Chapter 6
Sustainable Development for the Healthcare Industry: Vantage Point from Emerging Economies

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The health of nations is more important than the wealth of nations
William James Durant.

Introduction

Product quality is only one aspect of the bigger picture that includes product safety as an equally or more important element when it comes to the sustainability of pharmaceuticals. To ensure the safety and quality of health-care-related products, in addition to ethical commercialization practices, has been the never-ending task of various regulatory bodies around the world.

For example, the Taiwan Food and Drug Administration (FDA) that emulates the model of the US FDA, was in the process of implementing a new regulation for all raw material imports of drugs. The suppliers/sellers had to register their product via local Taiwanese partners with the Taiwan FDA by submitting documentation of their product profile. I had first-hand exposure to this process, as I was co-ordinating efforts for the company I was working for, to file for Taiwanese drug master files (DMFs) for future active pharmaceutical ingredient (API) supplies. Later, there was another expedited regulation to provide the product documentation apostilled by the Taipei Economic and Cultural Centre to issue import permits. (These announcements were made in Chinese on the Taiwan FDA website (Taiwan FDA 2013) with no other international references.) This is a welcome change as it would ensure compliance and thus, the goal of safety along with quality is achieved. Regulations have become highly essential and without these, it is hard to imagine how the health-care industry would have evolved in the global market place. Besides, regulations in several cases are also legally binding, which forces the companies to adhere and maintain a high level of transparency and stability.

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P. A. Morgon (ed.), *Sustainable Development for the Healthcare Industry,*
Perspectives on Sustainable Growth, DOI 10.1007/978-3-319-12526-8_6

When we look at product pricing, we observe in emerging markets, least developed countries (LDCs) and low-income countries (LICs), the price of multinational corporation (MNC) products is on the higher side compared to the prices of products from Emerging Market Players (EMPs). Many, if not all, of Sandoz's and Mylan's generics are priced higher than those generics from local manufacturers/home-grown companies.

In this chapter, we are going to explore how sustainability in commercializing pharmaceuticals could be achieved by focusing on regulations and effective governance.

Sustainable Commercialization

Sustainable commercialization is the process of commercializing products in a way that does not disturb or destroy the biosphere and the econosphere we habitate. What this means is commercialization, which encompasses several processes like production of raw materials, packaging, distribution, and selling should be done in a thoughtful and meaningful way that just does not operate on the objective of revenues and profits, rather a core purpose, which is the long-term value creation for all stakeholders instead of only the shareholders should be the goal.

Discussing how investors behave in emerging economies is interesting, especially profit booking being prevalent in emerging markets, after the stock hits its new high or does better than the past few trading sessions, many investors off load their positions, unless there is a clear bull run or a new product approval. Though this behaviour is not exclusive to pharma and health-care stocks, this has been the case across.

Roles Played by MNCs Versus Local Manufacturers in Emerging Economies

Emerging markets have become the hot favourites of MNCs for the past few years, with Bayer and Sanofi leading in 2013 in emerging markets revenues (Top 10 Drugmakers in Emerging Markets 2013). MNCs and home-grown/local companies play varied roles on the ground with each contributing and addressing a different need within the broader need of supplying quality and safe medicines.

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The below table points out that different players have different cards to play (MNCs versus EMPs) in the healthcare business. Local companies with their strong presence and adjustability to the existing business environment play a major role or a more important role than MNCs in meeting requirements of patients that form the major part of mid-low-income countries. MNCs on the other hand have got resources and innovative medicines that can tend to niche segments of patients.

Contrasting MNCs and EMPs in emerging economies		
Element[a]	MNCs	EMPs
Presence	Weak	Strong
Global network	Strong	Weak
IP (intellectual property)	Strong	Weak
Compliance to regulations	Strong	Weak
Adjustability[b]	Weak	Strong
New products	Strong	Weak
Pricing	Weak	Strong

[a] The weak and strong status of MNCs and EMPs in the above table are relative to one another.
[b] Adjustability refers to be able to adjust business to a great degree to operate in the local environment.
MNCs multinational corporations, *EMPs* Emerging Market Players

We have seen quite a deal of consolidation of businesses between these two groups in the last decade, for example: Abott's Piramal acquisition, Sanofi's Shantha acquisition, Takeda's Multilab and a few others. There have also been acquisitions of companies based in advanced economies by EMPs (global players from emerging markets). This could be attributed to leveraging each other's strongholds, for example, when an EMP acquires a company in an advanced economy, the EMP gets access to the market that supports the better price for products; likewise, when an MNC acquires an EMP, it gets access to a low-cost manufacturer, new market, existing setup, human resources that are aware and have been operating in local business environment.

