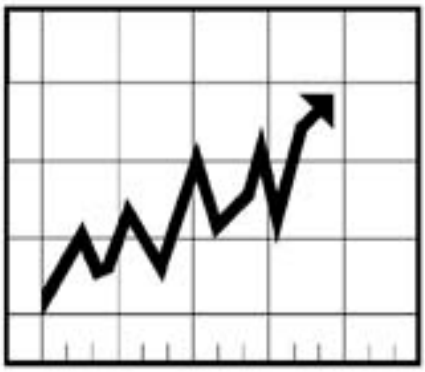
Health Canada Santé Canada



# NHPD Status of Submissions Quarterly Report

## Special Issue - Quarters 1 and 2

(April 1, 2008 to September 30, 2008)

Canada

# NHPD Status of Submissions Quarterly Report

**Quarters 1 and 2 (April 1, 2008 to September 30, 2008)**

The *NHPD Status of Submissions Quarterly Report* is a publication of Health Canada's Natural Health Products Directorate (NHPD), the federal department responsible for the regulation of natural health products sold in Canada. The purpose of this report is to provide the Canadian public with statistical data on the product and site licence applications received and processed by the NHPD.

The *NHPD Status of Submissions Report* is released every quarter to the Canadian public via the NHPD's electronic bulletin. Subscribe to the NHPD e-bulletin at **www.healthcanada.gc.ca/nhpd_bulletin**

**Reporting Schedule*:**

- 1st Quarter: April 1 to June 30
- 2nd Quarter: July 1 to September 30
- 3rd Quarter: October 1 to December 31
- 4th Quarter: January 1 to March 31

*Based on fiscal year, not calendar year.

**Questions, comments or feedback** regarding the content of the *NHPD Status of Submissions Report* may be addressed to **NHPD_DPSN@hc-sc.gc.ca**.

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# Performance Summary and Highlights

Since the implementation of the *Natural Health Products Regulations* in January 2004, Health Canada has received 31,868 Product Licence Applications (PLAs). Of this total, over **18,300 PLAs have been completed, including the issuance of over 8800 Product Licences.** Health Canada has committed itself to addressing 60% of the total PLA backlog (9706) by March 31, 2009. The remaining 40% will be addressed by March 31, 2010.

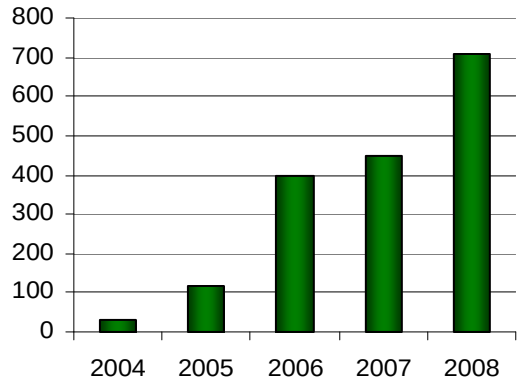
HIGHLIGHT

**8800**
NHPs licensed since 2004

**18,370**
PLAs completed since 2004

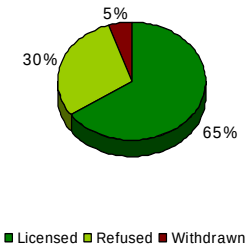
## Performance on the Rise: Monthly Completion Rate and Licensing Rate at Highest Point Ever

**PLA Monthly Completion Rate**

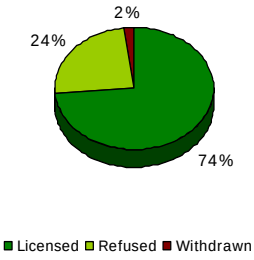



Over the past four years, a number of improvement measures have been implemented, which have enabled the NHPD to **increase its monthly completion rate seven fold**; taking it from an average 100 PLAs per month in 2004-05 to 700 PLAs per month in 2008. In addition, the **product licensing rate has doubled** in the past year while the rate of applications refused and/or withdrawn has remained relatively unchanged.

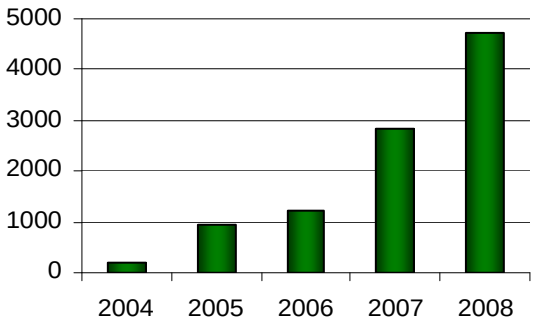
**2007 Completed**




**2008 Completed**




**Product Licences Issued per Year**




## Reasons for Refusal

- 36% of PLAs failed to meet basic application requirements.
- 33% of PLAs were refused when applicants did not respond to a request for further information.
- 24% PLAs were refused when the applicant's response to a request for further information did not meet the requirements.
- 4% were refused when significant changes were made to the product itself in response to a request for further information (i.e. an "unsolicited change").
- 3% did not meet the definition of a NHP.

