysia, the Philippines and in India for 9 years.

Integrating nutrition into food and agriculture strategies:
Arguably the two largest issues that face humanity are climate change and nutrition/health. Agriculture and food approaches are key to mitigation and adaptation to climate change while also being at the heart of our nutrition and health. The following approaches provide a glimpse into emerging trends in the arena of nutrition in food and agriculture:

Understand nutrition by variety:
Nutrition levels of crops and other foods can vary significantly just by the variety selected. The nutrition levels of seeds are rarely even measured or recorded. We know we can triple the amount of iron in millet, just by the variety selected. This is a massive variation and can contribute to overcoming anaemia which is at alarming levels across different age groups, especially among women. The GoI implemented an innovative initiative a few years ago when they set a minimum level of iron for any pearl millet variety to be allowed to be released by the government authorities. The challenge is to build the data, awareness and branding around the different varieties.

Benefits of biofortification: Going a step ahead of understanding varieties, is biofortification which refers to breeding new varieties taking micro or macro nutrients into account like iron, protein etc. This is a natural way to ensure availability of more nutritious foods. In the past, breeding typically focused on traits like yield and pest and disease resistance and drought tolerance. Now there is greater attention to including nutrition in breeding programs. The challenge is receiving a premium price or even being recognized since the farmer can't see the nutrients in the seed and the consumer can't see it in the food.

Switching to whole grains - a healthier alternative to refined grains: A major loss of nutrients happens when we refine our grains. White refined rice is typically empty calories and a major cause of diabetes because the stripping of fibre leaves the rice with a high Glycemic Index (GI). Whole wheat not only has good fibre levels but also many nutrients. However, when refined to e.g., atta, it can do more harm than good. We need to relearn our cooking and tastes familiar to us, to appreciate whole grain foods. Stronger labelling, certification and promotions can help highlight the importance of whole grains.

Giving fillip to natural farming and natural foods: Organic farming became popular, and so has natural farming. Similarly, natural foods, i.e., without artificial additives and preservatives, are increasing in popularity. A challenge in India is to further develop systems that are more robust so that something claimed natural is genuine.

Ultra-processed and the new protein foods: Health problems like obesity, which is increasing globally and cardiovascular disease, which is the number one cause of death worldwide, is impacted by the popularity of junk foods and ultra-processed foods. The huge rise in popularity of fake meats, is often positioned as a health food yet consumers are unaware of the ultra-processing and chemical additives that are needed to turn a legume into something that looks and

tastes like meat. More is needed to ensure consumer awareness and labelling foods more accurately.

Nutrition washing: 'Green washing' is a term that represents products that through branding and packaging present themselves as being environmentally sustainable, yet this is not substantiated. This can also happen for the nutrition of the food, creating 'nutrition washing'.

Nutrition sensitive agriculture: What we grow typically represents what we eat. There has been more attention on designing and supporting agriculture that is not only focused on yield productivity but also on supporting more nutritious and diverse foods in agriculture and in our diets.

Diet based solutions: There are three main ways to tackle the nutrition our human bodies need – supplements, fortification of food or healthier diets. Supplements and fortification typically use artificial chemicals but are often needed in an emergency situation. Long term solutions should be based on sustainable solutions of supporting healthier diets. This is tougher to achieve but is not a Band-Aid solution and instead a sustainable solution. It will need holistic and supportive policies to support this and healthy foods that are affordable and accessible to all.

Popularizing smart foods in India starting with millets: This is a big new trend in India and likely to spread globally. In March this year the UN General Assembly unanimously approved 2023 as the International Year of Millets, a proposal led by the GoI. Many initiatives are being planned and 2023 is likely to be the turning point for major global attention to millets. Millets are known as smart foods because they are good for you (nutritious and healthy), good for the planet (environmentally sustainable) and good for the farmer (as they are climate smart and able to grow with minimal water and minimal inputs). The largest studies on the nutrition of millets just released this year show that they have an average low GI and can help reduce the risk of diabetes. Also, the studies have shown that millets reduce cholesterol, triacylglycerol, blood pressure and BMI (Body Mass Index), overall reducing the risk of cardiovascular disease. The next in the series of these studies, soon to be released, show that millets also reduce anaemia and help with growth of children. Millets do not have as well-developed value chains and standards like the big staples, so much needs to be undertaken to have them reach the global status they deserve.

