COST RECOVERY:
Can You Financially Survive Cost Recovery Under the Self-Care Framework?

Prepared by Shawn Buckley LL.B., President of the Natural Health Products Protection Association on April 11, 2019.

Health Canada is moving forward with the Self-Care Framework which will repeal the *Natural Health Products Regulations* and regulate natural health products under a single set of regulations with chemical non-prescription drugs and cosmetics.

Health Canada has made it clear that once natural health products are regulated with chemical non-prescription drugs as Self-Care products, that natural health companies will be charged fees for licensing (i.e. there will be cost recovery). Health Canada's rational is that they cannot continue to charge the chemical drug companies fees, and not charge natural health companies fees, when both are under the same regulations with the same requirements for licensing.

In fact, once the *Natural Health Product Regulations* are repealed, Health Canada will have no choice but to charge the fees found in the *Fees in Respect of Drugs and Medical Devices Regulations*. Natural health products are exempted from the Fee Regulations. Once natural health products are "Self-Care" products, the Fee Regulations will apply.

No one can say for certain what the cost recovery fees will be. However, it may be naive to think that Health Canada is going to reduce the fees for the chemical pharmaceutical companies once the Self-Care Framework is in place. If Health Canada does not reduce the current fee structure for the chemical pharmaceutical companies, then the current fee structure is an accurate guide for what natural health companies will have to pay once the Self-Care Framework is implemented.

Current Fees

To offer an understanding of current fees, some common hypotheticals are set out below. Using those hypotheticals, under the current *Fees in Respect of Drugs and Medical Devices Regulations* there are the following fees:

- **fees for the processing of product licences**. The fees range significantly from $355,579 to $19,921. The smallest fee of $19,921 is for applications based on published data only;

- **yearly licensing fees** of $1,200 per licenced product;

- **yearly establishment licence fees per building of**:

    - **$65,422** for a typical **manufacturer** who both imports and distributes. This is reduced to $48,564 if the manufacturer distributes but does not import. It is reduced to $31,706 if there is no importing or distributing;

    - **$54,888** for a **packager or labeller** who both imports and distributes but does not manufacture. This is reduced to $38,030 if there is no importing. This is reduced to $21,172 if there is no importing or distributing;

    - **$16,858** for an **importer** who only imports;

    - **$16,858** for a **distributor** who only distributes products, at least one of which the distributor holds the product licence for.

Note that these are **yearly** fees. Unlike section 36(2) of the *Natural Health Product Regulations* which allow for 2 and 3 year site licences, site licences under the chemical drug regulations must be renewed yearly (see Regulation section C.01A.009).

Also note when reviewing the *Fees in Respect of Drugs and Medical Devices Regulations*, SOR/2011-79, that the fees set out in the Schedules have increased by 2% a year starting in April 2012. The fees listed in this Paper are the fees as of April 1, 2019. They all increase by 2% every April 1.

Disclosure of sales records and accounting costs

The fees charged can be reduced if they exceed various percentages of sales. To determine this, accounting records in accordance with generally accepted accounting principles must be provided. For example, for product licence fees, subsection 11(3) provides:

> 11(3) Within 60 days after the end of the fee verification period, the person must provide the Minister with sales records in regard to the sales of the drug in Canada during the fee verification period, prepared in accordance with generally accepted accounting principles, and a document signed by the individual responsible for the person's financial affairs certifying that the records were so prepared.

The costs associated with providing any required accounting records to Health Canada will vary from business to business and so these costs are not accounted for in this Paper.

Whether persons are concerned with providing Health Canada with sales records is also dependent upon their individual situation.

This paper is limited to product and establishment licensing costs. It is not addressing the costs of administrative penalties, the imposition of the chemical drug standards of evidence, and the strengthening of GMP requirements.

Under the Self-Care Framework there will be additional costs due to:

- administrative penalties which will be imposed to cover the costs of inspections and enforcement;
- increased costs to comply with the chemical drug standards of evidence once the standards of evidence are harmonized (the last phase in the Self-Care Framework); and,
- increased costs to comply with harmonized GMP requirements.

These fees are not addressed in this Paper.

Fees for the processing of product licences

Remember that, for the most part, under the Self-Care Framework traditional use evidence will not be allowed to support an efficacy claim (see the NHPPA Discussion Paper called the Repeal of *Natural Health Products Regulations*).

The fees for having Health Canada process licences depends upon the type of application.

