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ASIO Journal of Medical & Health Sciences Research (ASIO-JMHSR)

Volume 8, Issue 1, 2025: 01-17

COVID-19 & THE MEDICAL DEVICE REGULATIONS IN THE PHILIPPINES

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ARTICLE INFO

Article's History

Received: 2nd January, 2025
Accepted: 12th April, 2025

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ABSTRACT

The objective of this study is to consolidate existing documents from the Philippine regulatory bodies controlling the Medical device regulations and draw observation on emphases, innovation and response of the Philippine government in relation to medical device regulations during the early stage of COVID-19 pandemic. To do this, an exhaustive collection of related memorandums, announcements, press release, press statements, circulars, draft and advisories from January to August 2020 were gathered, tabulated, summarized and arranged chronologically from all the government agencies in the Philippines responsible for the control of medical devices. About this study, it can be observed that the regulations of the Philippine government as to medical devices are focused on 3 things: (1) Control of the prices of Protective Personal Equipments (PPEs); (2) Relaxing the regulations for import of medical devices to facilitate availability; and (3) Control on the proliferation of unregistered, uncertified, unnotified and misbranded medical devices used against COVID-19.It can be concluded thatthere is mostly proactive effort from the Philippine government in providing quality and adequately priced medical devices to Filipinos based on the documentary releases of its regulatory agencies.

Key words: *Medical device; Philippines; COVID-19; Medical device regulations; Regulatory affairs.*

How to cite this article?

Romeo C. Ongpoy, Jr., COVID-19 & the medical device regulations in the philippines, ASIO Journal of Medical & Health Sciences Research (ASIO-JMHSR), 2025, 8(1): 1-17.

INTRODUCTION

The supply of medical devices is vital in the combat against the COVID-19 pandemic. Medical devices though are regulated products by the government authorities and are carefully examined for standards before market release. In the Philippines, there are several agencies that monitor medical devices including the Department of Health (DOH) and Food and Drug Administration (FDA) for medical devices registration (and certification); Dangerous Drugs Board (DDB), Department of Environment & Natural Resources (DENR) and the Philippine Drug Enforcement Agency (PDEA)where these agencies also cover In-vitro Diagnostics(IVDs)which are also classified under medical devices; Philippine Nuclear Research Institute (PNRI) for medical device use in relation to radiation; Bureau of Customs (BoC) for importation matters; National Telecommunications Commission (NTC) and Optical Media Board (OMB) for those devices using WiFi and softwares respectively; and the National Reference Laboratories (NRLs) for validations of critical IVDs. There are some agencies above though that are not involved in COVID-19 based regulations owing to their scope but the Center for Device Regulation, Radiation Health & Research (CDRRHR) of the Philippine FDA has been centralto the monitoring of medical devicesand implementing the corresponding regulations in the Philippines. This research is undertaken to examine

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

the regulations of the FDA in the time of pandemic and how is it facilitating availability of essential medical devices which are very much needed in the time of COVID-19.

There has been memorandum, circulars and other documents released by the authorities on the control of Philippine medical devices but not consolidated in one paper to properly see the sequence and the cumulative effort of the Philippine government in the regulation of medical devices in the first months of COVID-19 in the country between January to August 2020, this paper is providing this very much needed summary. In this paper, the memorandums, announcements, press release, press statements, circulars, draft and advisories were gathered, tabulated, summarized and arranged chronologically to be able to observe closely the emphases, innovations, response and other important findings from the mentioned documents. It is hoped that the observations from this consolidated work may help in constructively providing feedback to the betterment of the local medical device guidelines; this can also be a source of information where authorities both local and foreign may learn and most importantly, help in the combat against the COVID-19 pandemic where medical devices are essential.

1.0. January to March 2020

The first confirmed case of COVID-19 in the Philippines from a Chinese tourist was reported in January 30, 2020 [6]. After a day, the first COVID-19 related issuance in Philippine government came out which is the Price Freeze on Essential Emergency Medicines. The memorandum aims to implement the Price Freeze on Essential Emergency Medicines in the entire country to protect the public from profiteering, hoarding, cartels and the likes in times of COVID 19. The legal basis for this is reiterated which is section 6 of RA 7581 (Price Act) and as amended by RA 10623 (An act Providing Protection to Consumers by Stabilizing the Prices of Basic necessities and Prime commodities and by Prescribing measures against Under price Increase During Emergency Situations and the Like Occasions) [5]. On the 5th of January, the price freeze was reiterated and a list of the controlled medical supplies are attached in the memo including N95 mask, disposable mask, sterile gloves of different sizes, nebulizers, nebulizing kit for different demographics and oxygen cannula for different demographics as well [3]. The price freeze was further amended last March 5, where Safety Googles are added in the Medical device list on top of the previously mentioned devices [5]. A press release was made on March 9 for the Issuance of a Certificate of Exemption (Marketing Authorization in most countries) to a local SARS CoV-2 PCR detection kit developed by the University of the Philippines & National Institutes of Health (UP NIH) that is developed by local scientists and funded by the Department of Science and Technology (DOST) [7]. The previous price controls where again emphasized as prices where specifically ranged by March 12. Prohibition of online selling of essential emergency medical supplies beyond the national price ceiling N95 masks should be from 45 to 105 PhP; Disposable face masks should be from 3 to 12 PhP; Sterile gloves should be from 295 to 450 PhP; Nebulizers should be from 1,495 to 3,980 PhP; Neb kit pedia should be from 63 to 142 PhP; Neb kit adult should be from 87 to 120 PhP; Oxygen cannula neonatal should be from 24 to 50 PhP; Oxygen cannula pedia should be from 18.50 to 53 PhP and Oxygen cannula adult should be from 24 to 60 PhP [8]. Still on March 12, the guidelines for obtaining Special COVID kit certification were released. The requirements for the Special Certifications of COVID-19 kits are letter of intent, valid LTO, fee of 500 PhP and product registration of kit from a mature regulatory agency like the US FDA in the USA or HSA in Singapore [9]. Although there are already guidelines for special certification of COVID-19 diagnostic kits, on March 15 the government clarified that there is still no registered COVID 19 kit available because there is so far no company who applied for registration and assures the public that once there is an application, it will be processed without delay. Further, the requirements for registration of imported kits are: License to Operate (LTO) and a Certificate of Product Registration (CPR) from any mature regulatory body abroad. Currently, Research Institute of Tropical Medicine (RITM) uses a PCR kit donated by WHO and the Philippines also uses the locally developed test kit from UP NIH and DOST [10]. By March 16, hand sanitizers are also closely monitored by FDA. The FDA releases the list of notified companies manufacturing hand sanitizers. At this point, there are already 122 manufacturers and 190 brands. The FDA also urges to report the manufacturers that are not registered through eReport at

