



MedTech GATEWAY

#Access2MDInsights
April 2018, Issue #6

Cherry Blossoms seasons in many countries appears to last just a little while longer, even in the UK where areas around London in Notting Hill, Kensington were also in full bloom. Medical Technology news and updates are also coming in full bloom too!

Access-2-healthcare aims to keep everyone up-to-date to the latest medical technology industry and regulatory news/updates to provide pertinent information useful to practices within the Medical Device industry

In This Issue

Regulatory RoundUp *PMDA's increase in review fees, China challenging the IMDRF standards status quo, EU calling for experts, and many more*

In-Country Focus *Indonesia's first biotechnology center, Medtech's Got Talent at the finals, Singapore's healthcare's vulnerability to inflation*

Industry Insights *Drug-delivering drones, breakthrough biosensor technology, first MD independent of human interpretation*

Product Commercialisation Advice *Going-to-market: Not as mysterious as it seems*

REGULATORY ROUND-UP

The top regulatory news affecting the healthcare sector worldwide

<p>EUROPEAN UNION: Experts called to sign up to the liability and new technologies group Learn More</p>	<p>JAPAN: MD companies are now facing higher PMDA review fees</p> <p>The increase in fees will affect several categories of medical devices with fees increase reaching up to 20%. Learn More</p>
<p>AUSTRALIA: TGA provides guidance on updating IVD Notifications Learn More</p>	<p>CHINA: China's expertise in MD industry challenge existing IMDRF standards</p> <p>China marks its role in rule-making with a proposal to revise existing IMDRF standards. Learn more</p>
<p>INDIA: Medical Device applications grouped for more organised applications Learn More</p>	<p>CANADA: Some disinfectants and sterilants to face stricter regulations</p> <p>The change is brought about by Health Canada's decision to classify some disinfectants and sterilants as Class II Medical Devices. Learn More</p>

Do you have any questions on upcoming regulations or regulatory approval needs?

[ASK OUR REGULATORY TEAM](#)

IN-COUNTRY FOCUS

We dedicate this part of our newsletter to give you a peek in the in-country happenings or news in parts of the world where we have local presence

AUSTRALIA

<p>TGA releases latest list of suspended MD's and IVD's in the ARTG</p> <p>Stakeholders to follow the rules to ensure they retain their existing conformity assessment Learn More</p>	<p>Australia's largest MD accelerator program's finalists battle it out</p> <p>Medtech's Got Talent 2017 is about to conclude with finalists showcasing best talents for funding Learn more</p>
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CHINA

<p>China responds to growing threats of foreign made innovator drugs</p> <p>China pushes to promote generic drugs through a new policy package Learn More</p>	<p>Taking things a notch higher in healthcare-internet collaboration</p> <p>The country's efforts to grow internet powered healthcare continue Learn More</p>
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INDONESIA

<p>President Jokowi one with health ministry for proper child health</p> <p>The president talks about addressing issues on child stunting during his work visit in Sukabumi Learn More</p>	<p>A first in the country: biotechnology center opens in Depok</p> <p>UI collaborates with Daewong Indonesia to bring forth the biosimilar based laboratory Learn More</p>
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President Jokowi during his work visit at Sukabumi. Photo taken from Ministry of Health Republic of Indonesia website.

GERMANY

<p>Germany to share expertise to boost Azerbaijan's medical tourism</p> <p>A business forum was held in Baku and included 130 medical tourism companies in the attendees Learn More</p>	<p>Study shows majority of Germans see loneliness as a major problem</p> <p>As based on a recent study of 16,000 respondents, but 57% do not see this as political issue Learn More</p>
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MALAYSIA

<p>A promise fulfilled with the launch first Halal laboratory</p> <p>MyHAC launches to help certify Halal products more efficiently Learn More</p>	<p>Health insurance scheme brewed to cater the needs of the poor</p> <p>MOH's Voluntary Health Insurance Scheme is said to launch this year Learn More</p>
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PHILIPPINES

<p>Dengvaxia patients given priority as more probable SE cases surface</p> <p>Dengvaxia express lanes are implemented in hospitals and costs shouldered by Philhealth and DOH Learn More</p>	<p>Malacanang approves closure of Boracay island</p> <p>The closure is said to allow rehabilitation of the island following the surfacing of environmental issues Learn More</p>
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SINGAPORE

<p>HSA issues public warning on adulterated products found overseas</p> <p>Consumers are advised caution in buying health products online Learn More</p>	<p>SG 4th in Asian countries with highest medical inflation prospects</p> <p>This is despite the MOH taking important steps to address the problem Learn More</p>
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THAILAND

<p>A royal engagement: Princess Chulabhorn visits Penn</p> <p>The princess has long been involved with the university, but has now plans to open more opportunities Learn More</p>	<p>Thailand to become the economic engine room of Asia</p> <p>The country has committed to a 20-year plan that will enable it to become a global business hub Learn More</p>
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Have an in-market question or need a local market study? Click on the respective country link and check with our team members

