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BioMarketing Insight Newsletter

Creating Markets and Marketing Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I covered "Cybersecurity - You're Going to Get Hacked, It's Just of Matter of When: How to Protect Yourself." If you missed last month's article, click here to read it.

This month newsletter, Pharm IQ interviewed yours truly (me) on "Medical Device Unique Device Identification: What you need to know." Each question will be separate to make reading a little easier.

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on June 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
BioMarketing Insight

In This Issue

Developing a Product?

Medical Device Unique Device Indentifications (UDIs): What You Need to Know

What impact does the FDA's final rule on UDIs have on the medical device industry, US and Global?

What are the key business benefits of implementing UDIs?

What is the main challenge facing UDI implementation over the next 3 years?

What are the broader implications of UDI regulations on the healthcare industry?

Should the pharmaceutical and medical device industries share the same identification systems and standards?

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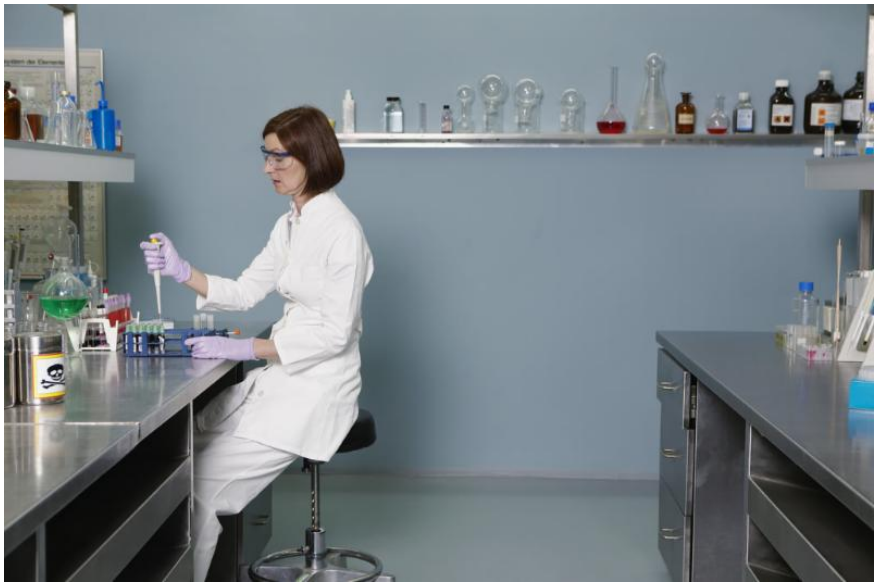
[Marketing Strategies]

[Previous Newsletters]

Developing a Product?



If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product, contact me for an appointment.

Top

Medical Device Unique Device Indentifications (UDIs): What You Need to Know

In this Pharma IQ interview, Regina Au from BioMarketing Insight shares her insights on the current UDIs for medical devices landscape and the impact of the FDA's final rule on UDIs on the medical device industry, both in the US and on a global scale. Au also reveals the 5 key business benefits for medical device manufacturers.

Why is the FDA requiring all medical devices to have a Unique Device Identification (UDI)?

There are many reasons why the FDA is requiring medical devices to have a UDI. However, the overall purpose is transparency of information. The uniformity will hopefully lead to better efficiency and ultimately lead to better patient care. The initiation of investigating how to implement this system started with the FDA Amendments Act (FDAAA) of 2007.

The current medical device manufacturers ID system information is required by the FDA, but each manufacturer has their own identification system (i.e. bar, 2D, QR or RFID codes) and ID numbers. Needless to say, it can be cumbersome to track a product back to the manufacturer or identify which patient had a device if the information was not readily or easily accessible. The UDIs will be downloaded to the Global UDI Database (GUDID) for everyone to use and each company and device will have their own UDI to eliminate any confusion in identifying the company or device.

The FDA has been planning to implement this system for a while after a number of task force inquiries, open forums and pilot programs were run to determine the best way to implement this system. It wasn't until electronic medical records were mandated could this UDI system be realized. When medical records were still on paper, it would have been a challenge to implement this system.

According to the FDA, the benefits of a UDI system to the industry, consumers, health care providers and health care systems when fully implemented are the following:

- Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reducing medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enhancing analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust postmarket surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Providing a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Leading to the development of a medical device identification system that is recognized around the world.

For healthcare systems, the UDIs in addition to the benefits above will provide more information to the healthcare providers and patients who are more knowledgeable and savvy about their own health. The insurance providers should be in favor of the UDI system because they are trying to make information and cost more transparent for the patient. Since the insurance providers are passing more of the cost onto the patient, the patient will be involved with the decision making process.

In addition, the UDI system is suppose to make inventory and cost control more efficient as well as making billing more accurate and improve data on devices.

Top

What impact does the FDA's final rule on UDIs have on the medical device industry, both in the US and on a global scale?

The implementation of the UDI system is an enormous undertaking which is why the FDA is phasing in the process over several years. A roadmap was developed to help facilitate the transition to UDIs. As with implementing most new systems, it will take a while to work out all the kinks or exceptions to the rules.

The cost to implement this system can be significant depending on the current system the medical device company has and the amount of changes that need to be incorporated. The cost to implement the system includes not only software, hardware, changes to the manufacturing process, training of all employees and time to input all the required data into the GUDID, but the cost to implement the whole process by the date the FDA has set.