## Key Drivers for Success: Monograph Development and Streamlining Review Processes

The improvements experienced over the past two years are attributed in large part to the increased number of monographs available to applicants. Since January 2007, 91 monographs were revised and updated and 24 new monographs were created. In total, there are 117 monographs which have accounted for over 4330 Product licences issued by Health Canada.

HIGHLIGHT

117 monographs = 4330 Product Licenses

Given the key role monographs play in facilitating the review and processing of PLAs, the NHPD continues to develop new monographs, focussing particularly on the new generation of "product monographs" for multi-ingredient products, which are known to represent the majority of products found on the Canadian NHP market.

HIGHLIGHT

Licensing: 5-10 days

For HMs Labelling Standards and Trans-DINs.

The recent introduction of a simplified attestation system certain types of products, including some Homeopathic Medicines (HMs) and Transitional DIN NHPs, has also contributed tremendously to improved performance and licensing. Under this new approach, these product types are licensed within a matter of days (5 to 10) and the resources required to assess them have been considerably reduced.

Looking at the successes achieved thus far through the use of an attestation system, the NHPD is further exploring how this model can be used to facilitate the licensing process for certain types of NHPs, including the potential role other sources of domestic and international information, such as international pharmacopeias and foreign regulatory standards.

## Status of the Product Licence Application Backlog

The PLA Backlog is concentrated primarily in the non-traditional and traditional queues, as the NHPD has managed to effectively streamline the review processes for the other remaining queues. Respectively, of the PLAs that remain with the NHPD for assessment, 70% are of the non-traditional type and 21.1% are of the traditional type.

HIGHLIGHT

95%

Of 2004-05 Backlog Completed

The NHPD has completed over 95% of the 2004-2005 PLA Backlog. Efforts are now focussing on the non-traditional and traditional PLAs that are still in queue for assessment.

HIGHLIGHT

80%

Non-Traditional PLAs have undergone an initial assessment with new process (started May '08)

To specifically address the issues with the non-traditional stream and to respond to demands from the NHP Industry to streamline processes, the NHPD is piloting a simplified Information Request Notice (IRN) process. Under this new process, the evidence portion of non-traditional PLAs undergoes an initial screening against an Evidence Criteria Checklist to determine whether or not the information provided is critically deficient. This new approach enables Health Canada to identify critically deficient PLAs at the onset of assessment with minimal effort and to send feedback to applicants quickly rather than letting the files sit in the assessment queue for lengthy periods of time without progress.

Streamlining the IRN process in this way has enabled the NHPD to re-focus its assessment resources and expertise and complete the initial assessment of 80% of the current non-traditional backlog within a matter of months.

# Statistics

**Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed for Quarters 1 and 2 (April 1, 2008 to September 30, 2008).**

Note – "Completed" includes all submissions that were licensed, refused or withdrawn by the applicant.

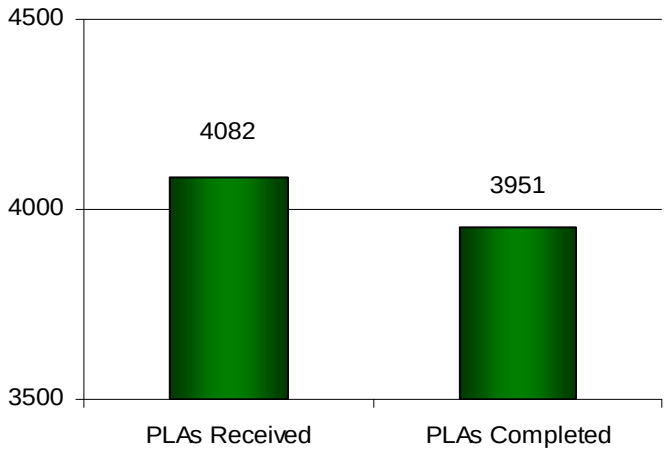



**Chart 2 – Total Number of Product Licence Applications (PLAs) Licensed, Refused and Withdrawn for Quarters 1 and 2 (April 1, 2008 to September 30, 2008).**

