CAPRA WORKSHOP REPORT

TO FILE OR NOT TO FILE: PROGRESSIVE LICENSING

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Submitted by:

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EXECUTIVE SUMMARY

Health Canada is developing a Progressive Licensing Framework that aims to equip the Canadian healthcare system with instruments for modern and innovative drug regulation. As part of the development of the Framework, Health Canada is seeking advice from key stakeholders. One such group is represented by CAPRA (the Canadian Association of Professional Regulatory Affairs) who, in collaboration with Health Canada, hosted a workshop on April 25th, 2007 to discuss elements of the proposed Framework.

Through the course of the workshop, participants discussed four key topics:

1. **Life-Cycle Management** – An approach that continually monitors the potential safety, quality and effectiveness of a drug, allowing for an ongoing evaluation of the benefits and risks throughout the drug's life-cycle.
2. **Evidence-Based Approach** – Evidence of the safety, efficacy and quality of a drug will continue to be crucial for decision-making. In addition, decisions will also consider a benefit/risk assessment and allow for the incorporation of other types of evidence (e.g. experiential) over the drug's life-cycle.
3. **Good Planning** – A mechanism that will manage the collection and analysis of new information throughout the entire regulatory life-cycle of a drug. It will include the requirement that a life-cycle management plan be filed for all drugs.
4. **Accountability** – This is defined as the ongoing requirement to justify drug decisions made by Health Canada and the industry.

In their discussions, several cross-cutting themes were highlighted by participants:

- Harmonization with other countries, provinces and the Common Drug Review was seen as being crucial to the success of the Framework. Without this, people were concerned that there would be limited incentives for companies to invest resources in meeting the new requirements, e.g. developing the life-cycle management plan.
- Improved communications both within Health Canada and between industry and Health Canada was seen as both a potential strength of the new Framework and a critical success factor. Coupled with this was the importance of a consistent and coordinated approach across Health Canada, with standardized implementation of new practices.
- It will be important to strike a balance between the protection of confidential commercial information (particularly in a drug's early stages of development) and disclosure/transparency. Participants raised concerns about who would have access to sensitive information and when.
- There needs to be more elaboration of the key concepts and information about how the processes will be implemented, including their applicability to different product types, e.g. traditional drugs versus new drugs.
- The interest in the Framework and its potential both for timelier reviews and for facilitating earlier patient access to a drug was tempered by concerns about the difficulty of collecting adequate life-cycle data through such mechanisms as Adverse Drug Reaction (ADR) reporting.

The next steps in the development of the Progressive Licensing Framework include mock framework exercises to test out different proposals in filing, licensing, and post-market reviews; and a one-day workshop in June on pharmaceutical quality.

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INTRODUCTION

Health Canada is modernizing the regulatory system for drugs. It is developing a Progressive Licensing Framework[1] that aims to provide the Canadian healthcare system with instruments for the modern and innovative regulation of drugs. It will go beyond the traditional pre-market evaluation of a drug to a system that supports access to promising new drug therapies while continuously monitoring and reassessing for potential safety, quality, efficacy and effectiveness throughout the product life-cycle. The framework will encompass the regulation of pharmaceuticals and biologics, including prescription and non-prescription products.

As part of the development of the Framework, Health Canada is seeking advice from key stakeholders. One such group is represented by CAPRA (Canadian Association of Professional Regulatory Affairs). A pharmaceutical industry organization, CAPRA's mission is to provide a forum in which pharmaceutical regulatory affairs professionals can interact and keep abreast of the ever-changing regulatory environment in Canada. Its mission has expanded to include both federal and provincial regulatory affairs for pharmaceuticals, biologics, medical devices, herbals, veterinary medicines, and radio-pharmaceuticals.

In collaboration with Health Canada, CAPRA hosted a workshop on the Progressive Licensing Framework. Held April 25th, 2007 in Montreal, Health Canada's objectives of the workshop were:

- to engage with the primary users of the regulatory system and inform them about the Progressive Licensing Framework;
- to gather feedback on specific components of the project; and
- to validate and confirm what was heard at an Open Space workshop held in November of 2006.

The workshop was attended by 207 participants from across the country. The list of companies they are affiliated with is provided in Appendix A. It was a collegial gathering and people were very engaged. The professionally-facilitated workshop began with two overview presentations to lay the groundwork for roundtable discussions on four key topics[2]:

1. life-cycle based approach;
2. an evidence-based approach;
3. good planning as an approach to drug regulation and
4. accountability as a foundation for drug regulation.

