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Ottawa, Ontario
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Summary of 2013 R&D Spending and Investments by Rx&D Members

In connection with the Association Members Survey project related to pharmaceutical spending, we enclose our *Summary of 2013 R&D Spending and Investments by Rx&D Members* - an update to the 2010 Survey (the "Updated Survey"). We caution that the information in this report is not intended to be used for any investment decisions or to be part of an evaluation of financial or investment potential. We further caution that this report was prepared for specific purposes as noted in our engagement letter with the Association and that the Updated Survey should be read in its entirety, excerpts should not be used, and readers are cautioned that the results may not be appropriate for uses outside of the scope as outlined above. KPMG disclaims any liability for failing to adhere to these cautions.

SCOPE AND OBJECTIVES

In 2014, the Association engaged KPMG to update the results from the 2010 Survey previously developed and undertaken by KPMG to include fiscal 2013 data. The 2010 Survey, which remained unchanged for the Updated Survey, was jointly prepared by KPMG, the Association and a Steering Committee chaired by Industry Canada and made up of members from the Association, Industry Canada, the Patented Medicine Prices Review Board ("PMPRB"), and the Canadian Institutes of Health Research ("CIHR"). The survey process was administered by KPMG. KPMG compiled the results of this Updated Survey and has detailed the information reported by Updated Survey participants in summary form along with the 2012 and 2011 Survey data. KPMG has not audited the information contained in this report which was provided to KPMG directly from Survey participants.

KPMG's administration of the 2010 Survey, compilation of the results and work with the Steering Committee included:

- obtaining details of R&D spending submitted to the PMPRB;
- conducting phone interviews with certain Survey respondents to determine their understanding of the Survey questions and processes used to report amounts and avoid double counting; and
- agreeing certain Survey data reported amounts.

The scope of the Surveys and completion of the results were made under the terms of engagement letters between KPMG and the Association. The procedures developed and performed do not constitute audits and, therefore, KPMG expresses no opinion on the Survey data results or of the procedures performed.

The Steering Committee provided KPMG with the following industry background as part of the 2010 Survey.

BACKGROUND

The nature of pharmaceutical research and development ("R&D") activity has undergone significant change due largely to the changing business model of the pharmaceutical industry. However, the way pharmaceutical R&D in Canada is measured has not.

In Canada, pharmaceutical R&D is measured and reported by both Statistics Canada and the PMPRB. Each agency applies a somewhat different methodology and analyzes different target populations in an effort to fulfill their mandates.

In the case of Statistics Canada it has a role to report on Canadian pharmaceutical manufacturing innovation that happens within a firm to be used for international comparisons and domestic policy. The PMPRB has a role to report on R&D spending, by companies who sell pharmaceutical products associated with patents, and uses a legislated reporting standard allowing company R&D performance comparability over time.

While these agencies capture a large part of Canadian pharmaceutical R&D activities, it was postulated by the Association that industry R&D spending and varied investments occur that do not fit in the existing measurement and reporting models.

The Steering Committee

In January 2011, the Association undertook a project to work with Industry Canada to establish a group that would include members from the PMPRB, the CIHR, the Association and Industry Canada. This group would help identify the nature and size of the pharmaceutical industry's investment spending in Canada by conducting a Survey of the Association members. They agreed to form a Steering Committee (Chaired by Industry Canada) that guided the project and the original terms for this report.

The Steering Committee and the Association agreed on the need to gain a better understanding of the full spectrum of Canadian pharmaceutical R&D spending and other investments and produce a report based on a survey. The survey data would provide information on Association members R&D and investments not normally captured by PMPRB or Statistics Canada to broadly inform policy-makers.

The Steering Committee established a technical Working Group to assist in the development of the Survey questionnaire and to provide advice to the Steering Committee and KPMG on the scope of the data to be collected and on potential measurement and collection issues. This Working group included representatives from the Association, Industry Canada, PMPRB, and CIHR. Government analysts and industry financial officers also assisted the Working group in scoping the technical aspects of the desired R&D and other investment measurements.

KPMG assisted the Steering Committee with the Survey development, administered the Survey and compiled the results.

The results of the 2010 Survey that came out of these efforts, jointly funded by the Association and CIHR, provided an initial understanding of R&D and other investments made by Association members. The results of the updated 2013 Survey provide a comparative analysis of this data, as well as some provincial allocations for certain portions of the Survey as requested by the Association.

THE 2010 SURVEY

KPMG and the Steering Committee developed the questions to be included in the 2010 Survey and the methodology to be employed by KPMG to conduct the Survey and compile the results.

A broad list of the types of potential R&D and investments that Association members have made, which are not reported to PMPRB under the existing regulations, was developed and circulated amongst the Working Group for discussion and analysis. After numerous iterations, a final version of the desired data for Survey purposes was approved by the Steering Committee. The changes incorporated separating the Survey into three distinct sections.

Types of R&D and Other Investment Data to be Surveyed by Association Members

Three areas of expenditures on R&D and other investments in Canada were requested of the Survey respondents, as follows:

- Section 1: R&D Expenditures and Investments that Qualify for SR&ED Tax Credits
- Section 2: R&D Expenditures and Other Investments that Do Not Qualify for SR&ED Tax Credits
- Section 3: Non-R&D Expenditures Which Are Part of the Industry's Investments in Canada

Data was compiled on expenditures incurred by Association Member companies during their fiscal periods 2010, 2011,2012 and 2013. Only direct costs were to be reported (i.e. no overhead amounts).

Methodology

KPMG provided educational webinars to Rx&D members prior to the 2010 survey launch. The webinars were used to give respondents instructions on how to complete the on-line survey. The instructions included:

1 Explaining what data each question was looking for;
2 Describing the importance of using consistent and standardized reporting; and
3 Highlighting the importance of not duplicating amounts.

The respondents received the power point presentation prior to the webinar for their review and preliminary comments. Participants were encouraged to ask questions during the webinars.

The Survey was conducted by KPMG using an online, secure and confidential submission form.

As part of the Survey design, each question had an area for the respondents to note any comments or questions they may have. Each Survey question contained a link to a confidential email which the respondents could use to send a request directly to KPMG in order to clarify any comments or answer any questions they may have.

Once the Survey was completed, the results were sent directly to a secure and confidential repository at KPMG.

The following details the three Survey Sections and the various questions posed to the Survey respondents.

Section 1 R&D Expenditures and Investments that Qualify for SR&ED Tax Credits

Question 1.1: Expenditures eligible for SR&ED tax credits based on the *Income Tax Act* (Canada) on December 1, 1987.

- These are the expenditures covered by the criteria used for PMPRB reporting purposes pursuant to the 1987 SR&ED criteria as per PMPRBs legislative mandate to report under the Patented Medicines Regulations. The amounts reported should be equal to the amounts reported by PMPRB filers on their Form 3 for the totals noted in Block 5 (current expenditures) and Block 6 (capital expenditures). SR&ED for this purpose is outlined in and guidance is provided for completing Form 3 in the PMPRB Guide (see Appendix 2).

Question 1.2: Additional expenditures above and beyond those amounts reported in Question 1.1 which are eligible for SR&ED tax credits based on the 2010 criteria pursuant to subsection 248(1) of the *Income Tax Act* (Canada). Note that the 2012 Federal Budget has made changes to some of the criteria included for SR&ED purposes that will impact 2013 and future years.

