# List of Revised Fees for Health Products

**Revised fees are applicable to applications submitted on and after 1 July 2024**

## Contents

# Medical Devices

## Medical Devices Registration

| PRODUCT REGISTRATION AND EVALUATION FEES FOR MEDICAL DEVICES | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Class B** | |
| (i) Application fee | $560 |
| (ii) Immediate route fee | $1,000 |
| (iii) Abridged route fee | $2,010 |
| (iv) Full route fee | $3,900 |
| (v) Full route (Priority Review Scheme* Route 1) | $4,420 |
| (vi) Full route (Priority Review Scheme* Route 2) | $5,660 |
| **Class C** | |
| (i) Application fee | $560 |
| (ii) Immediate route fee | $3,340 |
| (iii) Expedited route fee | $3,340 |
| (iv) Abridged route fee | $3,900 |
| (v) Full route fee | $6,250 |
| (vi) Full route (Priority Review Scheme* Route 1) | $7,000 |
| (vii) Full route (Priority Review Scheme* Route 2) | $9,000 |
| **Class D** | |
| (i) Application fee | $560 |
| (ii) Expedited route fee | $5,930 |
| (iii) Abridged route fee | $6,250 |
| (iv) Full route fee | $12,000 |
| (v) Full route (Priority Review Scheme* Route 1) | $13,600 |
| (vi) Full route (Priority Review Scheme* Route 2) | $17,500 |
| **Class D with a registrable drug** | |
| (i) Application fee | $560 |
| (ii) Abridged route fee | $10,600 |
| (iii) Full route fee | $75,600 |

**Refer to Priority Review Scheme page for more details*

| ANNUAL RETENTION FEES FOR MEDICAL DEVICES LISTED ON SINGAPORE MEDICAL DEVICE REGISTER (SMDR) | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Class B | $39 |
| Class C | $67 |
| Class D | $134 |
| Class D with a registrable drug | $134 |

| CHANGE OF REGISTRANT | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Application fee for change of registrant | $880 |

## Dealer's Licences for Medical Devices

| DEALER'S LICENCE APPLICATION AND AMENDMENT | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **New application for or annual renewal of dealer's licence** | |
| Manufacturer | $1,110 |
| Importer | $1,110 |
| Wholesaler | $1,110 |
| **Amendment application for dealer's licence** | |
| Manufacturer | $168 |
| Importer | $168 |
| Wholesaler | $168 |

## Change Notification

| CHANGE NOTIFICATION | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Class B** | |
| Administrative Changes | $560 |
| Review Changes | $560 |
| **Class C** | |
| Administrative Changes | $560 |
| Technical Changes | $1,890 |
| **Class D (including devices with a registrable drug)** | |

| | |
|---|---|
| Administrative Changes | $560 |
| Technical Changes | $3,120 |

## Free Sale Certificates

| **FREE SALE CERTIFICATES** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| Application fee | $57[#] |
| Processing fees:<br>• for one device and one country<br>• for each additional device<br>• for each additional country | <br>$57[#]<br>$57[#]<br>$57[#] |

## Special Access Route

| **SPECIAL ACCESS ROUTES** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| Unregistered devices requested by qualified practitioners | $168 |
| Unregistered devices requested by a licensed PHMC | $390 |
| Import for re-export of unregistered devices | $280 |
| Unregistered devices for non-clinical purpose | $280 |

## Pre-Market Consultation

| **PRE-MARKET CONSULTATION** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| Medical device development consultation | $530[#] for each device per consultation, for up to two hours |
| Medical device pre-submission consultation | $210[#] for each device application per consultation, for up to one hour |

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# Therapeutic Products

## Therapeutic Products Registration

| PRODUCT REGISTRATION VIA NEW DRUG APPLICATION (NDA) | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **a) Screening Fee** | |
| (i) Abridged/Verification Evaluation Route | $610 |
| (ii) Full Evaluation Route | $3,060 |
| **b) Evaluation Fee** | |
| **(i) Abridged Evaluation Route** | |
| - NDA-1 & NDA-2 | $11,600 |
| - NDA-3 | $6,030 |
| **(ii) Verification Evaluation Route** | |
| - NDA-1 & NDA-2 | $17,100 |
| - NDA-3 | $6,030 |
| **(iii) Full Evaluation Route*** <br> - NDA-1, NDA-2 & NDA-3 <br> **All fees for full evaluation route are charged per NDA submission package which can contain one or more NDA to register the product or product line.* | $83,100 |
| **c) Annual retention fee (per registered product)** | $330 |

