

# Status of Applications Quarterly Report

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**Quarter 4**  
(January 1, 2010 to March 31, 2010)

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**Quarter 4 (January 1, 2010 to March 31, 2010)**

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

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The *Status of Applications 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.

**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 Applications Quarterly 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 until the end of March 2010, Health Canada has received 47,997 Product Licence Applications (PLAs). Of this total, **37,751 (79%) PLAs have been completed, including the issuance of 20,149 Product Licences which represents 26,094 products.** The remaining completed applications were either refused by NHPD or withdrawn by the applicant. In total, 1149 companies have received a product licence to date.

### Highlights

**20,149**

NHPs licensed  
since 2004

**37,751**

PLAs completed  
since 2004

To date, 77% of applications in “backlog” and 69% of “regular workload” applications have been completed or are in the process of being completed. In addition, 99% of “backlog” applications and 78% of “regular workload” applications have been addressed (see Appendix A for definitions).

During this quarter, the number of non-addressed backlog applications was reduced to less than 200 (reduction of almost 600 applications from last quarter). Of the remaining 178 applications in backlog, all are considered halted and NHPD continues to focus on resolving these issues.

While the priority is addressing and completing backlog applications, NHPD continues to report improvement with regards to regular workload applications. As mentioned above, 69% of regular workload applications are now complete and only 22% of regular workload applications have not yet been addressed.

## Quarter 4 (January 1, 2010 to March 31, 2010)

During this quarter, a total of 3,667 PLAs were completed, 55.7% (2,044) of these completions resulted in product licences, 35.3% (1,293) were refusals and the remaining 9.0% (330) of completions were as a result of the applicant withdrawing the application.

Of the 1,293 applications refused this quarter, the reasons were as follows:

- 34% failed to meet basic application requirements.
- 31% were refused when applicants did not respond to a request for further information.
- 30% were refused when the applicant's response to a request for further information did not meet the requirements.
- 3% were refused when quality, safety and/or efficacy issues were identified.
- 1% did not meet the definition of a NHP.
- <1% were refused as a result of significant changes having been made to the product itself in response to a request for further information (i.e. an "unsolicited change").

### Highlights

**2,044**

NHPs licensed  
during Quarter 4

**1,293**

PLAs refused  
during Quarter 4

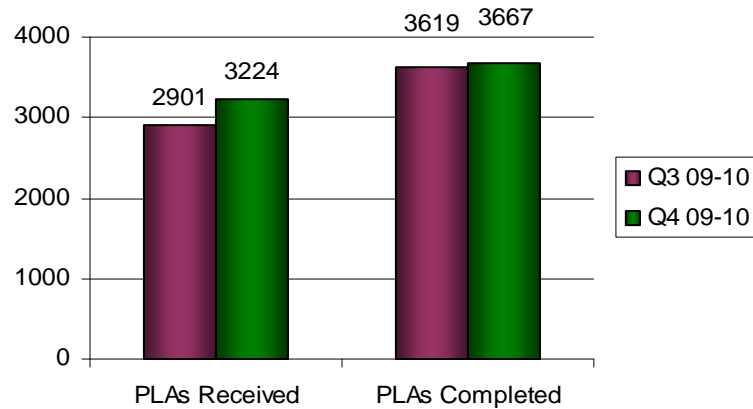
**330**

PLAs withdrawn  
during Quarter 4

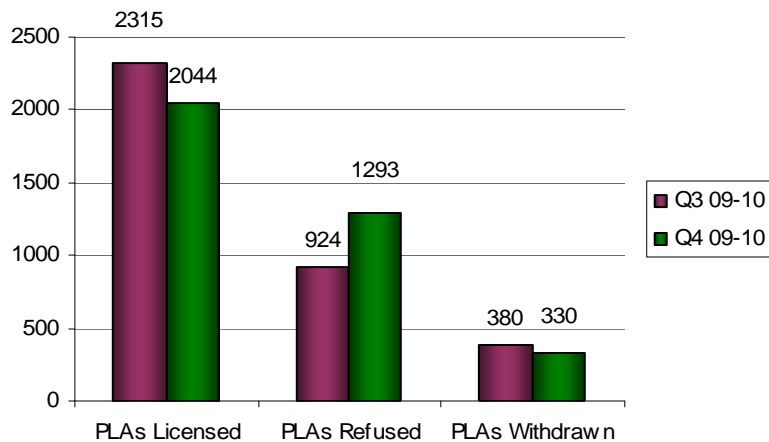
## Quarter 4 Statistics (January 1, 2010 to March 31, 2010)

**Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 4**

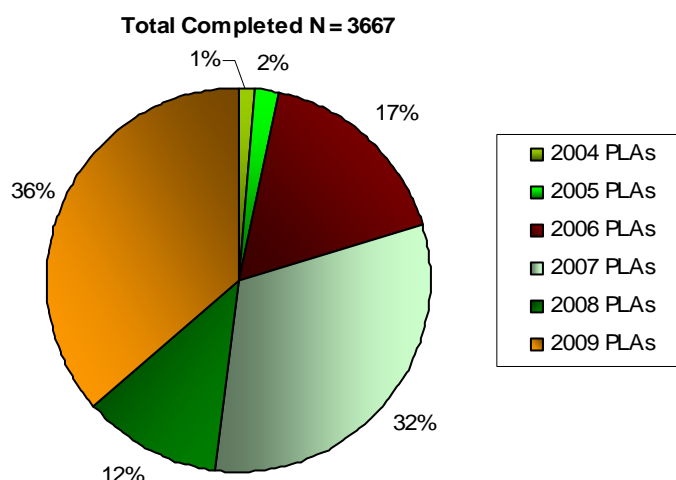
Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



**Chart 2 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 4 (Licensed, Refused or Withdrawn)**

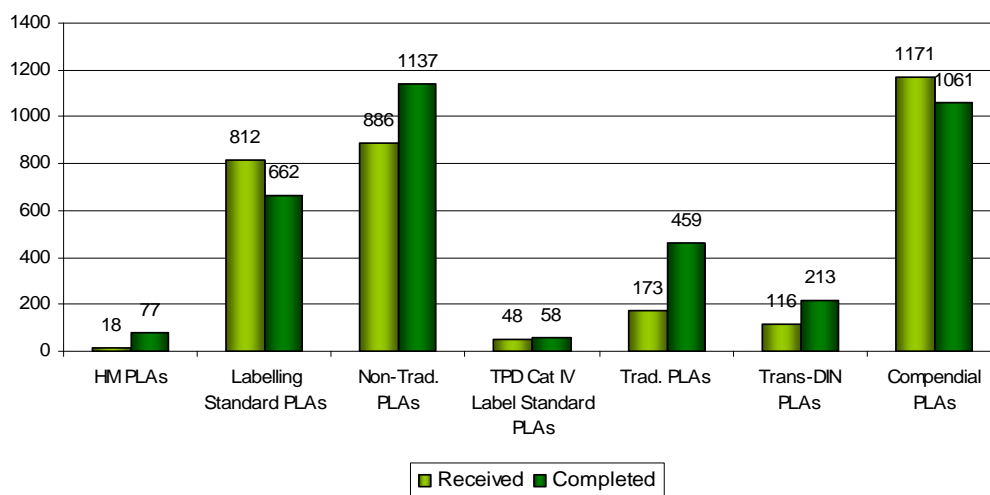


**Chart 3 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 4 (by Year of Application)**



**Chart 4 – Total Number of Product Licence Applications (PLAs) - by application type - Received and Completed during Quarter 4**

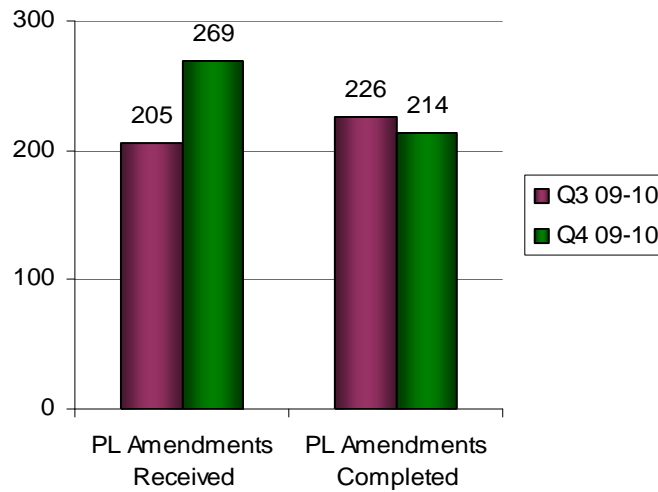
Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



