Philippine Association of Medical Device
PAMDRAP
Regulatory Affairs Professionals

MINUTES OF THE MEETING

Meeting Title:	**22nd GMM**		
Date:	26 November 2021	**Time:**	12:00 NN – 1:00 PM
Minutes Taker:	Giselle Regio Documentation Committee	**Location:**	Online zoom meeting
Attendees:	Engr. Ma. Cecilia Matienzo (speaker), Member Companies		

I. MEDICAL DEVICE REGULATORY UPDATE

Topic 1: Update on Implementation of AO 2018-002

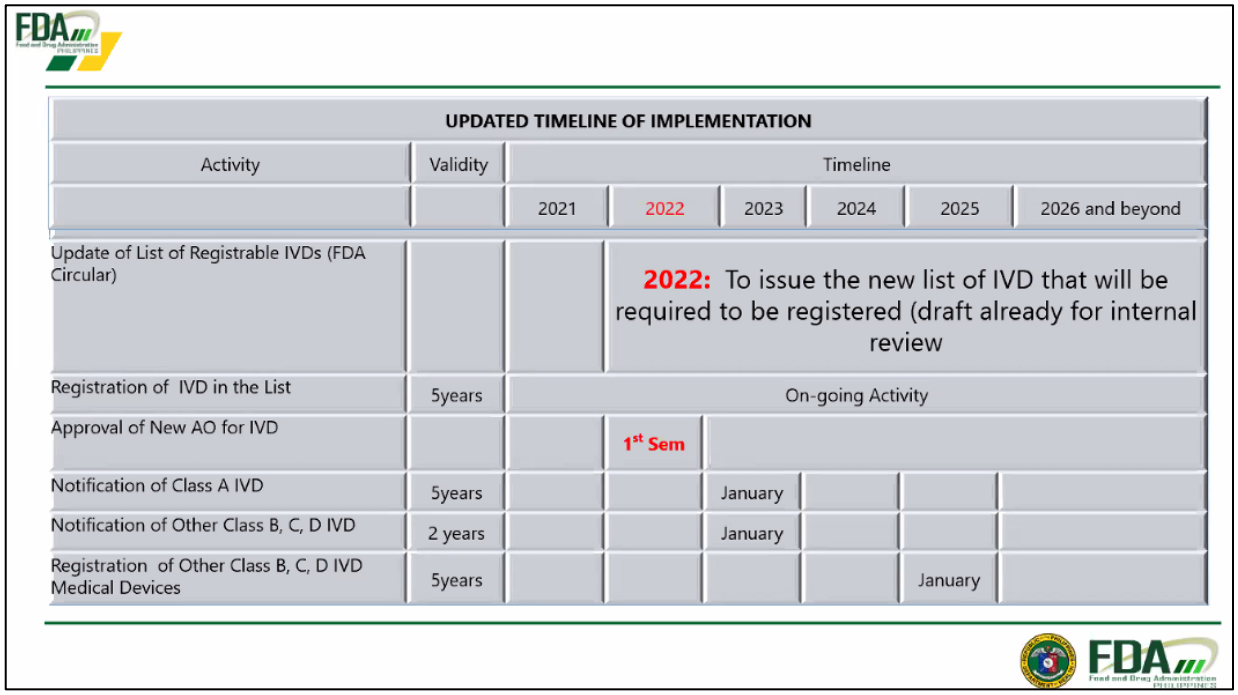
Timeline for implementation:

1. **For General Devices:**

Implementation of 2018-002

TIMELINE OF IMPLEMENTATION							
Activity	Validity	Timeline					
		2020	2021	2022	2023	2024	2025 and beyond
GENERAL MEDICAL DEVICE							
Preparation and approval of Issuance of the Phase implementation (FDA Circular)		September	FDA Circular 2021-002 is issued on				
Registration of MD in the List as Per FDA Circular 2020-001	5years	On-going Activity					
Notification of Class A Medical Devices	5years	On-going Activity					
Notification of Other Class B, C, D Medical Devices	2 years		March				
Registration of Other Class B, C, D Medical Devices	5years				March		