| PRODUCT REGISTRATION VIA GENERIC DRUG APPLICATION (GDA) | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **a) Screening Fee** | |
| (i) Abridged/Verification Evaluation Route | $610 |
| **b) Evaluation Fee** | |
| **(i) Abridged Evaluation Route** | |
| - GDA-1 | $4,280 |
| - GDA-2 | $2,450 |

| PRODUCT REGISTRATION VIA GENERIC DRUG APPLICATION (GDA) | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **(ii) GDA Verification Evaluation Route** | |
| - GDA-1 | $10,600 |
| - GDA-2 | $5,500 |
| **(iii) GDA Verification Evaluation Route (CECA Scheme)** | |
| - GDA-1 | $10,600 |
| - GDA-2 | $5,500 |
| **c) Annual retention fee (per registered product)** | $330 |

## Therapeutic Products Post-Approval Variation Application

| POST-APPROVAL VARIATION APPLICATION | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **a) Major Variation Application (MAV-1)** | |
| (i) Screening Fee | |
| - Abridged/Verification Evaluation Route | $560 |
| - Full Evaluation Route | $2,780 |
| (ii) Evaluation Fee | |
| - Abridged Evaluation Route | |
| - for first strength | $6,030 |
| - for subsequent strength | $3,060 |
| - Verification Evaluation Route | |
| - for first strength | $8,850 |
| - for subsequent strength | $3,060 |
| - Full Evaluation Route | $51,600 |
| **b) MIV-1** | |
| - Abridged/ Verification Evaluation Route | $610 |

| CONSIGNMENT APPROVAL | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Import and supply of registered Therapeutic Product on consignment basis | $280 per consignment |

## Manufacturer's Licence for Therapeutic Products

| MANUFACTURER'S LICENCE FOR THERAPEUTIC PRODUCTS | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Application Fee for, or for Renewal of, a Manufacturer's Licence for:** | |
| (a) manufacture of external preparations only (non-sterile) | $1,670 |
| (b) manufacture of oral preparations only (non-sterile) | $1,670 |
| (c) manufacture of external and oral preparations only (non-sterile) | $2,230 |
| (d) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in paragraphs (a), (b), (c) | $3,340 |
| (e) primary packaging (with or without secondary packaging) | $1,110 |
| (f) secondary packaging only | $660 |
| **Application Fee for Amending a Manufacturer's Licence:** | |
| (a) without site inspection | $57 |
| (b) with site inspection for a manufacturer carrying out packaging only | $560 |
| (c) with site inspection for all other manufacturers | $1,110 |

## Importer's and Wholesaler's Licence for Therapeutic Products

| IMPORTER'S LICENCE FOR THERAPEUTIC PRODUCTS | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Application fee for, or for renewal of, an importer's licence for:** | |
| (a) any therapeutic product (full scope) | $560 |

| | |
|---|---|
| (b) any therapeutic product imported under the following restricted activities only (limited scope):<br>(i) for non-clinical purpose<br>(ii) for export only<br>(iii) for supply to a ship or an aircraft leaving Singapore | $220 (annual licence for multiple consignments)<br><br>$111 (licence per consignment only) |
| **Application fee for amending an importer's licence:** | |
| (a) without site inspection | $57 |
| (b) with site inspection (full scope) | $330 |

| **WHOLESALER'S LICENCE FOR THERAPEUTIC PRODUCTS** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| Application fee for, or for renewal of, a wholesaler's licence for any therapeutic product | $560 |
| **Application fee for amending a wholesaler's licence:** | |
| (a) without site inspection | $57 |
| (b) with site inspection | $330 |

| **BUNDLED NEW AND RENEWAL FEE FOR IMPORTER'S LICENCE AND WHOLESALER'S LICENCE FOR THERAPEUTIC PRODUCTS** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| Bundled new and renewal fee of the importer's licence (full scope) and the wholesaler's licence | $1,000 |

## GMP Conformity Assessment for Therapeutic Products

| **GOOD MANUFACTURING PRACTICE (GMP) CONFORMITY ASSESSMENT OF OVERSEAS MANUFACTURERS OF THERAPEUTIC PRODUCTS** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| GMP Evidence Evaluation (per manufacturing site) | $660 |
| Quality System Dossier (QSD) Evaluation (per manufacturing site) | $4,970 |

| On-site GMP audit of a manufacturer located in: | |
|---|---|
| (a) an ASEAN country (per manufacturing site) | $18,600 |
| (b) an Asian country (outside of ASEAN) (per manufacturing site) | $20,600 |
| (c) a country outside of Asia (per manufacturing site) | $24,600 |