- In general, the data requested in Question 1.2 relates to SR&ED eligible labour amounts incurred outside of Canada (i.e. up to a maximum of 10% of the total Canadian labour amount claimed for SR&ED purposes) as well as leased and capital equipment that is used between 50% and 90% for SR&ED performed in Canada (see Appendix 3).

Question 1.3: Was added to accommodate those Association members that are not required to report to PMPRB and therefore do not otherwise make any distinctions between Questions 1.1 and Question 1.2, as well as for other amounts that were otherwise unreported to PMPRB. The purpose of having this question was to avoid having a total Survey amount for Section 1.1 that significantly differed from the total PMPRB figure for Association member reported amounts.

Section 2 R&D Expenditures and Other Investments in Canada that Do Not Qualify for SR&ED Tax Credits

Question 2.1: Expenditures similar to those identified, but not included, in Question 1.2:

- Additional salaries of Canadian personnel directly engaged in SR&ED eligible work performed outside Canada above and beyond the 10% amount that was reported in Question 1.2;
- The cost of new capital equipment utilized less than 50% of its useful life for R&D; and

- The cost of leased capital equipment utilized less than 50% of its useful life for R&D.

Question 2.2: Additional cost of individuals charged to a Canadian payroll for services performed in Canada (i.e. the individual either receives a Canadian T4 slip or those that are paid by a related foreign company but for which their salary costs are charged to a Canadian entity) above and beyond that which is already reported in Section 1, but which have a direct impact on the R&D function in Canada.

Question 2.3: Investments in used equipment utilized in R&D activities in Canada (i.e. only include the cost of the actual percentage utilized in R&D).

Question 2.4: Amounts paid by a Canadian company to Canadian pharmaceutical service providers related to the portion of milestone payments, management fees, etc. which have been excluded from SR&ED reporting because the payments related to management, etc. of foreign trials (i.e. only include amounts above and beyond those which have already been reported in Section 1).

- For clarity, this question only asked Survey respondents to include the portion of milestone payments, management fees, etc. that relate to foreign trials that are not be reported in Section 1 and should not include the payments/funding made for the actual foreign trials. The portion of the milestone payments, management fees, etc. that relate to Canadian trials should already have been reported in Section 1 along with the payments/funding of the actual Canadian trials.

Question 2.5: Foreign entity payments (i.e. made by a related entity to the Survey respondent) made for R&D to be conducted in Canada by other companies or organizations (i.e. the funding from the foreign entity does not flow to the related Canadian entity, but rather directly to an arm's length Canadian R&D performer). This question targets the inclusion of the Canadian portion of foreign R&D funding.

Question 2.6: Lease/rental costs related to research facilities infrastructure only (e.g. buildings, labs, etc. but excluding land) which are not already reported in Question 1.2 or Question 2.1. The inclusion amount should be based on the portion of R&D square footage of the infrastructure over the total square footage.

Question 2.7: Other R&D related activities: only include direct costs of employee labour and contract payments (i.e. exclude indirect costs such as support or supervision labour costs, overhead, research marketing studies, etc.). This question targets the following items and should only be reported where the R&D activities are clearly defined and are part of research studies conducted in Canada:

- Pre-competitive research
- Economic and/or cost analysis component of pharmacoeconomic studies
- Pharmacovigilance research studies
- Collection of epidemiology information and/or screening established databases
- Research in bioethics or other social sciences or humanities
- Comparative effectiveness studies/trials
- Regulatory affairs/administration expenses in clinical trials application
- Post launch or post-regulatory approval surveillance of new drugs as part of NOC/c commitment

Question 2.8: Investments made for Canadian venture capital.

Question 2.9: Payments made for University Chair Endowments (i.e. Ph.D. and post-doctoral fellowships).

Question 2.10: Donations to Canadian charities for the purpose of conducting health research (e.g. Heart and Stroke Society, Canadian Diabetes Association, Canadian Breast Cancer Foundation, Canadian AIDS Society).

Question 2.11: Donations, grants and non-commercial sponsorships to entities that promote the health and well-being of Canadians for support of documented research funding activities, as follows:

- Associations/Societies of Health Professionals;
- Patient Advocacy and Health Promotion & Education Groups;
- Direct Service Agencies;
- Hospitals and Health Clinics; and
- Hospice & Palliative Care Programs.

Question 2.12: Other expenditures which have not otherwise been reported for R&D incurred in Canada.

Section 3 Non-R&D Expenditures Which Are Part of the Industry's Investments in Canada

Question 3.1: Similar to Question 2.11 related to donations, grants and non-commercial sponsorships to entities that promote the health and well-being of Canadians, but which is for non-R&D funding/activities.

Question 3.2: Product donations at factory gate list price, (i.e. medicines provided through compassionate use and special access programs for use in Canada).

Question 3.3: Community programs - contributions that address human welfare and social needs such as United Way / Centraide, deliver community-based amateur sports and recreation programs, and celebrate local community events, festivals and other activities.

Question 3.4: Education - contributions that support and promote education/training at the primary, secondary and post-secondary levels, including scholarships, fellowships, bursaries, etc. (but excluding payments for education at the graduate and post-graduate levels (i.e. Ph.D. and post-doctoral fellowships as these should be reported in Question 2.9).

Question 3.5: Environment - contributions that promote environmental responsibility, recycling, conservation, reclamation and land and wildlife preservation.

Question 3.6: Arts and Culture - contributions that support the arts and other cultural activities in Canada such as opera and ballet companies, symphonies, museums, broadcasters and theatres.

Procedures Performed by KPMG

Question 1.1: For the Updated Survey, KPMG obtained from 28 of the total of 32 Survey respondents, a copy of its signed and filed Form 3 report on R&D expenditures submitted to the PMPRB for 2013 (i.e. as

required under the *Patented Medicines Regulations*) in order to agree the amounts reported in the 2013 Survey data to that which was reported to PMPRB in Block 5 (Current R&D) and Block 6 (Capital Expenditures). For the 2010 Survey, KPMG performed the same procedure noted above on Question 1.1 for 16 of the total 37 Survey respondents.

For the 2010 Survey, KPMG also performed the following additional procedures in order to obtain approximately 80% coverage of the total dollar amounts reported in Sections 1 and 2.

Question 1.2 and 1.3 and Section 2: KPMG conducted phone interviews with respondents and spoke with members of the company personnel who were tasked with the completion of the 2010 Survey data in order to:

- determine that the Survey respondents understood what each question was directed towards in order to obtain consistent reporting;
- understand the process the Survey respondents used to obtain and complete each question of the 2010 Survey data and avoid double-counting of any figures; and
- agree the amounts reported in the 2010 Survey to various forms of company provided data (i.e. financial statements, accounting system reports or summaries, and/or other internal calculations and communications).

In general, KPMG found that the interviewed Survey respondents understood the 2010 Survey purpose, and appeared knowledgeable of the data requested and importance of consistent, appropriate and non-double counting of the Survey data. The respondents began with their 2010 PMPRB reported amounts and were able to identify amounts that were excluded from such reporting in order to identify the additional amounts being requested in the 2010 Survey. KPMG did not perform the above procedure for the Updated Survey.