[1] For more on the Progressive Licensing Framework, visit the website www.healthcanada.gc.ca/pl
[2] These four topics are also the four core principles underlying the Progressive Licensing Framework.

Participants worked at round tables on the first two topics. This was followed by lunch and a brief plenary to share highlights. People then chose a different table to work at and discussed the last two topics. A final plenary gathered highlights and offered closing comments. The agenda is provided in Appendix B.

OPENING PRESENTATIONS

David K. Lee, Director of the Office of Patented Medicines and Liaison (Therapeutic Products Directorate) and Project Director for Progressive Licensing for Health Canada, provided an overview of the proposed Framework. He noted that while the current regulatory model tests a drug before it goes to market, the Progressive Licensing Framework recognizes that knowledge about a drug grows over time. Therefore the new model would also evaluate a drug after it is on the market, and throughout its entire life-cycle. He reviewed the four guiding principles for the Progressive Licensing Framework:

1. **Life-Cycle Management** – An approach that continually monitors the potential safety, quality and effectiveness of a drug, allowing for an ongoing evaluation of the benefits and risks throughout the drug's life-cycle.
2. **Evidence-Based Approach** – Evidence of the safety, efficacy and quality of a drug will continue to be crucial for decision-making. In addition, decisions will also consider a benefit/risk assessment and allow for the incorporation of other types of evidence (e.g. experiential) over the drug's life-cycle.
3. **Good Planning** – A mechanism that will manage the collection and analysis of new information throughout the entire regulatory life-cycle of a drug. It will include the requirement that a life-cycle management plan be filed for all drugs.
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Further to questions of clarification on life-cycle management and the implementation of the framework, the main issue raised in the Question and Answer period following the presentation was Adverse Drug Reactions (ADR). ADR reporting is a critical aspect of post-market pharmacovigilance and hence an important source of information for life-cycle management. Concerns focussed on the current voluntary nature of ADR reporting and the role of physicians and other health professionals in completing and filing such reports.

The second presentation was made by Mike Ward, Manager of the International Programs Division of the Therapeutic Products Directorate at Health Canada. He focussed on the need for and development of the pharmacuetical product quality component of the Progressive Licensing Framework. He examined the concept of Quality by Design (QbD) which can be defined as a "Deliberative design effort from product conception through commercialization" (M/ Nasr, FDA, 2007). QbD fits a life-cycle management approach and could be seen as integral to good planning. A number of implentation considerations were raised including the possibility that more than one approach may be needed to handle both traditional and new products.

In the discussion following the presentation, concerns focussed on the relationship between quality and effectiveness and on the benefits and challenges of coordinating quality by design (QBD) with other countries, including issues around proprietary

information. It was also clarified that there will be only one framework that would cover all product lines (e.g. including pharmaceuticals and Over the Counter products (OTCs)). Natural health products (NHPs) are not included at this point but the appropriate Health Canada directorate is pursuing a complimentary process and is currently conducting a review[3] of the NHP regulations.

Following the presentations, participants were invited to move to a table to discuss the first two topics. For each topic, four questions were posed and comments collected on worksheets:

1. Does the proposed approach make sense to you? Any areas for clarification?
2. What opportunities does this new approach present for you?
3. What potential obstacles might it present?
4. Do you have any suggestions for improvement?

LIFE-CYCLE BASED APPROACH

Life-cycle planning is a process that supports the ongoing collection of information about a drug throughout its life-cycle. Globally drug regulatory agencies are adopting a life-cycle approach to allow for continuous monitoring of the safety, effectiveness and quality of a drug. This also enables regulators to reassess benefit-risk profiles as more knowledge is gathered. Effective and timely communication of this new knowledge to health professionals, patients and the public would be an essential component of a life-cycle strategy. Another crucial element would be "early planning and engagement" where the manufacturer would meet with Health Canada (HC) to discuss plans for marketing in Canada, clinical testing or to discuss drugs that are being developed. The development of a "life-cycle management plan" for each new drug would be a possible requirement under this approach.

