Getting The Words Right:
Device Documentation And Translation In Asia

The medical device sector has seen increasing harmonization of regulations on both a global and regional basis.

Nonetheless, market-entry requirements retain a significant degree of localization, particularly in relation to product labeling and documentation. Asia is no exception. For device companies prepared to negotiate the obstacles, though, the potential rewards of a huge and diverse market are considerable.

Underpinning these opportunities are population growth and aging; westernized lifestyles and disease profiles (e.g., cardiovascular disease, obesity, diabetes); efforts to boost health-care spending, infrastructure and coverage; a rapidly expanding middle class; and demand for innovation.

Accelerating economies, particularly in large markets such as Japan, China and Korea, evolving health-care systems, and higher education levels among medical professionals and consumers, are sharpening demand for more advanced products. This includes innovations such as smart mobile devices with digital apps.

"Health-care in general is improving on a continuous basis in China," comments Sheena Dempsey, managing director of RWS Life Sciences, a translation services provider. "That means more hospitals, physicians and general practitioners will have access to a greater range of tools, technologies and medical devices to use with their patients."

As cost and regulatory pressures slow market growth in the west, device companies are turning their attention to vast under served populations in countries such as China and India. The total market for medical devices in the Asia Pacific region is expected to increase from an estimated $108.9 billion in 2016 to $156.6 billion by 2021, with a five-year compound annual growth rate of 7.1%.

Harmonization And Regulations

Device regulations in Asia are starting to converge under the influence of initiatives such as the ASEAN Medical Devices Directive (AMDD) or the models and guidelines developed by the International Medical Device Regulators Forum (IMDRF) and its predecessor, the Global Harmonization Task Force (GHTF).

In parallel, though, individual countries such as India, China, Malaysia, Vietnam, Singapore and the Philippines are either introducing or updating their own device-specific regulations, with inevitable variations in approval requirements and timelines.

Implementation of the AMDD is proceeding by stages. Ratification by all 10 ASEAN member states is occurring at differential speeds, and is influenced by sharp disparities in economic development and regulatory capacity between countries such as Malaysia or Singapore on the one hand, and Cambodia, Laos or Myanmar on the other.

More Rigor, Documentation

In some cases, regulatory reforms in Asia should clarify and facilitate market access: in India, for example, where until recently more burdensome drug regulations also applied to devices. Nonetheless, new regulations also mean increased rigor in device approvals, closer attention to compliance, and more demand for documentation, whether for product registration or labeling and directions for use.

"There will be more standardization and documents that come with that," Dempsey comments. "And invariably they will need to be translated, by the medical professionals who understand the health authorities and the regulations for the particular market they're being submitted to."

Device reforms also need to accommodate digital disruption and the rapid growth of consumer-oriented devices and apps for health tracking or disease monitoring. These not only introduce regulatory gray areas but shift the emphasis of labeling from medical professionals to home users.

"I think in the foreseeable future, the emergence of new types of healthcare products will blur the lines between the people who manufacture medical devices and consumer companies that develop healthcare products," predicts Waldemar Frank, vice-president, Global Solutions Management at RWS Life Sciences. "It's going to be a real challenge for regulatory authorities to properly wrap their arms around that."

With innovative features appearing on devices all the time, some regulators in Asia may struggle to keep pace with technological change. Even existing device regulations take time to bed in, leaving manufacturers exposed to last-minute reversals.

"Even an established and effective regulatory framework is challenged by the driving force of constant innovation, which complicates timely application and enforcement," Frank comments. "The reaction might include new regulatory amendments, rejections or additional requirements, and multiple rounds of clarification with device manufacturers."

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This ultimately puts more onus on the manufacturers to control the risks of innovation by determining how much and what type of documentation will ensure informed, appropriate and safe product use.

A Broader Audience

Documentation and translation for medical devices in Asia will also need to take into account a much broader audience in each market, including local languages for consumer-oriented devices.

"The shift to the consumer means higher demand for translation across multiple markets," Dempsey says. "In the medical field, where devices are being used by the practitioners and clinicians, some countries will live with English. But once you shift down even to nurses and nurse practitioners, who may not have English as a second language, they will require translated materials."

The same goes for devices targeted directly at consumers. "As new revolutionary consumer products will give consumers more control over managing their health, consumers will have a much stronger and more diverse voice in the design and localization of these products," Frank points out.

Moreover, there is growing expectation in the internet age that supporting documentation for devices will be available in multiple formats. "That could be app-based, HTML- or web-based, so they can refer to it online," Dempsey notes. "And more people want 24-hour access to content. You will still have packaging and labeling: that's required by law in most countries. But the end-user will go to the internet for more information or to get instructions."

With character-rich Asian languages, accommodating mobile technology in translations of device labeling or instructions can be problematic. "We have clients that design mobile devices for professional use," Frank relates. "Because of screen limitations, you can't display as much information as you would like to. For example, these clients routinely ask for our help to resolve regional keyboard challenges: can we leave out certain characters or symbols for certain languages to save space and still ensure ease of use?"

Localizing Software

Another consequence of device digitalization is more emphasis on software components and how they are presented. "It used to be that software was just a piece of the medical device," Frank points out. "Now, certain types of software are considered to be their own medical device."