[Australia](#) | [EU](#) | [Indonesia](#) | [Malaysia](#) | [Philippines](#) | [Singapore](#) | [Thailand](#)

INDUSTRY INSIGHTS

Medical Technology Industry and innovation news worldwide



A Zipline drone delivers blood package in Southern Rwanda. Photo: CYRIL NDEGEYAI/AFP/GETTY IMAGES

<p>Star trek-like capabilities in biosensor devices is now a possibility</p> <p>The Whispering Gallery Mode Biosensor's highly sensitive measuring capabilities are driven by its ability to ID individual nanoparticles Learn More</p>	<p>DUBAI HEALTHCARE: DHA signed MOU with CCC to expand cooperation in healthcare Learn More</p>
<p>FDA approves first medical device using AI to detect Diabetes-related eye problems</p> <p>The IDx-DR are the first of its kind to provide a final screening decision independent of a clinician to interpret results. Learn More</p>	<p>SHIRE ONCOLOGY LINE SOLD: Shire sells oncology business to Servier for \$2.4 Billion Learn More</p>
<p>Drone, the "Uber" in healthcare delivery</p> <p>With speed up to 128kph, Zipline's delivery drone is instrumental to their mission of bringing life-saving medicine to the far areas of the world Learn More</p>	<p>SEEDSTARS SUMMIT: Tech startups from emerging countries compete for finals Learn More</p>
	<p>LeMaitre-SYMMETRY: LeMaitre Vascular Divests General Surgery Product Lines Learn More</p>

JOURNEY TO PRODUCT COMMERCIALISATION

This section of our Newsletter is dedicated to provide readers with expert guidance on product commercialisation. We will discuss a useful advice a month, on a different step of the product development process.

For this issue, we will get useful tips on **Going-To-Market**.



GO TO MARKET STRATEGY

Not as mysterious as it seems

We always stressed that a proper **Go-to-Market strategy** for healthcare involves the integration of the 5 key elements:

1. Market Segment
2. Reimbursement
3. Regulatory Pathway
4. Intellectual Property
5. Clinical Activities

A Go-to-market strategy follows the same methodology as the 'path of least resistance'

'Resistance' – defined as the summation of:

- Time
- Cost (including opportunity cost)
- Organisational effort

Many Go-to-Market strategies fail because of the lack of integrated considerations of all factors involved. For example:

Change in intended clinical workflow -> Change in intended use -> change in device classification -> change in regulatory pathway

Change in intended use -> change in market segment -> change in reimbursement

Change in technology -> change in IP filing strategy -> change in market segment, device classification -> change in regulatory strategy

So, although its not as straightforward, as long as there is the right expertise who has the comprehensive skillset and not a "tunnel-vision" approach, there can be a reasonable chance you'd get a predictable answer.

Missed our product commercialisation advice from the last issues? **CLICK HERE.**
Concept | Prototype | QMS | Design and Development | Ready for manufacture

If you have more questions on the topics share, just reach out to us.

[I WOULD LIKE TO KNOW MORE](#)

GS MEDICAL PACKAGING INC.

COMPANY SPOTLIGHT

30 Years of High Quality Medical Packaging and Sterilization Products

GS Medical Packaging Inc. has been in medical packaging and sterilization product industry for close to 30 years. It is a well established medical packaging manufacturer, specialized in a wide variety of high quality sterilization packaging, medical packaging and infection control products.

You now can explore a potential partnership with **GS Medical Packaging** or search more company information through a NO-cost, low-risk method for sourcing channels and new partners - Partners' Portal. [Sign up](#) now and explore your possibilities

<p>ACCESS-2-HEALTHCARE PHOTO COMPETITION</p> <p>Our photo competition is still open!</p> <p>Remember, to qualify, 2 elements must be present - healthcare and medical technology</p>	<p>Would You Like to Join Us?</p> <p>Market Access Specialist (Hanoi, Vietnam) Project Manager (Singapore) Software QA Engineer - Medtech (Germany)</p> <p>Apply Here or Here. Due date: 30 Apr 2018</p>
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WE TAKE YOUR FEEDBACK.

We have prepared a short survey for the newsletter. This survey can help us improve our future releases with regards to content, relevance and design - to enhance the reading experience for you.

Every opinion matters so don't forget to click the link below to answer the survey.

[TAKE ME TO THE SURVEY](#)

Access-2-Healthcare helps medical technology companies gain market entry in various countries. Learn more about us through our [Slideshare](#) and our [website](#)

MISSED OUR LAST ISSUE?
In our past issues, we have tackled about the top regulatory news that affect the healthcare industry worldwide: **MDSAP, ISO13485: 2016, IMDRF AE Codes and EU MDR/IVDR** to name a few. [Click to view the MARCH 2018](#) newsletter.

