How Regulatory Changes Are Driving The Future Of The Medical Device Industry

February 2019

HOW REGULATORY CHANGES ARE DRIVING THE FUTURE OF THE MEDICAL DEVICE INDUSTRY

Given the aging population in developed countries, coupled with declining birth rates, higher life expectancy, and an increasing prevalence of lifestyle diseases and economic development in emerging markets, there is a rising demand for medical devices. The industry is forecasted to grow at a CAGR of 5% over the next decade[1]. With this growth, regulatory bodies worldwide are working on transforming their processes to make them faster and streamlined while also focusing on improving device safety and data quality.

INDUSTRY CHALLENGES

With growth comes challenges, which themedical device industry is currently facing. Some of the industry's most pressing challenges are outlined below:

- **Recurring patient safety concerns:** As per a recent publication by the International Consortium of Investigative Journalists on a global investigation of medical device safety, over 1.7 million injuries and almost 83,000 deaths related to medical devices have been reported to the U.S. Food and Drug Administration (FDA) over a 10-year period[2].
- **Increasing pricing pressure:** There is an increasing downward pressure on pricing. Governments worldwide are trying to control costs and reduce their healthcare expenditures. Hospitals are under high pressure to showcase value and efficiency while reducing costs. Now the decision-maker is not the healthcare professional (HCP) but the purchasing department of hospitals, changing the way medical devices are priced and valued.
- **Cybersecurity threats:** The connected nature of devices exposes them to the risk of getting hacked. The FDA advised medical device manufacturers to identify risks and vulnerabilities associated with their devices and take appropriate action to mitigate them. The FDA also listed cybersecurity as one of its top priorities in their Regulatory Science Priorities Report for 2017[3]. The report talks about a need for a common scoring system that could be used to rate the devices on their vulnerability. It also suggests that research should be conducted to identify what kind of software modifications compromise the device safety.

Given these challenges, it has become more critical than ever for manufacturers to practice increased transparency in the way the devices are priced and to better showcase value and outcomes. Also, they must ensure that all the patient data is encrypted and that firewalls are in place to lessen the possibility of data being compromised.

Keeping in mind the challenges listed above, the regulatory bodies worldwide are making changes in their systems and processes to better deal with the needs of the changing market. This report looks at the recent changes in the medical device regulatory environment in some of the major global markets.

THE U.S.

STREAMLINED FDA DE NOVO PROCESS

The FDA approval process has been streamlined, resulting in more de novo applications being processed at a faster pace.

Originally, the de novo pathway was not too popular when it came to the medical device approval process in the U.S. It involved a cumbersome process of submitting a 510(k) application and then waiting for that application to be rejected based on a not substantially equivalent (NSE) determination after which manufacturers would resubmit under the de novo process.

The FDA has now changed the process by not requiring a 510(k) application and NSE determination. Now, as per the guidance issued by the FDA in October 20174, if the marketers believe that there is no existing predicate device and that their device can be classified under Class I or Class II, they can directly apply for the de novo process. They must do a thorough risk assessment, have a mitigation strategy in place and involve a regulatory expert early on in their submission process to increase the likelihood of approval.

This revision in the pathway has made the approval process streamlined, leading to an increased number of successful de novo applications. The new process also mandates the FDA to decline or approve and classify the request within 120 days, thereby making the process faster.

A faster and less stringent de novo pathway is a better option for manufacturers if their medical device meets the criteria for application.

ACCESS TO FDA UDI INFORMATION

The FDA has made key enhancements involving better data access and quality in the Unique Device Identification (UDI) database, the Global Unique Device Identification Database (GUDID).

The FDA has always been at the forefront when it comes to legislative requirements related to the UDI database. The FDA recently released the GUDID version 2.3.2[5], which includes fields like “FDA Premarket Submission Number” and “Supplement Number”. These fields will be associated with device numbers and can be accessed by the public. This means that at the time of submitting their device for approval, manufacturers will not have to undergo the cumbersome process of researching the regulatory pathways that their competitor devices went through. They can easily access the information through AccessGUDID and OpenFDA databases. Now, they also allow the submission owners to review and update the records as needed, giving them greater control over the content of the records pertaining to their devices. Additionally, this makes the process of updating and correcting the records much faster and easier.

OVERHAUL IN FDA APPROVAL SYSTEM

The FDA has recently announced their plans to overhaul their approval system which came into practice in 1976. The Medical Device Safety Action Plan[6] lays out the steps the FDA has taken, along with its plans to improve device safety.