## Other Therapeutic Product Certificates (GMP / GDP Certificates, CPP etc)

| **OTHER THERAPEUTIC PRODUCT CERTIFICATES (GMP / GDP CERTIFICATES, CPP ETC)** | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| **GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE** | |
| Application for GMP Certificate (valid for 3 years) | $6,570[#] |
| Each additional GMP certificate not requiring further assessment | $220[#] |
| **GOOD DISTRIBUTION PRACTICE (GDP) CERTIFICATE** | |
| Application for GDP certificate (valid for 3 years) | $3,900[#] |
| Each additional GDP certificate not requiring further assessment | $220[#] |
| **CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP)** | |
| Application for Certificate for a Pharmaceutical Product (CPP) | $111[#] |
| **STATEMENT OF LICENSING STATUS (SLS)** | |
| Application for Statement of Licensing Status (SLS) | $111[#] |

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## Controlled Drugs / Psychotropic Substances Licences and Authorisation

| LICENCES AND AUTHORISATIONS FOR CONTROLLED DRUGS / PSYCHOTROPIC SUBSTANCES | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Licence to Manufacture Controlled Drugs** | |
| Application for a licence to manufacture controlled drugs | $560 |
| Application to amend the licence<br>(a) with site inspection<br>(b) without site inspection | <br>$220<br>$57 |
| **Applications to Import and Export Restricted / Psychotropic Substances, Licence to Import / Export Controlled Drugs and Licence to Sell Controlled Drugs** | |
| Application for licence to sell controlled drugs by wholesale | $560 |
| Application to amend the licence to sell controlled drugs by wholesale<br>(a) with site inspection<br>(b) without site inspection | <br>$220<br>$57 |
| Application for a licence to import controlled drugs | $111 |
| Application for a licence to export controlled drugs | $111 |
| Application for approval to import therapeutic products (including clinical research materials) containing psychotropic substances | $111 |
| Application for confirmation of authorisation to import a psychotropic substance | $111[#] |
| Application for approval to export therapeutic products (including clinical research materials) containing psychotropic or export licence for psychotropic substances | $111 |
| Application for certificate of approval for import of a therapeutic product or confirmation of authorisation to import a restricted substance | $111[#] |

## Form A Poisons Licence

| FORM A POISONS LICENCE FOR NON-PHARMACISTS | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Application for Form A Poisons Licence (FAPL) | $290 |
| Form A Poisons Licence (1-year validity) | $111 |
| Application to amend FAPL | $39 |

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# Cell, Tissue or Gene Therapy Products (CTGTP)

## CTGTP Notification or Registration

| NOTIFICATION OF CLASS 1 CTGTP | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Notification fee | $95 |

| REGISTRATION OF CLASS 2 CTGTP VIA NEW DRUG APPLICATION (NDA) | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **a) Screening Fee** | |
| (i) Abridged Evaluation Route | $600 |
| (ii) Full Evaluation Route | $3,050 |
| **b) Evaluation Fee** | |
| **(i) Abridged Evaluation Route** | |
| - NDA-1 & NDA-2 | $13,900 |
| - NDA-3 | $5,900 |
| **(ii) Full Evaluation Route**<br>- NDA-1, NDA-2 & NDA-3<br>*(Note: All fees for full evaluation route are charged per NDA submission package which can contain one or more NDA to register the product or product line.)* | $82,900 |
| **c) Annual retention fee (per registered product)** | $330 |

| FEES FOR OTHER APPLICATIONS OR PROCEDURES | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Pre-market consultation for CTGTP registration | $210[#] |
| Change a registrant of a CTGTP | $158 |
| Overseas Good Clinical Practice (GCP) inspection | $11,400 |
| SAR*: Import of an unregistered Class 2 CTGTP for named patient use | $240 |
| SAR*: Import of a registered CTGTP on a consignment basis | $270 per consignment |

## CTGTP Post-Approval Variation Application

| POST-APPROVAL VARIATION APPLICATION | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **a) Major Variation Application (MAV-1)** | |
| (i) Screening Fee | |
| - Abridged Evaluation Route | $550 |
| - Full Evaluation Route | $2,730 |
| (ii) Evaluation Fee | |
| - Abridged Evaluation Route | |
| - for first strength | $7,900 |
| - for subsequent strength | $3,050 |
| - Full Evaluation Route | $51,400 |
| **b) Minor Variation Application 1 (MIV-1)** | |
| (i) Application fee | $2,730 |
| **c) Minor Variation Application 2 (MIV-2)** | |
| (i) Application fee | $400 |

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**SAR: Special Access Route*

