Medical Device Regulatory Update

Medical Device Control Office
Department of Health
The Government of Hong Kong SAR

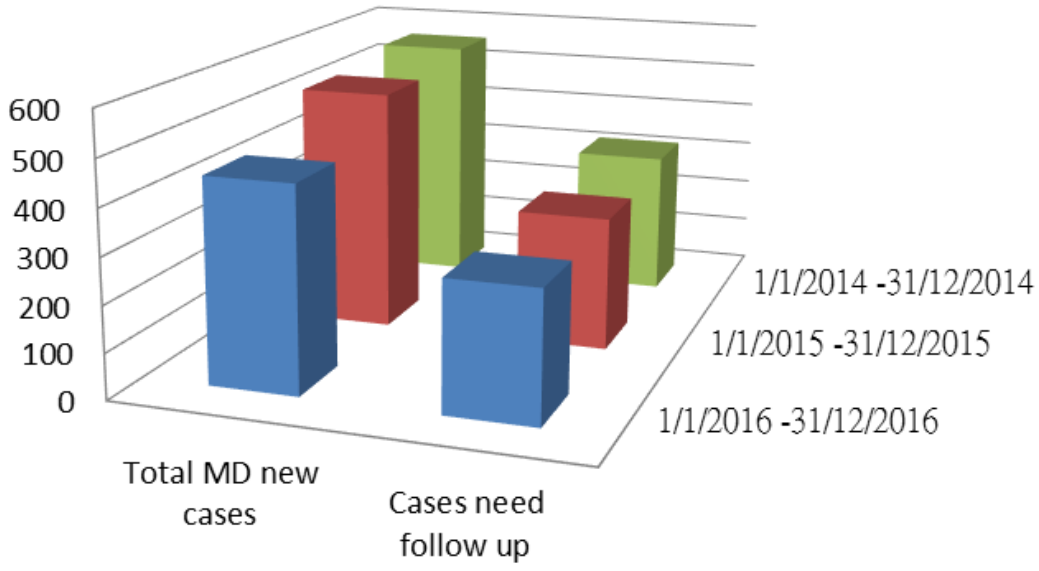
28 April 2017

Matters related to Legislative Proposal

- Consultant's recommendations on use control of selected medical devices and the finalised regulatory proposal of medical devices reported at the Health Panel meeting of the LegCo on 16 Jan 2017
- Meeting medical device industry representatives on further details of the finalised regulatory proposal in Jan – Mar 2017

MD Listing under MDACS

Result of Initial Screening



	Total MD new cases	Cases need follow up
1/1/2016 -31/12/2016	445	283
1/1/2015 -31/12/2015	532	293
1/1/2014 -31/12/2014	558	319

MD Listing under MDACS

Change - Renewal of listed equipment implemented on 1 January 2017

- Mainly an administrative process, through provision of essential document (business registration & etc)
- **Involve a declaration on application details**
- Need to submit the overdue change application within a short time period if applicable
- 'Change' will be handled separately and to be submitted when situation arise
- **So far, the process is smooth**

Medical Device Control Office
Renewal Form for Listed Medical Devices

To: **Medical Device Control Office**

For official use only	
Date Received (dd/mm/yyyy):	
Application No.:	

Particulars of Application		
1	HKMD No.	
	Make	
	Model	
	Company Name	
	Contact Person	
	Telephone	
	E-mail	
2	A copy of valid Business Registration Certificate (number: _____) is enclosed.	
3	There are active recalls, field safety corrective actions or adverse incidents (local and worldwide) ☐ No ☐ Yes. Details are provided in separate sheets.	
4	There is change to the listing details since last approval ☐ No ☐ Yes (Please go to 4(i))	
	(i) Change application of the devices is submitted to MDCO ☐ Yes ☐ No. We will submit change application within 10 calendar days.	

Declaration

We acknowledge that the listing details of this renewal application would be the same as the last approved version. Approval of this renewal application does not imply the approval of any change application in progress.

We confirm that:

a. The applicant remains designated as Local Responsible Person by the manufacturer;

b. The applicant remains aware and complies with all device listing conditions (e.g. Post market surveillance);

c. All certifications / licences (e.g. ISO 13485 certificate for manufacturing site and recognized marketing approval) relating to the listed device remain valid and will be submitted to MDCO upon request; and

d. The information contained in this renewal form is true and correct.

Signature of Applicant:

Name: _____

Position: _____

Date (dd/mm/yyyy): _____

Company Chop

MD Listing under MDACS

Change – Change of legal manufacturer

- The change is classified as a major change in the device
- It is classified as a new device and a new application is required
- Provision of the old / existing listing number could facilitate us to retrieval the relevant information
- Implemented
- Change in address, phone and etc are still under the category of change

MD Listing under MDACS

Possible change

Change in Importer requirement

- Evaluation of the capability of the medical devices manufacturer
- Evaluation of the safety, efficacy and quality of the medical devices to be imported
- Incoming and outgoing goods inspection

MD Listing under MDACS

Possible change

Addition of intended use at website of MDCO.

What is the limitation?

- length
- style of writing
- promotion (world smallest)
- discrimination (replacing the previous)

Traders under MDACS

Office Address

- Request for information on all relevant addresses of LRP is in progress
- Request for information on all relevant addresses of other traders will follow

MDACS Statistics

Device vetting process

- An overall reduction of the whole vetting cycle is noted
- Reduction in stages of the process when comparing to last year
- Any suggestion?

Thank you !