Solutions should not be in a silo: Lastly, is the overall approach needed when any of these issues or solutions are tackled. Nutrition and health are very important however, food and agriculture solutions should take a 'smart food triple bottom line' where any solution devised should ensure that it is good for you, planet and farmer, in unison.

ACTIVITIES SPOTLIGHT

1. QCI realizes that the best way to improve the prospects of agriculture in the country is to address food safety, workers health and safety, environment management, and quality of produce. For this, QCI came up with the IndGAP Scheme that not only assists the big farmers but also helps the smallholders to practice good agricultural practices in their farm.

   QCI seeks to benchmark IndGAP to GLOBALG.A.P. for which APEDA has signed an MoU last year and subsequently approved a grant to cover the cost of benchmarking. Benchmarking would result in improvement in quality of produce, awareness regarding good agricultural practices and reduction in the transaction cost for exports. The Spices Board, GoI, has appreciated the value of food safety in spices and has given a grant for marketing and certification of projects under IndGAP.

Figure 1 : *Meeting between APEDA and QCI*

2. PADD developed a scheme, based on FSSAI guidelines, for approval of Hygiene Rating Audit Agencies (HRAAs) with an aim to help consumers make informed decisions regarding food outlets where they prefer to eat by encouraging businesses to improve hygiene and safety standards. The recognised agency will verify compliance with food hygiene and safety procedures laid down by the Food Safety and Standards Authority of India (FSSAI).

   QCI has observed a spurt of enquiries from the various entities to join the initiative by applying as an HRAA.

Figure 2 : *Approval of first HRAA*

3. Voluntary Certification Scheme for Medicinal Plant Produce (VCSMPP) is designed to introduce Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) in India's medicinal plants sector and enhance confidence in produce quality among the buyers and consumers.

   39 trainings completed for various stakeholders, including technical training of CBs and master trainers, sensitization workshops and good agricultural and field collection practices workshops for farmers and collectors.

   51 POPs have been processed for medicinal plants of commercial importance.

   12 Projects for setting up of 'Demonstration Plots' identified for internalization of PoPs which would be offered for pilot certification.

Figure 3 : *VCSMPP Training in Pathankot, Punjab*

Figure 4 : *VCSMPP GAP workshop at Balangir, Odisha*

Figure 5 : *VCSMPP GAP workshop at Pratapgarh, Uttar Pradesh*

Figure 6 : *VCSMPP GFCP workshop at Korba, Chhatisgarh*

Figure 7 : *VCSMPP workshop at Giridih, Jharkhand*

4. Indian Certification of Medical Devices Scheme (ICMED) is a voluntary quality certification scheme for medical devices to enable the medical device industry to demonstrate adherence to the best international standards and enhance its credibility in the world market.

   170+ participants witnessed the launch of ICMED Plus. It would provide the much-needed institutional mechanism to assure quality of medical devices and fill the interim regulatory gap.

   Full report here: https://www.pib.gov.in/PressReleasePage.aspx?PRID=1728368

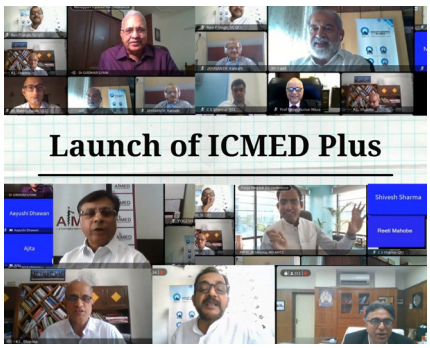

Figure 8 : *Launch of ICMeD Plus*

5. RPAS Scheme was approved by the Directorate General of Civil Aviation (DGCA). Sensitisation/Training Program on certification scheme for RPAS was organised which witnessed a whooping participation from over 225+ participants.

