LRP Panel Meeting
Medical Device Division Update

Medical Device Division
Department of Health
The Government of The Hong Kong SAR

16 April 2021

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Department of Health

Personnel Updates

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Section 1: Pre-market	
Vetting Officers	Mr. Rex HUI (Left since Apr 2021)
	Ms. Regina LI (Left since Apr 2021)
Screening Officer	Mr. FUNG Chi Wai (Resumed in Dec 2020)

Section 3: Post-market	
Case Officers	Dr. Jonathan LAW (Since Nov 2020) [Replacing Dr. Canon TSANG]
	Ms. Emmie LAI (Since Nov 2020) [Replacing Mr. FUNG Chi Wai]

Personnel Summary

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Section Head	**3**
Medical & Health Officer	1
Electronics Engineer	3
Physicist	1
Scientific Officer	9
Registered Nurse	2
Research Officer	0

MDACS Statistics

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Figures	2019	2020	Changes	2021 Q1
Received applications	1782	1747	-2.0%	461
Received new applications of IVDMD	57	149	161.4%	26
Approved applications	1454	1458	0.3%	368
Approved new applications of IVDMD	24	37	54.2%	9
Approved Board meeting	24	21	-12.5%	5
Received new applications for traders	24	24	0%	6

MDACS Updates

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- Regular update for Asian Medical Device Nomenclature System (AMDNS) resumed
- Extension of trial schemes
- Recognitions of marketing approval obtained from member countries of the EU and UK after BREXIT (More information in later slide)
- Update of GNs and the corresponding Forms will be published in mid Apr 2021

Trial Schemes for listing application of medical devices

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Trial Schemes	Extended deadline
■ Accepting marketing approval obtained from the National Medical Products Administration	30 June 2021
■ Accepting marketing approval obtained from the Ministry of Food and Drug Safety of Korea	30 June 2021
■ Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device	31 December 2021

Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device (Rev.: Dec 2020)

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- Two amendments include:
  - ~~Requirement for the independent regulatory agencies' approval to be obtained for at least three years~~
  - ~~Requirement to have at least one substantially equivalent device listed under the Medical Device Administrative Control System (MDACS)~~

Recognitions of marketing approval obtained from member countries of the EU and UK after BREXIT

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- Recognitions of marketing approval obtained from member countries of the European Union (CE Mark) under the MDACS
  - Continue to accept CE Mark obtained from the current 27 member countries of the European Union
  - Continue to accept CE Mark obtained from UK-based Notified Body by 30 Jun 2023 provided that the certificate is issued before 1 Jan 2021

Arrangements under COVID-19

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- Face-to-face workshops and seminars are temporarily suspended
- Online talks on listing application have been launched since Dec 2020
  - https://www.mdd.gov.hk/english/events/events.html
  - next workshop will be held on 27 Apr 2021
- LRP and traders on-site inspections are temporarily suspended
- Some officers are re-deployed to other services
- Enquiry channel remains unchanged
  - Tele. : 3107 8484
  - Email: mdd@dh.gov.hk or mdd_info@dh.gov.hk

Reminders for application submission

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- Submit renewal application (at least 3 months) before the expiry date
- Update of LRP contact information
  - 15% of the email address given from the traders are undeliverable
- Check the validity of the submitted documents
- Ensure sufficient documents for IVDMDs
  - Ensure the classification is Class B, C or D
  - Submit free sale certificates from EU countries for IVDMDs with EU self-declared IVDMDs ONLY
    - If the IVDMDs are registered with other MDACS recognized marketing approval, EU self-declared route cannot be utilized
  - Submit sufficient document for supporting the performance claims
  - Ensure the right version of essential requirement checklist

Reminders for application submission

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Item	Name of Document	Remarks
1	Application Form (A001)	- Please refer to the ISO 13485 for a complete legal manufacturer's name.
2	Application Form (B001)	- Contact information of public enquiry should be "xxxxxxx". - Fax number should be "xxxxxxx".
3	LRP's ISO 13485 (B003)	- Expired, please resubmit.
4	Application Form (C001)	- Duplicate of device name. - Please clearly and correctly present the information.
5	MDS-01 (C002)	- Document not included in the submission.
6	Application Form (C003)	- Please provide one AMDNS code and term.
7	Application Form (C009)	- Name of the first manufacturing site should be the same as the ISO 13485.
8	Device Labels (C013)	- Labels of some models missing, please resubmit.
9	Essential Principles Declaration of Conformity (D001)	- No signature, please resubmit. - Please submit a copy with our new division name.
10	Application Form	- Please resubmit the original form.

Reminders for application submission

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3	**Particulars of the Device**		
	(a) Model name(s) / product code(s) of device(s) *(Please indicate Addition/Deletion/Amendment* of device(s) in the existing Certificate of Listing, if any)**	☐	
	(b) Intended use / Indications for use	☐	
	(c) Contraindications	☐	
	(d) Device labeling (including instructions for use, device package labels and Special Listing Information) *(Please provide details on changes(s) to content of the instructions for use)*	☒	**Update IFU and label**

Form MD-Change (Rev. 6/2020) 1

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It is suggested to provide a separated attachment for listing the detailed changes of the labelling if there are many changes

Reminders for application submission

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- Provide comparison table / summary of changes for change applications
- Timely submit the post-market surveillance report for high risk devices
- Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese
- Under the Consumer Goods Safety Regulation implemented by the Hong Kong Customs and Excise Department
  - where consumer goods or their packages are marked with, or where any labels affixed to or any documents enclosed in their packages contain, any warning or caution with respect to their safe keeping, use, consumption or disposal, such warning or caution shall be in both the English and the Chinese languages

Matters related to Legislative Proposal

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- Refinement of the Medical Devices Bill is in progress and planned to be submitted to the Legislative Council later

COVID-19 Vaccination Programme

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- The Government is implementing a territory-wide COVID-19 Vaccination Programme free of charge for all Hong Kong residents.
- The priority group of the Programme has been extended to persons who aged 30 [16/18] years or above from mid-March 2021
- For personal protection and to safeguard public health, the Government encourages you and your employees belonging to the priority groups to receive the vaccination.
- More information on the Programme can be found at https://www.covidvaccine.gov.hk/en/ or enquiry hotline at 3142 2366.

Deceptive E-mail Alert

- Spam e-mails with the following sender address:

DH_Enquiry_Public/DH/HKSARG were reported from the members of the public to DH

- DH clarified that no such e-mail has been issued by the DH

Please be careful !!

THANKS