Section 3: KPMG did not undertake any specific procedures for the 2010 Survey or the Updated Survey on Section 3 data reported by the survey respondents other than to compile the results reported.

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UPDATED SURVEY RESULTS

Participation

Only Association members participated in the Survey. A total of 32 companies responded to the Updated Survey.

2 of the 32 Survey respondents had not reported R&D investments to PMPRB but were included in the Updated Survey results.

Several entities did not respond and are therefore not included in the Updated Survey results.

Pharmaceutical R&D Expenditures and Investments by Association Members

A summary of the Updated Survey data is provided below (see Appendix 1 for a detailed summary as well as Appendix 1.A for provincial allocations of certain survey questions):

- The Updated Survey reported total 2013 expenditures of $1.276 billion ($1.332 billion and $1.301 billion for the 2012 and 2011 Survey respectively).

- The Updated Survey reported $698.9 million ($831.3 million and $906.4 million for the 2012 and 2011 Survey respectively) of 2013 expenditures that are traditionally reported to PMPRB. While the largest of these Updated Survey expenditures are reported as being incurred in the provinces of Quebec and Ontario, there are amounts that were reported in each of the other Canadian provinces (see Appendix 1.A for details).

- The Updated Survey reported an additional $5.2 million ($1.3 million and $600,000for the 2012 and 2011 Survey respectively) of 2013 expenditures that may qualify for SR&ED tax credits, which are not part of what was reported to the PMPRB as the regulatory mandate of PMPRB only captures the 1987 SR&ED criteria and is limited to patentees.

- The Updated Survey reported an additional $317 million ($278 million and $173 million for the 2012 and 2011 Survey respectively) of 2013 R&D expenditures and other investments that do not qualify for SR&ED tax credits and therefore are not reported to the PMPRB. This includes amounts paid to persons engaged in various R&D activities, studies required for regulatory and reimbursement approvals as well as research-related donations. While the largest of these Updated Survey expenditures are reported as being incurred in the provinces of Quebec and Ontario, there are amounts that were reported in each of the other Canadian provinces (see Appendix 1.A for details).

- The Updated Survey reported other 2013 expenditures of $254.5 million ($221 million and $221 million for the 2012 and 2011 Survey respectively). These expenditures include: additional donations to charities and entities that promote health and well being of Canadians of $71 million ($71 million and $79 million for the 2012 and 2011 Survey respectively); product donations to patients through compassionate use and special access programs of $178 million ($142 million and $133 million for the 2012 and 2011 Survey respectively); and community, educational, environmental and arts and cultural investments in Canada.

Survey Question/Section	2013 Updated Survey reported amounts in CDN (rounded)	2012 Updated Survey reported amounts in CDN (rounded)	2011 Survey Reported amounts in CDN (rounded)
Question 1.1 R&D Reported to PMPRB on Form 3	$698,900,000	$831,300,000	$906,400,000
Question 1.2 and 1.3 R&D and Investments Eligible for Tax Credits	5,200,000	1,300,000	600,000
Section 2 R&D and Other Investments Not Eligible for Tax Credits	317,000,000	278,000,000	173,000,000
Section 3 Non-R&D Expenditures but Other Investments in Canada	254,500,000	221,000,000	221,000,000
Total Pharmaceutical R&D Expenditures and Investments	**$1,275,600,000**	**$1,331,600,000**	**$1,301,000,000**

Limitations of Survey Results noted in 2010 Survey

Limitation #1 – Several companies were unable to complete the Survey because they do not report to PMPRB and therefore were not able to generate the data required to complete the Survey in the time frame requested.

- Only patentees of medicines being sold in Canada are required to report to PMPRB, therefore, Association member companies that conduct research but are not selling a patented medicine do not report even though they may have significant R&D expenditures.
- As a result, those companies that do not have the necessary internal reporting systems required for PMPRB reporting were not able to participate in the Survey and therefore the total amounts reported in Section 1 and 2 may be understated.

Limitation #2 - The timeframe for reporting R&D expenditures to PMPRB is not aligned with timeframes for Canada Revenue Agency. This generated some issues for both PMPRB reporters and other companies, which affected the process of and delayed the Survey results.

- For PMPRB purposes, patentees are generally required to file their Form 3 by March 1st following each calendar year whereas for tax purposes, companies are generally required to file for SR&ED tax credits within 6 months after their tax year end, which is June 30th for most of the Survey respondents.
- As a result, companies are required to perform some estimation/forecasting for PMPRB reporting, as well as for the Survey completion purposes, given that their actual R&D reporting for tax credit purposes is not due until at least 4 months after the PMPRB filing due date (i.e. entities can file for R&D tax credits up to 18 months after their tax year end).

Limitation #3 - PMPRB and CRA use different criteria for R&D, (1987[1] versus the current subsection 248(1) of the *Income Tax Act* (Canada) – see Appendix 3) which represented complexities relative to reporting and completing the Survey. This reported difference was $5,200,000.

Limitation #4 - The Survey only included Association member companies. Other biopharmaceutical companies that may conduct R&D in Canada were not included.

Limitation #5 – Not all of the various identified types of data that could have been surveyed was included in the final submission for approval by the Steering Committee. As such, additional amounts are being spent on other categories of R&D and other investments that were not captured in the Survey.

Limitation #6 – The entities surveyed often can be large and complex entities and as such, not all of the surveyed data may have been readily available to capture all of the amounts that could have otherwise been reported.

Limitation #7 – KPMG only performed procedures noted above for certain Sections of the Survey and only for certain Survey respondents. Additional procedures for all respondents on Section 3 and any part of the Survey for the other Survey respondents may impact the amounts above.

Additional Findings (2010 Survey and Updated Surveys)

Finding #1 – There are additional amounts being invested in Canada by Association members above and beyond the amounts currently being reported to PMPRB.

Finding #2 – Allowing more time for companies to respond to PMPRB could improve response rate and accuracy (i.e. aligning the reporting deadline to the SR&ED deadline).

Finding #3 – Non-Association members involving pharmaceutical companies that conduct R&D in Canada have not been measured in the Survey, which may represent additional R&D investments in Canada.

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The comments contained in this report are based on the facts, assumptions and representations stated herein. You have represented to us that you have provided all facts and circumstances that you know or have reason to know are pertinent to this report. If any of these facts, assumptions or representations is not entirely complete or accurate, it could have a material effect on our comments. Our comments take into account the applicable provisions and judicial and administrative interpretations of the relevant taxing statutes, the regulations thereunder and applicable tax treaties. Our comments also take into account all specific proposals to amend these authorities or other relevant statutes and tax treaties publicly announced prior to the date of our report, based on the assumption that these amendments will be enacted substantially as proposed. Our comments do not otherwise take into account or anticipate any changes in

[1] The PMPRB utilizes the 1987 SR&ED criteria as per its regulatory mandate to report under the Patented Medicines Regulations

law or practice, by way of judicial, governmental or legislative action or interpretation. These authorities are subject to change, retroactively and/or prospectively, and any such changes could have an effect on the validity of our comments. Unless you specifically request otherwise, we will not update our comments to take any such changes into account.

KPMG's comments are for the sole use of the Association. The comments are based on the specific facts and circumstances and the scope of KPMG's engagement and are not intended to be relied upon by any other person. KPMG disclaims any responsibility or liability for any reliance that any person, other than the Association, may place on these comments.