A big part of this plan is to implement a more active surveillance system as opposed to the current passive system. Currently, doctors, patients, hospitals, and manufacturers report the issues as they arise to the FDA. With this process, the FDA is not able to get a real-time update on the issues, and in many cases the issues are under-reported. The FDA has decided to implement an active system called National Evaluation System for health Technology (NEST)[6]. This will rely on real-world evidence from insurance claims, electronic health records, patient registries, etc.

In addition, medical devices will be marked with a unique code so that they can easily be identified and pulled off the market if a batch or model malfunctions.

Given that the FDA just made this announcement, it may take years for the changes to be fully implemented, but device manufacturers should be prepared for the imminent changes and start strengthening their device safety and quality evidence to meet these raised expectations.

THE EU

NEW EU REGULATIONS

New EU regulations are projected to establish a more robust and modernized legislative framework to ensure better public health management.

Existing directives that regulate the medical devices being approved and marketed in the EU are being replaced by new regulations: Regulation (EU) 2017/745 for medical devices and Regulation (EU) 2017/746 for in vitro diagnostic (IVDs) medical devices which will be in effect May 2020 and May 2022[7] respectively.

There were multiple shortcomings with the existing regulations that called for an overhaul:

- The EU still follows systems and rules that were put in place decades ago and have not been updated along with technical and scientific progress.
- Access to evidence regarding product safety and performance is not readily available to patients and physicians.
- Tracking devices to their suppliers is not always possible.
- Regulatory directives are interpreted and implemented differently by various EU nations.

To address these challenges, a new set of regulations have been put into place with some of the updates including better transparency, a system of unique identification which will enable traceability, stricter Post Marketing Surveillance requirements, etc.

One of the most important parts of these regulatory changes is the provision for traceability of medical devices. The new regulation requires the labeling of medical devices to include a UDI. This information will need to be submitted to a central UDI database and stored/ tracked by the manufacturers.

While the new regulations will bring a disruptive shift to the market, they may also be very costly for the medical device manufacturers to implement. Now, the companies will need to provide significantly more evidence to launch new products to market and, in some cases, keep existing products in the market. They will also need to relabel their products and keep data handy to be made publicly available when needed. This could significantly impact the bottom line of many big companies and could serve as a death blow for some of the smaller players.

The manufacturers will have three years to fully transition into this process, but it is essential they start now preparing themselves for these forthcoming changes.

CANADA

TRANSITION TO MDSAP AUDIT

Canada has replaced its existing Canadian Medical Devices Conformity Assessment System (CMDCAS) audit with the Medical Device Single Audit Program (MDSAP)[8]. All medical devices will need to be compliant with this new program to be considered safe and effective for use in Canada. All medical device manufacturers will need to undergo audits and collect certificates by the end of 2018, so they can legally sell devices in Canada. The MDSAP was launched by the International Medical Device Regulations Forum to conduct regulatory audits of Quality Management Systems (QMS) that will be mutually acceptable by several countries (Australia, Brazil, Canada, Japan, and the U.S. as of now), giving the company access to multiple markets at once. This certificate will not only show that a manufacturer is compliant to QMS but can also let one determine the class of the device. While it is voluntary in all other countries, Canada is the only nation that has made it mandatory.

This, however, is going to be a tedious and costly process for medical device companies who are now being quoted much higher prices for these audits compared to previous CMDCAS audits. This will make it less lucrative for medical device companies to sell in Canada and may lead to an exodus of some of the smaller companies from the Canadian market. Smaller companies are also usually the ones that are more innovative and create specialized products that big multinationals may not find any value in. In the end, patients will be the ones to bear the brunt of this regulatory change, with fewer medical devices being available at their disposal.

Health Canada is aware of these concerns and has been trying to relax some of their requirements. They have introduced a reduction in audit time for smaller companies, thus alleviating the burden on them. They have also relaxed their December 31st timeline by not requiring a certificate by then but instead asking companies to show that they expect to undergo the audit in 2019.

PRIORITY REVIEW

Health Canada reviewed their existing Priority Review Policy and concluded that it is unnecessarily complex. As a result, they and have decided to simplify the process by doing away with a separate form and introducing a priority review option in existing/new amendment application forms.

The option is applicable for Class III or IV medical devices that are intended for use in serious or life-threatening diseases and meet a previously unmet need. The screening will be done within 15 days, thereby leading to a shorter time to market for novel products.