1. Does the proposed approach make sense to you? Any areas for clarification?

In general, participants did feel that the approach made sense, but that the "devil is in the details", particularly in terms of implementation. Clarifications were needed for:

- Products - Will the life-cycle approach be applied equally to old (including traditional, grandfathered and "me-too" drugs) and new drugs? Will Natural Health Products be included? How will Orphan Drugs[4] be treated?
- Process – How much information will companies be required to submit to HC? What about the confidentiality of company data? When does the drug life-cycle begin? How binding is the life-cycle plan – or will it be considered a living document? What happens when a drug company is bought by another? What will it mean for the Health Canada Special Access program (SAP)[5]?
- Coordination and communication – Is the approach in-line with directions in the EU and the US? Are provinces involved? Can the CDR (Common Drug Review) be

[3] For more information, visit: http://www.hc-sc.gc.ca/ahc-asc/public-consult/consultations/col/nhprr-rpsn/index_e.html

[4] Orphan Drugs are those drugs used to treat rare diseases. A rare disease is usually considered to be one that does not affect more than 650 to 1000 people per million persons.

[5] SAP is a program which provides limited and timely access to therapeutic products that cannot otherwise be sold or distributed in Canada to practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, unavailable or offer limited options.

integrated with the Progressive Licensing Framework to reduce overall review time? How will internal HC communication between units and directorates be improved?

- Resources – Will HC be adequately resourced to handle the increased workload? What about the potential burden on small companies?

2. What opportunities does this new approach present for you?

Participants were optimistic that the approach could mean improved communications within HC and between HC and industry. This could lead to greater trust, better partnership and improved feedback and constructive guidance from HC. People also noted that patient access could come earlier with enhanced post-market commitments and that off-label indications could become real indications with use over time. The potential for greater alignment with other regulatory bodies internationally and with provinces was also frequently mentioned.

3. What potential obstacles might it present?

A key obstacle was potential resistance within companies to a perceived increase in workload and companies choosing not to license in Canada. This could be mediated by ensuring international alignment and recognizing that there were gains to be made in the longer-term, even though the workload might be increased in the short-term. There were also a number of concerns raised about the current inadequacies of Adverse Drug Reactions (ADR) reporting and its role in risk management. The active participation of health professionals was seen as key to having adequate and reliable reporting for life-cycle management. The confidentiality of drug company data was also frequently mentioned as a possible obstacle.

4. Do you have any suggestions for improvement?

Key suggestions included:

- Need to have flexibility for lower-risk products… but also need to define the boundaries on flexibility.
- The infrastructure and mechanisms for ADR need to be improved and resourced.
- Ensure there is an incentive for industry, e.g. international alignment, integration with CDR.
- There needs to be clear guidance (including guidance documents) and feedback from HC to ensure a consistent approach across HC departments. Within HC, communication needs to be improved and a change in mind set may be required.
- A balance needs to be struck between the protection of confidential data and transparency and disclosure.
- Ensure that the life-cycle plan is a living document (rather than a final, approved one) - able to be evolve and adapt over time.

In the plenary report-back, tables were asked to highlight a top recommendation. Several commented that they supported the life-cycle concept and a risk-based approach that could provide for some flexibility across products. In addition, a number of tables asked that guidance be descriptive rather than prescriptive. This would encourage earlier communications between a company and HC and a two-way

flow of information and ideas. Participants also stressed the need for a process map for the implementation of the Progressive Licensing Framework and the life-cycle approach.

EVIDENCE-BASED APPROACH

While high standards of quality, safety and efficacy will continue to form the evidence base of the Progressive Licensing Framework, it will also assess the overall benefits and risks of a drug. Maintaining a positive benefit-risk profile would be key to keeping a drug on the market. Profiles would be created using many types of evidence and could include clinical practice environments, availability and performance of other therapies, anticipated use patterns and manageability of risks. Under a more flexible approach to licensing, a positive benefit-risk assessment could see some drugs (e.g. Orphan Drugs) being released to market earlier than might have occurred previously.

1. Does the proposed approach make sense to you? Any areas for clarification?

While the use of evidence makes good sense, there were a number of areas requiring clarification in terms of an evidence-based approach. These included:

- Concepts - The concept of evidence needs to be explained and clarified as to how it might be applied with different products, e.g. will the requirement for evidence be different for Orphan Drugs or those that currently fall under SAP? What is the relationship between evidence-based and risk-based? How are they different? What is the distinction between effectiveness and efficacy? How will these be measured and appropriate information collected?
- Process - How is the quality of a product going to be monitored? How will effectiveness be measured for off-label use? How is this approach different from the current notice of compliance with conditions (NOC-C)? For example, if a product is approved under an evidence-based approach, will a notice of compliance (NOC) be forthcoming if all is well after a certain period of time? Will this approach improve review times?
- Products - What will be the impact on traditional drugs?