MNCs have faced their share of problems by acquiring EMPs. Integration is difficult post acquisitions due to no match between existing systems or processes between these two groups besides cross-cultural issues. There have been incidences in product quality failures, Sanofi's Shan5 (a product of Shantha Biotechnics acquired by Sanofi) was disqualified by the World Health Organization (WHO) following quality complaints or Ranbaxy which serves as a classic example for how things can go wrong, when Daiichi Sankyo acquired Ranbaxy, irrespective of what their due diligence revealed, they were ready to take a huge risk and enter unfamiliar waters, they went forward with the acquisition and years later, they ended up off-loading the company to another Indian company. Daiichi Sankyo took a big financial loss on this transaction besides loss of reputation and brand value.

The elements mentioned in the above table are dynamic and changing often with actions being taken by companies as a part of their strategy and the need to survive and deliver values. This is also dependant on overall global business and economic sentiment and changes occurring in the policy or guiding frameworks of business operations in various countries.

Presence EMPs have a solid presence in their countries of origin whereas MNCs are still to get their presence to match that of EMPs. Most of the EMPs begin their business manufacturing products that are less technically intense and graduate to advanced products as they gain capabilities in the form of capital and human resources.

Global Network MNCs have got an established presence in many countries around the world. EMPs' primary turf is home and once they reach size and means, they expand to foreign countries at least in the form of distribution points. We can find many EMPs that do business globally, for example, Dr. Reddys, Sun, and Abdi Ibrahim.

Intellectual Property MNCs thrive on strong intellectual property (IP) whereas EMPs primarily work with making copies of the innovator's products with an aim to launch post loss of exclusivity or patents and compete on price to gain market. Thus, EMPs have their stronghold on secondary IP in process patents, polymorphs and salts.

Compliance MNCs have global teams in place to check their compliance-related activities, as they are under constant scrutiny from various sources. Though EMPs comply to regulations, their focus is rather on growing revenues than on adding value.

Adjustability EMPs with their knowledge on local governance adapt their business to suit the existing environment compared to MNCs which struggle to align policies and processes. When EMPs expand their business beyond borders, they too find it difficult to adjust their business.

New Products This is home ground for MNCs which bring out innovative medicines often those addressing unmet medical conditions or rare diseases. In contrast, EMPs have not got the resources to indulge in research at this level to bring out innovative medicines in terms of both investment capital and scientific know-how. They rely mostly on generic versions of the innovator's products.

Pricing The costs of EMPs are lower than those of MNCs. The key contributor to costs besides material costs are those of wages and salaries that are on the lower side for EMPs. To offset this and price their products competitively, MNCs build capacities in emerging economies that sell locally.

Vantage Point

The discussion for this chapter is based on taking a vantage point into the emerging economies, which are fast changing, and how they respond to sustainable commercialization, if any. The factors affecting sustainable development and in turn sustainable commercialization have been narrowed down to regulations and governance, these being the drivers that operate at a bigger picture level towards the larger good. Government regulations and legislative requirements are significant drivers as any changes enacted in this direction are tracked by companies and this paves the way for their increased awareness which eventually going forward leads towards sustainable development for the industry. This view is supported by the research conducted by Francois Leeuw and Ilse Scheerlinck of Vrije University in Brussels who studied the factors that shape companies' corporate sustainability.

Regulations

More often than not, the regulations are unclear in emerging economies. Governments and regulatory bodies often initiate something which is not well planned and structured; the outcomes of such initiations are limited or nothing. This puts companies that already struggle with aligning their global regulatory strategy across markets in a tough spot. However, changes are happening at varied speeds, for example, the move towards electronic common technical document (eCTD) format for submissions is growing across the countries and this makes one regulatory aspect easier.

