

"Life starts all over again when it gets crisp in the fall."

Scott Fitzgerald

Access-2-Healthcare

Summer has come to pass and October around the corner - September is a hectic month filled with challenges. [Access-2-Healthcare](#) team is always bettering with new ideas - And we are happy to announce our new company introduction deck and updates on our website soon. Better days will return, which for now, is represented by this monthly newsletter about the happenings around the Healthcare and Medical Device Industry, and occasionally [about us](#).

## Regulatory Round Up

### PHILIPPINES



#### Philippines: Reference List of Class A Medical Devices

Philippines FDA released an FDA Circular 2021-017 on Reference List of Class A Medical Devices. This issuance aims to guide manufacturers, distributors, importers and all other concerned stakeholders regarding the list of medical devices classified as Class A and to help the industry determine the appropriate authorisation, specifically Certificate of Medical Device Notification (CMDN).

[Learn More](#)

### INDIA



#### India: List of medical device testing laboratory (MDTL) registered with CDSCO

On August 27, 2021, CDSCO published a notice on list of medical device testing laboratory which are registered with CDSCO to carry out test or evaluation on behalf of manufacturer. There are more applicants who are still undergoing evaluation and will be added into the list.

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### EUROPE



#### Europe: Guidance on performance evaluation of COVID-19 IVDs

The Medical Device Coordination Group (MDCG) published a guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices. It covers devices for detection or quantification of SARS-CoV-2 nucleic acid, antigens and detection or

quantification of antibodies against SARS-CoV-2. The document forms the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746.

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## SINGAPORE



### Singapore: HSA Guidance on Medical Device Unique Device Identification (UDI)

Singapore HSA released a Guidance on Medical Device Unique Device Identification (UDI) system on August 27, 2021. All medical devices that are supplied in Singapore are required to comply with the UDI requirements unless otherwise specified. The compliance date for the various phases is tentative based on the progress of earlier phases of implementation. By November 1, 2028 (7 years to go!), all medical devices must be labelled with UDI.

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## AUSTRALIA



### Australia: TGA reduces timeframe for publishing adverse event reports

Australia TGA is making reports for medicines and vaccines publicly available more quickly. The changes will reduce the time between AE reports being accepted into TGA database and published on DAEN from 90 days to 14 days.

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## EU's Notified Body Tracker

### Designated NBs

1. BSI (Netherlands) - 2797 ([MDR scope](#) & [IVDR scope](#))
2. BSI (UK) - 0086 ([MDR scope](#) & [IVDR scope](#))
3. CE Certiso (Hungary) - 2409 ([MDR scope](#))
4. DARE!!! Services (Netherlands) - 1912 ([MDR scope](#))
5. DEKRA Certification (Germany) - 0124 ([MDR scope](#) & [IVDR scope](#))
6. DEKRA Certification (Netherlands) - 0344 ([MDR scope](#))
7. DNV GL Presafe (Norway) - 2460 ([MDR scope](#))
8. DQS Medizinprodukte - 0297 - ([MDR scope](#))
9. GMED (France) - 0459 ([MDR scope](#))
10. IMQ (Italy) - 0051 ([MDR scope](#))
11. Intertek IMNB (Sweden) - 2862 ([MDR scope](#))
12. MDC Medical Device Certification (Germany) - 0483 ([MDR scope](#))
13. MEDCERT (Germany) - 0482 ([MDR scope](#))
14. NSAI (Ireland) - 0050 - ([MDR scope](#))
15. TÜV Rheinland LGA (Germany) - 0197 ([MDR scope](#))
16. TÜV Rheinland Italia SRL (Italy) - 1936 ([MDR scope](#)).
17. TÜV SÜD (Germany) - 0123 ([MDR scope](#))
18. TÜV SÜD (Germany) - 0123 ([MDR scope](#) & [IVDR scope](#))
19. UDEM Adriatic d.o.o. (Croatia) - 2696 ([MDR Scope](#))
20. Eurofins Expert Services Oy (Finland) - 0537 ([MDR scope](#)).
21. Eurofins Product Testing Italy S.r.l (Italy) - 0477 ([MDR scope](#)).
22. ISTITUTO SUPERIORE DI SANITA' (Italy) - 0373 ([MDR scope](#)).
23. SGS FIMKO OY (Finland) - 0598 ([MDR scope](#)).
24. Telefication B.V. also trading under the names Kiwa Telefication, Kiwa FSS products and Kiwa EMC (Netherlands) - 0560 ([MDR scope](#))

### Withdrawals

1. [DQS Polska](#) - 2282
2. [ECM Germany](#) - 0481
3. [GMED SAS \(France\)](#) - 0459
4. [Presafe \(Denmark\)](#) - 0543
5. [SGS United Kingdom Limited \(UK\)](#) - 0120



# In-Country Focus

## UNITED KINGDOM

### UK: Armed Forces charities to receive £5 million boost

The Prime Minister has announced today that Armed Forces charities will receive £5 million in additional funding to support those who have served, including those who may be struggling following recent events in Afghanistan.