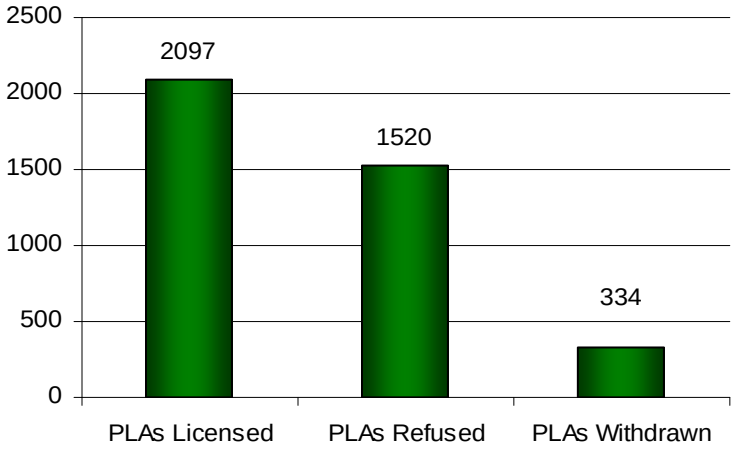


**Chart 3 – Total Number of Product Licence Applications (PLAs) Completed by Year of Application for Quarters 1 and 2 (April 1, 2008 to September 30, 2008).**

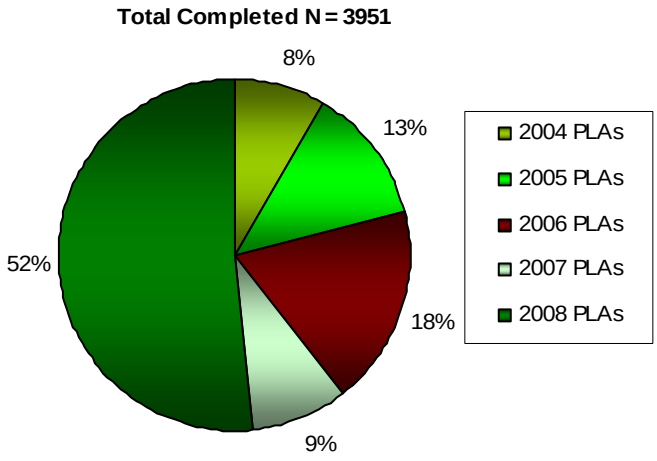
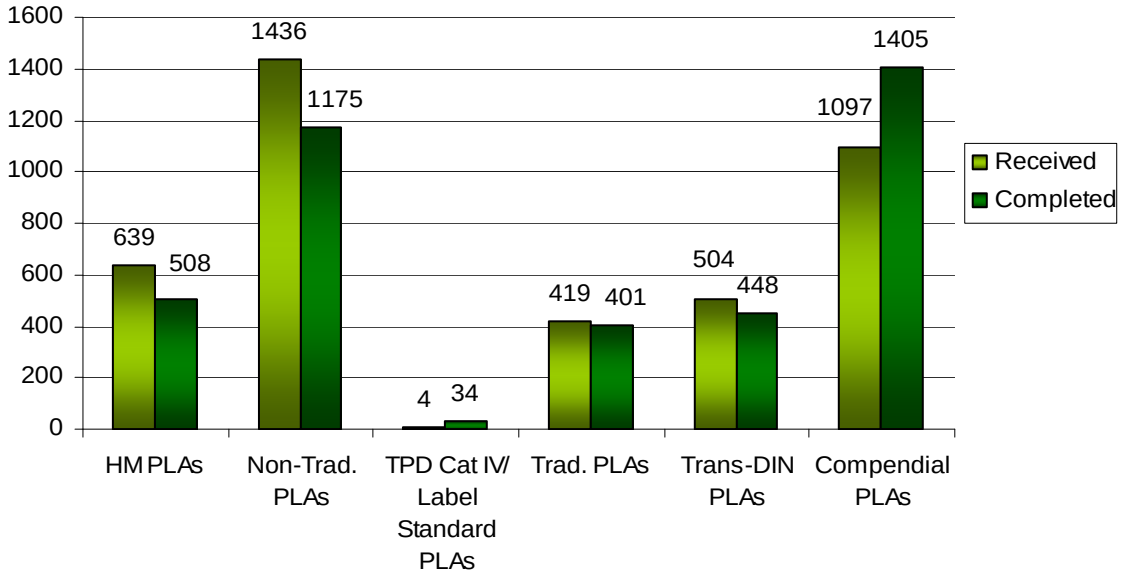



**Chart 4 – Total Number of Product Licence Applications (PLAs) Received and Completed for Quarters 1 and 2 (April 1, 2008 to September 30, 2008) by PLA Type.**

Note – "Completed" includes all submissions that were licensed, refused or withdrawn by the applicant.




* Refer to Appendix A for definitions of acronyms found in Chart 2.

**Chart 5 – Total Number of Site Licence Applications (SLAs) Received and Completed for Quarters 1 and 2 (April 1, 2008 to September 30, 2008).**

Note – "Completed" includes all submissions that were licensed, refused or withdrawn by the applicant.

