# ime)(HS

## ASX ANNOUNCEMENT

## COMPANY ANNOUNCEMENT

## IMEXHS receives FDA Clearance for commercialisation of Hiruko Essential in the USA market

### HIGHLIGHTS

- FDA has issued the Company clearance notification for Hiruko Essential software.
- Significant milestone achieved by IMEXHS in its international expansion and recognition.
- Accelerates US market entry strategy and leverages distribution agreement with IGMC Medical Technology Group announced on 15 July 2019.

**Sydney** — **5** August 2019 — **IMEXHS Limited** [ASX: **IME**] today announces that it has received a final device classification, clearing the Hiruko Essential software suite for commercialisation in the USA under the Code of Federal Regulations (CFR) 892.2020.

ImExHS can now market and sell the Hiruko Essential software suite into the US, the world's largest market for PACS and RIS software.

- The American College of Radiologists notes there are 39,811 accredited medical imaging facilities under its purview.
- IMEXHS's current soft launch strategy includes the distribution agreement with IGMC and the process of localising its Hiruko suite for the US market environment as the first step with a 5.5 year SaaS contract announced on 4 July 2019 with Rad One PSC in Puerto Rico.
- According to a report by Transparency Market Research, the opportunity in the global PACS and RIS market stood at US\$2.2 bn in 2015 and, was projected to rise at a 7.0% CAGR during the forecast period to be worth US\$3.9 bn by 2024. North America accounted for a leading share of just under 47% in the global PACS and RIS market in 2015.

Following a change of procedures by the FDA under the 21<sup>st</sup> Century Cures Act, the FDA has issued IMEXHS with a formal exemption under Code of Federal Regulations Title 21, Volume 8, as a Class I device, clearing the way for commercialisation in the USA.

Dr. German Arango, IMEXHS CEO, noted "The receipt of the FDA clearance represents an important milestone in the history of the Company, and will allow IMEXHS to accelerate our soft launch in the US market. Concurrently we will be working on a more detailed market entry plan. The FDA clearance is also an important recognition for IMEXHS in Central and Latin America and the timing is particularly opportune given our recent appointment of a distributor in Brazil".

Mr Gabriela Matute, IGMC President commented "We would like to congratulate IMEX on final the clearance for commercialisation in the USA."

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Hiruko Essential is a software-based device that receives digital images and data from various sources (e.g. Computed Tomography scanners, Magnetic Resonance scanners, ultrasound systems, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways, etc.). Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations using an embedded web-based viewer with image manipulation tools and strong data encryption to ensure a secure data transfer.

This product is an implementation of a DICOM<sup>®</sup> archive and image manager packed with a web-based viewer including basic image manipulation tools where its components are closely integrated to provide an implementation of many IHE actors and Integration Profiles to take advantage of HL7<sup>®</sup>. Hiruko Essential uses indexed information from DICOM headers for locating objects on the file system and it does not produce any original medical images. Hiruko Essential is designed to be deployed over conventional TCP/IP networking or cloud infrastructure utilizing commercially available computer hardware platforms and operating systems.

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#### **ABOUT IMEXHS**

**IMEXHS Limited [ASX: IME]** is a leading imaging Software as a Service (SaaS) and ancillary solutions provider. Founded in 2012, IMEXHS is known for its innovation in the imaging services market, offering flexible and scalable imaging solutions via its Hiruko branded suite of solutions for next generation Picture Archiving and Communications System (PACS) and integrated Radiology Imaging System (RIS). The Hiruko system is completely cloud based, vendor neutral and zero footprint with no need for installed software. Enhanced features such as a fully web-based voice recognition option and a zero footprint DICOM viewer are some of its advanced features. In addition to PACS and RIS, imaging technology and management systems can be provided on a Platform as a Service (PaaS) basis when packaged with equipment. The IMEXHS products are designed to increase productivity and save money for the users, with a scalable platform that is configured for the future, while enhancing patient outcomes. Please see www.imexhs.com

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