Thank you for the opportunity to work on this engagement and we trust you will find the above of value.

Respectfully submitted,

KPMG LLP

KPMG LLP
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Appendix 1

Summary of 2013 R&D Spending and Investments by Rx&D Members (with 2012 & 2011 comparative figures)

Question	Description	2011 $ Canadian	2012 $ Canadian	2013 $ Canadian
Section 1	**R&D expenditures and investments that qualify for SR&ED tax credits**			
1.1	Costs eligible for SR&ED tax credit based on the 1987 criteria	$ 906,479,580	$ 831,294,903	$ 698,942,076
	PMPRB Block 5 items (current R&D pertaining to Medicines)	*869,195,990*	*803,853,856*	*678,865,604*
	PMPRB Block 6 (capital R&D pertaining to Buildings and Equipment)	*37,283,590*	*27,441,047*	*20,076,472*
1.2	Additional costs eligible for SR&ED tax credits based on the 2010 criteria	$ 604,000	$ 1,319,883	$ 5,230,711
	Salaries of Canadian personnel directly engaged in SR&ED eligible work performed outside Canada	*529,000*	*1,076,172*	*4,958,397*
	Cost of new capital equipment utilized between 50% and 90% for SR&ED purposes	*75,000*	*243,711*	*245,342*
	Cost of leased capital equipment utilized between 50% and 90% for SR&ED purposes	-	-	26,972
1.3	Other costs eligible for SR&ED tax credits not reported (i.e. non-PMPRB filers and other unreported amounts)	$ -	$ -	$ -
	Section 1 Total	$ 907,083,580	$ 832,614,786	$ 704,172,787
Section 2	**R&D expenditures and investments that do not qualify for SR&ED tax credits**			
2.1	Similar items as in 1.2 above but for:	$ 1,151,634	$ 10,751,092	$ 3,637,052
	Additional salaries of Canadian personnel directly engaged in SR&ED eligible work performed outside Canada above and beyond the 10% noted in 1.2 above	1,151,634	10,751,092	*2,672,377*
	Cost of new capital equipment utilized less than 50% for R&D purposes	-	-	*964,675*
	Cost of leased capital equipment utilized less than 50% for R&D purposes	-	-	-
2.2	Additional cost of individuals charged to a Canadian payroll above and beyond that which is already reported in Section 1, but which have a direct impact on the R&D function in Canada	$ 33,086,122	$ 43,404,302	$ 72,057,732
	Additional levels of activities for administration & supervision of employees directly engaged in SR&ED	*25,222,932*	*36,207,363*	*65,223,512*
	Operational personnel	*7,863,190*	*7,196,939*	*6,834,220*
2.3	Investments in used equipment utilized in R&D activities in Canada	$ 2,315,998	$ -	$ -
2.4	Amounts paid to Canadian pharmaceutical service providers related to the portion of milestone payments, management fees, etc. which have been excluded from SR&ED reporting	$ 18,472,376	$ 42,178,653	$ 17,490,532
2.5	Foreign entity payments made for R&D to be conducted in Canada by other companies or organizations	$ 18,576,070	$ 50,159,511	$ 80,312,914
2.6	Lease/rental costs related to research facilities infrastructure which are not already reported in Question 1.2 & 2.1	$ 2,338,026	$ 1,378,533	$ 1,343,849
2.7	Other R&D related activities for direct costs of employee labour and contract payments (not otherwise reported)	$ 46,949,832	$ 58,313,233	$ 64,491,824
	Pre-competitive research (i.e. due diligence phase of work)	*745,337*	*6,082,728*	*147,000*
	Economic and/or cost analysis component of pharmacoeconomic studies	*10,813,127*	*8,256,014*	*11,283,665*
	Pharmacovigilance research studies	*489,602*	*499,902*	*3,375,622*
	Collection of epidemiology information and/or screening established databases	*11,008,442*	*17,620,764*	*19,258,007*
	Research in bioethics or other social sciences or humanities	-	-	-
	Comparative effectiveness studies/trials	*1,092,194*	*2,134,384*	*471,107*
	Regulatory affairs/administration expenses in clinical trials applicatior	*1,271,644*	*1,079,853*	*3,281,925*
	Post launch or post-regulatory approval surveillance of new drugs as part of NOC/c commitment	*21,529,486*	*22,639,588*	*26,674,498*
	Unallocated	-	-	-
2.8	Investments in Canadian venture capital entities (i.e. only non-PMPRB filers and non-RX&D members)	$ -	$ 17,544,000	$ -
2.9	Payments for University Chair Endowments (i.e. Canadian research supporting graduate & post-graduate levels)	$ 6,473,295	$ 14,264,822	$ 7,973,667
2.10	Charitable Donations directed toward R&D in Canada	$ 8,557,131	$ 10,814,281	$ 6,213,452
2.11	Donations, grants and non-commercial sponsorships to entities that promote the health and well-being of Canadians, which is for clear support of documented research activities (otherwise, see item 3.1)	$ 21,794,189	$ 25,605,832	$ 45,213,260
2.12	Other items not otherwise reported in Section 1 or 2, which are R&D expenditures in Canada	$ 13,383,920	$ 3,815,033	$ 18,187,058
	Section 2 Total	$ 173,098,593	$ 278,229,292	$ 316,921,340
Section 3	**Non-R&D expenditures which are part of the industry's investment in Canada**			
3.1	Donations, grants and non-commercial sponsorships to entities that promote the health and well-being of Canadians for non-research funding/activities	$ 78,675,728	$ 70,623,084	$ 70,758,252
3.2	Product Donations: medicine provided through compassionate use and special access programs	$ 132,926,991	$ 142,289,831	$ 177,946,215
3.3	Community programs: contributions that address human welfare and social needs such as United Way/Centraide	$ 4,326,819	$ 4,950,096	$ 4,105,716
3.4	Education: contributions supporting education/training at the primary, secondary and post-secondary levels	$ 5,051,172	$ 2,531,680	$ 1,006,202
3.5	Environment: contributions that promote environmental responsibility, recycling, conservation, reclamation and land and wildlife preservation in Canada	$ 321,949	$ 399,390	$ 701,298
3.6	Arts and Culture: contributions that support the arts and other cultural activities in Canada.	$ 34,565	$ 65,375	$ 36,788
	Section 3 Total	$ 221,337,224	$ 220,859,456	$ 254,554,471
	Total Sections 1, 2 and 3	$1,301,519,397	$ 1,331,703,534	$1,275,648,598

Appendix 1.A

Summary of 2013 R&D Spending and Investments by Rx&D Members
2013 Provincial Allocations