2. For IVDs:



UPDATED TIMELINE OF IMPLEMENTATION

Activity	Validity	Timeline					
		2021	2022	2023	2024	2025	2026 and beyond
Update of List of Registrable IVDs (FDA Circular)			**2022:** To issue the new list of IVD that will be required to be registered (draft already for internal review				
Registration of IVD in the List	5years	On-going Activity					
Approval of New AO for IVD			1st Sem				
Notification of Class A IVD	5years			January			
Notification of Other Class B, C, D IVD	2 years			January			
Registration of Other Class B, C, D IVD Medical Devices	5years					January	

Emphasis on Issuance of Authorizations for **(GENERAL)** Medical Device Products

- Only the following are qualified for **NOTIFICATION:**
  - Class A
  - Class B, C, D not in the list based on FDA Circular 2020-001-A
- Only the following are qualified for **REGISTRATION:**
  - Class B, C, D indicated in the list based on FDA Circular 2020-001-A

Issuance of Authorizations for IVD Medical Device Products

- The following provision is indicated in FDA Circular 2020-001.
- The list of registrable IVDs is based on FDA Memorandum Circular No. 2014-005, including the blood collection tube

> 5. The list of in-vitro diagnostic (IVD) medical devices that are registrable in Section B of FDA Memorandum Circular No. 2014-005 remains the same; however, the blood collection tube listed in Section A of the said FDA Memorandum Circular shall be added under the list of IVD since it has been re-classified as in-vitro diagnostic (IVD) medical devices based on the definition of IVD in the ASEAN AMDD.

Topic 2 : Update on Covid-19 Related Products

Covid-19 Test Kits:

- FDA Memorandum 2020-006 = Requirements for special certification
- FDA Memorandum 2021-009 = Standard required value for sensitivity and specificity for RT-PCR, antibody and antigen test kits
- FDA Advisory 2021-0684 = Process Flow

Covid-19 Related Medical Devices:

- Qualified for fast track processing however, applicant must follow existing regulatory requirements during submission
- Upon approval assessment, client can email cdrrhr@fda.gov.ph of the DTN number and product name so CDRRHR can put the application in the priority list.
- Currently, syringes and ventilators are in the fast track list

Topic 3: Update on LTO

FDA Advisory 2021-2634 "Pilot Implementation of FDA eServices Portal System for LTO Application of Retailers of Medical Devices within NCR"

- The following are required to secure the LTO as Medical Device Retailer:

FDA eServices Portal for LTO Application for Retailers of Medical Devices	
Location of Establishment	National Capital Region (Metro Manila)
LTO Establishment Application	Retailers of Medical Devices including; (1) Retail stores for medical devices; (2) Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System; (3) Sellers using online shopping website, social media platforms; (4) TV shopping companies that sell or offer to sell medical device directly to the general public; (5) Optical Shop; and (6) Drug outlets, such as drugstores and retail outlet for non-prescription drugs (RONPD) that also sell or offer to sell medical devices For this pilot run, drug outlets, such as drugstores and RONPDs with multiple outlets/branches within the National Capital Region shall be allowed to apply for a maximum of ten (10) outlets/branches only.

- There is ongoing FDA discussion whether there can only be one LTO for drugstores carrying both drugs and medical devices
- Medical device vending machines are currently out of scope of the pilot implementation however, they are still included in the list of medical device retailers
    - A guideline will also be released on which types of medical devices will be allowed to be sold in vending machines.
- Start of pilot implementation: 03 November 2021
- End of pilot implementation: 31 January 2022

Interim Application System for LTO

- FDA Advisory 2021-2903 "Interim application system in lieu of DICT system maintenance of LTO for FDA eServices"
- The system will be accessible on 22 November 2022 through https://eservices.fda.gov.ph

Topic 4: What's New?