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

ww.fda.gov.ph/eReport, through email at report@fda.gov.ph, via phone at (02) 857-1979 or (02) 857-1984 or at the FDA facility in Alabang [11]. Drug dispensing was also modified by FDA to be more accessible to those who need it the most like those vulnerable to COVID-19. In March 17, guidelines on the electronic means to avail of prescription drugs in drugstores for individuals vulnerable to COVID 19 is detailed in pursuant of RA 8792 which is the Electronic Commerce Act of 2000. Electronic prescription will be the same as written prescription prescribed by a licensed Physician and should be dispensed by the Pharmacy. Antibiotic, anti-infectives and antiviral preparations though will only be valid within 1 week of issuance. Dispensing will not also require actual presence of the patient but a letter of authorization and a Senior Citizen card or Person with Disability (PWD) ID may be presented with the ePrescription by claimed of the authorized subject [8]. As Community Quarantine was already declared in Manila by March 15, FDA transaction guidelines was released by March 17. There was adoption of alternative work arrangements and functions in skeletal workforce to ensure continuity of government service while protecting and limiting the FDA workforce. Initial LTO (License to Operate) applications of manufacturers of health products shall await pre-license inspection schedule as soon as the community quarantine in Luzon and/or respective Local Government Unit (LGU) of the establishment is lifted except for establishments with health products intended for COVID-19 purposes (PPEs, essential medicines, etc.). All LTO renewal applications received from March 1, 2020 to May 31, 2020 shall be given automatic extension of validity to another 4 months after expiration date of the LTO. At CDRRHR (Center for Device Regulations, Radiation Health & Research), suspension of initial application of LTO for radiation facilities, application of radiofrequency radiation desk-top evaluation, initial application of CPR for medical devices, IVDs, water purification system and healthcare waste system and application for variation of CPRs for medical devices and IVDs. However, the following application was accepted: COVID-19 related test kits following FDA memorandum number 2020-006 and Compassionate Special Permits (CSPs). Product Registration will be done online with high priority for products against COVID 19 through cdrrhr@fda.gov.ph. [13].

By March 19, commercial and donated products were also controlled through the guidelines for the identification, notification, evaluation, regulatory enforcement action, and review and monitoring of donated health products solely intended to address COVID-19 public health emergency. This circular only includes face masks (including N95), shoe covers, gloves, head covers, gowns, goggles/face shields, COVID-19 diagnostic test kits, alcohol (including hand sanitizers) and other health products that may hereinafter be identified and listed by the FDA. Documentary requirements are still the same as mandated in DOH AO 2007-007 (Guidelines on the Acceptance and Processing of Foreign and Local Donations During Emergency & Disaster Situations). Once documentary requirements are completed, a stamp that says “Received and Cleared for COVID 19 Donation Purposes” and shall be sufficient clearance from FDA but the products are still subject to post-notification evaluation and further regulatory or enforcement action from FDA. During the post notification process, prompt sample collection and submission will be made to the appropriate center and to the laboratory in case testing is required. For those requiring testing, results of evaluation will be forwarded to the Bureau of Internal Health Cooperation (BIHC) or other DOH office concerned. The receipt of the donation to the issuance of report shall not exceed 48 days. If product is unfit and/or unsafe, immediate regulatory or enforcement action shall be pursued in coordination with the concerned center (recall, seizure, and/or filing legal case). The Policy and Planning Services of the FDA oversees the conduct of this guideline. On March 20, five documents were released by FDA. One is the control of thermometers as there has been rampant online selling of Infrared thermometer for medical use and the FDA advises all healthcare professionals and the public to purchase and use only from those companies with Certificate of Product Registration (CPR). Clarifications may be made at cdrrhr@fda.gov.ph and reports maybe submitted through the usual route [15]. Second is that the FDA issues the 2nd updated list of notified hand sanitizers and registered topical antiseptics and antibacterials [16]. Third, the procedure for PPEs import was simplified at Customs. Face masks (including N95), shoe covers, gloves, head covers and gowns shall only need LTO and a proof of