Section 1 — R&D expenditures and investments that qualify for SR&ED tax credits

Question 1.1 — Costs eligible for SR&ED tax credit based on the 1987 criteria

	2013 $ Canadian TOTAL	PMPRB Block 5 items (current R&D pertaining to Medicines)	PMPRB Block 6 items (capital R&D pertaining to Buildings and Equipment)
Total - Provincial Allocations are as follows:	**$ 698,942,076**	*$ 678,865,604*	*$ 20,076,472*
NEWFOUNDLAND	**$ 3,315,150**	*$ 3,315,150*	*$ -*
PRINCE EDWARD ISLAND	**$ 32,008**	*$ 32,008*	*$ -*
NOVA SCOTIA	**$ 13,920,728**	*$ 13,920,728*	*$ -*
NEW BRUNSWICK	**$ 1,359,345**	*$ 1,359,345*	*$ -*
QUEBEC	**$ 238,770,094**	*$ 236,194,420*	*$ 2,575,674*
ONTARIO	**$ 344,698,713**	*$ 334,088,761*	*$ 10,609,952*
MANITOBA	**$ 4,013,089**	*$ 4,013,089*	*$ -*
SASKATCHEWAN	**$ 1,158,866**	*$ 1,158,866*	*$ -*
ALBERTA	**$ 62,362,204**	*$ 56,243,420*	*$ 6,118,784*
BRITISH COLUMBIA	**$ 29,311,879**	*$ 28,539,817*	*$ 772,062*
NWT, YUKON and NUNAVUT	**$ -**	*$ -*	*$ -*

Question 1.2 — Additional costs eligible for SR&ED tax credits based on the 2010 criteria

	2013 $ Canadian TOTAL	Salaries of Canadian personnel directly engaged in SR&ED eligible work performed outside Canada	Cost of new capital equipment utilized between 50% and 90% for SR&ED purposes	Cost of leased capital equipment utilized between 50% and 90% for SR&ED purposes
Total - Provincial Allocations are as follows:	**$ 5,230,711**	**$ 4,958,397**	**$ 245,342**	**$ 26,972**
NEWFOUNDLAND	**$ -**	*$ -*	*$ -*	*$ -*
PRINCE EDWARD ISLAND	**$ -**	*$ -*	*$ -*	*$ -*
NOVA SCOTIA	**$ 31,957**	*$ 31,957*	*$ -*	*$ -*
NEW BRUNSWICK	**$ 1,500**	*$ -*	*$ -*	*$ 1,500*
QUEBEC	**$ 21,560**	*$ 18,560*	*$ -*	*$ 3,000*
ONTARIO	**$ 245,804**	*$ 225,944*	*$ -*	*$ 19,860*
MANITOBA	**$ 1,500**	*$ -*	*$ -*	*$ 1,500*
SASKATCHEWAN	**$ -**	*$ -*	*$ -*	*$ -*
ALBERTA	**$ 4,928,278**	*$ 4,681,936*	*$ 245,342*	*$ 1,000*
BRITISH COLUMBIA	**$ 112**	*$ -*	*$ -*	*$ 112*
NWT, YUKON and NUNAVUT	**$ -**	*$ -*	*$ -*	*$ -*

Question 1.3 — Other costs eligible for SR&ED tax credits not reported (i.e. non-PMPRB filers and other unreported amounts)

2013 $ Canadian TOTAL
$ -

Total - Provincial Allocations - no amounts reported

Section 1 Total **$ 704,172,787**

Section 2 — R&D expenditures and investments that do not qualify for SR&ED tax credits

Question 2.7 — Other R&D related activities for direct costs of employee labour and contract payments (not otherwise reported)

	2013 $ Canadian TOTAL	Pre-competitive research (i.e. due diligence phase of work)	Economic and/or cost analysis component of pharmacoeconomic studies	Pharmacovigilance research studies	Collection of epidemiology information and/or screening established databases	Research in bioethics or other social sciences or humanities	Comparative effectiveness studies/trials	Regulatory affairs / administration expenses in clinical trials application	Post launch or post-regulatory approval surveillance of new drugs as part of NOC/c commitment
Total - Provincial Allocations are as follows:	**$ 64,491,824**	**$ 147,000**	**$ 11,283,665**	**$ 3,375,622**	**$ 19,258,007**	**$ -**	**$ 471,107**	**$ 3,281,925**	**$ 26,674,498**
NEWFOUNDLAND	***$ 503,105***	*$ -*	*$ 8,000*	*$ -*	*$ -*	*$ -*	*$ -*	*$ -*	*$ 495,105*
PRINCE EDWARD ISLAND	***$ 8,000***	*$ -*	*$ 8,000*	*$ -*	*$ -*	*$ -*	*$ -*	*$ -*	*$ -*
NOVA SCOTIA	***$ 274,841***	*$ -*	*$ 24,073*	*$ -*	*$ 8,036*	*$ -*	*$ 3,679*	*$ -*	*$ 239,053*
NEW BRUNSWICK	***$ 108,894***	*$ -*	*$ 8,000*	*$ -*	*$ -*	*$ -*	*$ -*	*$ -*	*$ 100,894*
QUEBEC	***$ 32,080,112***	*$ -*	*$ 2,795,535*	*$ -*	*$ 17,886,428*	*$ -*	*$ 205,606*	*$ -*	*$ 11,192,543*
ONTARIO	***$ 26,101,601***	*$ 147,000*	*$ 8,085,356*	*$ 3,375,622*	*$ 1,003,323*	*$ -*	*$ 107,747*	*$ 3,281,925*	*$ 10,100,628*
MANITOBA	***$ 373,470***	*$ -*	*$ 19,184*	*$ -*	*$ 9,592*	*$ -*	*$ 4,197*	*$ -*	*$ 340,497*
SASKATCHEWAN	***$ 100,065***	*$ -*	*$ 3,755*	*$ -*	*$ 1,877*	*$ -*	*$ 626*	*$ -*	*$ 93,807*
ALBERTA	***$ 4,163,454***	*$ -*	*$ 187,519*	*$ -*	*$ 90,759*	*$ -*	*$ 32,253*	*$ -*	*$ 3,852,923*
BRITISH COLUMBIA	***$ 762,282***	*$ -*	*$ 128,243*	*$ -*	*$ 257,992*	*$ -*	*$ 116,999*	*$ -*	*$ 259,048*
NWT, YUKON and NUNAVUT	***$ 16,000***	*$ -*	*$ 16,000*	*$ -*	*$ -*	*$ -*	*$ -*	*$ -*	*$ -*

Question 2.8 — Investments in Canadian venture capital entities (i.e. only non-PMPRB filers and non-RX&D members)

2013 $ Canadian TOTAL
$ -
$ -
$ -
$ -
$ -
$ -
$ -
$ -
$ -
$ -
$ -
$ -

Total - Provincial Allocations are as follows:
NEWFOUNDLAND
PRINCE EDWARD ISLAND
NOVA SCOTIA
NEW BRUNSWICK
QUEBEC
ONTARIO
MANITOBA
SASKATCHEWAN
ALBERTA
BRITISH COLUMBIA
NWT, YUKON and NUNAVUT

Appendix 2

Form-3 – Licensees, Revenues and Expenditures

General Information

Purpose

Section 88 of the *Patent Act* requires a patentee of an invention pertaining to a medicine (both patented and non-patented) sold in Canada to provide to the Patented Medicine Prices Review Board (hereafter referred to as the Board) information on scientific research and experimental development (SR&ED). Form-3 is designed to collect information on: the reporting patentee; the names and addresses of all licensees; gross revenue (net of taxes) from sales in Canada; and expenditures in Canada for SR&ED pertaining to all medicines for human and veterinary use.

Who must report?

All reporting patentees of medicines sold in Canada that filed a Form-2 during the calendar year must report gross revenues (net of taxes) and SR&ED expenditures on Form-3. Foreign residency of the reporting patentee does not remove the responsibility to report on Form-3. Foreign persons should report their gross revenues (net of taxes) from sales in Canada and expenditures on SR&ED in Canada as if they were Canadian taxpayers.