   The No-Permission-No-Takeoff (NPNT) test tool was launched for developers and CBs by Sh. Amber Dubey, Joint Secretary, MoCA on 2nd June 2021 to validate functionality. The tool is available at no-cost for one year. Link to the tool: https://npnt-tool.qcin.org/signUp

   The Drone Rules 2021 have been notified that cites QCI as being the exclusive body for specifying standards. The rules also cite QCI as the recommending authority based on which DGCA will issue type certificates.

Figure 9 : *Training Program on RPAS*

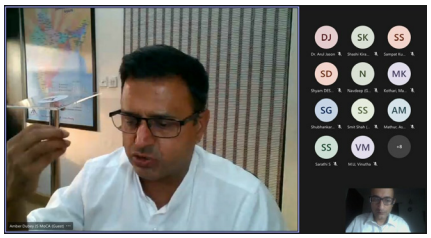

Figure 10 : *No-Permission-No-Takeoff (NPNT) Test tool launched by Sh. Amber Dubey*

6. ICRISAT has awarded QCI a project for design and development of Smart Food Certification Scheme.
   MoU has been signed with ICRISAT for design and development of certification Scheme on 'Smart Food' by Dr. Jacqueline d'Arros Hughes, Director General and Dr. Ravi P. Singh, SG, QCI.

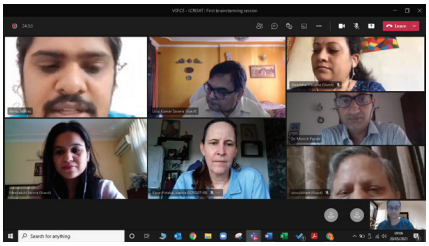

Figure 11 : *Brainstorming session on Voluntary Smart Food Certification Scheme (VSFCS)*

7. 7th week of Udyog Manthan organised by PADD. Webinars organised on 5 critical sectors: New and Renewable Energy, Air Conditioners, Fisheries, Aluminium and Set top Boxes.

8. TCHP - 2 days virtual training organised for evaluators and other staff of M/s CTTC.

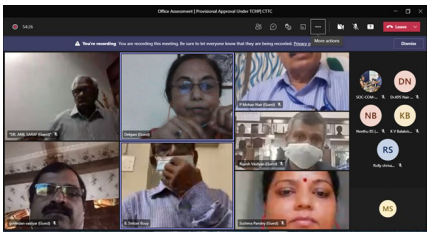

Figure 12 : *Virtual Training for CTTC under TCHP Scheme*

9. At the behest of the then Department of AYUSH, a voluntary product certification scheme for AYUSH products to enhance consumer confidence was designed by the Quality Council of India. Under the Scheme, any manufacturing unit can obtain a certification from a designated certification body (CB) and will be under regular surveillance of the certification body. The Scheme has two levels of certification: Standard and Premium.

   AYUSH Mark Technical Committee meeting was held to review the current scheme. More than 4500 products have been certified under AYUSH Mark Scheme.

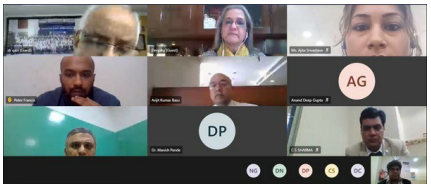

Figure 13 : *Technical Committee Meeting - AYUSH Mark*

10. The United Nations Development Programme (UNDP) has granted a project to QCI for intervention in bio-trade.

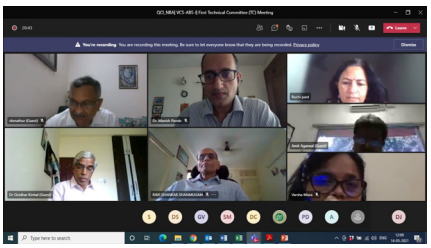

Figure 14 : *First Technical Committee Meeting of the project*

Figure 15 : *Cross-learning meeting between UNDP Costa Rica and QCI on bio-trade*