2. What opportunities does this new approach present for you?

People saw a number of benefits to this approach, including getting drugs to the market faster through earlier approvals and timely reviews. They suggested that the approach could provide a better mechanism for drugs that have a special access status such as Orphan Drugs or those provided through SAP. There was a hope expressed that it might facilitate rolling submissions. Finally there was enthusiasm for the idea that a product monograph could be enhanced over time as more was learnt about the product's effectiveness, including through off-label use.

3. What potential obstacles might it present?

There was concern that the data requirements could be onerous, particularly for smaller companies. People noted that data collection could require the cooperation of experts, health professionals and/or better access to ADR reports and database. Concerns were raised about how and who defines a risk signal that may require some action. Effective implementation and an adequate infrastructure would be important.

Other obstacles were workload expectations, resource issues and potential disincentive for industry, including the cost of Phase IV trials.

4. Do you have any suggestions for improvement?

Key suggestions included:

- More detailed guidance is required, including an example of how HC would implement this approach.
- Need to ensure consistency between HC units in application of approach and information shared.
- This approach can't contradict a risk-based approach.
- There needs to be flexibility for special access drugs through SAP or Orphan Drugs.
- Two-way communications between HC and industry will be crucial. Communication between HC units is also essential to alleviate the workload on the sponsors, for example, being asked the same questions by two different bureaus.
- Efficacy, not effectiveness, should be the basis for licensing.

In the plenary report-back, people emphasized that the collection and use of data must be meaningful. An appropriate definition of evidence will need to be developed, accepting that there is an evolution of evidence in some therapeutic areas. The bar for acceptable evidence, and indeed the whole approach, should be applied consistently across Health Canada. Harmonization with regulatory bodies internationally, as well as with provinces and CDR was again noted. The practice of ensuring good knowledge management was highlighted, including getting the "best science" in the room (including HC's internal experts). There was also a recommendation made that HC consult with those in the industry responsible for clinical development. Participants cautioned that the approach not become a never-ending NOC-C type of approval and asked that care be taken to ensure it does not overburden stakeholders and HC.

GOOD PLANNING

Good planning can be described as a well-structured approach to the generation and exchange of information throughout the entire regulatory cycle. It would be used as a mechanism to manage the collection and analysis of new information that emerges over a drug's life-cycle. Health Canada is suggesting that there would be a requirement to file a life-cycle management plan for all drugs [see section 3]. Such plans would include any intended further studies, a comprehensive risk management strategy, a paediatric investigation plan, etc.

Good planning is particularly important where the evidence threshold of a drug may vary or where a more flexible licensing approach may be warranted. A pre-submission body of key experts and decision-makers would determine whether a flexible departure is warranted for a drug or class of drugs. This body would also provide advice on the types of studies that would be acceptable for initial market authorization and on the life-cycle management plans submitted by the manufacturer. The Progressive Licensing Framework needs to ensure that the proposed knowledge requirements are fulfilled so that the on-going benefit-risk profile remains positive.

1. Does the proposed approach make sense to you? Any areas for clarification?

In general, participants suggested that the approach makes sense as most companies do good planning already. There were a few important caveats such as that the approach not be used for well-known drugs or that the type of initial information required be kept at a high level. Participants felt that more details were needed before they could endorse it. There was also a comment that industry does not support the approval of drugs that have not been proven safe and effective, using the current NOC-C requirements as the acceptable benchmark.

A number of areas for clarification were flagged including:

- Products - Are some products exempt, e.g. traditional drugs, OTCs and NHPs? How does the approach affect generic drugs? Medical devices?
- Process - How early does this start in a drug's development, e.g. before Phase 1? How does QbD relate to this approach? Would the life-cycle plan be considered a living document? How often would it need to be updated?
- Review - Who would be members of the pre-submission body? How much authority would they be given? How will proprietary information be safe-guarded?

2. What opportunities does this new approach present for you?

Participants noted that the approach could lead to quicker patient access to some drugs. There was a suggestion that it could replace SAP. People noted that the approach would flag deficiencies early on and clarify and communicate life-cycle expectations between HC and industry. Expectations from federal/provincial/PMPRB could also be clearly defined and aligned to eliminate overlapping responsibilities. Defining the design space (QbD) would help companies more forward with changes to the product.

