

# Status of Submissions Quarterly Report

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**Quarter 4**  
(January 1, 2009 to March 31, 2009)

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**Quarter 4 (January 1, 2009 to March 31, 2009)**

***Natural Health Products Directorate  
Health Canada***

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The *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 *Status of Submissions Quarterly 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](http://www.healthcanada.gc.ca/nhpd_bulletin)**

### **Reporting Schedule\*:**

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

\*Based on fiscal year, not calendar year.

**Questions, comments or feedback** regarding the content of the *Status of Submissions Quarterly Report* may be addressed to **[NHPD\\_DPSN@hc-sc.gc.ca](mailto: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 36,127 Product Licence Applications (PLAs). Of this total, **22,227 PLAs have been completed, including the issuance of 11,007 Product Licences.**

## Quarter 4 (January 1, 2009 to March 31, 2009)

During the past quarter, a total of 1675 PLAs were completed\*, of which 557 were refused for the following reasons:

### Highlights

**633**

NHPs licensed  
during Quarter 4

**557**

PLAs refused  
during Quarter 4

**485**

PLAs withdrawn  
during Quarter 4

- 43% of PLAs failed to meet basic application requirements.
- 26% of PLAs were refused when applicants did not respond to a request for further information.
- 26% PLAs were refused when the applicant's response to a request for further information did not meet the requirements.
- 3% did not meet the definition of a NHP.
- 2% were refused when significant changes were made to the product itself in response to a request for further information (i.e. an "unsolicited change").

\*As a result of a verification/correction of the data on the number of applications completed before Quarter 4 at the NHPD, the total number of applications completed since 2004 has increased by more than the 1675 applications completed this past quarter.

### Highlights

**11,007**

NHPs licensed  
since 2004

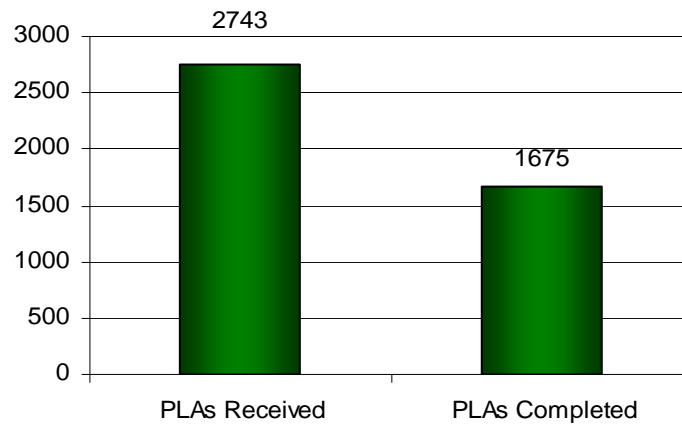
**22,227**

PLAs completed  
since 2004

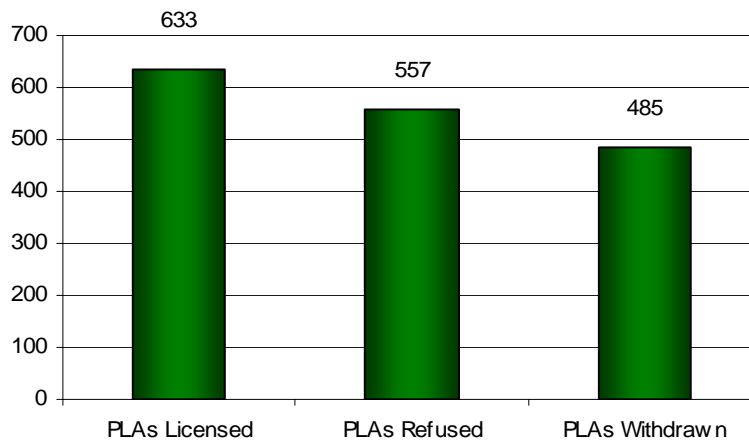
## Statistics

**Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 4 (January 1, 2009 to March 31, 2009).**

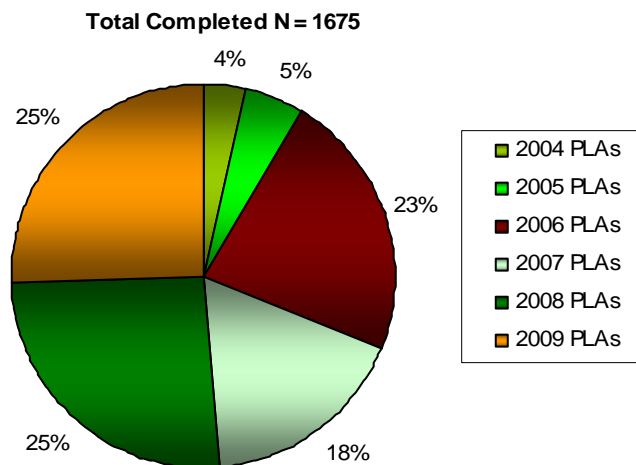
Note – “Completed” includes all submissions that were licensed, refused or withdrawn by the applicant.