The seven regulatory barriers that need to be overcome in emerging economies are western approval, local clinical development (LCD), certificate of pharmaceutical product (CPP), good manufacturing practice (GMP), pricing approval, document authentication and harmonisation (Wileman and Mishra 2010). Regulatory compliance along with harmonisation stands out as the barriers that are more relevant in this context of sustainability.

Harmonisation

Harmonisation of regulations should encompass and extend to all aspects of operations that are undertaken to bring a product to market and continue supplying it to different groups of customers; this includes, but is not limited to, regulations of clinical trials, pharmacopoeias, laboratory practices, manufacturing processes, site inspections, delivery/distribution practices and industrial safety practices.

Harmonising these regulations to the greatest possible extent would be a rewarding task for all stakeholders. This would pave the way to eliminate duplication of efforts especially in clinical trials, studies and let the best use of resources, which are almost, always limited be it time, capital or well-qualified human resources. Other

tangible and intangible results of harmonisation are reduced development times, less cumbersome approval processes across countries, decreased time to market which means faster availability of key medicines to patients (Honig 2013).

Regulatory inspections followed by reinspections of manufacturing and clinical trial sites could lead to unnecessary or duplicated efforts and consume critical resources. A multinational pharmaceutical company and those companies selling to companies in foreign countries (business to business, B2B) will go through multiple inspections from different countries and from different regulatory authorities in different regions. Food for thought of this practice is if there is any incremental value of the repeated inspections aimed with the same objective. If these duplicative tasks and efforts towards organizing and facilitating multiple audits and inspections could be eliminated, resources could be diverted to other critical aspects like safety, quality and efficacy.

There has been significant progress in the area of harmonisation since such initiatives were started by various organizations like International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PICS), African Medicines Regulatory Harmonization (AMRH), Pan American Network for Drug Regulatory Harmonization (PANDRH), Organisation for Economic Cooperation and Development's Mutual Acceptance of Data (OECD's MAD), International Medical Device Regulators Forum (IMDRF). However, the destination is still a long way away and efforts have to be carried out ahead in all aspects especially by both public departments and private organizations that are required in allocating resources for this endeavour.

ICH has contributed greatly to the world of regulatory harmonisation. In addition to the founding member countries of the USA, Japan and those in EU, ICH has invited permanent members from Regional Harmonisation Initiatives (RHIs; like Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Gulf Cooperation Council (GCC), PANDRH, East African Community (EAC)) to participate in meetings to harmonise regulations across non-ICH countries (ICH 2014).

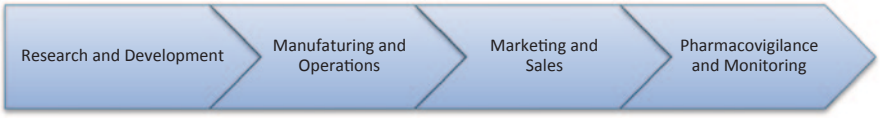
Compliance

We have discussed how harmonising of several aspects of regulations is worthwhile for the industry and patients. Compliance to regulations or even better,

harmonised regulations is vital as the healthcare industry including pharmaceuticals is under increased critical examination from not only regulatory bodies but also B2B customers in many countries. These could be in the form of audits, visits, reviews or investigations. It does not look like it will get any easier; rather it looks like this is going to get more intense with the fact that there still are many occurrences of failed audits and major observations resulting in export bans or calls for other correctional procedures like product recalls. Besides, with the growing social security implementations by several countries, growth is anticipated in public procurement schemes, which calls for rigorous regulatory enforcement and regulatory compliance.

Financial regulatory compliance for those companies that are publicly listed is another vital aspect of companies for business continuity in the long term. Most of the companies are exposed to accounting risks and face a threat that could harm shareholder value in markets. These have led to the rise of chief compliance officers in MNCs and this concept is still at a nascent stage in companies from emerging economies.

Pharmaceutical companies have to adhere to regulations set by bodies at different levels, i.e. regional, national and international and at all stages of the product life cycle right from research and development (R&D), manufacturing operations to distribution, marketing and pharmacovigilance. Ensuring these at all levels in multiple territories is a complex yet essential task for companies.



A consolidated value chain in pharmaceuticals that needs to comply to regulations at every stage.