application for notification such as electronic acknowledgement for customs release. For foreign donations, clearance from FDA shall not be needed. These include companies, other than medical device establishments, with employees who use facemasks in the performance of their jobs and are strictly for company use [17]. Fourth, there was an amendment of online selling of over-priced medical devices. Amendment of the Price freeze to include sterile gloves per pair (size 6.5, 7, 7.5 and 8) with range from 18 to 21 PhP as well as safety googles with range from 30 to 55 PhP [18] and lastly, FDA is alarmed of the growing misinformation on hand sanitizers online. The FDA warns the public of hand sanitizers and topical antiseptics and antibacterials that did not went through notification at FDA which are sold online at Facebook Marketplace, Lazada & Shopee. FDA is encouraging the public to be vigilant and always check the product label as to the full ingredient listing, country of manufacture, name and address of the manufacturer, batch number, manufacturing and expiration dates and special precautions to be observed when in use. FDA further encourage reporting of these unnotified products [19].

Ventilators and related products were increasingly needed by the hospitals so there was already ease in its importation by March 23. Ventilators, respirators and their respective accessories which are imported to the country for commercial purposes will only need to present LTO to the BoC for customs release. For donations of the same products, which is used for COVID-19 FDA clearance will not be required prior to release [20]. It is important to note that there is still no approved COVID-19 commercial diagnostic kit by March 24 so the FDA released an advisory in Filipino language that there is still no registered COVID 19 kit available because there is so far no company who applied for registration and assures the public that once there is an application, it will be processed without delay. Further, the requirements for registration of imported kits are: License to Operate (LTO) and a Certificate of Product Registration (CPR) from any mature regulatory body abroad. Research Institute of Tropical Medicine (RITM) uses a PCR kit donated by WHO and the Philippines also uses the locally developed test kit from UP NIH and DOST [21]. By March 25, there were shortages of alcohols so compounding in drugstores were allowed. The circular states that retail drug outlets may prepare alcohol-based products such as hand sanitizers through compounding as provided under RA 10918 (Philippine Pharmacy Act). That the compounding should be based on USP 795 and the Guide to Local Production of WHO – Recommended Handrub Formulations. FDA further states that the formulation should contain alcohol/ethanol, glycerol and hydrogen peroxide and discourages addition of fragrance so the quality of the finished product is not compromised. Compounding record and Master formulation should also be kept. A sample primary labeling is also attached with the circular as well as the USP formulations [22]. A press statement was issued by March 26 to address the proliferation of unregistered COVID-19 kits. The FDA is expediting the processing of COVID-19 kits and understands the urgency of the pandemic but does not want to compromise the quality and safety of the kits imported without scientific evidence and proper documentary basis. Test kits that did not go through FDA will not be released by customs [23].

Ventilators were officially included in the listing of health products in circular 2020-009 by March 27, the circular was amended to include ventilators, respirators and their respective accessories as health products used to address COVID-19 public health emergency [24]. On the same day, the FDA encourages the public to report at covidresponse@fda.gov.ph for matters related to COVID 19 products that are unregistered/unnotified (usually sold online), very high prices of health products, suspected fake, questionable food and drugs and other similar issues [25]. On March 30, do it yourself hand sanitizers were observed by FDA online and the agency warned the public of instructional videos on Do-It-Yourself Hand sanitizers/Disinfectants that are circulating that they pose more risk to the public like the use of rum and bleaching agent as ingredients. FDA reminds the public that production of such products must come from a licensed FDA manufacturer with adequate facilities and licensed personnel equipped with appropriate PPEs. Hand washing was also stressed by FDA as a more effective sanitizing method than the mentioned DIYs [27]. On March 31, FDA Philippines endorses the WHO link on off-label use of medicines for COVID 19 stating that: off-label use is subject to national laws and regulations, should be case-to-case

basis, discourages unnecessary stockpiling of medications that may create shortages of approved medicines to those needing the drug and that it can be ethically appropriate to offer individual patient experimental interventions on an emergency basis outside clinical trials provided that no proven effective treatment exists.

