PRI

Pharmacare Review
Implementation

FORMULARY REVIEW

Final Report

November 2005

Prepared by Business Management &
Stakeholder Engagement Branch

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Summary of Proposed Changes to Formulary Management Processes

PharmaCare's Formulary Management (FM) project has included consultation with stakeholders (public, health care professionals and drug manufacturers) to gather suggestions and identify priorities. Three main priority areas emerged: improving FM process effectiveness and efficiency, transparency and communication. The following is a summary of proposed PharmaCare FM strategies that address these priority areas.

Effectiveness and Efficiency

- Revised terms of reference for DBC – expand membership; establish fixed dates and locations for meetings etc.
- Establish performance targets in Therapeutic Initiative contract
- Senior Pharmacist to make listing decisions for generic drugs
- Implement redesigned business processes.
- Install a drug submission tracking system.
- Implement a performance measurement system to monitor, report, and improve the timelines associated with the drug review process.

Transparency

- Adopt a fixed schedule for Drug Benefit Committee (DBC) meetings with clear deadlines for submissions. This will allow stakeholders to anticipate timelines for processing the drug submissions and communicating the outcomes.
- Redefine the requirements for submissions and post a submission check list on the PharmaCare website.
- Publish a process handbook that clearly defines the review process on the PharmaCare website and update it regularly.
- Publish the terms of reference for the DBC and Therapeutic Initiative (TI) on the PharmaCare website. The terms of reference will define the mandate, scope, responsibilities, reporting structure, composition, membership, meetings, and approximate meeting schedule, etc.

Communication

- Issue an acknowledgement of receipt for each drug submission (excluding generics).
- Publish the status of each drug submission on the PharmaCare website.
- Hire an FM Business Manager with the mandate to maintain an ongoing dialogue with drug manufacturers and other stakeholders.
- Allow manufacturers to request status updates directly from the FM Business Manager.
- Update the web-based benefit list and make it more user-friendly.

The following stakeholder suggestions require further analysis and are referred for future consideration:

- Rotate clinical advisors
- Allow industry to meet with committee members to discuss submissions
- Publish DBC recommendations

The following stakeholder suggestions have been considered and are not supported:

- Do not require a committee review for CDR drugs
- Process drug submissions in parallel with Notice of Compliance (NOC) processing

Report Objectives

This is a draft Final Report outlining improvements to Formulary Management (FM) practices, processes, and procedures.

The purpose of this report is to articulate a re-engineered formulary process that maximizes capacity. Key features of the new process include:

- managing through structured / formalized processes;
- managing through the appropriate delegation of responsibilities;
- utilizing streamlined decision points;
- increasing the transparency of FM processes;
- continuing to use an evidenced-based approach to making listing decisions; and
- using appropriate technology.

Participants

Meetings, interviews and workshops were conducted with a number of Ministry of Health staff and executives from PharmaCare as well as other business units. In addition, several meetings were held with stakeholder groups including:

- Better PharmaCare Coalition
- BC Pharmacy Association
- Canadian Association of Chain Drug Stores
- BC Medical Association
- Rx&D (and member companies)
- CGPA (and member companies)

Project Objectives

The PharmaCare program plays an integral role in British Columbia's public health care system. In order to continue to provide access to high quality patient care in a cost-effective manner, it is critical that the evidence-based program policies be supported with business processes that are effective, efficient, and transparent.

In 2003/2004, a Program Review was carried out to examine current processes and identify opportunities for improving the effectiveness and efficiency of the PharmaCare program. One of the areas highlighted for enhancement through the Program Review was the Formulary Management process. As a result, planning began in the summer of 2004 and the Formulary Management project was initiated in 2005.

The key objectives of the project are defined as follows:

- re-engineer formulary business processes and procedures to achieve greater efficiency;
- maintain an evidence-based process;
- integrate appropriate stakeholder involvement into the formulary process;
- ensure project recommendations are feasible within Ministry timelines, capacity and resources; and
- ensure project recommendations are cost-effective and sustainable.

Scope

The focus of this project includes only the Formulary Management review process, which operates within the context of the larger PharmaCare program.

PharmaCare processes that are *outside* the scope of this project include:

- Special Authority
- Policy Development & Management
- PharmaCare Operations – HIBC

The policies that define the evidence-based review process are also *out-of-scope* of this project.

The development of the revised Formulary Management process will build on work completed to date. It will be carried out in two phases:

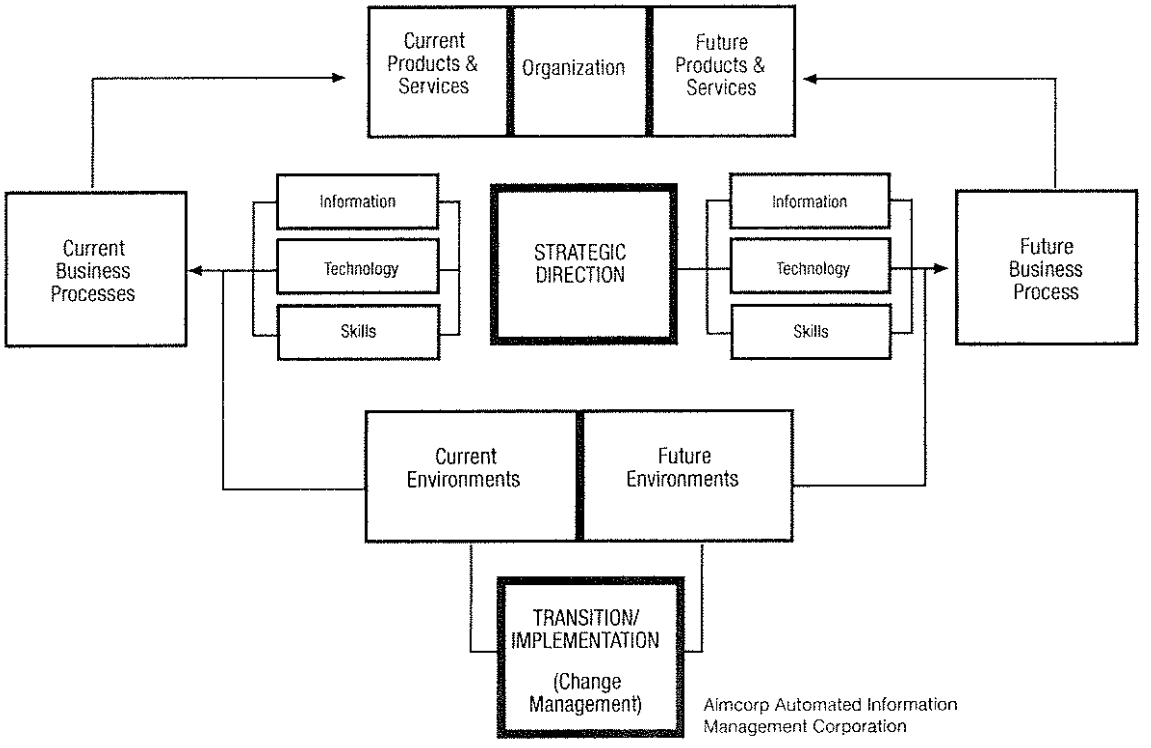
Phase 1

- Review and document current Formulary Management processes and procedures
- Analyze the current process for gaps, inefficiencies and duplications
- Develop interim report
- Conduct multilateral meeting with stakeholders
- Provide overview of interim report
- Gather information and input from stakeholders