For most pharmaceutical companies in the world with no exception for those arising out of emerging economies, the primarily focus of their business is the USA, the reason for this being, the USA is the world's largest market for pharmaceuticals in addition to being one of the few countries that supports free-market-based pricing. For these companies wanting to do business in the USA, strict compliance is essential now more than ever as the consumer protection branch of the Department of Justice (DoJ) has indicated that current good manufacturing practice (cGMP) enforcement would be a top priority (Burgess and Kang 2013).

In 2013, Ranbaxy pleaded guilty and agreed to pay US$ 500 million (US$ 350 million to settle False Claims Act (FCA) lawsuit and US$ 150 million for related felony charges), for allegedly selling adulterated drugs that violated cGMPs. This is one of the only two FCA settlements based for failing to comply with cGMPs under the Food, Drug, and Cosmetic (FDC) Act (Burgess and Kang 2013). This case stands as the recent evidence to what could go wrong in cases of non-compliance.

Governance

Good governance is an essential factor for economic growth and sustainable development at all levels and within all sectors of society (Anello 2008). Governance in emerging economies is often overwhelmed by the numerous challenges they face and the limited resources at disposal, often resulting in unnecessary bureaucracy and unclear guidelines and regulations for conducting business. For example, the Indonesian Government's plan to expand social security coverage to the entire 250 million odd population has been unclear from the beginning. The local pharmaceutical manufacturers expected that the government would invite bids for tenders to supply drugs to the government that would be used as a part of this social security scheme. The local companies started discussions and negotiations with suppliers of APIs for the lowest prices guessing that the quantities would be huge. The suppliers started working out detailed plans based on the volume-based business rather than staying on or focussing on the value-based business. However, this ended with nothing ever realizing concretely and the few products that did receive invitations from the government received only a fraction of the projected quantities. While this stays as one recent example on how uncertainty plays a major role in emerging economies, we can find many others.

On the other side of things, there were instances in countries like Mexico where tenders have been issued for public procurement of medicines by government agencies. However, these have faced their set of issues in the way of anticompetitive practices like bid riggings that caused huge losses to government coffers indirectly having an effect on the consumers. In 2010, the Federal Competition Commission of Mexico (CFC) inquired into the public procurement tenders by Mexican Institute of Social Security (IMSS) between 2003 and 2006 and this investigation revealed that several firms that participated in the tenders were involved in anticompetitive practices that resulted in higher procurement prices for the IMSS. Six pharmaceutical companies were penalised for a total of 151.7 million Mexican pesos, which was the maximum amount allowed by law at that time (Competition Policy and Public Procurement 2012).

Under the umbrella of governance, three elements that affect sustainable commercialization to a great extent are compulsory licensing, prevalence of counterfeit drugs and pricing controls.

Compulsory Licensing

In the recent past, we have seen instances where governments in emerging countries have employed various ways to get patented products to their patients. Brazil, India, Indonesia and Thailand, all have at various instances issued compulsory licenses (CLs). Though Trade-Related Aspects of Intellectual Property Rights (TRIPS) and World Trade Organization (WTO) permit this under circumstances of health calamities and disease breakouts, CLs have been used to invalidate IP in regular situations. Governments justified their actions portraying this as making products affordable or to make them accessible and thus improve public health. Companies on their behalf have followed tiered pricing to make way for affordability.

It is interesting to note that most of today's advanced economies including the USA, Canada, France, Belgium have used CLs in the past for different objectives to different extents. Compulsory licensing of medicines in instances of non-urgency has to be limited by governments to safeguard IP and to promote scientific research. The real risk that compulsory licensing could discourage foreign investments and development of advanced technologies by making other economic environments more attractive to firms in technology-exporting countries has to be considered in great detail before issuing licenses. The absence of national and regional systems of innovation and reliance on compulsory licensing can mask structural problems in these countries and make them harder to solve in the long run (Reichman and Hasenzahl 2003).

Another aspect of CLs tends to be the quality of medicines produced by these licensees in emerging economies. The quality of production of these local firms is lower than that of the patent holder. An example of this is the compulsory license of Kaletra issued by the Thailand government to the Government Pharmaceutical Organization (GPO). The quality of GPO's product was subpar and the global fund which granted US$ 133 million to GPO in 2003 to upgrade facilities withdrew support in 2006 after GPO failing to meet WHO quality standards (Bond and Saggi 2012).

