LIST OF UPDATES FOR DRGD SECOND EDITION, SEPTEMBER 2016, REVISION JANUARY 2019

(November 2018 Updates)

*** Please note that this monthly list of updates will only be updated in the full version of DRGD in January 2019 revision. However, the effective dates are as stated below in the respective column.**

NO.	UPDATES		EFFECTIVE DATE
	SECTION/ APPENDIX	DETAILS	
1.	**SECTION A: GENERAL OVERVIEW** **1.4 MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE PRODUCTS** **1.4.2 CLASSIFICATION CRITERIA**	**Amendments** as highlighted in Attachment 1.	**30 Oktober 2018**

<table>
<tr><th>NO.</th><th colspan="2">UPDATES</th><th rowspan="2">EFFECTIVE DATE</th></tr>
<tr><th></th><th>SECTION/ APPENDIX</th><th>DETAILS</th></tr>
<tr><td>2.</td><td><u>APPENDIX 4</u>:

GUIDELINE ON REGISTRATION OF HEALTH SUPPLEMENTS

SECTION F: SUPPLEMENTARY DOCUMENTS

• Finished Product Quality Control (FPQC)</td><td><u>Addition</u> on omission of Total Aerobic Microbial Count (TAMC) for products containing probiotics at Section F: Supplementary Documents (as highlighted in yellow);

4. Tests for Microbial Contamination, as shown in Table 14 below:
<table>
<tr><th>Route of Administration</th><th>TAMC

(CFU/g or CFU/ml)</th><th>TYMC

(CFU/g or CFU/ml)</th><th>Specified micro-organisms</th></tr>
<tr><td>Non-aqueous preparations for oral use</td><td>NMT 2 x 10^3</td><td>NMT 2 x 10^2</td><td>Absence of Escherichia coli (1 g or 1 ml)</td></tr>
<tr><td>Aqueous preparations for oral use</td><td>NMT 2 x 10^2</td><td>NMT 2 x 10^1</td><td>Absence of Escherichia coli (1 g or 1 ml)</td></tr>
</table></td><td>15 November 2018</td></tr>
</table>

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Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU/g or CFU/mL.	NMT 2 x 10^4	NMT 2 x 10^2	Not more than 10^2 CFU of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of *Salmonella* (10 g or 10 ml) Absence of *Escherichia coli* (1 g or 1 ml) Absence of *Staphylococcus aureus* (1 g or 1 ml)

Notes:
TAMC : Total Aerobic Microbial Count (May be omitted for product containing probiotics)
TYMC : Total Yeasts & Moulds Count
NMT : Not more than

[Reference: British Pharmacopoeia 2012]

Attachment 1

Table III: MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE (MDDCI) PRODUCT CLASSIFICATION DECISION

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
13	**General-body orifice lubricant**	Lubricant intended to facilitate entry of a diagnostic or therapeutic device into a body orifice by reducing friction between the device and the body; Lubricant during catherisation, probing,endoscopy, changing fistula catheters,intubation,and prevention of iatrogenic injuries to the rectum and colon. E.g ancillary local anaesthetic: lidocaine	**MEDICAL DEVICE** ~~(If it incorporates an ancillary pharmacologically active substance, it will be classified as **Device-Drug combination product regulated as MEDICAL DEVICE**~~	**MDA**
26	**Soft tissue filler/ Dermal filler**	To correct cutaneous contour deformities of the skin (e.g., moderate to severe facial wrinkles and folds such as nasolabial folds, scars), particularly in cases of aging or degenerative lesions.	**MEDICAL DEVICE** ~~(If it incorporates an ancillary local anaesthetic eg. lidocaine, it will be classified as a **Device-Drug combination product regulated as MEDICAL DEVICE)**~~	**MDA**
27	**Synthetic fluid tissue**	As a submucosal implant in the urinary tract for urinary	**MEDICAL DEVICE**	**MDA**

	reconstructive material	incontinence or vesicoureteral reflux. It may also be injected into the vocal cords to treat the effects of paralysis, atrophy, or scarring. After application, this device cannot be reused.	~~(If it incorporates an ancillary pharmacologically active substance eg. local anaesthetic such as lidocaine, it will be classified as a **Device-Drug combination product regulated as MEDICAL DEVICE**)~~	