Phase 2

- Document revised process
- Develop preliminary implementation framework
- Present draft final report to stakeholders
- Provide opportunity for stakeholders to give feedback on draft final report

Business Process Re-engineering Methodology



This methodology is designed specifically for conducting Business Process Re-engineering (BPR) reviews in service environments. It has a broader perspective with the focus on improving productivity and proficiency on a continuous basis, optimizing the performance of business processes by taking advantage of relevant information and compatible technologies, and capitalizing on the skills and expertise of personnel. It describes an integrated, enterprise-wide approach to renewing services through optimizing the current business practices and applying information technology to improve the overall performance.

This methodology is based on the following concepts and philosophies:

- The information engineering concept – treating information as a strategic resource (James Martin);
- The principle of continuous improvement requires a paradigm shift, involving everyone, employees and managers alike, and ensures the ongoing rearranging and redesigning of elements of the organization as well as processes;
- the Activity Based Costing/Management (ABC/M) methods to cost activities, products, and services;
- the Alternative Service Delivery (ASD) methods by ensuring service delivery analyses are based upon all options, internal and external;
- the ISO 9000 concept by adopting the three elements – documenting the business processes, following the documented business processes to operate the business, and auditing to ensure the accuracy and consistency of these processes; and
- Total Quality Management following Business Objectives, Performance Measurements, Production and Delivery, Skills Requirements, Management Role, Organizational Structure, and Authority.

This methodology provides:

- **Flexibility:** customize the methodology to meet the specific business requirements with the intention to produce the best results and make necessary changes without jeopardizing the objectivity.
- **Consistency:** eliminate redundancy among business processes, removing the bottlenecks and ensuring smooth information flow.
- **Relevancy:** sustain relevancy in linking, merging, eliminating business processes to improve overall productivity and proficiency.

Methodology Overview

This methodology consists of four phases:

PHASE 1 – Current Environments (AS-IS MODEL)

This phase documents the current activities and practices through working sessions, meetings, interviews, and documentation. As a result, the AS-IS Business, Information, Technology, Organizational Models and various Matrices are developed in the modeling tool. The observations made during this phase are documented and communicated to the next phase.

The following is defined for each documented business process:

- Corporate definition for Function, Process, and Activity
- Service/product supported by Process
- Internal/External clients
- Resources consumed (optional)
- Current technology (systems, networks, etc) used
- The Information Flow associated with each process
- Organizations involved in each process and their role (organizational structure)
- Geographic location
- Any regulatory or administrative authorities exercised
- Level of service expected based on any Service Level Agreements (SLAs) in place

PHASE 2 – Strategic Directions

This phase defines the mission, vision, goals, objectives, strategic drivers, critical success factors, and performance measures in order to establish the strategic directions for the subsequent phases. It also defines and documents the expectations for the functionality of each process, highlighting the quantifiable parameters that become the strategic drivers for optimizing the total environments. In some cases, it also includes conducting a Strength, Weakness, Opportunity, and Threat (SWOT) analysis. Strategic direction will help to establish the parameters for the target environment that the TO-BE model will attempt to meet. This phase is done in parallel to Phase 1.

PHASE 3 – Future Environments (TO-BE MODEL)

This phase establishes the business rationale for the services, then determines how the services will be delivered. The strategic directions and strategic drivers help to create the future model.
The following analyses are conducted:

- **Effectiveness and Efficiency Analysis:**
  Each business process is tested to determine if the process is supporting the mandate (Effectiveness) and if it is being done efficiently (Efficiency). The answer to these questions will help to flag each business process and associated activities accordingly.

- **Seamless Services Analysis:**
  All business processes are reviewed to determine the possibility of conducting required processes through a single window, eliminating functional barriers. This requires redesigning the way services are now provided, including a focus on client service and client satisfaction.

- **Streamlining Analysis:**
  The process between the initiation of functions and their completion is streamlined. This will require re-aligning staff functions from task-oriented to results-oriented, and potential reinvestment in staff training.

- **Optimization of Process Flows:**
  Each valid business process is reviewed, evaluated, and optimized vertically and horizontally, identifying opportunities for re-engineering. This includes the identification of methods/techniques for improvement, elimination of unnecessary activities, identification of outsourcing opportunities, identification of activities for merging/grouping, and exploration of revenue generation opportunities.

- **Review of Best Practices:**
  Relevant best practices from similar organizations are reviewed to identify and apply lessons learned.

- **Identification of Technology Opportunities:**
  Automation opportunities to further streamline business processes and integrate business information will be identified to support the redesigned business processes. The following technologies may be explored:
  - Electronic Commerce;
  - Internet Technologies including Portals;
  - Smartcard;
  - Wireless Technologies; and
  - Expert Systems.

- **Identification of Alternate Service Delivery (ASD) Opportunities:**
  An analysis is conducted to determine whether or not there are any opportunities for ASD.

As a result, the TO-BE model is created, including the business, process, information, technology and organizational models. Performance indicators are set up for each redesigned process.

PHASE 4 – Transition/Implementation/Change Management Strategies

A final analysis is conducted to identify the recommended changes required to bridge the gap between the AS-IS models and the proposed TO-BE models. Models and business cases are assessed to determine the final process, information technology, and legislation re-alignments required. Recommendations are developed to deal with the organizational re-alignment, identifying the organizational structure and training requirements to support the proposed TO-BE model. Legislation roadblocks are analyzed and documented to include an assessment of potential for influencing the legislation and the course of action necessary for clearing the roadblock.