Reporting Period and Due Dates

Report Form-3 information annually; the due date is as follows:

Reporting Period	Due Date*
January 1 to December 31	March 1

* If a due date falls on a weekend the due date shall be the next business day.

The information to be submitted to the PMPRB must be provided using the electronic forms (including layout and file type) that are downloadable from the PMPRB Web site, under Regulatory.

Completed forms must be sent to the Board's e-mail address: compliance@pmprb-cepmb.gc.ca

Research and Development

Criteria of Eligibility

Research and development (R&D) expenditures reported on Form-3 must meet the criteria for claiming an **investment tax credit** in respect of scientific research and experimental development as set out in subsections 37(1) and 127(9) of the *Income Tax Act* and section 2902 of the *Income Tax Regulations* as they read on December 1, 1987. The term "Research and Development" as it appears on the reporting forms should be interpreted as meaning Scientific Research and Experimental Development (SR&ED).

It does not matter if the patentee actually files an income tax return for the reporting year in question, or if any of the research and development tax credits are actually claimed. Individuals and corporations who are not Canadian taxpayers should complete Form-3 as if they were Canadian taxpayers.

Revenue Canada publishes guidelines to claiming an investment tax credit for SR&ED expenditures. Whenever possible, the guidelines outlined in these materials should be used to report SR&ED expenditures on Form-3. Refer to the following documents as they read on December 1, 1987:[5]

Subsections 37(1) and 127(9) of the *Income Tax Act*

Sections 2900 and 2902 of the *Income Tax Regulations*

Revenue Canada Form T661

Interpretation Bulletin No. IT-151R3

Information Circular No. 86-4R2.

5 These documents are available by contacting the Secretary of the Board or the Compliance Officers.

Appendix 2

Definition – Scientific Research and Experimental Development

Scientific Research and Experimental Development may be defined as a "systematic investigation or search carried out in the field of science or technology by means of experiment or analysis". Technology refers to the systematic study of the application of scientific knowledge to industrial processes or product development.[6]

There are three main categories:

Basic research
Work undertaken to advance scientific knowledge without a specific practical application in view;

Applied research
Work undertaken to advance scientific knowledge with a specific practical application in view; and

Development
Use of results of basic or applied research to create new materials, devices, products or processes, or to improve existing ones.

Activities such as engineering or design, operations research, mathematical analysis or computer programming, and psychological research are eligible only if such activities directly support basic or applied research, or eligible development activities. Examples of **activities that cannot be included as SR&ED include**:

- market research or sales promotion;
- quality control or routine testing of materials, devices or products;
- research in the social sciences or humanities;
- prospecting, exploring or drilling for, or producing, minerals, petroleum or natural gas;
- commercial production of a new or improved material, device or product, or the commercial use of a new or improved process;
- style changes; or
- routine data collection.[7]

Expenditures – Scientific Research and Experimental Development

Note that only expenditures made **in Canada** on SR&ED carried on **in Canada** are allowed; to qualify as SR&ED expenditures on Form-3, the expenditures must conform to criteria for claiming the investment tax credit for scientific research and experimental development as set out in subsections 37(1) and 127(9) of the *Income Tax Act* and section 2902 of the *Income Tax Regulations* as they read on December 1, 1987.

Amounts that would normally qualify for a deduction (but not an investment tax credit) under subsection 37(2) as it read on December 1, 1987 (Research outside Canada) should not be included on Form-3. Foreign travel expenditures, including the salaries and benefits of a Canadian employee undertaking foreign travel, and any other expenditure that relates to SR&ED carried on outside Canada are all deemed to be "Research outside Canada". Therefore these are not to be included with SR&ED expenditures on Form-3. This is the case even if the expenditures were made in Canada, for example to a Canadian sub-contractor. Patentees who are uncertain as to whether to include certain expenditures as SR&ED expenditures on Form-3 should call Board Staff for advice.

Block-1
Year to which Information Applies

Enter the calendar year to which the information applies.

Block-2
Identification of the Reporting Patentee

State the name and address of the reporting patentee; in other words, the name and address of the company completing this form.

A reporting patentee is either a current patentee or a former patentee (see pages 3 and 4 under Interpretations for further information).

6 Revenue Canada Taxation, Information Circular No 86-4R2, Scientific Research and Experimental Development, August 29, 1988 – para. 2.3.

7 Ibid., para 2.5.

Appendix 2

Block-3
Licensee(s)/Other(s)

Provide the names and addresses of all licensees with whom the reporting patentee has a license (including compulsory license) or other agreement that entitles that person to exercise any rights in relation to a patent and which person sells a patented medicine in Canada.

Block-4
Revenues

Total Gross Revenues of the Reporting Patentee from all Sales of Medicines in Canada

Report the total gross revenues (net of taxes) from all sales of medicines[8] sold in Canada for human and veterinary use, that have a Drug Identification Number (DIN) under the *Food and Drug Regulations* or which have been approved for sale to qualified investigators or through Health Canada's Special Access Program under those Regulations. This includes both patented and non-patented medicines, whether sold by prescription or "over the counter" and whether for human or veterinary use.

Gross revenues from the sales of medicines should be reported on an accrual basis, i.e., in the year the product was shipped or left the plant gate.

Total Gross Revenues Received from all Licensees/Others in Canada

Report the total revenues (net of taxes) received (including royalties and license fees) from all licensees/others listed in Block 3, from the sale in Canada of medicines for human and veterinary use.

Revenues from licensees/others, in the form of license fees or royalties may be reported on an accrual basis (i.e., the year in which the medicines were shipped) or on a cash basis (i.e., the year the royalties were actually paid) but reporting should be consistent from year to year.

Block-5
Research and Development Pertaining to Medicines

Non-Capital Expenditures Incurred by the Patentee

Non-capital expenditures do not include general administrative expenses or factory overhead expenses that would have been incurred even if SR&ED had not been carried out. Expenses must all, or substantially all, be linked to SR&ED. All, or substantially all, means at least 90% of the time. For example, if a reporting patentee rents a photocopy machine that will be used approximately 50% of the time for SR&ED; no portion of the rental payments is considered to be an expenditure that is directly attributable to SR&ED. **The following cannot be included as non-capital expenditures in Block-5 under any circumstances:**

- capital expenditures or depreciation expenses (see Block-6)
- entertainment expenses
- advertising or selling expenses
- convention expenses
- legal or accounting expenses
- membership dues or fees
- fines or penalties
- expenditures made to acquire rights in, or arising out of, research and development (e.g., patent or registration fees)

Allowable non-capital expenditures should be broken out into the following categories:

A. Wages and salaries

Only include wages and salaries (and other related costs such as benefits) paid to employees who:

- are actually doing research work
- are directly supervising research work, or
- are directly supporting research work.

These expenditures must:

- include employee benefits and
- exclude bonuses or other remuneration based on the profits of the company.

8 Consult Glossary, on page 26, for definition of "medicine as" it applies to Form-3.

B. Direct material

All costs are to be the net laid-down price after deducting trade discounts, etc.

C. Contractors and sub-contractors

This category only covers contractors hired to carry out SR&ED on the reporting patentee's behalf. The expression "on the reporting patentee's behalf" distinguishes contractors from other expenditure categories such as payments to universities and granting councils.