## Dealer's Notice for Dealing in Minimally Manipulated CTGTP

| DEALER'S NOTICE | Revised Fees *(effective 1 July 2024)* |
|---|---|
| New dealer's notice submission | $95 |
| Changes to a dealer's notice | No fees applicable |

## Dealer's Licences for Dealing in CTGTP which are Not Minimally Manipulated

| IMPORTER'S AND WHOLESALER'S LICENCE APPLICATION, RENEWAL AND AMENDMENTS | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **New Licence Application** | |
| a) Importer's licence (full scope) | $1,470 |
| b) Importer's licence under the following activities only (limited scope):<br>(i) for export only<br>(ii) for scientific education, research and development, or non-clinical purpose | $220 (annual licence for multiple consignments)<br><br>$116 (licence per consignment only) |
| c) Wholesaler's licence | $1,470 |
| d) Both importer's licence (full scope) and wholesaler's licence | $2,630 |
| **Licence Renewal** | |
| a) Importer's licence (full scope) | $550 |
| b) Importer's licence under the following activities only (limited scope):<br>(i) for export only<br>(ii) for scientific education, research and development, or non-clinical purpose | $220 (annual licence for multiple consignments) |
| c) Wholesaler's licence | $550 |
| d) Both importer's licence (full scope) and wholesaler's licence | $990 |

| Licence Amendment | |
|---|---|
| a) Amend an importer's licence (full scope) or wholesaler's licence with technical assessment | $1,160 |
| b) Amend an importer's licence or wholesaler's licence without technical assessment | $126 |

| MANUFACTURER'S LICENCE APPLICATION, RENEWAL AND AMENDMENTS | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **New Licence Application** | |
| a) Manufacturer's licence | $22,200 |
| b) Manufacturer's licence (secondary packaging only) | $10,800 |
| **Licence Renewal** | |
| a) Manufacturer's licence | $13,600 |
| b) Manufacturer's licence (secondary packaging only) | $3,780 |
| **Licence Amendment** | |
| a) Amend a manufacturer's licence with technical assessment | $5,300 |
| b) Amend a manufacturer's licence (secondary packaging only) with technical assessment | $2,840 |
| c) Amend a manufacturer's licence without technical assessment | $189 |
| d) Amend a manufacturer's licence (secondary packaging only) without technical assessment | $189 |

## GMP Conformity Assessment of Overseas Manufacturers of CTGTP

| GOOD MANUFACTURING PRACTICE (GMP) CONFORMITY ASSESSMENT OF OVERSEAS MANUFACTURERS OF CTGTP | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Verification of compliance with GMP Standard (for overseas CTGTP Manufacturer) | $650 |
| GMP On-Site Inspection of an Overseas CTGTP Manufacturer | $31,700 |

## Other CTGTP Certificates (GMP / GDP Certificates and CPP)

| OTHER CTGTP CERTIFICATES (GMP / GDP CERTIFICATES AND CPP) | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE FOR CTGTP** | |
| Application for GMP Certificate | $22,200[#] |
| Application for GMP Certificate without technical assessment | $220[#] per copy |
| **GOOD DISTRIBUTION PRACTICE (GDP) CERTIFICATE** | |
| Application for GDP certificate | $3,890[#] |
| Application for GDP Certificate without technical assessment | $220[#] per copy |
| **CERTIFICATE OF A PHARMACEUTICAL PRODUCT FOR CTGTP** | |
| Application for Certificate for a Pharmaceutical Product (CPP) | $116[#] |

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## Chinese Proprietary Medicines Dealer's Licences and Certificates

| DEALER'S LICENCES OF CHINESE PROPRIETARY MEDICINES | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Import Licence** | |
| Application fee for a new licence | $560 |
| Licence fee for each subsequent year | $560 |
| Application to amend a licence | |
| (a) with site inspection | $330 |
| (b) without site inspection | $57 |
| **Wholesale Dealer's Licence** | |
| Application fee for a new licence | $560 |
| Licence fee for each subsequent year | $560 |
| Application to amend a licence | |
| (a) with site inspection | $330 |
| (b) without site inspection | $57 |
| **Manufacturer's Licence** | |
| Application fee for a new licence for | |
| (a) Manufacture of either an external preparation OR oral preparation | $1,670 |
| (b) Manufacture of both an external preparation AND oral preparation | $2,230 |
| (c) Primary assembly | $1,110 |
| (d) Secondary assembly only | $660 |
| Licence fee for | |
| (a) Each subsequent year for | |
| (i) A manufacturer of either an external preparation OR oral preparation | $1,670 |
| (ii) A manufacturer of both an external preparation AND oral preparation | $2,230 |
| (iii) A primary assembler | $1,110 |
| (iv) A secondary assembler only | $660 |
| Application to amend a licence | |
| (a) with site inspection (for manufacturers) | $1,110 |
| (b) with site inspection (for assemblers) | $560 |
| (c) without site inspection (for manufacturers/ assemblers) | $57 |