The proposed changes will be analyzed against the AS-IS model to determine (quantify) the potential impact on the current functional structure and the potential efficiency gains. The proposed TO-BE model will also be analyzed against the Strategic Directions as well as the overall expectations of stakeholders.

The proposed TO-BE model is analyzed again to identify implementation considerations, issues and plans. These elements are assessed to produce a high-level implementation strategy for the identified opportunities, identifying key activities, potential costs, timelines and inhibitors.

PharmaCare Formulary Management Overview

Who we are

The Formulary Management Unit of PharmaCare is responsible ensuring that decisions to list drugs on the provincial formulary are evidence-based and cost-effective. The FM Unit manages the processes related to reviewing and making listing decisions for the following:

- New Chemical Entities
- New Combinations
- New Indications for Old Drugs
- Modifications to Coverage
- Line Extensions
- Generic Drugs

Drug Benefit Committee members and Therapeutic Initiative members were also consulted. In addition, interviews and site visits were also conducted with drug plan managers from other provincial jurisdictions.

Understanding PharmaCare Formulary Management Business Structure

The business structure of the Formulary Management Unit can be explained through an examination of the linkages between the unit's business function (managing the provincial drug formulary), business processes (service activities, support activities, and business sustaining activities as defined below) and corresponding activities/sub-activities.

Business Functions: the units of business processes that organizations pursue in order to meet their mission and objectives. They are defined as the largest unit of business processes in an organization. For example, "Manage Drug Formulary" is a business function.

Business Processes: a group of business activities that are designed to perform certain tasks in an organization to support the purpose of a business process. For example, "Review and List Trade Name Drugs", and "Review and List New Generic Drugs" are the business processes that support the business function, "Manage Drug Formulary".

Business Activity: a unit of work performed within an organization. Activity is an action that consumes resources. Activity could represent a number of logical business sub-activities. For example, "Coordinate Submission Activities", and "Prepare for DBC Meeting" are the activities that support the business function, "Review and List New Trade Name Drugs".

Business Sub-Activity: If a business activity becomes complex and complicated, it is divided into several sub-activities. Similar to a business activity, a business sub-activity is also designed to produce a specific result. It is initiated by a particular kind of event, has a well-defined beginning and end, and is usually completed in a relatively short period of time. For example, "Conduct Drug Coverage Survey", and "Provide Comparator Lists and Expert Reviewer Lists", are sub-activities that support the business activity, "Coordinate Submission Activities".

Service Activities: all activities directly supporting the service. For example, "Review and List New Generic Drug Submission".

Business Sustaining Activities: all activities performed to sustain the business. For example, "Attend Weekly Management Meetings".

Support Activities: all activities performed to support the Service Activities and Business Sustaining Activities. For example, "Receive and Log New Drug Submissions".

In order to gain an understanding of the complexity and linkages of the various functions within the Formulary Management process, the summary table below lists the number of functions, processes, activities and sub-activities that are occurring in the Formulary Management unit.

Description	Business Function		Business Processes		Business Activities		Business Sub-Activities	
	CURRENT	FUTURE	CURRENT	FUTURE	CURRENT	FUTURE	CURRENT	FUTURE
Service Activities	1	1	3	3	7	13	31	112
Business Sustaining Activities			5	1	22	8	22	37
Support Activities			5	1	25	4	25	19
Totals	1	1	13	5	54	25	78	168

Explanation

The following analyses were conducted on the business processes and activities that were documented and presented in the Interim Report:

- Effectiveness and Efficiency Analysis
- Seamless Services Analysis
- Streaming Analysis and
- Optimization of Process Flows

As a result of these analyses, some business processes and activities were:

- Deleted
- Merged
- Added
- Redesigned (modified)

Each business process is supported with an adequate number of activities and sub-activities. This has resulted in an increase in the overall number of defined activities. The purpose of doing this is to provide a comprehensive business structure that maximizes productivity and ensures the delivery of high-quality outputs.

Technology Requirements

Current Technology

- **Formulary ProjectLink node** – a dedicated PharmaCare intranet site that is used for sharing information in a secure environment
- **LAN Foldering System** – this is used to share documents within work units

- **Standard Software**
    - MS Word
    - MS PowerPoint
    - MS Excel
    - MS Access
    - HP Scanner
    - Adobe Acrobat
    - Teleconferencing
    - Internet/Intranet
    - Email

The Formulary Management Unit has internally developed, designed, and is currently using a Drug Submission Tracking System that is based in MS Excel. This system can be improved upon and/or replaced with a more sophisticated system in the near future.

Future Technology

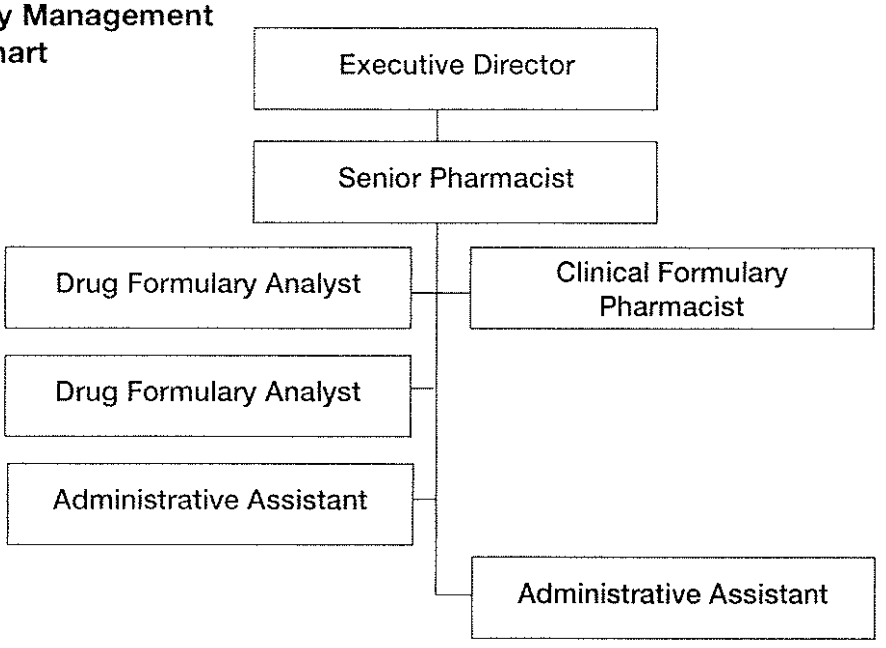
- Drug Submission Tracking System – to keep track of Drug Submisions at various stages of processing
- Knowledge Management System – collect and store meaningful information to share with users with the same interest