Figure 16 : *Discussion on the project*

11. The SAARC Regional Training by SAC, with PADD, QCI as its technical partner, was held on 24-25 May, 2021. It was graced by Dr. Muhammad Abdur Razzaque, MP, Hon'ble Minister, Ministry of Agriculture, Bangladesh and Dr. S.K Malhotra, Agriculture Commissioner, Ministry of Agriculture, India.

    Representatives from 8 SAARC nations participated in the Regional Training organised by the SAARC Agriculture Centre (SAC). It focused on developing capacity on understanding the process of GAP certification in SAARC nations.

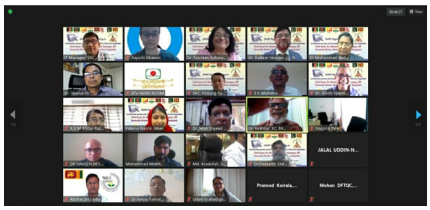

Figure 17 : *Training by SAARC Agriculture Centre and QCI*

12. Dr. Manish Pande (Director & Head, PADD, QCI), member, Chilli Task Force Committee, participated in the meeting chaired by Hon'ble RS MP Shri GVL Narsimha Rao. He emphasised on the importance of GAP in Spices and how IndGAP ensures quality and safety in spices.

13. Dr. Manish Pande, Director & Head of PADD, QCI, shared his views during the Online International Conference on 'Conservation, management and sustainable utilization of Lesser-Known Plants (LKPs)'.

Figure 18 : *International Conference on 'Conservation, management and sustainable utilization of LKPs'*

14. **NGCMA GLP Cell**

    PADD assists National Good Laboratory Practices Compliance Monitoring Authority (NGCMA) for the effective implementation of Good Laboratory Practices (GLP) certification programme. Security testing and existing module work of GLP Portal has been completed.

    Total of 51 GLP inspections have been conducted till date.

Figure 19 : *Training for Study Directors of GLP Test Facility*

15. QCI was entrusted upon by National Commission for Protection of Child Rights (NCPCR) to empanel fact finding cum audit agencies for protection of child rights, particularly against child labour in Indian industry and supply chain. The empanelled agencies in turn will be conducting independent fact-finding exercises and studies pertaining to sectors, industries, premises that are prone to child labour in order to establish facts and to mitigate any non-compliance found during the studies.

    QCI signed an MoU with National Commission for Protection of Child Rights (NCPCR) for conducting child labour audits/fact findings in different sectors and industries. MoU was signed by Dr. Ravi P. Singh, SG, QCI and Sh. Priyank Kanoongo, Chairperson, NCPCR.

Figure 20 : *MoU signed between NCPCR and QCI*

16. **Development of Conformity Assessment Systems and Resources for protection of CII for NCIIPC**

    Agreement signed between QCI and National Critical Information Infrastructure Protection Centre (NCIIPC) for development of conformity assessment framework for strengthening cyber security in Critical Information Infrastructure (CII) in power sector.

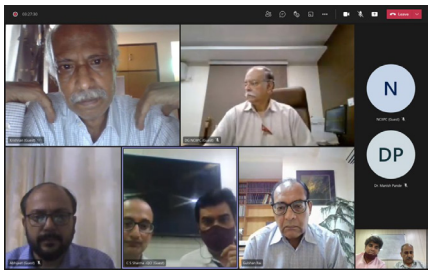

Figure 21 : *Steering Committee Meeting of NCIIPC Project*

17. **Third-party evaluation of National Mission on Cultural Mapping and Roadmap - Ministry of Culture**

    Desktop based evaluation was done for the extension of the scheme on National Mission on Cultural Mapping, in conjunction with PPID. Report has been approved by the Ministry of Culture.