2.0. April

FDA issued an advisory at the first day of April that COVID-19 test kits are strictly for the use of Medical Professional. The kit may be acquired by general public through a prescription from a licensed physician. The conduct and interpretation of result must also be done by a licensed physician [28]. On the same day, FDA also clarified that COVID-19 test kits must be acquired through a prescription from a licensed physician from a licensed hospital or drugstores. Online sale is prohibited and the conduct and interpretation of result must also be done by a licensed physician. Improper dispensing and other violations maybe reported at covidresponse@fda.gov.ph [30]. One of the most important documents for COVID-19 was also released which is the Creation of Bayanihan One Stop Shop (BOSS) in compliance to RA 11469 (Bayanihan Act) to streamline processes in importing COVID-19 commodities was released by April 2. This will hopefully fix problems like the confusion and misinformation of the public on procedures for commercial importations of COVID-19 critical commodities by private entities and the continued operation of the government in a "silo system" that lengthens the importation process. A single window will accept online applications for COVID-19 commodities both for FDA & BoC. The process in FDA for application for LTO is a 3-step process, including submission and evaluation, payment, and issuance of eLTO, all processed online. The process for importation is also a 3-step process and also done electronically, these processes are submission and evaluation, payment, and clearance and release of shipment [1]. The COVID-19 critical PPE commodities include gloves, gowns, coveralls, body suits, face masks, goggles, face shields, shoe cover, head cap/cover and boots. Other specific medical devices include adhesives, preformed anchor, bandage, base paste, reusable cannula, caps, non-mercurial clinical thermometer, cotton, dressing, flowmeter of all types, gauze, gloves, lubricating gel for internal and external use, luer lock, nasal spray, nasopharyngeal airway, stop cock, sterile surgical drape, syringe without needle and medical tape [31]. Amendment to FDA Circular No. 2020-006 Entitled "Guidance for Applications and Transactions at the Food & Drug Administration in the Light of the Community Quarantine Declaration" Issued on 17 March 2020 was issued April 2. The circular is about the FDA transactions during community quarantine. It clarifies that CDRRHR services include processing of COVID-19 test kits, PPEs and x-ray facilities and clearance; product registration, CSPs and sales promo permit. LTO, Certificate of Product Registration (CPR), and certificate of Product Notification (CPN) with validity until March 1, 2020 to June 30, 2020 shall be given additional 4 months validity extension from the date of expiration of the market authorization. All applicants are required to apply for renewal within the given extension period. CPR compliance and sales promo permit correspondence may be emailed to fdac.pacd@fda.gov.ph. COVID 19 applications, CSP and notification of sources will be emailed to fdac.letters@fda.gov.ph. Submissions may be done through scanned copy of the documentary requirements and proof of payment, notarization of required documents shall be waived during the ECQ period, a format for email correspondence is also provided in thecircular that requires the type of application and center concerned, 14-digit document tracking number, schedule given by FDAC, proof of payment, product category, product classification and type of application. Payments shall follow FDA Circular No. 2017-010 (New Collection Policy & Procedure). Bancnet online payment facility transactions are accepted at FDA as long as it bears the Document Tracking Number (DTN). Payment concerns will be coursed to cashier@fda.gov.ph. All release of documents inquiries will be coursed to records@fda.gov.ph [31].

FDA also announced by April 3 that it approved the RT-PCR for the detection of COVID-19 manufactured by HealthTek, Inc. for commercial use. This was the

previously developed in collaboration with UP-NIH and funded by the DOST [32]. The procedure for PPE clearance was then updated by April 6. PPEs for commercial use (face mask including N95, shoe covers, gloves, head covers and gowns) only requires LTO for customs release. Donated products will not require FDA clearance. All companies who have imported PPEs under this advisory and will continue to distribute PPEs for commercial purposes after the pandemic shall apply for Certificate of Medical Device Notification (CMDN) within 3 months after the lifting of Proclamation Number 922 s. 2020 declaring a state of public health emergency throughout the Philippines [33]. On top of the ease in PPE import, local manufacturing is encouraged. By April 8, a memo on Interim manufacturing was released, it says that all establishments that intend to manufacture PPE, ventilators and respirators are required to secure an LTO as a medical device manufacturer. Manufacturers who intend to continue to produce PPE, ventilators and respirators for commercial use shall apply for product notification/registration within 3 months after the lifting of the state of public health emergency throughout the Philippines. The development, design, functionality/performance testing, product validation, risk management, sterilization, clean room environment, clinical trial (whichever is applicable), and other considerations in the manufacture of these products shall be guided by the following: Philippine National Standards (PNS),Applicable International Standards (ISO or IEC) in the absence of PNS and the technical requirements for registration of these medical devices as stated in AO Number 2018-0002. Initial application requirements include accomplished application form and declaration and undertaking, proof of business name registration, site master file (for manufacturers), risk management plan and payment. Application process includes filing, evaluation and the mandatory pre-opening inspection [34].

April also marks the start of the proliferation of unregistered, unnotified and uncertified medical devices in the Philippines. By April 8 as well, FDA released a press statement informing the public that there is currently no registered drug or vaccine that are licensed specifically for use in COVID-19 treatment or prevention. There are on-going clinical trials though like the Solidarity trial in which the Philippines is contributing [35]. The price freeze was again emphasized by the DOH come April 14. Prices of selected essential emergency medicines and medical devices used in COVID-19 were adjusted including cover all gown (Hazmat) from 210 PhP to 1200 PhP, surgical cap from 200 PhP to 250 PhP, sterile disposable gown from 200 PhP to 300 PhP, non-sterile gown from 300 PhP to 200 PhP, oxygen tank 5 lbs from 2200 PhP to 3400 PhP, oxygen tank 15 lbs from 3800 PhP to 5000 PhP, pulse oximeter from 1000 PhP to 2000 PhP for pedia and 2500 PhP for adult, thermal scanner is at 3400 PhP, Infrared non-contact thermometer for head is at 4500 PhP and safety googles remain at 180 PhP (Department number 2020-0144-A) which on the following day reiterated once more so that dissemination and necessary steps to address COVID 19 pandemic spread must be made (Department memorandum 2020-0144-A). On the other hand, additional payment channel was made by April 16 which is an additional temporary measure to facilitate payment at FDA through Landbank payment with account name FDA RA 9502 Special Fund and account number 032-1030-58. Payment transactions subjected to this channel are subject to validation of deposit/transfer and will be posted on the next banking day once credited by Landbank. Proof of payment and order of payment or DTN will be emailed to cashier@fda.gov.ph [38]. On the same day, FDA clarifies the varying diagnostic methods in the market for COVID-19, it says that there are 16 Rapid test kits approved as of April 16, 2020 and these kits are independent from each other and each product has different specifications, kits are also manufactured by different companies in various countries and in various settings. These kits though detect 1, 2 or all of the antibodies which are total antibody, IgG and IgM.