- Formulary ProjectLink node
- LAN Foldering System
- Standard Software

*Changes are indicated in red

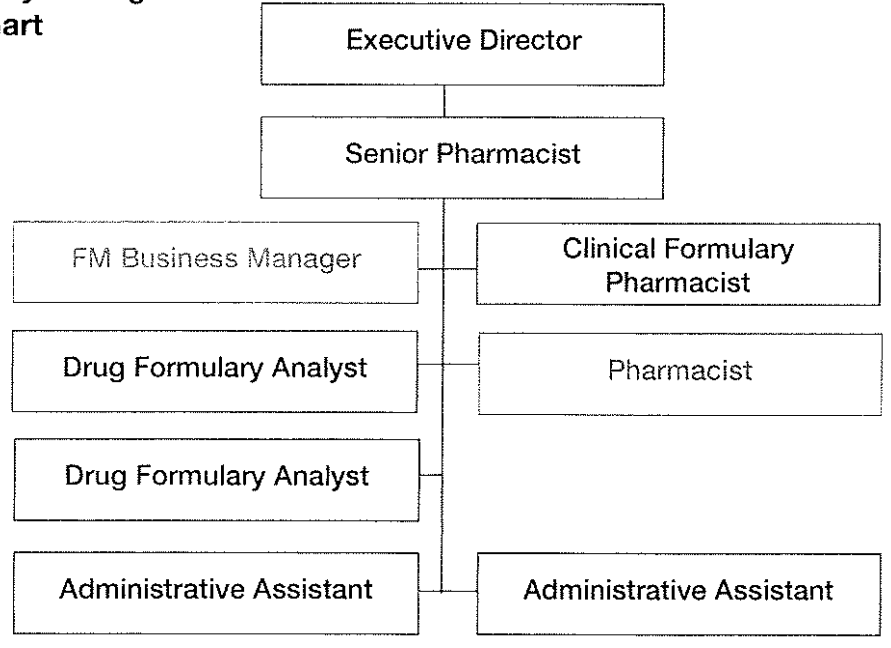
Personnel Requirements

Current Formulary Management Organizational Chart



*Shaded boxes indicate new positions as of March 2005

Proposed Formulary Management Organizational Chart



*Red boxes indicate proposed new positions

Proposed Functions

FM Business Manager

The proposed new Business Manager will primarily be responsible for non-clinical management activities including stakeholder relations related to FM, correspondence, and the management of internal business supporting activities. The Business Manager will also be responsible for managing the Analysts, monitoring their performance and ensuring the timely completion of research and analysis.

Pharmacist

The proposed new Pharmacist will primarily be responsible for the review and listing decisions related to CDR and Non-CDR Drugs. Activities will include (but not be limited to) interacting with the DBC and TI as required, preparing briefing materials and reviewing correspondence. The new Pharmacists may also be called upon to assist with the review and listing of the Generic Drugs.

Materials Requirements

Current materials

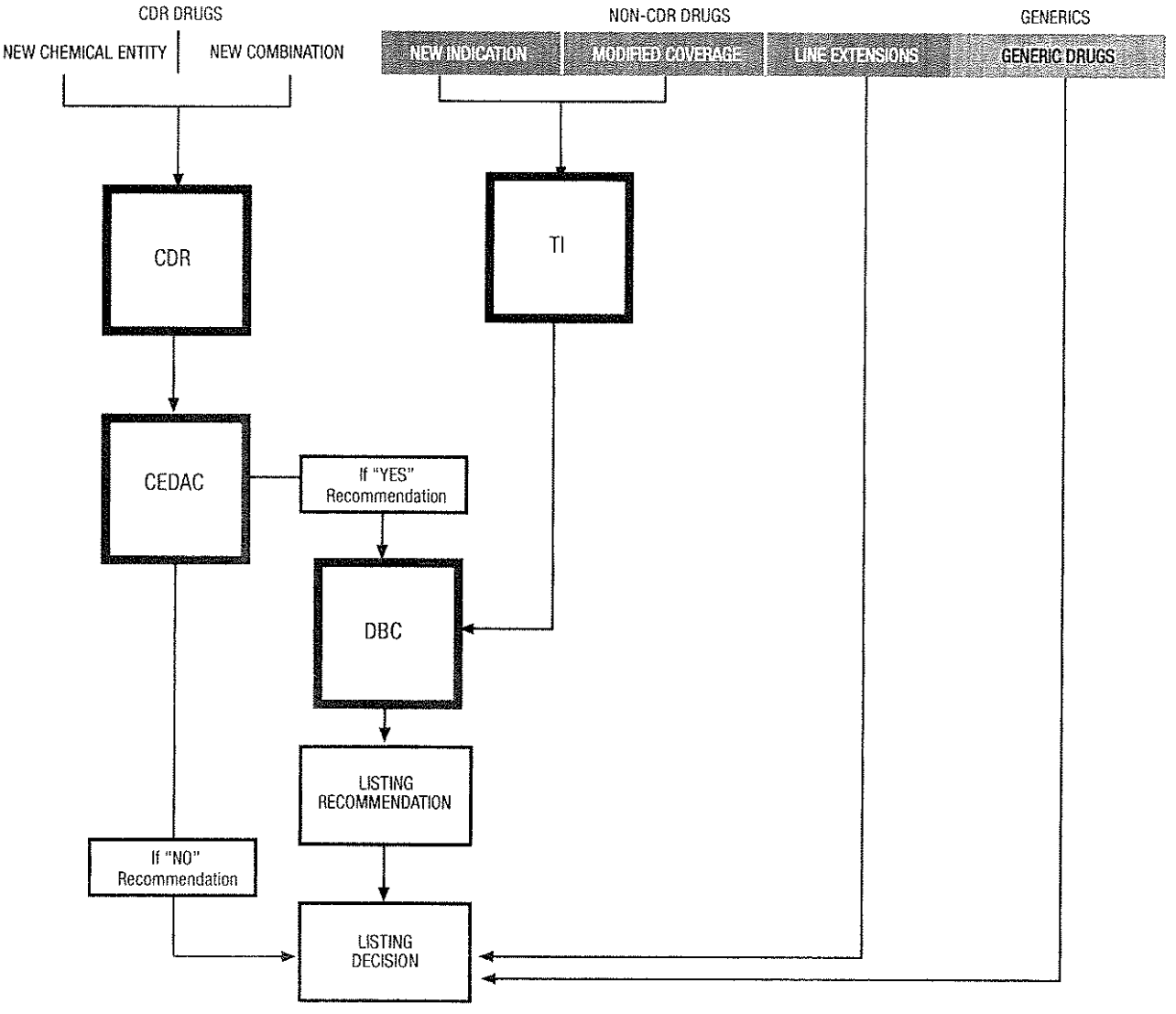
- Documentation for generic drug review process
- DBC TOR (2002)

