# APPENDIX 1: THE ILLUSTRATIVE TABLE OF DRUG-MEDICAL DEVICE/MEDICAL DEVICE-DRUG COMBINATION PRODUCT

**Table 1 : Example of Drug-Medical Device Combination Product Classification**

| NO | PRODUCT | INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA) | CATEGORY | CUSTODIAN AGENCY |
|---|---|---|---|---|
| 1. | **Drug-Eluting Beads** (Produced from biocompatible polyvinyl alcohol hydrogel modified with sulphonate groups in phosphate buffered saline.) | It is an embolic agent which is intended to be loaded with a chemotherapy agent, eg. doxorubicin for the purpose of treatment of malignant hyper vascularized tumour(s) by embolisation of vessels and occlusion of blood flow supplying malignant hyper vascularized tumour(s) and as a secondary action, delivers/elutes a local, controlled, sustained dose of the chemotherapy agent directly to the tumour(s). | If the beads are sold separately from the drug, it will be classified as **MEDICAL DEVICE**<br><br>If the beads and drug are packaged and sold together, it will be classified as **Drug-Medical Device combination product regulated as DRUG** | **MDA**<br><br>**NPRA** |
| 2. | **Drug - Delivery Products Regulated as Drug Products** (eg. insulin prefilled pen/ syringes, asthma inhalers, intrauterine contraceptives whose primary purpose is to release progestogens) | To administer pharmacologically active substance | **Drug-Medical Device combination product regulated as DRUG**<br><br>**NOTE:**<br>The device component will be regulated on a case to case basis. | **NPRA** |

**Table 2 : Example Of Medical Device-Drug Combination Product Classification**

| NO | PRODUCT | INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA) | CATEGORY | CUSTODIAN AGENCY |
|---|---|---|---|---|
| 1. | **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**<br><br>(If it incorporates an ancillary local anaesthetic eg. lidocaine, it will be classified as a **Medical Device-Drug combination product regulated as MEDICAL DEVICE)** | **MDA** |
| 2. | **Synthetic fluid tissue reconstructive material** | As a submucosal implant in the urinary tract for urinary incontinence or vesicoureteral reflux.<br><br>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. | **MEDICAL DEVICE**<br><br>(If it incorporates an ancillary pharmacologically active substance eg. local anaesthetic such as lidocaine, it will be classified as a **Medical Device-Drug combination product regulated as MEDICAL DEVICE)** | |
| 3. | **Dental Products** | | | |
| | ***i. Root canal filling incorporating antibiotic*** | To seal the canal and disinfect the dentinal walls by diffusing through dentine. The antibiotic provides ancillary actions as bactericidal antibiotic and anti-inflammatory | **Medical Device-Drug combination product regulated as MEDICAL DEVICE** | **MDA** |

| NO | PRODUCT | INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA) | CATEGORY | CUSTODIAN AGENCY |
|---|---|---|---|---|
| | | agent to assist in reducing pain and in maintaining a bacteria-free environment within the root canal. | | |
| 4. | **General Purpose Surgical or Barrier Drapes** (A sterile protective covering made of natural or synthetic materials, or both.) | To isolate a site of surgical incision or a surgical field from contamination (e.g., microbial, substance) in various clinical settings (e.g., in an operating room or catheterization laboratory). The device may also be used to protect a patient from heat/flame during a surgical procedure. This is a reusable or single use device. | **MEDICAL DEVICE** (If it incorporates an ancillary pharmacologically active substance, it will be classified as **Medical Device-Drug combination product regulated as MEDICAL DEVICE)** | **MDA** |
| 5. | **Drug-Eluting Stents (DES)** | For use in angioplasty or coronary stenting procedures. | **Medical Device-Drug combination product regulated as MEDICAL DEVICE** | **MDA** |
| 6. | **Drug-Eluting Beads** (Produced from biocompatible polyvinyl alcohol hydrogel modified with sulphonate groups in phosphate buffered saline.) | It is an embolic agent which is intended to be loaded with a chemotherapy agent, eg. doxorubicin for the purpose of treatment of malignant hyper vascularised tumour(s) by embolisation of vessels and occlusion of blood flow supplying malignant hyper vascularized tumour(s) and as a secondary action, delivers/elutes a local, controlled, sustained dose of the | If the beads are sold separately from the drug, it will be classified as **MEDICAL DEVICE**<br><br>If the beads and drug are packaged and sold together, it will be classified as **Drug-Medical Device** | **MDA**<br><br>**NPRA** |

| NO | PRODUCT | INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA) | CATEGORY | CUSTODIAN AGENCY |
|---|---|---|---|---|
| | | chemotherapy agent directly to the tumour(s). | **combination product regulated as DRUG** | |
| 7. | **<u>General-body orifice lubricant incorporating an ancillary local anaesthetic</u>** (e.g.lidocaine) | Lubricant intended to facilitate entry of a diagnostic or therapeutic device into a body orifice by reducing friction between the device and the body;<br>Lubricant during catherisation, probing, endoscopy, changing fistula catheters, intubation, and prevention of iatrogenic injuries to the rectum and colon. | **Medical Device-Drug combination product regulated as MEDICAL DEVICE** | **MDA** |
| 8. | **<u>Enteral Feeding Kit</u>** *(containing Iodine Pack drug)* | A collection of sterile devices that includes tubing and other materials intended to administer nutrient liquids directly into the stomach, duodenum, or jejunum of a patient by means of gravity or an enteral pump. | **Medical Device-Drug combination product regulated as MEDICAL DEVICE** | **MDA** |

*Note: Table 1 and Table 2 are examples of combination product classification. These examples are non-exhaustive.