| CERTIFICATES OF CHINESE PROPRIETARY MEDICINES | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Certificate for Export** | |
| Certificate for Exporter of Chinese Proprietary Medicines (Free Sale Certificate) | $111[#] |
| **Good Manufacturing Practice (GMP) Certificates** | |
| GMP certificate (valid for 3 years) | $6,570[#] |
| Each additional GMP certificate not requiring further assessment | $220[#] |

## Cosmetic Products Notification and GMP Certificate

| NOTIFICATION AND GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE FOR COSMETIC PRODUCTS | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **(a) Notification and re-notification of cosmetic products for application around the eyes or on the lips, for oral or dental care or hair dyes containing diamine compounds** | |
| (i) Single product or each of the first 3 variants of a product | $28 |
| (ii) Each of the 4th and subsequent variants of a product | $8 |
| **(b) Notification and re-notification of other cosmetic products not mentioned in (a)** | |
| (i) Single product or each of the first 3 variants of a product | $13 |
| (ii) Each of the 4th and subsequent variants of a product | $8 |
| **Good Manufacturing Practice (GMP) Certificate** | |
| (a) Application for a GMP Certificate | $4,440[#] |
| (b) Application for each additional GMP Certificate which does not require further assessment of conformity with any Good Manufacturing Practice Standard | $220[#] |

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## Oral Dental Gum Registration, Manufacture, Import and Wholesale

| REGISTRATION, MANUFACTURE, IMPORT AND WHOLESALE OF ORAL DENTAL GUM | Revised Fees *(effective 1 July 2024)* |
|---|---|
| **Registration** | |
| Application fee for registration of an oral dental gum | $18 |
| Annual retention fee for the retention of the registration of an oral dental gum | $13 |
| Application fee for the Authority's approval of any change concerning a registered oral dental gum mentioned in regulation 25(1) of the Health Products (Oral Dental Gums) Regulations | $18 |
| **Manufacture, Import and Wholesale** | |
| Application fee for, or to renew: | |
| - A manufacturer's licence | $880 |
| - An importer's licence | $880 |
| - A wholesaler's licence | $880 |
| - An importer's licence and a wholesaler's licence | $1,110 |
| Application fee for the Authority's approval of any change affecting a licence mentioned in regulation 24(1) or (2) of the Health Products (Oral Dental Gums) Regulations | $18 |

## Retail Pharmacy Licence

| RETAIL PHARMACY LICENCE | Revised Fees *(effective 1 July 2024)* |
|---|---|
| Application fee for, or for renewal of, a pharmacy licence | $560 |
| Application fee for the Authority's approval under Regulation 3(1)(b)(ii) or 4(1)(b)* in respect of a retail pharmacy if made on a separate occasion from an application for a pharmacy licence in respect of that same retail pharmacy | $330 |
| Amend retail pharmacy licence<br>(a) With site inspection<br>(b) Without site inspection | <br>$330<br>$57 |
| * Note for the Health Products (Licensing of Retail Pharmacies) Regulations:<br>Regulation 3(1)(b)(ii) indicates the supply by retail sale of any specified health products via special mode (e.g. secured box for self-collection)<br>Regulation 4(1)(b) is for the regulation of telepharmacy services | |

## Medical Advertisements & Sales Promotion Permits

| PERMITS FOR MEDICAL ADVERTISEMENT & SALES PROMOTION | **Revised Fees** *(effective 1 July 2024)* |
|---|---|
| **Application for a permit for:** | |
| (a) a still media advertisement | $111 |
| (b) a sound media advertisement | $111 |
| (c) a light and sound media advertisement | $220 |
| (d) a sales promotion | $111 |
| **Permit for:** | |
| (i) the first year for | |
| (a) a still media advertisement | $111 |
| (b) a sound media advertisement | $111 |
| (c) a light and sound media advertisement | $111 |
| (d) a sales promotion | $111 |
| (ii) each subsequent year for | |
| (a) a still media advertisement | $222 |
| (b) a sound media advertisement | $222 |
| (c) a light and sound media advertisement | $331 |
| (d) a sales promotion | $222 |
| Application to amend a permit | $57 |
| Transfer of medical advertisement/ sales promotion permit | $18 |