Future Materials

- **Drug Submission Tracking System User Manual** – manual will describe the operational procedures for the system
- **Template for the DBC and TI Requirements** – a template to follow for preparing drug submissions packages to DBC and TI
- **Checklist for drug submission requirements** – this check list will spell out each requirement to determine whether or not each drug submission meets those requirements
- **Schedule/Calendar and FAQs** – to be published on the PharmaCare Web site
- **Performance Management Check List** – will be part of the process to monitor and report performance that will include the items that are critical to the FM operation
- **Knowledge Management System User manual** – will describe the operational procedures for the system

PharmaCare Formulary Management Process:

Overview

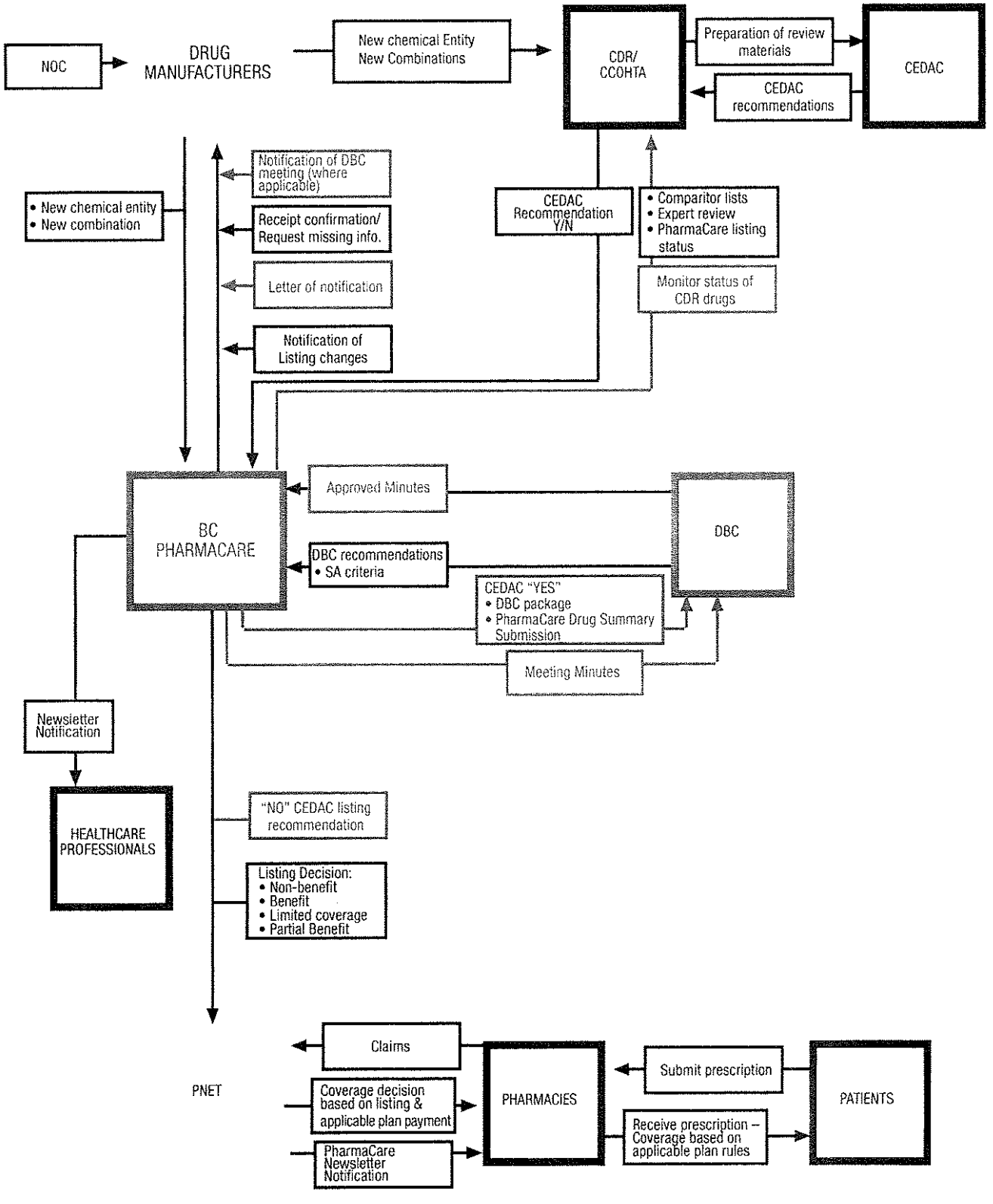

CDR DRUGS
NEW CHEMICAL ENTITY
NEW COMBINATION
NON-CDR DRUGS
NEW INDICATION
MODIFIED COVERAGE
LINE EXTENSIONS
GENERICS
GENERIC DRUGS
CDR
TI
CEDAC
If "YES" Recommendation
DBC
LISTING RECOMMENDATION
If "NO" Recommendation
LISTING DECISION