3. What potential obstacles might it present?

The global nature of most pharmaceutical companies means that clinical development is often not done in Canada. This may make it difficult for the Canadian arm to have access to development information early on. Indeed, there may be company resistance if there is not harmonization internationally on the need for a life-cycle management plan. There was concern about the level of resources required by both industry and HC - for example in the areas of case by case reviews and annual reporting. The need for appropriate training to ensure an adequate talent pool for industry to draw on was noted. There was a caution about planning too far in advance given rapid changes in technology. Finally there needs to be enough financial incentive to commit the required resources – people worried that this may not be the case in some areas such as rare diseases.

4. Do you have any suggestions for improvement?

<u>Key suggestions included:</u>

- The advantages for a corporation need to be expanded on. Harmonization internationally and with provinces would be essential to justify the costs of developing the plans.

- Communication is key. HC needs to take a team approach and ensure continuity and coordination across divisions. There needs to be a good mechanism for knowledge transfer within HC and with industry.
- There needs to be more details and a better defined process. Perhaps a pilot should be conducted before it is rolled out to industry.
- The applicability of the approach to generic drugs needs to be outlined.
- The plan must be a living document, with a focus on information and knowledge-sharing, rather than on enforcement.
- Ensuring confidentiality of information is essential.
- The benefits of having the plan reviewed by a larger cross-section of people, including patient group representatives, need to be determined. Having too broad an input early on may not be useful or desirable.

In the plenary report-back, several tables stressed the importance of communication – between HC and industry and within HC. One group suggested that the Therapeutic Products Directorate (TPD) have a core team that's involved with a particular drug submission from start to finish to ensure knowledge transfer. Another groups suggested that the topic be renamed "good communication of planning". The importance of global harmonization was emphasized as was the suggestion that the plans not be required too early on in the drug development process.

ACCOUNTABILITY

Accountability refers to the on-going requirement to justify decisions concerning drugs that are made by Health Canada and industry. This includes decisions regarding clinical trials, marketing authorizations, labelling and post-market activities. Specific mechanisms to ensure accountability will be embedded into the life-cycle process to ensure consistency and transparency. Examples of accountability could be justifying why a drug has qualified for a flexible licensing process or clearly stating the basis for any conditions set upon market authorization. Accountability would also include a well-structured periodic review of the framework itself.

1. Does the proposed approach make sense to you? Any areas for clarification?

Participants were generally supportive of the approach. A number of areas were flagged for clarification:

- Concepts - What is the definition of accountability? Right now it seems to apply only to HC. How is industry expected to demonstrate accountability? What is the difference/interaction between accountability and transparency? How is this approach different than the current Summary Basis of Decision?
- Confidentiality - What does the term "publicly" mean? How much transparency is required with the public? What about proprietary information? How does Access to Information (ATI) connect?
- Process - More clarity is required as to "specific mechanisms". Who will do the mandatory periodic review of Progressive Licensing Framework and how often will it be done? Will it mean a change in regulations each time, as this could become burdensome for all?

2. What opportunities does this new approach present for you?

A common thread throughout the discussion was the expectation that the focus on accountability would lead to timelier and higher quality review of a dossier. It should also lead to greater clarity in decision-making and more opportunity to share what's being learnt about what works and what doesn't. Follow-through and commitment on advice HC is giving would be enhanced and would be seen in tangible ways. For example, at the time of submission, HC would respect the advice it provided in pre-submission discussions and industry would be accountable for having taken the advice. Participants also noted that greater transparency and accountability might improve the industry's public image and increase public confidence in the products.

3. What potential obstacles might it present?

There were concerns raised about the balance between confidentiality of information with accountability and transparency. For example, some suggested that there needs to be more data protection for non-patented drugs. The possibility of increased liability was noted as were worries that information released may be taken out of context and misinterpreted by health professionals and/or the public.

4. Do you have any suggestions for improvement?

Key suggestions included:

- Greater clarity about industry's accountability.
- Roles and responsibilities for the entire process need to be defined. The accountability of health professionals in ADR also needs to be considered.
- Add resources to the Summary Basis of Decision areas.
- Clarify the point in the life-cycle where accountability will be monitored, how often and by whom.
- Detail the mechanisms that will be used to ensure accountability. For example, could accountability to industry for a timely and quality review be enforced by an ombudsman-type role?

In the plenary report-back, a number of tables reinforced the notion that accountability needs to be at least two-way, for HC and industry. Some suggested it should be broader than this and include other stakeholders such as health professionals.