By 3rd week of April, Research Institute of Tropical Medicine (RITM) was officially tasked to evaluate FDA approved COVID-19 antibody test kits. “Reliability of the kits are important and should be tested locally” according to the then FDA Director General Enrique Domingo and RITM as the National

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

Reference Laboratory (NRL) for emerging infectious diseases is mandated to perform evaluation of infectious diseases. One of the most important landmark regulations for medical devices during the COVID-19 pandemic in the Philippines which is the establishment of certification and validation of COVID-19 diagnostic kits was also released April 20. It says that all COVID-19 antibody test kits (rapid test kits, point-of-care, lateral flow, ELISA, GICA, CLIA, among others) with Special certification from FDA shall undergo RITM validation as part of post-marketing surveillance. Three hundred (300) pieces of samples will be submitted to RITM within 30 days of the notice of submission from RITM and cost of testing will be borne by the company. FDA will revoke special certifications that will not go through validation testing [41]. To recognize the growing need of x-ray devices, special permit for loaner unit mobile x-ray devices intended for use in the diagnosis of COVID-19 patients in need of immediate imaging procedures and medical response will be granted. The requirements are letter of intent, application form, copy of on-loan agreement between the user and the supplier, copy of official receipt or certificate of subscription of the personal dose monitor from the provider of personnel dose monitoring service, copy of valid professional regulation commission (PRC) license of all the radiologic technologists and calibration certificate of the loaned mobile x-ray machine. Application will be through cdrrhr.rrd@fda.gov.ph or cdrrhr@fda.gov.ph [42].

WHO press release was linked to the FDA PH website announcing that the Department of Health in the Philippines is participating in the WHO Solidarity trial and that it has been approved by the Single Joint Research Ethics Board (SHREB) last April 17. The trial will test the safety and effectiveness of the four possible therapies in treating COVID-19, compared to standard of care, these are: (1) the investigational antiviral drug Remdesivir, (2) the antimalarial drug Chloroquine or Hydroxychloroquine, (3) the antiretroviral drug used for HIV which is Lopinavir with Ritonavir and (4) Lopinavir with Ritonavir plus Interferon beta-1 alpha. The trial will be conducted in at least 20 level 3 hospitals nationwide. By April 24, document on releasing of FDA authorization and payment thru fund transfer was released. Scanning of authorizations and sending them through email of the authorized personnel will only be accommodated if there is a request because some requestors visit the CDRRHR after the email of the document which defeats the purpose of the community quarantine. Payment using Landbank account must be under account number 032-1030-58 and the proof of payment must be emailed to the FDA cashier also, On-Coll payment slip must be used at Landbank and not the Cash deposit slip [44]. Import of respiratory devices was also emphasized as they are used in treating COVID-19 patients and must therefore be expedited at customs. The company importing such devices will only need to show their LTO at customs and foreign donations will not require clearance from FDA [45]. In the same day, respiratory therapy devices was also included in the previous guidelines on identification, notification, evaluation, regulatory enforcement action and review and monitoring of donated health products solely intended to address COVID 19 on top of the previously identified devices. By the end of the month, unregistered thermometers are proliferating, and FDA warns the public of circulating unregistered Infrared thermometer identified as Lerkonn Infrared Thermometer [47].

3.0. May

The month of May marks the influx of uncertified, unregistered and unnotified medical devices. This includes (1) Unregistered Infrared thermometer (FDA advisory 2020-807), (2) Uncertified COVID-19 test kit identified as “Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test” (FDA advisory 2020-812), (3) Unregistered medical devices identified as Pharmaline Monitor Digital Thermometer and Microlife Digital Jumbo LCD Thermometer [48], (4) Unregistered medical devices identified as Benetech Non-Contact Infrared Thermometer, Aicare Infrared Thermometer and Sejoy Infrared Forehead Thermometer, (5) Unregistered medical device identified as Cawono D380 Non-Contact IR

Thermometer, (6) Unregistered medical device with unapproved and misleading health claims, identified as Biomask Flat +, (7) Unregistered product identified as Richskin Case Germs Away with Vitamin E Ethyl Alcohol 70% Solution, (8) Uncertified COVID-19 test kit identified Femometer COVID-19 IgG/IgM Rapid test cassette, and (9) Unregistered product identified as Topcare Digital Infrared Ear Thermometer.