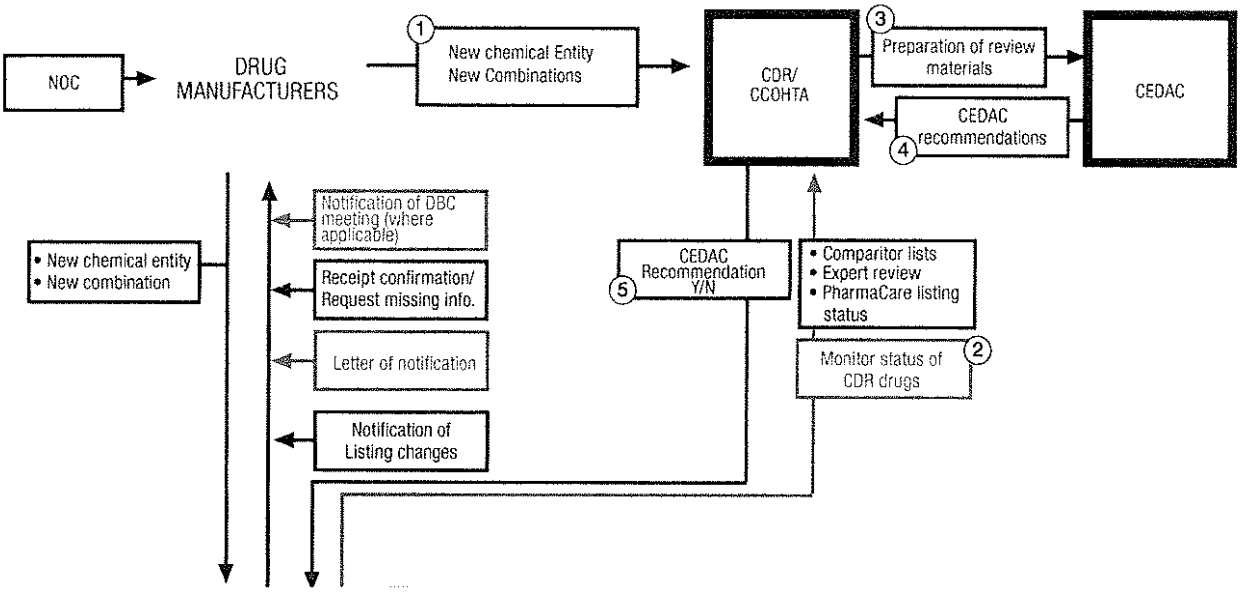
PharmaCare Formulary Management Process:

CDR-Dependent Process

PharmaCare Formulary Management: CDR-Dependent process

Changes in process are indicated in red





CHANGES

A. PharmaCare will monitor the status of drugs under CDR review in order to facilitate workload planning.
B. The potential impact of CDR Drugs Under Review will be determined.

POTENTIAL BENEFITS

- FM will be better prepared for the workload resulting from CDR-reviewed drugs
- Potential drug issues will be identified earlier in the review process.
- Overall efficiency of the drug review process will increase by being more proactive (less reactionary).

Process

1. After receiving a Notice of Compliance (NOC) from Health Canada for a new chemical entity or a new combination, drug manufacturers must submit an application to the Common Drug Review (CDR) Directorate of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), if they wish to seek listing approval from federal, provincial or territorial health ministry drug plans.

Associated Tasks (Business Activities)

- *PharmaCare receives the CEDAC recommendations through the CDR/CCOHTA*
- *PharmaCare exchanges information with CDR / CCOHTA on the following topics:*
  - *identified comparator*
  - *identified expert review*
  - *current listing status of comparators*

Process

2. PharmaCare will maintain a record of Drugs Under Review by CDR in an electronic tracking system. Information is kept current based on information on CDR notifications sent via email to all F/P/T health ministry drug plans as members of the Advisory Committee on Pharmaceuticals (ACP)

3. CDR receives applications from drug manufacturers and the CDR process undertakes a systematic review of the available clinical evidence and a review of the pharmacoeconomic data. The CDR requires evidence of comparative effectiveness and cost effectiveness. This review information is forwarded to the Canadian Expert Drug Advisory Committee (CEDAC) who provide a listing recommendation for all participating F/P/T drug plans with the exception of Quebec

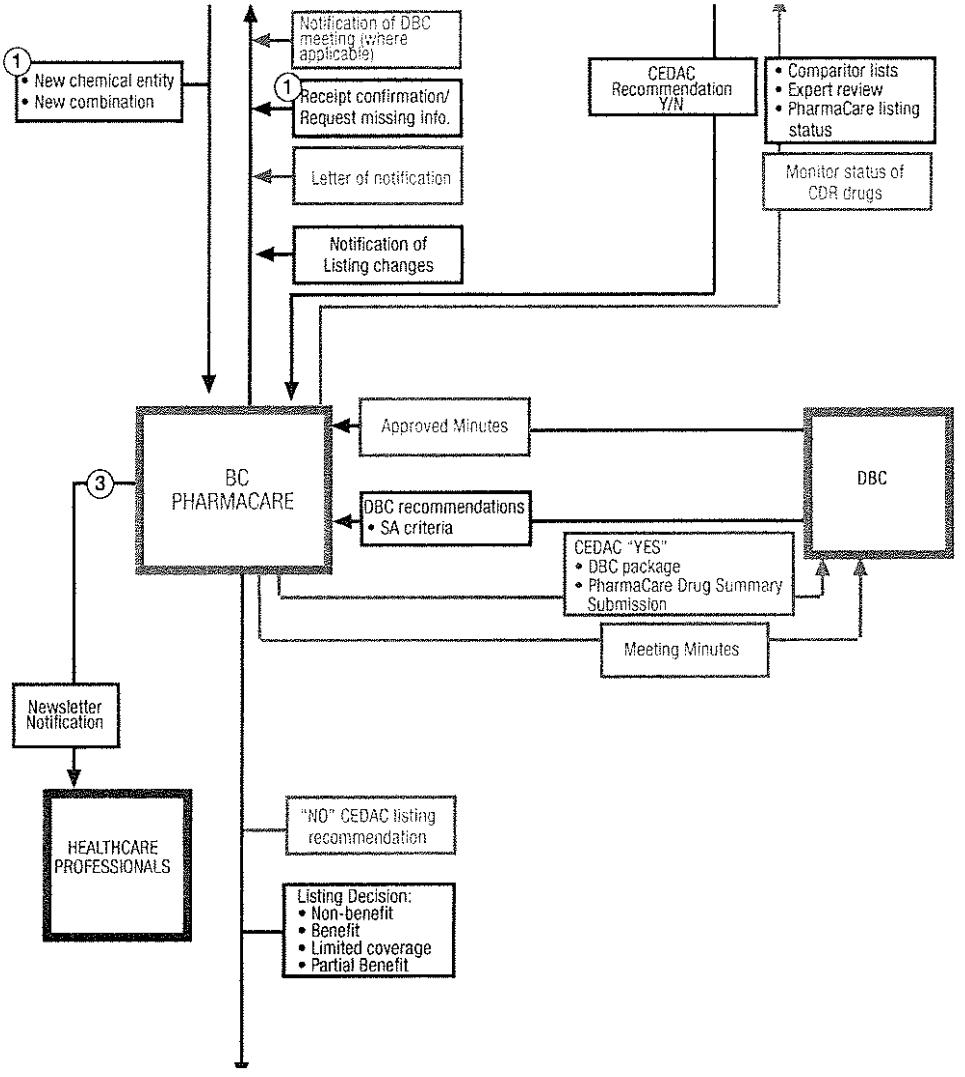
4. CEDAC forwards listing recommendations to the CDR.
   All CEDAC recommendations are published on the CDR's public website:
   www.ccohta.ca/cdr/cdr_sub_tracking

5. The CDR forwards CEDAC's listing recommendations to federal/provincial/territorial drug programs (except Quebec). Recommendations are either:

   YES – BC PharmaCare considers the CEDAC recommendation in the context of existing PharmaCare policies, programs, priorities and resources.