CONCLUSIONS AND NEXT STEPS

Both Health Canada and CAPRA representatives made closing comments, thanking delegates for their input and deliberations throughout the day. The next steps in the process of developing the Progressive Licensing Framework include a number of mock framework exercises (May-June, 2007) to test out different proposals in filing and licensing and a one-day workshop on pharmaceutical quality regulation to be held June 28, 2007.

Evaluation forms were completed and responses indicate a high degree of satisfaction with the event. In particular people appreciated the opening presentations and the

presence of Health Canada staff. They valued the high level of participant interaction in the round table discussions. A few commented that they found some of the topics/ideas were too conceptual and preliminary to consult on, as it was difficult to see how they would be applied or what difference they would make in practice. Others were pleased that Health Canada was bringing the ideas forward for discussion while they were still at a conceptual level.

APPENDIX A– PARTICIPATING COMPANIES

Company
Abbot Laboratories
Alberta Cancer Board – Cross Cancer Institute
Alcon Canada Inc.
Allergan Inc.
Alpharma Canada Corporation
Altana Pharma
Amgen Canada
Apotex
Astellas Pharma Canada Inc.
AstraZeneca Canada Inc.
Bausch & Lomb
Baxter Corporation
Bayer Inc.
Bimeda –MTC Animal Health Inc.
Biogen Idec Canada Inc.
BiomedEx
Boehringer Ingelheim (Canada) Ltd.
Bristol-Meyers Squibb Canada
CanReg Inc.
Carexa Inc.
Ceruleus Inc.
Cobalt Pharmaceuticals
Draximage
Draxis Pharma
Elanco Animal Health
Eli Lilly Canada
Erfa Canada Inc
Ferring Inc.
Galderma Canada
Genepharm Inc.
Generex Biotechnology
Genpharm Inc.
Genzyme Canada Inc.
Gilead Sciences Canada Inc
GlaxoSmithKline Inc.
Graceway Pharmaceuticals
Health Canada
Hoffmann-La Roche Ltd
Internet Canada Ltd
Janssen-Ortho Inc
Johnson & Johnson Inc.
Mayne Pharma Canada Inc.
McCarthy Consultant Services
McNeil Consumer Healthcare

Merck Frosst Canada Inc.
Novapharm Ltd
Novartis Pharmaceuticals Canada Inc.
Novo Nordisk A/S
Novo Nordisk Canada Inc.
Novopharm Ltd
Organon Canada Ltd
Paladin Labs Inc.
Pfizer Canada Inc.
Pharmaceutical Partners of Canada
Pharmaffair Inc.
Pharmascience Inc.
Phibro Animal Health
Procter & Gamble
Purdue Pharma
Quality and Compliance Service Inc.
Ratiopharm Inc.
Sandoz Canada
Sanofi Pasteur
Sanofi-aventis Canada Inc.
Schering-Plough Canada Inc
Serono Canada Inc
Shire BioChem Inc.
Solvay Pharma Inc.
Spectrum Medical Market Consultants
Stiefel Canada
Talecris Biotherapeutics, Inc
Tevaa Neuroscience
UB Pharma
UCB Inc
Valeant Canada Ltd.
Vetoquinol Canada Inc.
Virbac ATT, Inc.
Wyeth Canada Inc

APPENDIX B– WORKSHOP AGENDA

TO FILE OR NOT TO FILE

Post Approval Changes and Progressive Licensing
Le Centre Sheraton Montreal
April 25, 2007

8:00-8:30 *Continental Breakfast*

8:30-8:35 *Opening Remarks*

8:35-9:35 **Presentation on the Progressive Licensing Framework**
David K Lee, Office of Patented Medicines and Liaison, TPD

9:35-10:05 **Modernization of the Quality Regulatory Framework**
Mike Ward, International Program Division, TPD

10:05-10:30 *MORNING BREAK*

10:30-10:45 **Explanation of World Cafe Concept: Discussion of Progressive Licensing Framework**
World Cafe Facilitator

10:45-12:15 **Discussion on Progressive Licensing Framework: Part 1**
1. Life-Cycle based Approach 2. Evidence-based Approach

12:15-1:30 *LUNCH*

1:30-2:00 **Report Back to Plenary**

2:00 – 3:00 **Discussion on Progressive Licensing Framework: Part 2**
3. Good Planning

3:00-3:15 *AFTERNOON BREAK*

3:20 – 3:45 **Discussion on Progressive Licensing Framework: Part 2**
4. Accountability

3:45-4:15 **Report Back to Plenary Session**

4:15 *Closing Remarks*