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## UNITED STATES

### US: Vice President Kamala Harris Opens New CDC Southeast Asia Regional Office in Vietnam

Vice President Kamala D. Harris today launched the U.S. Centers for Disease Control and Prevention Southeast Asia Regional Office in Hanoi, Vietnam, at a ceremony that included the U.S. Secretary of Health and Human Services, U.S. CDC Director, and Deputy Prime Ministers and Health Ministers from eleven countries. The new Regional Office strengthens CDC's ability to meet its mission of protecting Americans and people of the region by responding more rapidly to health threats wherever they occur and building key relationships to tackle shared health priorities. Vice President Harris reinforced the U.S. commitment to regional health security cooperation and renewed previous calls to action on pandemic preparedness and response

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## CHINA

### China: Legislation to better protect doctors

China's top legislature passed a law on Friday protecting the lawful rights and interests of physicians. Song Fang, an official from the National People's Congress Standing Committee's Legislative Affairs Commission, said the top purpose of the legislation is to protect the rights and interests of physicians.

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## UNITED STATES

### US: CDC Announces More Than \$300 Million in Funding to Support Community Health Workers

The Centers for Disease Control and Prevention (CDC) awarded more than \$116 million in year one, of a three-year, \$348 million program, to organizations for community health worker (CHW) services to support COVID-19 prevention and control. CDC also awarded more than \$6 million of a four-year \$32 million program for training, technical assistance, and evaluation. CHWs are frontline public health workers who have a trusted relationship with the community and are able to facilitate access to a variety of services and resources for community members. Availability of this funding was [announced on March 25th](#) as part of a larger effort to improve health equity in CDC's response to the COVID-19 pandemic.

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## PHILIPPINES

### Philippines: DOH: SRA FOR 20,000 HCWS DOWNLOADED; WORKING TO PROVIDE SRA TO MORE ELIGIBLE HCWS

The Department of Health (DOH) on Thursday said that the Special Allotment Release Order (SARO) for the P311 million-worth of Special Risk Allowance (SRA) has now been downloaded to its Centers for Health Development (CHDs). The said funds will benefit additional 20,208 healthcare workers. These funds transferred to the CHDs will then be released to their respective local government units and private health facilities in the next few days. The 311M is the first batch of fund transfers for the grant of SRA to hospitals and health facilities that have earlier submitted an additional list of eligible healthcare workers.

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## Industry Insights

## JAPAN

### Japan: Japan's PHC, formerly Panasonic Healthcare, announces US\$1.8 billion IPO

PHC Holdings Corporation (headquarters: Minato-ku, Tokyo, Japan, President & CEO: John Marotta) has today announced the approval by Tokyo Stock Exchange, Inc. (the "TSE") for the listing of the shares of its common stock (the "shares") on the First Section of TSE. The scheduled date for the listing of the shares is Thursday October 14, 2021, on or after which date the shares will be available for trading on the TSE.

[Learn More](#)

## UNITED STATES

### US: Baxter to Acquire Hillrom, Expanding Connected Care and Medical Innovation Globally

Baxter International Inc., a leading global medical products company, and Hillrom, a global medical technology leader, today announced that the companies have entered into a definitive agreement under which Baxter has agreed to acquire Hillrom for \$156.00 per share in cash for a total equity value of approximately \$10.5 billion and a total enterprise value of approximately \$12.4 billion, including the assumption of debt

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## INDIA

### India: Sher-I-Kashmir Institute Of Medical Sciences (Skims) & Medtronic Partner To Open Surgical Skills Lab In Srinagar

Sher-I-Kashmir Institute Of Medical Sciences (SKIMS) and India Medtronic Private Limited, a wholly owned subsidiary of Irish firm Medtronic, have announced their partnership for a new Surgical Skill Lab at SKIMS, India. The lab was e-inaugurated by Chief Secretary UT, J&K, Dr. Arun Kumar Mehta (IAS) in the presence of Director SKIMS/EOSG, Dr. A.G Ahangar, Prashant Krishnan, Sr. Director, Surgical and ENT Therapies, Medtronic India and other key dignitaries. Expanding on its commitment to address capacity and awareness barriers, the Surgical Skill Lab will help in the training and development of young surgeons in the Union Territory of Jammu and Kashmir, India.