   NO – F/P/T Health Ministers have determined that a CEDAC recommendation against coverage of drug would be respected by all jurisdictions and the drug would not be included for coverage by any jurisdiction.

For additional information on the CDR process go the CDR website: www.ccohta.ca/cdr_process_e_cfm



CHANGES

A. CDR-CEDAC "No" recommendations, will no longer be forwarded to DBC.

B. Immediately upon receipt, relevant submission information will be prepared with PharmaCare Drug Submission Summary and uploaded to a secure website, accessible only by Formulary Management and DBC members.

C. Formulary Management will issue the following communication to Drug Manufacturers:
   - Confirmation of receipt
   - Notification of date of DBC meeting at which submission is scheduled to be reviewed
   - Notification of Listing Decision

D. PharmaCare Drug Submission Summary is provided to DBC members prior to DBC meeting.

POTENTIAL BENEFITS

- Speeds overall process by focusing only on CDR "Yes" recommendations.
- Improves process by providing DBC members with access to relevant submission information.
- More comprehensive and predictable communication about drug submissions will increase the transparency of the review process and minimize the number of requests for status updates.
- Facilitates DBC members' review of Submissions.
- Will reduce time required to seek clarification from DBC members.

E. A PharmaCare pharmacist will take the minutes of the DBC meetings. F. DBC meeting minutes will be completed within 5 business days and DBC will approve minutes within 5 days of receiving them. G. New Terms of Reference will be developed for the DBC. Key points will include: • A fixed, regular schedule for DBC meetings • Fixed locations for DBC meetings • Defined anticipated response time for meeting minutes approval • Set timeline for PharmaCare to provide DBC package to DBC members. H. Allow for DBC membership expansion and appointment term limits. I. Provide more comprehensive rationale in Letters of Notification. J. At the discretion of PharmaCare, drug manufacturers may be invited to submit proposals for PLAs. This will only occur after a "YES - with conditions" listing decision has been communicated to the manufacturer.	• Ensures that DBC recommendations are confirmed within 2 weeks of DBC meetings. • Fixed schedule and location will reduce logistics challenges. Greater structure will allow for estimates of time required to process submissions and increase overall transparency. • Provides DBC with ability to access expertise as required. • Providing drug manufacturers with FM rationale for listing decision will reduce inquiries and allow FM to focus on reviewing submissions. • Enhances the clarity of the listing decisions and allows for performance management of PLA negotiation Process

Process

1. Upon the conclusion of the CEDAC evaluation process, drug manufacturers provide their submissions for new chemical entities and new combinations to PharmaCare for listing consideration. Note: prior to this step PharmaCare must have already received the CEDAC recommendation from the CDR.

2. PharmaCare sends a receipt confirmation to the drug manufacturers to acknowledge the receipt of a submission. If a submission is incomplete, the drug manufacturer is responsible for ensuring that all of the requirements are met. Review does not proceed until the submission is complete.

3. Upon reciept of a CEDAC "no" recommendation, a briefing note is prepared for ED/ADM. Drug is subsequently listed on PharmaNet as a non-benefit.

4. PharmaCare Drug Submission summary containing key information is prepared for each drug submission on the DBC meeting agenda

Associated Tasks (Business Alternatives)

Receipt of Drug Manufacturer Submission:

- *PharmaCare receives drug manufacturer submission for new chemical entity or new combination*
- *Submission is date stamped*
- *Completed submission is accepted by PharmaCare for review*

Initial Processing of Drug Manufacturer Submission by PharmaCare

- *Drug Submission Status Document (MS Excel) is updated*

5. The drug manufacturer is sent a letter indicating the date on which the DBC will review drug submission.

6. DBC members are provided with a PharmaCare Drug Submission Summary that includes key information about each drug submission on the agenda for the DBC meeting.

7. The DBC provides PharmaCare with a listing recommendation.

8. The BIA is completed based on input provided by DBC.

9. DBC returns approved minutes to PharmaCare.

10. Based on the processes listed above, PharmaCare reviews the DBC recommendation and BIA in the context of existing PharmaCare policies, programs, priorities, and resources when making a listing decision. Prior to making a listing decision, any outstanding drug issues must also be resolved. A drug may be listed as either a: full benefit, limited coverage benefit subject to Special Authority criteria, non-benefit, or partial benefit.

11. At the end of this stage of the FM review process, a Letter of Notification is sent to the drug manufacturer to advise of Listing Decision: approval or rejection and the rationale for the decision.

12. At the discretion of PharmaCare, drug manufacturers may be invited to submit proposals for PLAs. This will only occur after a "YES - with conditions" listing decision has been communicated to the manufacturer.

- *Entry made in New Drug Under Review (NDUR) list*

PharmaCare FM review of Drug Manufacturer Submission

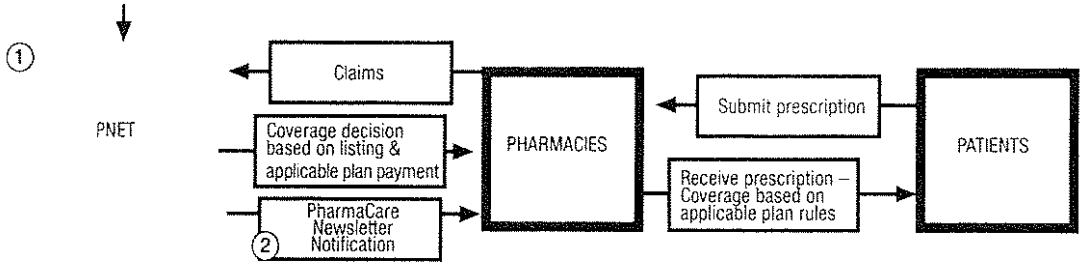
- *Submission is prepared for DBC*

PharmaCare Listing Decision

- *PharmaCare receives listing recommendation from DBC*
- *Depending on listing recommendation, BIA may be completed*
- *Executive Director provides final approval of Listing Decision*
- *Drug Submission Status Document is updated to reflect listing decision*
- *Listing Decision is sent to PharmaCare Information Support - HIBC for entering into PharmaNet*

Drug Manufactures are Notified of Listing Decision

- *PharmaCare prepares Letter of Notification based on listing decision (rejection or approval)*
- *Letter of Notification is reviewed and approved*
- *PharmaCare sends out Letter of Notification to drug manufacturer*



CHANGES – no changes proposed

Process Steps

1. The PharmaNet Data system is updated to reflect new FM decisions. Products and their associated listing and benefit status are reflected in the system, including price changes, modifications, and deletions.