One solution to the problem of access and affordable medicines is pooled procurement strategy; this is explained as several emerging economies coming together and leveraging economies of scale in their negotiations with companies for deep discounted prices for the increased market size. This collaborative approach could work in favour of both parties as governments can benefit when these companies make local investments to serve these patient bases and thus also act as means to promote research instead of discouraging it while innovator companies benefit by holding their exclusive rights (Reichman 2009) and to make the pie even bigger could negotiate tax breaks on their investments.

Counterfeit and Spurious Drugs

Counterfeit and spurious drugs besides being a menace for public health also cause enormous losses to companies. This is in addition to the health risks they carry to

those who consume. Counterfeit and spurious drugs have been in existence since decades in both advanced and emerging countries. It is estimated that about 15% of the medicines sold globally outside of advanced economies are counterfeit and this rises to 50% in certain parts of Africa and Asia (Sridhar and Gostin 2010). The efforts of various organizations and agencies including International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a WHO global initiative with member countries, to curb these have yielded mediocre results especially because of the failure of co-ordinated governance in this direction.

There are many statistics on the size of counterfeit medicines or how much in revenue loss they account for and the deaths they cause globally. The important thing next to avoidable loss of life is counterfeit drugs destroying the value of an industry and how technology can be used to fight this by not relying completely on governance or governments to tackle the problem. Sproxil, Pharmasecure and others serve as examples of how existing technology coupled with industrial partnerships could be leveraged to safeguard the interests of drug consumers. The product package is labelled with a scratch-off unique number which could be texted to a hotline and a return message will confirm the authenticity of the product (Rosenberg 2014).

Stringent regulatory control of drugs as well as stringent enforcement by national regulatory authorities contributes significantly to the prevention and detection of counterfeit and spurious drugs (WHO 2012). A good question to re-ask by the governments in emerging economies would be: (1) if the prevalence of counterfeit and spurious drugs is attributed to their cheaper price or (2) inadequate awareness of safety and dangers of consumption of these. Also, a more focussed global collaboration, coordination and cooperation between countries would address the issue of these counterfeit and spurious drugs to a better extent.

Pricing Controls

Price controls of pharmaceuticals are prevalent in both advanced and emerging economies. A major concern of price controls has been its effect on pharmaceutical research, and how it could potentially impact the outcomes of future research. This has been validated to various extents by several researchers, one of whom says that product price cuts of 40–50% would result in reduced R&D projects by 30–60% (Abott and John 2005). In another report by the US department of commerce, the pricing controls employed by the OECD countries resulted in revenue losses estimated at US$ 18–27 billion to pharmaceutical firms which in turn resulted in R&D reduction by US$ 5–8 billion annually. These reductions in billions of dollars in R&D have resulted in an estimated 3–4 fewer new molecular entities annually,

which is a great loss to all stakeholders (Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation 2004). Based on the estimated cost of developing new drugs, trend and rate of approval of new drugs, this capital investment could have paved the way for these companies to come out with a greater number of newer medicines.

Additionally, it has also been noted that drugs account for 12 % of overall health-care costs (Farrell et al. 2008), for 7 % which makes the cost contribution to the overall health-care expenditure by hospital outpatient and inpatient care, physician and clinical administration and other delivery services much higher than the cost contribution of drugs. Thus, drugs account for a small percentage of overall health-care costs (Hooper 2008). While the above-mentioned figure is with reference to the USA, the case in emerging economies could be comparable. Governments in emerging economies could focus on working towards alternate means to reduce health-care costs, for example universal health-care schemes and mandating health insurance by creating health funds could be explored and economic models could be worked out. This would keep an industry that is so essential alive and growing in addition to promoting competitive research.

The widely accepted DiMasi study puts the cost of producing a drug and releasing it to the market to be around US$ 800 million, which is unlike products in many other industries. This huge upfront cost along with long lead times often with no guaranteed success puts enormous pressure on the companies comprising pharmaceutical industry. With no financial incentive, companies would be reluctant to invest in research, the direct outcome of which could be reduced number of new products. This could turn out as a blow to the many existing unmet medical conditions.