By May 15, RITM released a document on Biosafety Guidelines for COVID-19 testing laboratories Using GenXperts and reminds those processing COVID-19 specimens to adhere to WHO Laboratory Safety Guidance related to COVID-19 including meeting the core requirements of a basic containment laboratory, that sample prior loading to cartridges must be done in a certified and maintained biological safety cabinet class 2, a dedicated area for donning and doffing PPE must be identified, SOP must incorporate specific biorisk mitigation control measures including emergency response and incident reporting, laboratory workflow and practices following the clean to dirty principle must be maintained at all time, proper PPEs must be worn and a fit tested NIOSH-approved filtering face piece respirator that provides a level of filtration of 95% or greater (like N95 or equivalent must be used). Enhancements from the minimum guidelines may also be made like directional airflow in the laboratory, requirement of negative pressure; anteroom, specific training, specific practices and the use of additional PPEs like face shield, dedicated laboratory shoes, shoe cover and hair cover. Alcohol and other sanitizer products were included in the price monitoring and that alcohol (ethyl and isopropyl alcohols at 70%) of specific quantities and packaging should not go beyond the ceiling price, reiterating the price freeze. FDA was later concerned of the quality of the medical devices used for the COVID-19 pandemic that is now adequate in quantity by this month. The requirement to secure an LTO is reiterated then the application for the Certificate of Product Notification (CPN) for ventilators and respirators for manufacturers and Certificate of Product Registration (CPR) for most PPEs. It is also emphasized that the requirements based on AO No. 2018-002 (Guidelines Governing the Issuance of the Authorization for a Medical Device based in ASEAN Harmonized Technical Requirements) will be followed as well as the Philippines National Standards and ISO or IEC in the absence of PNS. The procedure for customs release is also reiterated in this document. On the other hand Philippine Drug Enforcement Agency (PDEA) released document on the conduct on their processes where PDEA outlines the detailed steps and reminder on how to submit SAR/DADIN online during the duration of GCQ and the detailed steps and reminder on how to apply for S/P license during the duration of GCQ, the procedure is a mix of face-to-face and online application (PDEA website post, 2020). Lastly by April 30, reissuance of the guidelines on the Identification, notification, evaluation, regulatory enforcement action, and review and monitoring of donated health products solely intended to address COVID-19 public health emergency to include ventilators, respirators, their respective accessories and respiratory devices in the circular and to extend the circular effectivity until December 2020 from May 2020.

4.0. June

The cases of unregistered, unnotified and uncertified medical devices continues to surge this month some of the published cases include: (1) Uncertified COVID-19 test kit identified as DeepBlue COVID-19 (SARS-COV-2) Antibody Test Kit) [60], (2) Unregistered medical device identified as Miniland Thermosense Forehead and Ear Contact Thermometer [61], (3) Uncertified COVID-19 test kit identified as Testsealabs One Step Rapid Test-SARS-COV-2 IgG/IgM Test Cassette [63], (4) Uncertified COVID-19 test kit identified as WIZ BIOTECH Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2, (5) Unregistered medical devices identified as Non-Contact IR Thermometer, and (6) unregistered medical devices identified as Yuwell Clinical Digital Thermometer (YT308) and Yuwell Clinical Thermometer [66].

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

COVID-19 specimen storage and guidelines was released this month of June. In this regulation, RITM clarifies that testing laboratories must determine the disposition of specimen used for laboratory diagnosis of SARS-CoV-2. Disposition pertains to destination of specimen and information including its storage, transfer, destruction, and disposal after the desired lab procedure. An algorithm is provided in the guideline for easy reference. On June 3, temporary contact numbers at FDA were released while the landline numbers are temporarily disabled from June 4 to June 15, 2020. Adding up to the unfortunate outage is the system maintenance from June 12, 2020 by 8 AM to June 15, 2020 by 6 AM and the ePortal, FDA website and FIS were affected in the outage. Updates from PDEA include the detailed steps and reminder on how to submit SAR/DADIN online during the duration of GCQ and a reminder on how to apply for S/P license during the duration of GCQ, the procedure is a mix of face-to-face and online application. DDB on the other hand is expressing support to follow the "Guidelines for Infection Prevention & Control (IPC) in Drug Abuse Treatment & Rehabilitation Facilities". Lastly, FDA releases the list of notified medical face maskson June 19 and there are 17 face mask brands from 5 different companies. A link in the advisory is also provided by FDA to check on updated list.

5.0. July

The cases of unregistered, unnotified, uncertified and misbranded medical devices are continually reported but decreased for this month, the reported cases include: (1) Unregistered medical device products including Forehead Thermometer TG8818A in Foreign Characters and Forehead Thermometer in Foreign Characters [74] (2) Unregistered medical device identified as UNI-T UT300R Non-Contact Infrared Thermometer Thermal [75], (3) Unregistered medical device product identified as Mokarway HT801 Thermometer Thermal Scanner Non-Contact Forehead [76], (4) Unregistered medical device product identified as Electronic Thermometer TD138 [78], (5) Misbranded face masks in Foreign Characters identified as Fu Le Bang disposable mask, Flag World Face mask and an unnamed mask [84] and (6) Unregistered medical device identified as Leelvis Non-contact Electronic Thermometer.