CHINA

CHANGES TO ORDER NO. 650

The Chinese Ministry of Justice has recently published a draft amendment to Order No. 650[9], which is the current Medical Device Regulations in China. Some of the noteworthy changes include:

- Defined Marketing Authorization Holder and their obligations:
  - Ensure products satisfy quality and safety requirements.
  - Must submit self-inspection reports each year.
  - Establish an adverse event reporting system.
  - Can distribute devices without obtaining distribution approval.

- Clinical Evaluation Reforms:
  - Category I and II devices – No clinical evaluation needed.
  - Category III devices – Clinical evaluation needed unless safety established.
  - Foreign clinical evidence can be submitted. Chinese studies only required for devices that are high-risk or support life.
- Distributors of Class II medical devices do not need to file for a record if they do not pose a significant risk.
- Plan for a UDI system for all medical devices.
- Ban on importing and distributing used medical devices.
- Stricter penalties on non-compliance.

The new regulations will make it easier for companies to enter the Chinese market, but they will need to invest in their QMS to ensure they adhere to all the required standards.

AUSTRALIA

REGULATORY CHANGES FOR IMPLANTABLE MEDICAL DEVICES

The Therapeutic Goods Administration (TGA) will require permanently implantable device manufacturers to provide implant cards and information leaflets to patients. New devices will need to follow this guideline starting December 2018, while existing devices have until December 2021[10] to implement this mandate.

Patient implant cards will be provided post-surgery to the patients who have been implanted with the device. The implant cards will contain details including device name, model number, and manufacturer contact details. Leaflets will also accompany the device and provide product information, proper product use, and the indications and type of people that should use the device. This will put additional burden on medical device manufacturers as some of the mandatory information required may not be readily available from the outset.

TGA also moved surgical mesh devices to Class III requiring them to submit reclassifications and comply with leaflet requirements. This will bring the Australian requirements closer to the European Medical Device Regulations.

PRIORITY REVIEW FOR CUTTING EDGE PRODUCTS

TGA has issued guidance that qualifying medical devices and IVDs will undergo priority review that would include products that meet the following conditions:

- Used in serious medical conditions.
- Have a unique intended purpose compared to other listed devices in the Australian Register of Therapeutic Goods (ARTG).
- Provide a significant clinical advantage or use a breakthrough technology.

Review of priority applicants will be completed in 20 business days, significantly shortening the time-to-market for deserving novel devices.

THE WAY FORWARD FOR MEDICAL DEVICE COMPANIES

Given the rapidly changing regulatory environment, it is now more important than ever for medical device companies to have a solid strategy in place to deal with the continuous updating of requirements. Mentioned below are some of the steps medical device companies can take to navigate through this evolving market:

- **They must involve local regulatory experts from the very beginning of product lifecycle.** Different countries may have different regulatory requirements and ensuring that they are all being met maybe tricky. A local expert will ensure they are compliant with all requirements and avoid getting into trouble with regulatory authorities.
- **With multiple major markets now focusing on ensuring traceability of medical devices, manufacturers must have unique device identifiers for all their devices so that they are easy to track in case of any issues.** Companies should work in tandem with experts to get an efficient and cost-effective system in place which is compliant with the regulatory requirements.
- **Medical device companies should ensure that they have a solid system for data collection that is encrypted and stored in a secure environment which maintains patients' privacy and helps the manufacturers better understand their devices and be ready for any future regulatory changes.** They should, of course, keep in mind the local regulations regarding data collection and take patients' consent where needed.
- **Many of the regulatory changes could be tedious and costly to comply with; hence medical device companies should do an initial, thorough assessment of the requirements including monetary, time, and opportunity costs and then conclude if it is worth investing in that geography or not.**
- Given the increasing competition, there is downward pressure on pricing. **It is essential for medical device manufacturers to showcase the outcomes and value from their devices, and practice increased transparency in the way the pricing is calculated.**

In closing, a medical device manufacturer must not only be aware but also be prepared for the latest regulatory updates. They should have a specialized team in place to ensure that their devices are meeting all the standards and they are storing all the related data accurately and securely. They must work in tandem with knowledgeable experts right from the commencement of product development such that all the regulatory requirements pertaining to product safety and quality are met.

With so many regulatory updates taking place around the world, it is easy for firms to miss out on important compliance mandates or feel lost regarding interpretation and implementation of certain directives. In such cases, thought leaders that have decades of experience in the market could prove to be highly effective in guiding medical device companies to navigate through this maze.

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