D. Other direct costs

Include only the incremental general administrative and/or factory overhead costs incurred solely as a result of carrying on SR&ED activities.

E. Payments to designated institutions

Under this category, report payments to an approved university, college, research institute or other similar institution, to be used by that institution for SR&ED related to the reporting patentee's class of business. Amounts paid to carry out SR&ED on the reporting patentee's behalf should not be included here, but under section C pertaining to contractors and sub-contractors.

F. Payments to granting councils

Under this category, report payments to each granting council for eligible SR&ED activities. A granting council is an approved organization that pays an association, institution or corporation to do SR&ED related to the reporting patentee's class of business. Approved granting councils include:

- *Natural Sciences and Engineering Research Council*
- *Canadian Institutes for Health Research (formerly the Medical Research Council)*

G. Payments to other organizations

Include payments to other organizations for SR&ED related to the reporting patentee's class of business and not included under "E" (designated institutions) or "F" (granting councils) above.

Block-6
Total Capital Expenditures

Buildings – Annual Depreciation

Patentees should report annual depreciation of buildings used for SR&ED in Canada. The annual depreciation should be calculated at the rate of 4% of the qualifying capital cost per year over a maximum of twenty-five years. Depreciation is applied beginning with the year in which the building was purchased or acquired.

If a building was built or purchased to be used partly for SR&ED and partly for other purposes, and a **specific area** within the building is allocated solely for SR&ED use, a reasonable portion of the building's original cost can be used to calculate annual depreciation. Calculate the applicable portion of the building's cost by applying the proportion of SR&ED floor-space, to total floors space to the total original cost of the building.

> For example, a 1000 square meter building originally costing $400,000 has a 250 square meter wing allocated entirely for SR&ED activities. Since 25% (250 of 1000) of the total floor-space is devoted to SR&ED, calculate annual depreciation based on $100,000 (25% of $400,000). Annual depreciation would be 4% of $100,000 = $4,000.

If a building was originally used for purposes other than SR&ED, but is converted for SR&ED use, the cost of the conversion may be depreciated as above. However, do not include any part of the building's original cost in the reported annual depreciation.

To calculate the total annual depreciation of all buildings (and eligible conversion costs) dedicated to SR&ED, the annual depreciation of each should be calculated separately, and then totalled.

Total Capital Expenditures in the Year (buildings)

This line refers to capital expenditures made on buildings. Report total capital expenditures made during the reporting year on buildings in Canada to be used for SR&ED. Do not include capital expenditures made on land.

Appendix 2

If a building was built or purchased to be used partly for SR&ED and partly for other purposes, and a **specific area** within the building is allocated solely for SR&ED, a reasonable portion of the building's total cost can qualify as a capital expenditure on SR&ED. If part or all of an existing building is converted for SR&ED, the conversion costs may qualify as a capital expenditure on SR&ED. However, no part of the building's original cost or of its un-depreciated capital cost is eligible.

Equipment (capital expenditures)

Capital expenditures on equipment must be made in Canada. When an asset is purchased from a supplier outside Canada and is imported and used for SR&ED in Canada, the expenditure is considered to be made in Canada. Normal accrual accounting principles will apply to capital expenditures for SR&ED.

Expenditures on equipment partly used for SR&ED and partly used for other purposes may be included only if it can be demonstrated that **all, or substantially all** of the equipment's use is for SR&ED. "All, or substantially all" means the equipment is used at least 90% of the time throughout its expected useful life for SR&ED.

Block-7
Type of Research and Development – Medicine for Human Use

List expenditures (non-capital only) on SR&ED in Canada for medicines for human use according to "type of research" and "who carried out the research". The following definitions may help in interpreting the meaning of the categories "type of research" and "who carried out the research". These definitions also apply to Block-8.

Type of R&D

Basic Research

Basic – chemical
Systematic investigation undertaken to advance knowledge in chemistry by means of experimentation or analysis, without any practical application in view.

Basic – biological
Systematic investigation undertaken to advance knowledge in biology by means of experimentation or analysis, without any practical application in view.

Applied Research

Manufacturing processes
Experimental development of new or improved manufacturing processes in support of basic or applied research.

Note: Preclinical and Clinical Trials
Generally, preclinical trials involve animal testing while clinical trials involve human subjects. However, preclinical and clinical trials often overlap. Some drug evaluations may not follow the phases of evaluation described here. Reporting patentees should strive to report according to the phases defined below.

Preclinical Trials I
- Acute toxicity – single administration to two or more animal species
- Detailed pharmacological studies (main effect, side effects, duration of effect, etc.)
- Specifications or analysis of active substance
- Stability of active substance
- Specifications of inactive substances

Preclinical Trials II
- Pharmacokinetics
- Chronic toxicity (two animal species)
- Reproduction toxicological studies
- Mutagenicity and carcinogenicity studies
- Synthesis of active substance on technical scale
- Development of final dosage form(s)
- Analytical evaluation of final dosage form(s)
- Stability of final dosage form(s)
- Production of clinical samples
- Sub-chronic (sub-acute) toxicity (other animal species)
- Supplementary animal pharmacology
- Carcinogenicity trials
- Supplementary animal pharmacology

Appendix 2

Clinical Trials Phase I
- Tolerance in healthy volunteers
- Pharmacokinetics in humans

Clinical Trials Phase II
- First controlled trials on safety and efficacy in patients
- Chronic toxicity

Clinical Trials Phase III
- Therapeutic large scale trial at several trial centres for final establishment of therapeutic and safety profiles
- Proof of efficacy and safety in long term administration
- Demonstration of therapeutic advantages, if any
- Clarification of any interactions with concomitant medication
- Chronic toxicity (if required)

Other Qualifying R&D

This includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development."

Other qualifying research includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

Categories Describing Who Carried Out Research

Reporting Patentee
Reporting patentee is either a current patentee or a former patentee (see definitions on pages 3 and 4 under Interpretations). If you are no longer a patentee but were a patentee during part or all of the year Form-3 covers, you are required to report as a former patentee.

Other companies
Include corporations, resident in Canada, undertaking research on behalf of the reporting patentee, or research in the same class of business as the reporting patentee. Corporations carrying out the research do not have to be at arm's-length from the reporting patentee.

Universities
Include universities, colleges and other institutions, such as research institutes, approved under the *Income Tax Act*.

Hospitals
A facility licensed, approved or designated as such by a federal, provincial or territorial government.

Note: Hospital vs. University

There may be some uncertainty as to whether to classify, as hospital or university, research carried out in a teaching hospital or when scientists doing the work are affiliated with both a hospital and a university. If it can be ascertained where the monies for the research are being handled/managed (i.e., through the university or through the hospital), then these amounts should be assigned to reflect this. When payment is made directly to a scientist or other researcher with dual affiliations, the amounts should be included under the category that best describes the setting where the research took place.

Others
This category is reserved for expenditures that do not logically fit into any of the other categories.

Block-8
Type of Research and Development – Medicine for Veterinary Use

Expenditures (non-capital only) on SR&ED in Canada, pertaining to medicines for veterinary use, are to be listed according to "type of research" and "who carried out the research". The definitions in Block-7 above may help you interpret the categories of "type of research" and "who carried out the research".