[Learn More](#)

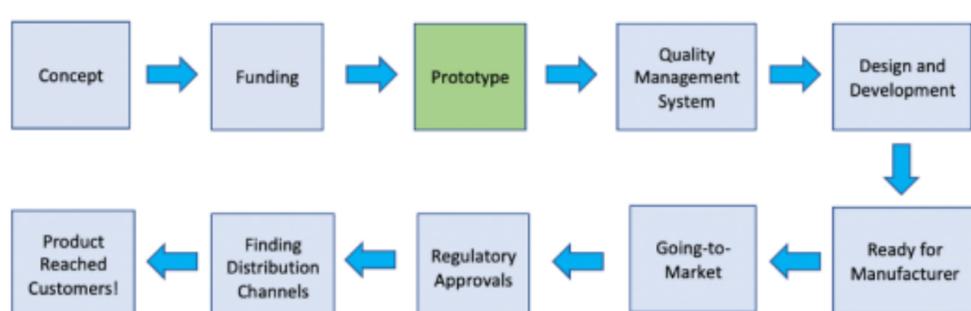
## UNITED STATES

### US: FDA Approves First-of-Its-Kind Stroke Rehabilitation System

The U.S. Food and Drug Administration today approved the MicroTransponder Vivistim Paired VNS System (Vivistim System), a first-of-its-kind, drug-free rehabilitation system intended to treat moderate to severe upper extremity motor deficits associated with chronic ischemic stroke—a stroke caused by a blockage of blood flow to the brain with long-lasting symptoms—using vagus nerve stimulation (VNS).

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## JOURNEY TO PRODUCT COMMERCIALISATION



### Prototype - Someone's got to pay for it!

There was once a client meeting where the plan was to establish a joint venture in a different country from the legal manufacturer.

There was a joint decision to further co-develop an existing device, and then for one of the partners to manufacture, the other to market and distribute.

There was much discussion about adapting the patent design, design history, customer requirements, which is all good. Draft drawings were made. All going fine.

Then the discussion went towards certain design features where standards compliance was pitted against device functionality. There was great discussion on whether we can not comply with the standard and still make a good product, or it is a must, what are marketing considerations, why can't we just do that, what are some design limitations, user limitations... kept going on and on.

But, what about the costs for the prototyping? Who pays for the design iterations, materials, prototyping tools, and gigs? Is that stated in the agreement? Hang on, what agreement?!??

All the theoretical talk was of no practical use if prototyping did not involve iterations, the good old-fashioned trial and error.

With all the technological advances, nothing beats hacking a prototype out, testing it for proof of concept, and refining the design to something that represents the best compromise of all the requirements. If it is a joint venture, it's imperative all these discussions on costs, responsibilities, and ownership of any invention, if any, is discussed and assigned accordingly.

Prototyping is not restricted to just start-ups, research teams. It happens for SMEs too, and in fact large corporations. Thus, in the medical device industry, the same fundamentals apply. Same design inputs, and always budget for engineering trials.

## Events

**We put together a collection of medical industry events around the world for the following month, just in case you may be interested. We take no commission for posting them - it is just our way to share information**

[Innovation in Health - Funding Health Panel](#)

October, 29, 2021 | 8:00 AM - 10:00 AM +08

[Medical Device Security: Challenges and Practical](#)

[Solutions](#)

October, 12, 2021 | 3:00 PM - 4:00 PM +08

[Future of Geotechnics - Technology, AI, Big Data](#)

October, 5, 2021 | 5:00 PM - 7:00 PM +08

[Basics of Market Access for Start-ups in Medical](#)

[Technology](#)

October, 4, 2021 | N.A

[Technology Enhanced Learning](#)

October, 11, 2021 | 23:00 - 00:00

[Technology and Serious Organised Crime](#)

October, 20, 2021 | 23:00 - 00:15 +08



We help medical technology companies with their product development, market launch and to gain market entry in various countries. Learn more about [US](#)



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