As software applications for medical diagnoses, image generation or data analysis take a growing share of the devices market, in Asia and elsewhere, manufacturers need to pay more attention to localizing software in different markets. "We see more demand for new languages for the written documentation, operational manuals, things like that," Frank comments

Previously, he notes, "you would translate documents into a set of languages but the software wasn't necessarily localized into these languages. You would operate English software, but use a Chinese manual for reference. It's becoming apparent that's no longer adequate just to meet regulatory compliance. And even if the regulatory authority lets you get away with it, the user may not."

With more reliance on user interface (UI), Dempsey points out, "there's going to have to be more control over it, more content presented through the UI and, depending on who's using the particular device, that content will have to be very heavily localized, translated and regulated, both for comprehensibility and to ensure instructions really meet the requirements of intended use."

As the consumer is "pulled more into the use of the product," device documentation will have to adjust for educational levels as well, Frank adds. "You have to phrase things differently, address how the navigation works. Consumers typically don't have any training in using the medical device, so you need to make it as simple as possible."

More Languages Too

Along with these challenges comes the need to tailor product labeling and other information to large populations speaking as many as thousands of languages or dialects. Asia is characterized by enormous geographical, ethnic, cultural and linguistic diversity.

While some countries (e.g., Singapore, Hong Kong) accept English-language labeling for devices, others insist on the local language or both English and local (e.g., Indonesia). "In India you've got a minimum of 14 but realistically 28 languages," Dempsey observes. "But if you go further East, each country has its own language, and in Southeast Asia there's no common language. So you are going to have to provide material in localized languages for each and every one."

In the large Chinese market, device documentation and labelling needs to be in Hong Kong Chinese as well as simplified Chinese, while traditional Chinese applies in Taiwan. Yet Korea, another substantial market, requires only one language.

As maturing markets in Asia build up their own device industries, companies are more likely to present documentation in their mother tongue, Frank notes. "More and more companies feel comfortable authoring in their native language, then translating, say, from Chinese into English, and using that as a baseline for translating to other languages. So we see a shift in the number of language combinations and the type of language combinations."

Companies must also be aware of local preferences and cultural sensitivities, such as different uses of symbols. "There rarely is any sensitivity in scientific or medical content, but it does have to be assessed," Dempsey observes. "And if you're addressing the patient or the consumer, you have to be very careful."

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Precision Is Paramount

Precision of language is paramount in supporting documentation for devices, where user education and compliance with labeling may be as important as product design or standards, particularly given the potentially disastrous consequences of device malfunction or misuse.

Ownership is another particular issue in Asian markets. That could be who has final say over written content or who does the translating. Device companies face "eternal challenges to mandate the usage of preferred suppliers such as ourselves," Frank says.

Asian clients can also be very particular about linguistic and stylistic nuances. With user documentation for devices, "they will pick over a lot of wording that might be a style issue," Frank says. "Even if you translate something into simplified Chinese, you might still have regional preferences in the word choices."

This increase in "preferential manipulation of translations"

raises the risk of off-label use. "The Chinese country office manager might decide to rewrite or add some new content," Frank explains. "His thought is: 'I know my clients and I want to expand on the description of this product's capabilities'. From a regulatory point of view, that's a big no-no, because the content hasn't officially been approved and filed with the authority, and you might present information that could represent false claims and off-label use."

Timing is another challenge. Often translators are brought in late in the product-registration cycle, when there is most potential for discrepancies, inaccuracies or ambiguities that could result in sub-optimal device use.

"We inherit everybody's delays," Frank comments. "So we have less time to accommodate last-minute changes, content additions, or requirements. It is not uncommon to suddenly be contacted by the client's regulatory-affairs professional to incorporate multiple instances of a critical warning in the user manual for a specific market, because it was finally confirmed that it's a requirement."

Labeling Headache

While the challenges of translating medical-device documentation in Asia go across the board, labeling is particularly demanding, not least because it must ensure that directions for use are fully understood by medical professionals and consumers at all levels of experience or education.

"It goes back to intended use," Dempsey notes. "If you don't have the packaging, the labeling, the inserts correct in English, let alone another language, you can get into all sorts of problems. And, of course, that would present liability issues."

Labeling is a delicate balancing act between translating to satisfy regulatory requirements and getting the words right for the local context. "So that's always going to be a headache," Dempsey says. "It's something we've done for many years but it's a different flavor of challenge to us in Asian markets."

Translating For Growth

By using a language services provider with extensive experience of regulatory affairs, documentation and communications for medical devices, companies can more easily manage their localization strategies in Asia, while making the most of the region's considerable growth potential.

"We have the presence in Asia, so we can liaise with either the subsidiaries of global companies or the native companies themselves, to help them through the journey of getting their product to market in their native country, or on a regional or global basis," Dempsey points out.

As Frank emphasizes, "we are essentially an extension of our client's regulated environment. They rely on us not only as a partner in advising on language compliance, and to help identify the potential for off-label use, but also to address the needs of their users. You can't just say, 'we can translate your documentation for you,' without having a thorough understanding of the regional market and regulatory environment."