**Chart 2 – Total Number of Product Licence Applications (PLAs) Licensed, Refused and Withdrawn during Quarter 4 (January 1, 2009 to March 31, 2009).**

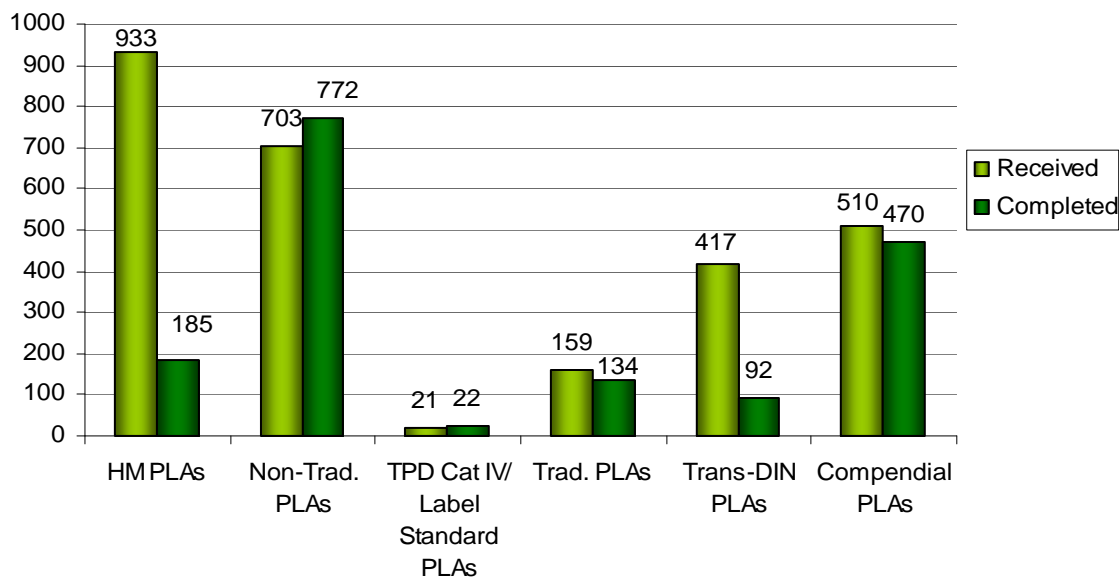


**Chart 3 – Total Number of Product Licence Applications (PLAs) Completed by Year of Application during Quarter 4 (January 1, 2009 to March 31, 2009).**



**Chart 4 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 4 (January 1, 2009 to March 31, 2009).**

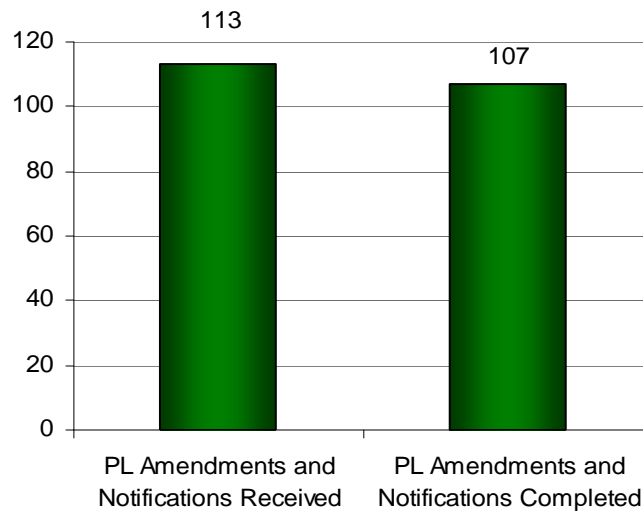
Note – “Completed” includes all submissions that were licensed, refused or withdrawn by the applicant.



\* Refer to Appendix A for definitions of acronyms found in Chart 4.