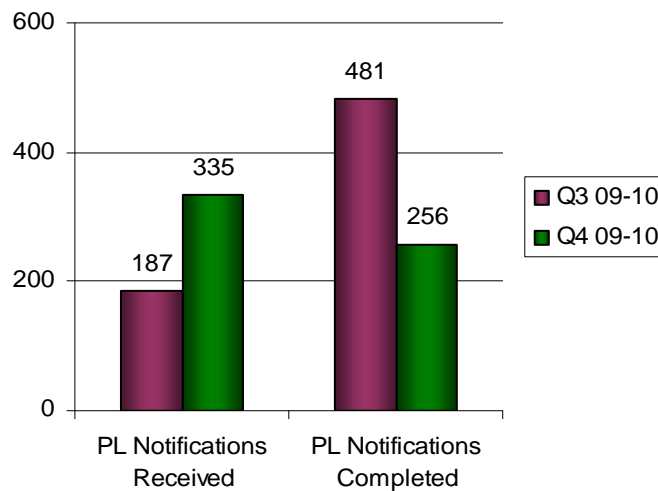
\* See Appendix A for definitions of acronyms found in Chart 4.

**Chart 5 – Total Number of Product Licence (PL) Amendments Received and Completed during Quarter 4**

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



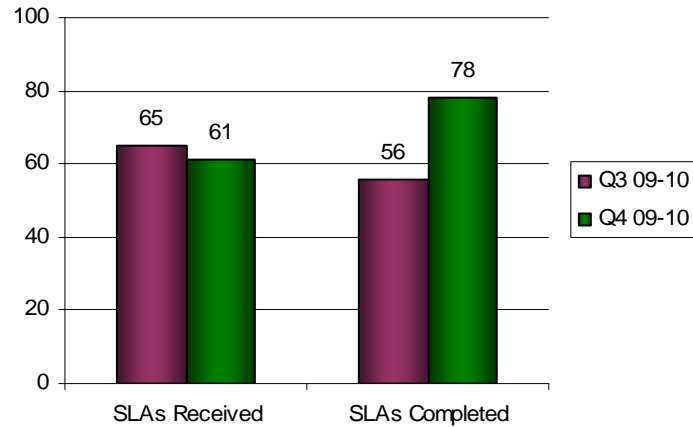
**Chart 6 – Total Number of Product Licence (PL) Notifications Received and Completed during Quarter 4**





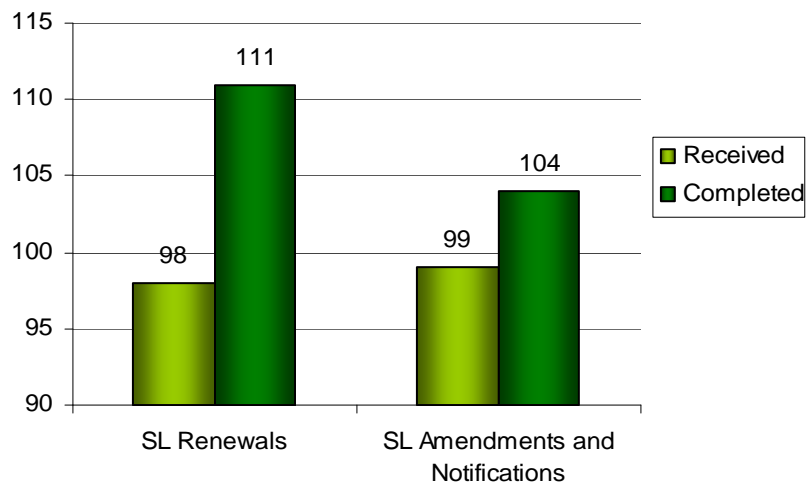
**Chart 7 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 4**

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



**Chart 8 – Total Number of Site Licence (SL) Amendments, Notifications and Renewals Received and Completed during Quarter 4**

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



## Update on the Product Licence Application Backlog and Regular Workload

As defined by the NHPD, the “backlog” consists of the 12,976 PLAs received before April 1, 2008 which were incomplete as of that date (i.e. the PLA was not licensed, withdrawn or refused). All other PLAs received on or after April 1, 2008 are considered regular workload and are not part of the PLA backlog the NHPD had committed itself to addressing by March 31, 2010. For the purposes of reporting, these are called “regular workload” PLAs. At this point, 99% of all backlog applications have been addressed – the remaining 1% are all halted pending resolution of issues surrounding safety and efficacy.

As a result of the implementation of the Non-Traditional & Traditional Process Improvement Projects and other improvement initiatives, the number of incomplete “backlog” PLAs now equals 2,921 PLAs, signalling a reduction of 77.5% from the original 12,976 PLAs.

### Highlights

**77%**  
reduction of the  
backlog

**99%**  
of backlog PLAs  
have been  
addressed

**Table 1: Total “Backlog” PLAs as of March 31, 2010**

Table 1 provides figures on the current status of the PLA “backlog”. Please note these numbers do not include amendments or notifications; however all backlog notifications and amendments are complete.