Guidelines on training on COVID-19 laboratory work was released by July 1 as a responsibility of the RITM to ensure knowledge and skills for the diagnosis, control, and prevention of infectious and tropical diseases reach the country health responders, the institute will be accepting laboratory training requests. The procedure is to send a formal letter with the full name, email address and contact information; the checklist of requirements will then be filled (attached in the guidance document), and the participant should present a negative COVID-19 PCR test result 24 hours prior to the training where the test conducted within the last 72 hours of the 1st day of training. Also in the same day, the number of notified hand sanitizers grow to 248 brands. A new and improved guideline for FDA operations was drafted by July 2 and still not finalized at that time. The FDA is drafting the circular on its business processes during the new normal. This involves symptom screening, wearing of face mask, filling up the health declaration form, following the arrows in the pathways and temperature check (should not be more than 37.5°C prior to entry in the premises). Online transactions are preferred but FDAC is open from 9AM to 4PM serving 20 clients at a time and Document Tracking Number (DTN) should be the reference number of the transaction. Inquiries may be directed to cdrrhr@fda.gov.ph. Cashier is open but cash trays will be used in handling money. A format is provided for CDRRHR transactions and fdac.pacd@fda.gov.ph and fdac.letters@fda.gov.ph will receive medical device queries, the latter for COVID-based queries. Radiation-base facility application will be through cdrrhr.rrd@fda.gov.ph. By July 6, PDEA outlines the detailed steps and reminder on how to apply for S/P license during the duration of GCQ, the procedure is now through email only and there is no one-time personal appearance. Guidelines for IVD evaluations and

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

other diagnostic supplies were released July 13. From this guideline, RITM will perform validation as post-marketing surveillance on COVID-19 test kits. Requirements for validation are the following: formal request for evaluation, product brochure, technical information, regulatory status, Instructions for Use (IFU), ISO/IEC, and contact information. Required number of samples and the fees for validation are also included in the guidelines and inquiries may be directed at ritmkitevaluation@gmail.com or calls at phone number +632 88072632 local 605 may be made. On July 15, FDA endorsed a WHO news release on the Vaccine Global access facility. According to WHO, more than 150 countries including the Philippines is involved in the cooperation to discover the vaccine against COVID-19. This involves the COVAX facility where vaccines, tests and treatments may be developed and manufactured as well as promoting fair access once produced.

In July 17, there further amendment to FDA Circular 2020-006 and 2020-006-A entitled "Guidance for Applications and Transactions at the Food & Drug Administration in Light of the Community Quarantine Declarations" Issued on 17 March 2020 & its Amendment Issued on 2 April 2020. The July amendment states that Notice of Deficiencies (NOD) may be complied within 3 months from the end of the compliance period. CAPA may be submitted to fdac.letters@fda.gov.ph. MA and certificates may be picked up at FDAC. However, if after 10 working days and the authorization is not yet picked up, this will be mailed thru courier to the registered mailing address of the company. For clients outside NCR, the documents will be mailed to the Regional Field Office (RFO). Request for scanned copy of LTOs and CPRs and sending them thru email will no longer be facilitated. In July 21, FDA released a statement on face masks with valve. The FDA stand on this is that FDA does not recommend the use of face masks with valve or valve-masks. The use of a face mask with a valve is not recommended during this COVID-19 pandemic because the person wearing the mask with a valve can be protected from the virus. However, if the person has the virus, he/she can infect other people. Also in July 21, rescission of FDA Circular No. 2020-011 entitled "Guidelines of Alcohol Based Sanitizer Formulations in Light of the Declaration of State of Calamity due to COVID-19" was made considering the regular supply of alcohol-based sanitizers has been restored, compounding of alcohol products by drugstores/pharmacies/boticas is no longer necessary according to FDA [92].

Payment through fund transfer has been updated by July 22 since Metro Manila has been down-graded to GCQ, online payment thru transfer of funds to FDA's Land Bank of the Philippines account will no longer be accommodated. As for validation of diagnostic kits for COVID-19, it was initially required that 300 test kits must be submitted to RITM for validation. However, based on the RITM guidelines dated July 13, the prescribed quantity of product for evaluation of SARS-CoV-2 / COVID-19 Antbody / Antigen kit must be good for 100 tests. For Serologic based (Rapid antibody and immunoassay) test kits and antigen-based test kits, performance testing is required by FDA as part of post-marketing surveillance. A caution on the purchase and use of unregistered vaccines for COVID-19 was released July 24 and FDA advises the public against the purchase and use of vaccines sold locally or online claiming to be safe and effective in preventing COVID-19 and that candidate vaccines for COVID-19 are still in the development stage. Suspicious claims, sale and advertisement claiming as vaccine for COVID-19 may be reported to FDA at covidresponse@fda.gov.ph.

6.0. August

The reported unnotified product reduced to only one medical device by August for the product Nitrile Disposable Gloves Powder-Free, Non-Sterile. The updated list of approved COVID-19 kits was also released. By August 20, the updated guidelines for application of authorizations at the Food & Drug Administration in light of the community

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

quarantine declarations were released. Some important medical device information in the guidelines include: LTO expiring on July 1, 2020 to December 2020 shall be given additional 4 months validity extension from the date of expiration of the market authorization; Renewal application received beyond 4-month validity extension up to a maximum of 120 days shall be subjected to surcharge as prescribed in RA 9711. Any application for renewal received thereafter shall be considered expired; Over the counter payments shall be suspended during the community quarantine thru On-Coll payment at Landbank of the Philippines branches; and the results of applications and scanned copy of FDA market authorizations and certificates shall be sent to the registered email of the company's authorized representative [92]. Upon the surge of COVID-19 cases in the Philippines, no face to face interaction at the Food and Drug Action Center (FDAC) on 24 August and until further notice was implemented. The announcement further states that FDA protects everybody including their employees by implementing no face to face interaction at FDAC, only online transactions through email shall be entertained and that drop boxes with appropriate labels shall be available at the main entrance of FDAC where clients can deposit their documents, packages, parcels and other related items. FDA also gave 8 mobile phone numbers for transactions from Monday to Friday by 9 AM to 4 PM.