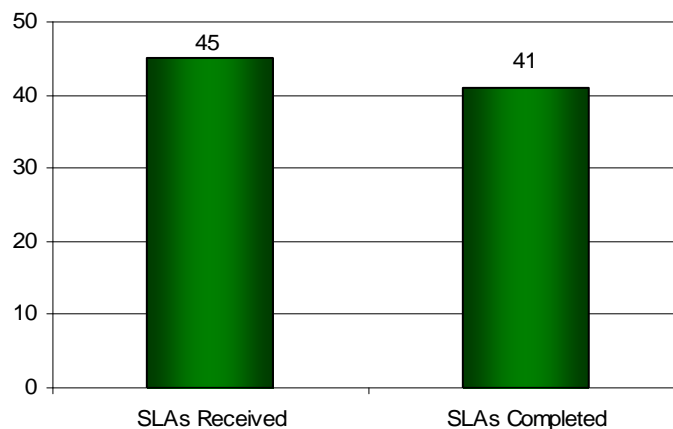
**Chart 5 – Total Number of Product Licence Amendments and Notifications Received and Completed during Quarter 4 (January 1, 2009 to March 31, 2009).**

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 5.

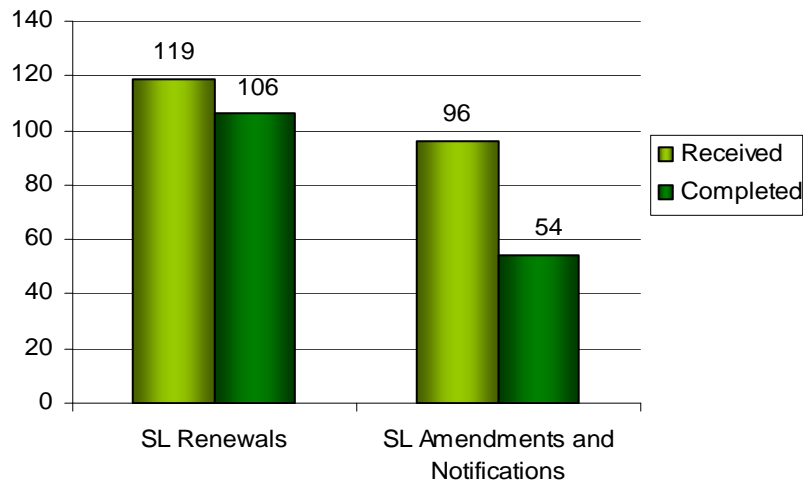
**Chart 6 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 4 (January 1, 2009 to March 31, 2009).**



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

**Chart 7 – Total Number of Site Licence Amendments, Notifications and Renewals Received and Completed for Quarter 4 (January 1, 2009 to March 31, 2009).**

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.



## Status Update on the Product Licence Application Backlog

As defined by the NHPD, the backlog consists of all PLAs received before April 1, 2008 which were incomplete as of that date. "Incomplete" includes PLAs for which the NHPD had not rendered a regulatory decision (i.e. the PLA was not licensed, withdrawn or refused) by April 1, 2008. All other PLAs received after April 1, 2008 are considered regular workload and are not part of the PLA backlog the NHPD has committed itself to addressing by March 31, 2010.

### Highlights

**35%**

Reduction of the backlog.

With the implementation of the new simplified Information Request Notice (IRN) process and other improvement initiatives, the backlog now numbers 8230 PLAs, signalling a reduction of 35%.

The table below provides figures on the current status of the PLA backlog.

Total Backlog	12,635 PLAs	
Status	Number	Percentage of Total Backlog
<b>Completed PLAs</b>	<b>4405 PLAs</b>	<b>35%</b>
• <i>Licensed</i>	1780	14%
• <i>Refused</i>	1676	13%
• <i>Withdrawn</i>	949	8%
<b>Outstanding (Remaining Backlog)</b>	<b>8230 PLAs</b>	<b>65%</b>
• <i>Undergoing an initial assessment against the evidence criteria.</i>	3512	27.8%
• <i>Have been placed in the appropriate review stream and are awaiting a full assessment of their safety, efficacy and quality (this includes PLAs that have undergone an initial assessment against the evidence criteria).</i>	2712	21%
• <i>Undergoing a full assessment of safety, efficacy and quality.</i>	1503	11.9%
• <i>Assessment complete.</i>	503	4%

## 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 <i>Compendium of Monographs</i>