Status	Number	% of Total (12,976)
Licensed	3,196	
In Licensing – administrative processing required	62	
Refused	3,897	
To Be Refused – administrative processing required	48	
Withdrawn by applicant	2,852	
<b>Addressed PLAs - Completed</b>	<b>10,055</b>	<b>77.5%</b>
Has received one or more Information Request Notice (IRN) or E-IRN	2,132	
Halted pending internal decision related to safety or efficacy	611	
<b>Addressed PLAs – Received one or more IRN or E-IRN</b>	<b>2,743</b>	<b>21.1%</b>
Require Initial Assessment to determine if file requires E-IRN	0	
To receive E-IRN	0	
Awaiting or undergoing full review	0	
Halted pending internal decision related to safety or efficacy	178	
Miscellaneous Administrative Issues	0	
<b>Non-Addressed PLAs</b>	<b>178</b>	<b>1.4%</b>

**Table 2: Total “Regular Workload” PLAs as of March 31, 2010**

Table 2 provides figures on the current status of all PLAs which were received on or after April 1, 2008 and are therefore not considered “backlog”. Please note these numbers do not include amendments or notifications.

Status	Number	% of Total (21,728)
Licensed	10,763	
In Licensing – administrative processing required	329	
Refused	3,215	
To Be Refused – administrative processing required	77	
Withdrawn by applicant	535	
<b>Addressed PLAs – Completed</b>	<b>14,919</b>	<b>68.7%</b>
Has received one or more Information Request Notice (IRN) or E-IRN	1,990	
Halted pending internal decision related to safety or efficacy	92	
<b>Addressed PLAs – Received one or more IRN or E-IRN</b>	<b>2,082</b>	<b>9.6%</b>
Applications (all types) recently received at NHPD	393	
Require Initial Assessment to determine if file requires E-IRN	2,012	
To receive E-IRN	24	
Awaiting or undergoing full review	1,685	
Halted pending internal decision related to safety or efficacy	597	
Miscellaneous Administrative Issues	16	
<b>Non-Addressed PLAs</b>	<b>4,727</b>	<b>21.7%</b>

## Update on Amendments and Notifications

Since January 2004, NHPD has received 1,541 notifications and 1,681 amendments. NHPD has completed 94% of notifications and 78% of amendments to date.

Of the amendments that have been completed, 91.7% resulted in a revised product licence, 2.4% resulted in a refusal and 5.8% were withdrawn by the licensee.

All backlog amendments have been completed. Table 3 provides figures on the current status of amendments which were received on or after April 1, 2008 and are therefore not considered "backlog".

**Table 3: Total "Regular Workload" Amendments as of March 31, 2010**

Status	Number	% of Total (1336)
Licensed	889	
In Licensing – administrative processing required	101	
Refused	19	
To Be Refused – administrative processing required	1	
Withdrawn by applicant	47	
<b>Addressed Amendments – Completed</b>	<b>1,057</b>	<b>79%</b>
Has received one or more Information Request Notice (IRN) or E-IRN	60	
<b>Addressed Amendments – Received one or more E-IRN or IRN</b>	<b>60</b>	<b>5%</b>
Applications recently received at NHPD (in processing)	93	
Awaiting or undergoing full review	77	
Miscellaneous Administrative Issues	49	
<b>Non-Addressed Amendments</b>	<b>219</b>	<b>16%</b>

## 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
Abbreviated Labelling Standard (AbLS):	Document created by NHPD outlining information about the established safety and/or efficacy of a product or ingredient
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>
Addressed:	When NHPD issues a Product Licence, Notice of Refusal, Information Request Notice or when the applicant withdraws their application, the application is considered to be "addressed".
Backlog:	All PLAs received before April 1, 2008 which were not complete as of that date
Completed:	When NHPD issues a Product Licence, Notice of Refusal or when the applicant withdraws their application, the application is considered to be "completed".
E-IRN:	Information Request Notice focusing on critical evidence deficiencies
Halted:	An application which cannot be further processed due to the need for an internal decision related to safety and/or efficacy
IRN:	Information Request Notice

Non-Traditional Process Improvement Project:	Project initiated by NHPD, in 2008, which involves screening Non-Traditional applications for critical evidence deficiencies through an initial assessment process
Traditional Process Improvement Project:	Project initiated by NHPD, in 2009, which involves screening Traditional applications for critical evidence deficiencies through an initial assessment process
Regular workload:	All PLAs received on or after April 1, 2008