Class III devices (highest risk devices) are required to have UDIs first and the proposed deadline is September 2015. The UDI must be on the outer packaging and the device itself. Issues can unexpectedly come up when there is an exception to the rules such as a totally bioabsorable implant. A manufacturer can apply a UDI to the outer package and the implant to ensure that the UDIs matches, but once the implant is reabsorbed in the body, there is no UDI to reference.

There is a significant impact on the medical device industry from an implementation and cost perspective to get this system up and running initially. Once the UDI system is up and running and all stakeholders (manufacturers, distributors, payers, providers, patients, healthcare systems and other important stakeholders) comply and actively participate, the medical field will see the benefits.

The European Commission (EC) is also looking to establish and promote a global UDI system by leading an Ad Hoc Working Group or a Global Harmonisation Task Force (GHTF) to draft recommendations and guidelines to ensure that the US UDI will be globally compatible. In leading by example, the EC hopes other member such as the Asia Working Harmonisation Party (AWHP) will follow suit.

Top

What are the key business benefits of implementing UDIs?

When the implementation of UDI is adopted by all stakeholders mentioned previously, then the supply chain distribution process will become more efficient because every valid Stock Keeping Unit (SKU) item will have its own identifier and therefore no confusion as to the manufacturer or device name and eliminate all invalid UDIs. The UDI will identify, at a minimum, the manufacturer, name and information of the device, batch number, date produced and expiration date.

Some of the key business benefits for medical device manufacturers:

I) Allow more accurate inventory and cost controls in tracking devices to the level of geographic location and usage and hopefully down to the level of the healthcare professional. This information is also useful for sales and marketing (S&M) in developing S&M strategies as well as the company's overall strategy.

II) Having a global UDI for all countries will save the company time and money once it's fully implemented from a manufacturing perspective. The ultimate goal is to make packaging requirements global as oppose to developing a separate label for each country or geographic location.

III) Allow easier and quicker recall of devices in terms of tracking, notification and getting the devices off the market sooner before any harm can be done.

IV) If UDIs can identify and avoid the purchase or usage of the counterfeit device, this will not only

decrease lost revenue but avoid a tarnished reputation for the brand manufacturer due to these devices. To identify a counterfeit device, a formal process must be in place for the whole supply chain process as well as educating the healthcare professionals and purchasing as to why counterfeit devices are dangerous even though they may be cheaper. The healthcare professional who orders the device must input the UDI of the device to verify its authenticity prior to use.

For example, the European Parliament adopted the Commission's proposal to trace medical devices using the Unique Device Identifier (UDI), with the belief that the system should enable effective post-marketing monitoring and protection against counterfeit devices as well as improve handling at various levels of the distribution chain. Implantable device manufacturers should include an implant card with their product for the healthcare professionals implanting the device.
Then these healthcare professionals would be responsible for registering all information contained in the implant card into the patient's medical records and give the card to the patient for his/her personal use. In addition to the UDI, the implant card would contain important information on the implanted device, such as principal characteristics, warnings, and potential adverse effects.

There must also be a mechanism where the counterfeit device company can't somehow substitute the brand manufacturer's UDI for their device since all UDIs are available to the public.

V) Generally, counterfeit devices are of lesser quality, poorer performance and questionable safety than the brand manufacturer's device which may cause an adverse event. Eliminating counterfeit devices saves the manufacturer time and money investigating these adverse events.

Top

In your opinion, what is the main challenge facing UDI implementation over the next 3 years?

The 3 main challenges are: 1) Buy-in from all stakeholders; 2) The actual process to implement UDIs by the designated deadline set by regulators; 3) Training everyone to incorporate the use of UDIs into their routine.

The biggest challenge is getting all stakeholders (manufacturers, distributors and those in the supply chain channels, healthcare professionals, healthcare systems, and FDA) to agree to incorporate the UDIs system and to agree on the specifics as to who, what, where and how. Each stakeholder may have different needs and wants, so the benefits to each stakeholder has to be significant since there may be an enormous upfront cost to make the necessary changes to incorporate the UDI system. The buy-in not only has to come from the companies and organizations, but the individuals within these companies and organization. This means from senior management down to the individual employees.

Implementing the UDI system will take time and adjustments in the transition period and each employee will need to be trained on the new systems until it is incorporated into their routine. Any new employees will also need to be trained as well.

Top

In your opinion, what are the broader implications of UDI regulations on the healthcare industry?

The implementation of the UDI regulation is to create efficiencies in all areas associated with UDIs: 1) inventory control - readily identifying expired or discontinued products; 2) medical records - additional information on the device and manufacturer; 3) billing - to ensure the correct device is being billed; 4) medical errors - avoid mistakenly using the wrong device or counterfeit device; and 5) monitoring devices with respect to usage, efficacy and adverse events.

The end result allows the healthcare professional more time for patient care by cutting down the administrative work. The additional information on devices also re-enforces transparency of information since patients are now more savvy about diseases and ideally taking a more active role in their own healthcare. The healthcare and life science (pharma/biotech/device/diagnostic) industry is moving towards a patient-centric focus. To build this relationship, there needs to be a partnership with all stakeholders keeping in mind that everything being done is for the benefit of the patient.

Top

Should the pharmaceutical and medical device industries share the same identification systems and standards?

Yes, it would make things more uniform and easier. Many pharma companies have a medical device division and with a number of combination products, the same identification systems and standards would make things a lot easier.

The pharma industry already has an identification system in place that is working. It makes sense to adapt this system to the medical device industry and make adjustments where needed.

Top

About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

Top