The fees until April 1, 2020 are as follows:

Fee Category	Description	Fee
New Active Substance	Submissions in support of a drug, excluding a disinfectant that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate, or polymorph.	$355,579
Clinical or Non-Clinical Data and Chemistry & Manufacturing	Submissions based on Clinical or Non-Clinical data and Chemistry & Manufacturing data for a drug that does not include a new active substance.	$180,101
Clinical or Non-Clinical Data only	Submissions based only on Clinical or Non-Clinical data for a drug that does not include a new active substance.	$84,059
Comparative Studies	Submissions based on comparative studies (e.g. Clinical or non-clinical data, bioavailability, pharmacokinetic and pharmacodynamic data) with or without Chemistry & Manufacturing data for a drug that does not include a new active substance.	$50,808
Chemistry & Manufacturing Data Only	Submissions based only on Chemistry & Manufacturing data for a drug that does not include a new active substance.	$24,023
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance.	$19,921
Labelling Only	Submissions of labelling material (i.e. does not include supporting clinical or non-clinical or Chemistry and Manufacturing data).	$3,238
Administrative Submission	Submissions in support of a manufacturer or product name change.	$338
Disinfectants	Submissions and applications that include data in support of a disinfectant.	$4,480
Drug Identification Number application - Labelling Standard	Applications attesting to compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.	$1,797

Yearly licensing fees

The fee for selling each drug with a licence (a DIN) is $1,200 until April 1, 2020.

Establishment Licences

The fees for establishment licences are **yearly** fees. Unlike section 36(2) of the *Natural Health Product Regulations* which allow for 2 and 3 year site licences, site licences under the chemical drug regulations must be renewed yearly (see *Food and Drug* Regulation section C.01A.009).

These yearly fees are per building, not per company.

The yearly fee varies depending upon factors such as:

- the activities conducted at the establishment (such as manufacturing or importing);
- the categories of products such as drugs and active ingredients, and
- the number of dosage form classes (for example capsules are a different dosage form class then liquids).

Manufacturing example

For example, a typical NHP manufacturer using active ingredients and making finished products in both capsule and liquid forms would face the following yearly charges per building prior to the annual 2% increase due on April 1, 2020:

- a basic fee of $18,107;
- an additional category fee of $4,538;
- the fee for two dosage classes of $9,061

This totals $31,706 per year, per building. There are additional fees if the manufacturer also imports. If the manufacturer imports as set out in the import example below, there would be an additional yearly per building fee of $16,858. In this scenario the per year per building cost is $48,564.

There are also additional fees if the manufacturer distributes at least one product for which the manufacturer holds a product licence. If the manufacturer is also a distributor, there is an additional yearly per building fee of $16,858. If there is also importing, the total is $65,422.

Packaging and/or labelling, but not manufacturing, example

A NHP company that packages and/or labels products in both capsule and liquid forms would face the following yearly charges per building, prior to the annual 2% increase due on April 1, 2020:

- a basic fee of $12,107;
- an additional category fee of $3,026;
- a fee for two dosage classes of $6,039

This totals $21,172 per year, per building. There are additional fees if the business also imports. If the manufacturer imports as set out in the import example below, there would be an additional yearly per building fee of $16,858. In this scenario the per year per building cost is $38,030.

There are also additional fees if the packager/labeller distributes at least one product for which the packager/labeller holds a product licence. If the packager/labeller is also a distributor, there is an additional yearly per building fee of $16,858. If there is also importing, the total is $54,888.

Importing example

A NHP company that only imports and distributes products in both capsule and liquid forms, and that imports from two sources which do not have equivalent site licences would face the following yearly charges per building prior to the annual 2% increase due on April 1, 2020:

- a basic fee of $7,551;
- an additional category fee of $1,891;
- a fee for two dosage classes of $3,778; and,
- a fabricator fee of $3,638

This totals $16,858

Note that if a manufacturer, packager or labeller also imports in line with this example, the total of this import fee is also owing in addition to a second fabricator fee of $3,638 (see sections 19(2) and 20(2) of the *Fees in Respect of Drugs and Medical Devices Regulations*).

This totals $20,496.

Distributor only

A NHP company that only distributes products in both capsule and liquid forms, and that holds the product licence for any of the distributed products would face the following yearly charges per building prior to the annual 2% increase due on April 1, 2020:

- a basic fee of $7,551;
- an additional category fee of $1,891;
- a fee for two dosage classes of $3,778, and
- a fabricator fee of $3,638

This totals $16,858

Resources

- Fees in Respect of Drugs and Medical Devices Regulations;
- Health Canada's Drug Establishment Licence fee document; and,
- Health Canada's Human Drug Submission and Application Review document.

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Calculating fees for your specific situation

When you review the *Fees in Respect of Drugs and Medical Devices Regulations* to determine the fees that apply in a specific situation, keep in mind the following:

- under section 17(1) you are to add all of the fees from section 19 to 25 to get a total;

- when importing drugs that need to be authorized in Canada at the building subject to an establishment licence, the fee in 21(b) is counted twice (see sections 19(1) and 20(2)).

Call for comment

This paper was prepared by Shawn Buckley of the NHPPA. Mr. Buckley does not normally cost out chemical drug licensing fees and establishment fees. He is happy to concede that there may be some errors. If you spot one, let us know and we will make corrections.