Extensive interference from government by controlling the product prices would result in decreased returns for these companies, most of which are publicly funded and could leave investors wary besides reduced revenues and incomes limiting the overall capital available to carry out critical operations and future research.

Closing Comments

Is sustainability/sustainable development really the issue of only the advanced markets with minor or no impact to the emerging economies? A little awakening of the senses, a little observation into the evolution of the industry and its progression into the future, a little understanding of how businesses are no more local and are inter-linked including the elements discussed in this chapter would tell us the answer is a no and so should the efforts addressing them be inter-linked and global (though they start local). Sustainable commercialization and sustainable development in the industry that is at the very front in saving lives are pressing issues globally that would move us collectively into the prospective or the not-so-prospective future.

The environment in which the health-care industry operates is becoming tougher and more stringent not just to safeguard public health but also to keep the actions of companies within the boundaries of compliance. Companies on their behalf would

want to come out with solid scientific data/evidence in support of the products they develop which would let them go to market smoothly and as a result provide value to all stakeholders.

There is huge room for improvement and to answer the question if EMPs with their intimate knowledge of the market are focusing on the right things or not, the simple answer would be no. Local companies, who predominantly happen to be manufacturers of generics, with comparatively low entry barriers and intense competition are extremely cost conscious. Hunger for profits and growth graphs towards the sky blurs certain key aspects of quality and safety which otherwise are essential. While on paper, the specifications of these products match the standards set by Pharmacopeia's and other regulators, several processes themselves are in question. Would the advanced markets like the USA or Japan ever accept these goods?

US FDA in January 2014 imposed a ban on the Toansa facility of Ranbaxy that manufactures APIs and prohibited all products manufactured using API from this facility to be sold to US consumers for failing to comply with cGMP. This is in addition to the ban on three other facilities of Ranbaxy located in Paonta Sahib, Dewas and Mohali. The direct results of these are many like loss of revenue and in the immediate aftermath severe erosion of shareholder value, the growing and unmanageable set of problems eventually led to Daiichi Sankyo deciding to sell its share to India-based Sun Pharma. Now that Ranbaxy is operating as part of Sun, in a culture that Ranbaxy calls home, we have to wait and watch how this evolves for stakeholders as well as shareholders.

Fuelled by patent expiries of blockbusters and key products of innovators, importance is being given to developing copies of these products, entering new markets that are primarily advanced markets, expanding reach and optimizing product costing across emerging markets, however, what is being missed is safety in operations, investments in enhancing quality, strict compliance to regulations, keeping pollution (releasing effluents into atmosphere and water bodies) in check, all of which form the heart of sustainability. When these things are given equal or more importance than growing top and bottom lines, supplying products that provide value beyond price and cost would be a possibility.

It would not be bold to say most companies in emerging markets are time bombs. These companies with thorough knowledge of local economics and industry can do so much more in building sustainable value instead of working towards short-term gains. Regulatory aspects have to be more thoroughly incorporated from development to commercializing and thus play a pivotal role in the companies' performance. Another important point to consider is that harmonisation of regulations across different countries has made progress over the years, however, it is still a long way before universal acceptance of a single set of regulations and their interpretations in varying contexts can be achieved. Though a herculean task, efforts in

this direction when pushed forward by stakeholders from industry, government and patient groups would pave the way for sustainability and be a leap in the right direction. Especially with the long product development cycles in the pharmaceuticals and devices industry, there is a greater possibility for regulations to change. In light of this, being aware of cross-market regulations for companies operating or doing business across several countries is the need of the hour.

In June of 2014, EU gave a green light to the Toansa facility of Ranbaxy that the US FDA had earlier in the year prohibited from selling to the US market. Though deficiencies were observed, European regulators expressed satisfaction with the corrective measures put in place after US FDA ban, while the US FDA commented post EU approval that their ban still holds. The European regulatory team opined there is no risk to public health from the deficiencies observed (Clarke 2014) and gave the Toansa facility a pass. In retrospect, two agencies from advanced countries are issuing differing assessments on products arising out of the same manufacturing facility. Could this be due to lack of cohesion in understanding of regulations? This calls for even more need to harmonise regulations globally.

The above-discussed imperatives collectively will drive the industry forward and help commercialize healthcare-related products sustainably.

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