Collaborative procedure between the WHO and national regulatory authorities in the assessment and accelerated national registration of WHO pre-qualified in vitro diagnostics

- The agreement with WHO is currently being prepared and discussions with the national reference laboratories are being finalized
- In case this agreement will ensue, there will be no performance evaluation needed prior to issuance of CPRs for WHO pre-qualified in vitro diagnostics. However, full documentation
- The implementation is planned for next year

FDA Advisory 2021-3084 "Abridged Processing of Applications for Registration/Notification of Medical Devices Approved by the Regulatory Authority of any ASEAN Member Country"

- Applied to all ASEAN Member Countries with issued CPR equivalent following the CSDT Technical Requirements based on AMDD
- Draft Policy:
  1. CPR equivalent is issued by the Regulatory Agency of the ASEAN Member Countries only
     - Or third-party (notified body) in Malaysia, since this is also recognized by the Malaysian Ministry of Health.
  2. The approval of the CPR is based on the CSDT technical requirements as stated in the ASEAN Medical Device Directive
  3. CPRs issue based on abridged approval based on other countries outside the ASEAN are not qualified
     - In Singapore, they have an abridged pathway wherein they base and consider the registration approvals from other non-ASEAN countries (ex: USA, Canada). If the product approval was based on this abridged pathway then, it is not qualified for the Philippines abridged pathway. This is because the product approval was not based on CSDT.
  4. Applicable only for Class B, C and D medical devices, either for notification or registration

Additional requirement:

- Declaration that the submitted CSDT Technical Requirements is the same as the one submitted to our counterpart regulatory agency who issues the CPR equivalent.
  - ➢ Must be issued by manufacturer or principal (not local importer)

- Procedure:
  1. Company to submit complete requirements based on AO 2018-002 the same procedure as the application
  2. CDRRHR to evaluate the compliance of the legal requirements and the completeness of the technical requirements except for the labeling requirements
  3. Labelling requirements will be evaluated based on the requirements as stated in AO 2018-002
  4. Will also be subjected for pre-assessment

On Follow Up and Application WITHOUT Action

- Email only to cdrrhr@fda.gov.ph only. Do not include other CDRRHR's email addresses otherwise, your email request will not be entertained.

Name of Company	Doc Track No.	Product Name	Date Applied	Last Status on DTN (remarkable)
* Indicate in the SUBJECT: APPLICATION with NO ACTION				
** Submit in excel format at cdrrhr@fda.gov.ph				
** November December 2020	** June July 2021			
CMDR, Variation, Renewal				

Q&A with Engr. Cecile Matienzo:

Question:	Answer:
When is the estimate time for release of PMAS guidelines?	Regulatory Impact Assessment (RIA) is actually the limiting step. All the rest of the requirements are already in place. Hopefully, by next year all pending drafts will be issued. Clinical Trial will be the next focus in the succeeding years.
Will the labeling guidelines also include software labeling?	Yes, including also e-labeling.
How long is the pre-assessment period for CMDN?	We are hoping to fast track it as soon as possible since we are currently hiring for more manpower. We encountered influx of CMDN applications and faced system difficulties.
Will the abridged pathway/type of review be extended to IVDs too?	AMDD does not have CSDT requirements for IVDs. It only has classification. We will tackle in the future meetings with ASEAN how to handle this.
Some evaluators request for documents that are not applicable for certain classifications of medical device	CDRRHR is currently crafting manuals/guidelines to help minimize human error during review. MCCM suggests to re-apply and stick with the requirements only.
On regulatory reliance, how does it affect the multiple CPRs on the systems? (In other countries, it is approved as a system but in PH it has multiple CPRs.)	We'll decide once we have seen the documents. In the meantime, submit as multiple CPR and make sure the components are clearly stated on the approval letter.
Regarding the e-Services, it was indicated that those who submitted before Nov 4 should resubmit	Those application which were paid already were forwarded to CDRRHRH for completion.