Block-9
Source of Funds for R&D

Detail sources of funds for non-capital expenditures and capital equipment expenditures according to the categories described below. The total source of funds reported in this block is to correspond to the total of non-capital expenditures and capital equipment expenditures (Block-5 and Block-6 (Equipment)).

Appendix 2

Form 3 - Revenues and Research and Development Expenditures
Provided Pursuant to Subsection 88(1) of the *Patent Act* and Sections 5 and 6 of the *Patented Medicines Regulations*, *1994*

1 Year to which Information Applies:

2 Identification of the Reporting Patentee*

Patentee Name:
Patentee Address:

* **Please see section 79(1) of *Patent Act* for the definition of a "patentee." Note that a patentee is any person entitled to the benefits of a patent or to exercise any rights in relation to a patent. This includes patent holders, licensees or others.**

3 Licensee(s)/ Other(s)**

Name:	Name:
Address:	Address:

Name:	Name:
Address:	Address:

Name:	Name:
Address:	Address:

Name:	Name:
Address:	Address:

** **Those persons with whom the reporting patentee has a license (including compulsory license) or other agreement that entitles that person to exercise any rights in relation to a patent.**

4 Revenues

	For human use	For veterinary use
Total gross revenues of the reporting patentee from all sales of medicines in Canada	$	$
Total gross revenues received from all licensees/others in Canada (eg: royalties and/or other fees)	$	$

5 Research and Development Pertaining to Medicines

Non-Capital Expenditures Incurred by the Patentee		
A. Wages and salaries		$
B. Direct material (expenditures on material and supplies directly used)		$
C. Contractors and subcontractors	Universities	$
	Other	$
D. Other direct costs (other expenditures that are directly attributable to R&D)		$
E. Payments to designated institutions (university, college, research institute or other)		$
F. Payments to granting councils		$
G. Payments to other organizations		$
	TOTAL	**0.00**

6 Total Capital Expenditures

Building		Equipment	
Annual depreciation (in accordance with section 5 of the Regulations)	$		
Total capital expenditures in the year	$	Total capital expenditures in the year	$

Appendix 2

7 Expenditures in Canada for R&D pertaining to medicines for human use, broken down by type and who carried out the R&D

Type of R&D	Patentee	Other Companies	Universities	Hospitals	Others
Basic - chemical	$	$	$	$	$
Basic - biological	$	$	$	$	$
Manufacturing processes	$	$	$	$	$
Preclinical trials I	$	$	$	$	$
Preclinical trials II	$	$	$	$	$
Clinical trials Phase I	$	$	$	$	$
Clinical trials Phase II	$	$	$	$	$
Clinical trials Phase III	$	$	$	$	$
Other qualifying R&D	$	$	$	$	$
Total	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

8 Expenditures in Canada for R&D pertaining to medicines for veterinary use, broken down by type and who carried out the R&D

Type of R&D	Patentee	Other Companies	Universities	Hospitals	Others
Basic - chemical	$	$	$	$	$
Basic - biological	$	$	$	$	$
Manufacturing processes	$	$	$	$	$
Preclinical trials I	$	$	$	$	$
Preclinical trials II	$	$	$	$	$
Clinical trials Phase I	$	$	$	$	$
Clinical trials Phase II	$	$	$	$	$
Clinical trials Phase III	$	$	$	$	$
Other qualifying R&D	$	$	$	$	$
Total	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

9 Source of Funds for R&D

Internal funds	$
Arm's length person	$
Not arm's length person	$
Federal government	$
Provincial government	$
Other (specify)	$
Total	**0.00**

10 Expenditures in Canada for R&D pertaining to medicines for both human and veterinary use, broken down by province/territory and who carried out the R&D

Province where R&D was performed	Patentee	Other Companies	Universities	Hospitals	Others
NFLD.	$	$	$	$	$
P.E.I.	$	$	$	$	$
N.S.	$	$	$	$	$
N.B.	$	$	$	$	$
QUE.	$	$	$	$	$
ONT.	$	$	$	$	$
MAN.	$	$	$	$	$
SASK.	$	$	$	$	$
ALTA.	$	$	$	$	$
B.C.	$	$	$	$	$
N.W.T.,Yukon and Nunavut.	$	$	$	$	$
Total	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

11 Certified By: **(in accordance with Section 7 of the *Patented Medicines Regulations, 1994*)**

I hereby certify that the information presented is true and correct.

Signature of duly authorized person for the reporting patentee

Name

Title:

Organization

Date:

E-Mail:

Telephone Number: Fax Number:

FORM-3 Revenues and Research and Development Expenditures Provided Pursuant to Subsection 88(1) of the *Patent Act* (XLS)

APPENDIX 3

2010 version of SR&ED Pursuant to Subsection 248(1) of the *Income Tax Act* (Canada)

> *"scientific research and experimental development" means systematic investigation or search that is carried out in a field of science or technology by means of experiment or analysis and that is*
> *(a) basic research, namely, work undertaken for the advancement of scientific knowledge without a specific practical application in view,*
> *(b) applied research, namely, work undertaken for the advancement of scientific knowledge with a specific practical application in view, or*
> *(c) experimental development, namely, work undertaken for the purpose of achieving technological advancement for the purpose of creating new, or improving existing, materials, devices, products or processes, including incremental improvements thereto,*
> *and, in applying this definition in respect of a taxpayer, includes*
> *(d) work undertaken by or on behalf of the taxpayer with respect to engineering, design, operations research, mathematical analysis, computer programming, data collection, testing or psychological research, where the work is commensurate with the needs, and directly in support, of work described in paragraph (a), (b), or (c) that is undertaken in Canada by or on behalf of the taxpayer,*
> *but does not include work with respect to*
> *(e) market research or sales promotion,*
> *(f) quality control or routine testing of materials, devices, products or processes,*
> *(g) research in the social sciences or the humanities,*
> *(h) prospecting, exploring or drilling for, or producing, minerals, petroleum or natural gas,*
> *(i) the commercial production of a new or improved material, device or product or the commercial use of a new or improved process,*
> *(j) style changes, or*
> *(k) routine data collection;"*

In general, there have not been significant changes to SR&ED since 1987. In summary, the ability to include limited additional salaries of Canadian employees that spend time outside of Canada on eligible activities has been added as well as the ability to include capital and lease costs that are used between 50% to 90% of the time on SR&ED activities (i.e. as opposed to just those which are used greater than 90% of the time). However, the 2012 Federal Budget has made changes to some of the criteria included for SR&ED purposes that impact what is eligible for 2014 and future years.

In general, the following are types of eligible expenditures for SR&ED purposes:

- Salaries of Canadian personnel directly engaged in SR&ED eligible work performed in Canada and limited outside Canada (i.e. maximum of 10% of total eligible SR&ED labour costs in Canada)
- Salaries of Canadian personnel directly supporting SR&ED eligible work performed in Canada for:
  - Engineering and Design
  - Operations Research
  - Mathematical Analysis
  - Computer Programming
  - Data Collection
  - Testing
  - Psychological Research

- Contract payments made to Canadian entities: commercial laboratories, private practitioners, consultants, manufacturing and other companies, or other research-performing organizations
- Materials consumed or transformed during the performance of SR&ED eligible work in Canada
- New capital equipment or leased equipment used 50% or more of its useful life dedicated to SR&ED