18. SDG Mapping report of Trinitea has been approved by the Indian Tea Association and Solidaridad and Impact Study report has been submitted to them.

19. Dr. Manish Pande, Director & Head of Project Analysis and Documentation Division (PADD) was nominated by the members of the **National Platform and Initiative Cooperation Network (NPIC Network)** to chair the network from 2020 – 2021. Webinar for national platforms and initiatives was held on 11th May 2021, hosted by the United Nations Forum on Sustainability Standards (UNFSS). QCI participated as the Secretariat of the India National Platform on Private Sustainability Standards (India PSS Platform) as the first national platform on PSS. Participants from all over the world joined to represent their national and regional standards bodies.

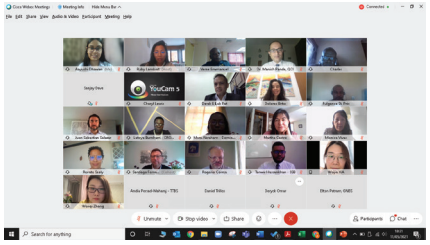

Figure 22 : *2nd National Platform and Initiative Cooperation Network (NPIC Network) Webinar*

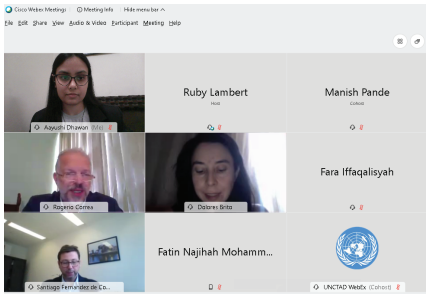

Figure 23 : *National Platform and Initiative Cooperation Network (NPIC Network) Webinar*

20. Mr. CS Sharma, Joint Director, PADD, QCI participated in 'Train the trainer' program organised by APAC under SANAP project.

Figure 24 : *Programme organised by APAC under SANAP project*

21. Mr. CS Sharma, Joint Director, PADD, QCI participated as an expert on personnel certification program during the APAC peer evaluation of Standard Malaysia.

22. 13th VQC on the theme: 'Protection of Child Rights: Towards a better future' was conducted on 27th August 2021 to explore the emerging 'best practices'.

Figure 25 : *13th VQC on Protection of Child Rights organised by PADD and NBQP*

23. VQC on Drone Sector conducted on 23rd July 2021 as a training program on RPAS Scheme for manufacturers, certification bodies and other industry stakeholders.

Figure 26 : *10th VQC on drones sector organised by PADD and NBQP*

24. PADD participated in the 'Vanijya Utsav - Capacity building programme & trade meet for FPOs/farmers & exporters', organised by APEDA in Varanasi. It was addressed by Dr. M. Angamuthu (Chairman, APEDA), Smt. Anupriya Patel (Union Minister of State for Commerce and Industry Govt of India) and Sh. Ravindra (MoS, Independent Charge Ministry of Stamp & Registration, U.P. Government) at Rudraksh International Cooperation and Convention Centre (RICCC) in Varanasi.

Figure 27 : *Dr. Manish Pande, Director &Head of PADD, QCI, addressing the stakeholders*

Figure 28 : *Dr. M. Angamuthu, Chairman, APEDA addressing the farmers, FPOs & other stakeholders*

PADD

THANK YOU

There is so much to look forward to...

PADD is growing and there is so much more to come! We have training workshops, conferences, trainings, webinars, new areas and innovations to look forward to in the coming months.

Here's your chance to feature in our newsletter!

Our next edition of PADD-Insights will focus on the broad-ranging theme of 'drone industry'. If you have ideas, story or note, please email to aayushi.dhawan@qcin.org by 30th November 2021.

We are excited to hear from you!

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