By August 24, the new normal draft on FDA operations was approved. Some of the guidelines include that there shall be no face-to-face interaction at FDAC, only online transactions through email shall be entertained. Office hours will be 9AM to 4PM Mondays to Fridays except during non-working holidays. The previous emails for the different FDA departments are consolidated in this advisory and it states that FDAC shall act on client inquiries within 24 hours. Templates for applications and compliance are also provided in this advisory [90]. In the same day, FDA clarified that Face shields are not regulated by them therefore no authorization or certification from FDA is needed to sell legally [91]. Conduct of Risk-Based local inspections in the light of the COVID-19 pandemic was released. This include: FDA inspectors may inspect establishments within the vicinity of their municipality or city of residence including nearby and accessible areas to minimize movement of inspector; Only high priority inspections shall be scheduled; low priority inspections shall be deferred and will be explained in a letter the reason for deferral and that a risk score will be assigned for each scheduled inspection based on the different criteria presented in the guidelines. Inspection may be classified as high risk and low risk. High risk will be for remote inspection or combined remote and on-site while low risk will be combined remote and on-site or on-site under agreed controlled conditions. Virtual conferencing will be used and documents may be transmitted via file sharing in platforms like Google drive [92]. In August 25, FDA reiterates the granting of 20% discounts to senior citizens including vitamins and minerals supplements per AO 2012-0007. Violators shall be subjected to appropriate action based on RA 9994 (Expanded Senior Citizens Act of 2010) [93]. The electronic prescription guidelines was also extended to December 31, 2020 by the FDA [94]. List of approved Rapid antibody test kits for commercial use was released that states that there are already 88 approved Rapid antibody test kits as of August 28, 2020; a list of approved PCR based test kits for commercial use was also released and states that there are already 85 approved PCR based test kits as of August 28, 2020; Lastly, a list of approved Immunoassay test kits for commercial use was released and states that there are already 59 approved immunoassay test kits as of August 28, 2020.

7.0. DISCUSSION

The medical device industry regulations in the Philippines during the early stage of COVID-19 (January to August 2020) are generally centered into 3 important points: (1) The control of the prices of the medical devices which was emphasized 8 times in the documents presented even before the first case of COVID-19 surfaced in the Philippines and may be observable in other parts of the world as well like India (100); (2) There is an effort to ease restrictive import processes for PPEs used against COVID-19 like face masks, gloves and later respirators and even for business licensing. The WHO (World Health Organization) and WTO (World Trade Organization) have been criticized to better their regulations on this (98); (3) It can also be noted that the regulatory agencies particularly the FDA-PH is monitoring closely the market for the proliferation of unregistered, uncertified, unnotified and misleading medical devices that are growing in the time of the pandemic that is also observed in other parts of the world like Ukraine (99), there is therefore a pro-active effort from the government to make essential medical devices available to the public during first months of the COVID-19 pandemic.

The modification in administrative operations of the FDA are centered to COVID-19, while this is understandable and practical, business processes are disrupted like the usual registration of products and licensing inspections which did not happen in Singapore and Malaysia. On top of these, phone and other communication outages may be noted in the documents presented in this paper which are supposed to be vital in the new socially distanced environment. The processes for certifying COVID-19 diagnostic kits are also made faster not only in the evaluation time spent by the authorities but by the fact that the Philippine evaluators avoid assessment duplication made by reliable and mature health ministries by recognizing the foreign Marketing Authorization (MA) which is one of the main goals of the ASEAN integration. It can also be noted that the creation of a one stop shop to facilitate License to Operate (LTO) and MA is possible upon the arrival of the product in the Philippines and should be considered of maintaining even after COVID-19, there is faster and undeniably better cooperation between FDA and the Bureau or Customs which does not usually happen before COVID-19. The support of the government agencies to e-Prescriptions, alcohol-based products compounding, validated local diagnostic kits development, local manufacturing flexibilities of PPEs and even mobile x-ray facilitation cannot be undermined as well. It can also be noted that there is a regular update on the approved diagnostic kits for COVID-19 from FDA. Also, the validation requirement for imported COVID-19 diagnostic kits as part of the Post-marketing surveillance (PMS) is reasonable and necessary to protect public interest but the delay in the validation brought about by the surge in COVID-19 cases in the Philippines and the delay of essential validation resources may affect the business chain and therefore public health.

This study is focused only on medical devices, there are also local developments when it comes to drugs and clinical trials which are supported and also held in the Philippines so to assess the local supply and regulations of health products, this paper may not be enough. It can also be noted that this paper is only covering the first months of COVID-19 in the Philippines, that is from January to August 2020 because the goal of this paper is to assess the response of the government during the early stages of COVID-19.

Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239

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Doi: 10.2016-74831794; DOI Link :: https://doi-ds.org/doilink/04.2025-24871234/ASIO-JMHSR/V8/I1/RCO/239