LRP Panel Meeting
Medical Device Division Update

Medical Device Division
Department of Health

9 October 2020

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Department of Health

Personnel Updates

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Department of Health

Section 1: Pre-market	
Officer-in-charge	Mr. Yorkie CHOW (Senior Electronics Engineer) (Since Nov 2019)
Secretary	Mr. Marco WONG (Before Feb 2020) Ms. Kay WONG (Feb 2020 ~ Sep 2020) Mr. Kelvin SZE (Since Oct 2020)
Vetting Officers	Mr. Kelvin CHOW (Since Dec 2019) [Vide Mr. Alex CHOI]
	Mr. Marco WONG (Since Feb 2020)
	Mr. Rex HUI (Since Jul 2020)
	Ms. Regina LI (Since Jul 2020)
	Mr. Jeremy WONG (Since Oct 2020) [Replacing Ms. Kay WONG]

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Personnel Updates

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Section 2: Regulation	
Officer-in-charge	Mr. Alex CHOI (Senior Electronics Engineer) (Since Dec 2019)
Section 3: Post-market	
Officer-in-charge	Dr. Kelvin LOW (Senior Medical & Health Officer) (Since Oct 2020)
Case Officer	Mr. FUNG Chi Wai (Since Sep 2020)

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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	2

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MDACS Statistics

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Figures	2019 (Jan-Sep)	2020 (Jan-Sep)	Changes
Received applications	1384	1364	-1%
Received new applications of IVDMD	45	102	127%
Approved applications	1137	1078	-5%
Approved new applications of IVDMD	17	15	-12%
Approved Board meeting	19	16	-16%

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Arrangements under COVID-19

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- Regular workshops and seminars are temporarily suspended
- LRP and traders on-site inspection 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

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Reminders for application submission

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- Submit renewal application (at least 3 months) before the expiry date
- Update of LRP contact information
- 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 EU self-declared IVDMDs
  - Submit sufficient document for supporting the performance claims
  - Ensure the right version of essential requirement checklist

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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, for example:
  - Mechanical heart valves;
  - Implantable pacemakers, their electrodes and leads;
  - Implantable defibrillators, their electrodes and leads;
  - Implantable ventricular support systems;
  - Implantable drug infusion systems;
  - Tissue Reconstruction Materials;
  - Drug Elution stent

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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	31 December 2020
■ Accepting marketing approval obtained from the Ministry of Food and Drug Safety of Korea	31 December 2020
■ Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device	31 December 2020

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Matters related to Legislative Proposal

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- The final report of Joint Subcommittee relating to the regulation of devices and development of the beauty industry was issued on 11 Dec 2019 (https://www.legco.gov.hk/yr19-20/english/panels/dbi/reports/dbi_rpt.htm)
- Refinement of the Medical Devices Bill is in progress and planned to be submitted to the Legislative Council later

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THANKS

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