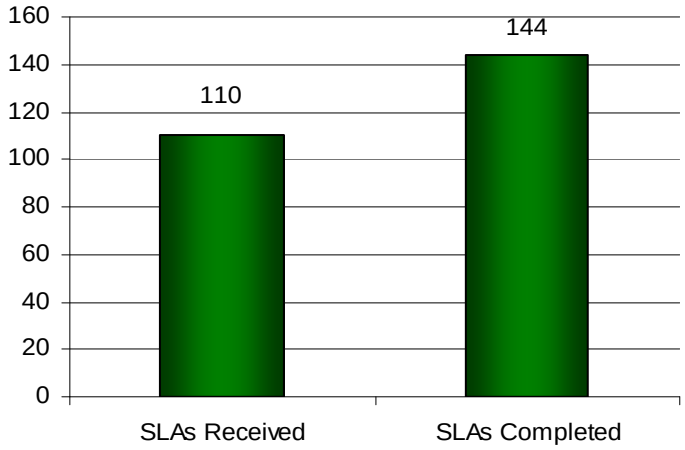
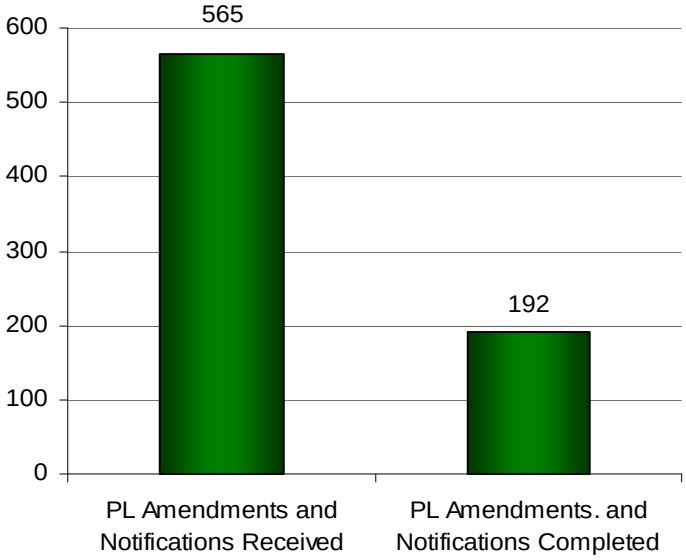



**Chart 6 – Total Number of Product Licence Amendments and Notifications Received and Completed for Quarters 1 and 2 (April 1, 2008 to September 30, 2008).**

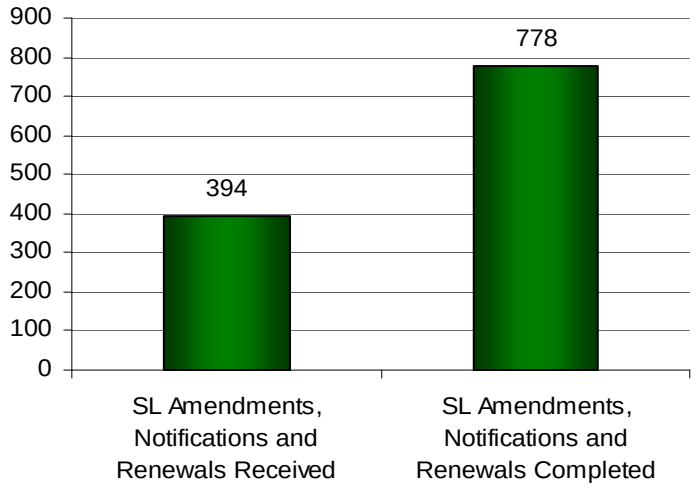
Note – "Completed" includes all submissions that were licensed, refused or withdrawn by the applicant.




* Refer to Appendix A for definitions of acronyms found in Chart 6.

**Chart 7 – Total Number of Site Licence Amendments, Notifications and Renewals Received and Completed for Quarters 1 and 2 (April 1, 2008 to September 30, 2008).**

Note – "Completed" includes all submissions that were licensed, refused or withdrawn by the applicant.




* Refer to Appendix A for definitions of acronyms found in Chart 7.

# Appendix A – Acronyms and Definitions

| | |
|---|---|
| PL: | Product Licence |
| SL: | Site Licence |
| PLA: | Product Licence Application |
| SLA: | Site Licence Application |
| DIN: | Drug Identification Number |
| NHPD: | Natural Health Products Directorate |
| HM PLA: | Homeopathic Medicines Product Licence Application |
| Non-Trad. PLA: | Non-Traditional Product Licence Application |
| Trad. PLA: | Traditional Product Licence Application |
| TPD Cat IV / Label Standard PLA: | Product Licence Application citing a Category IV Monograph or Labelling Standard from the Therapeutic Products Directorate |
| Trans-DIN PLA: | Transitional DIN Product Licence Application |
| Compendial PLA: | Product Licence Application citing a monograph found in the NHPD's *Compendium of Monographs* |