2. PharmaCare provides a notification in the PharmaCare newsletter to health care professionals and pharmacies to advise them of the listing decisions including new entries in the PharmaNet system.

Associated Tasks

PharmaNet System Updated

- *PharmaCare Information Support - HIBC enters Listing Status into PharmaNet*
- *PharmaNet is updated to reflect additional listing decisions for claims adjudication processing*

PharmaCare Newsletter

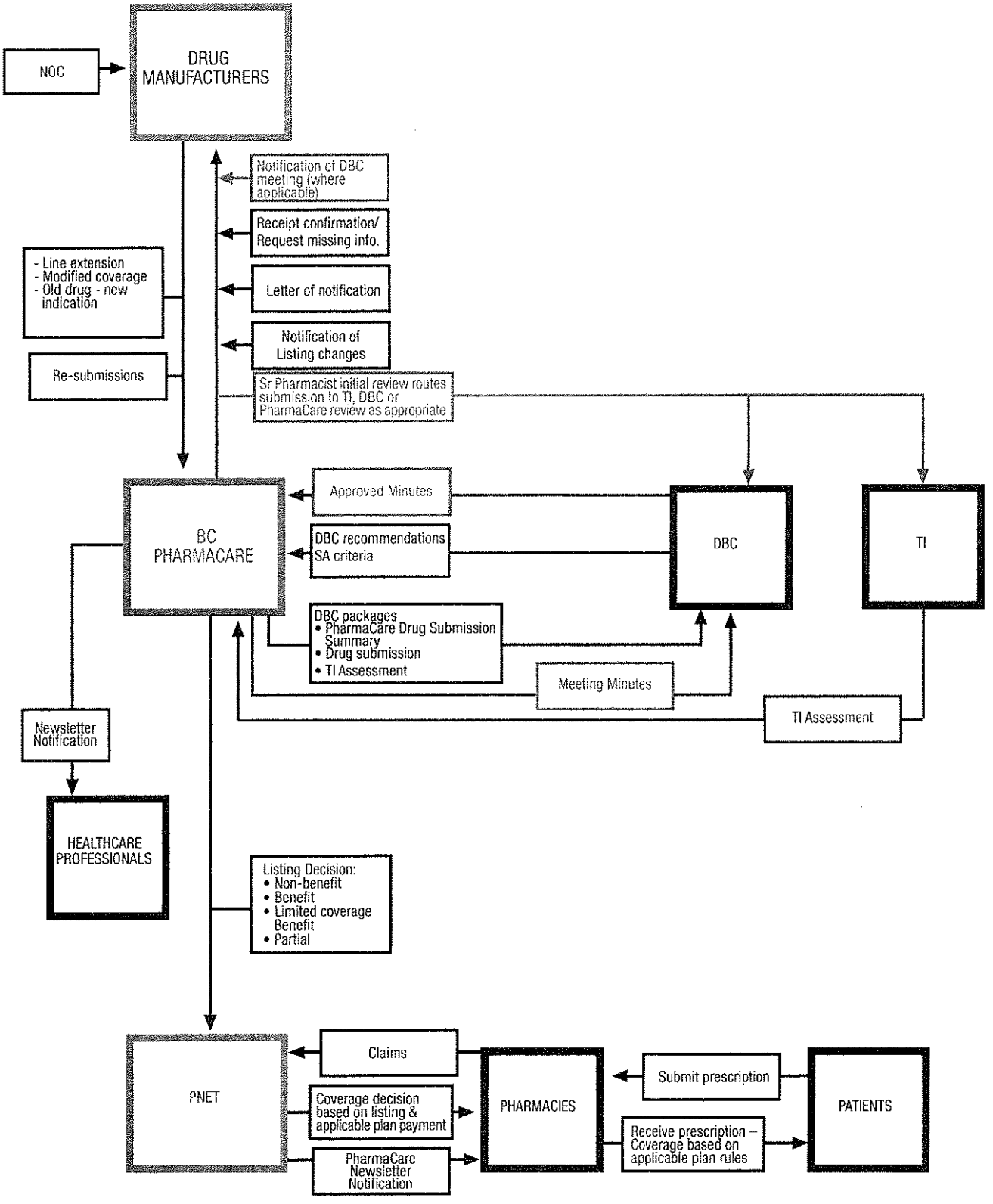
- *New listing decisions are included in PharmaCare Newsletter*

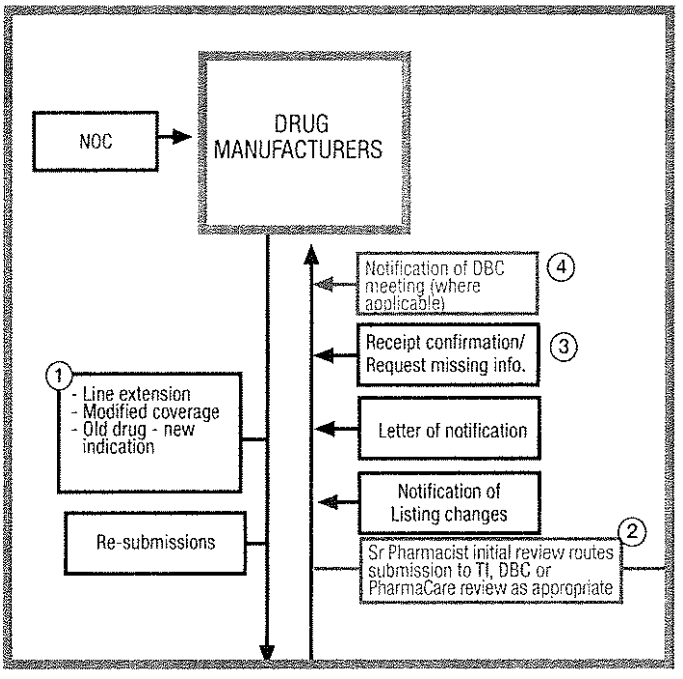
PharmaCare Formulary Management Process:

Non CDR-Dependent

PharmaCare Formulary Management: Non CDR-Dependent Process

Changes in process are indicated in red





CHANGES

A. Upon receipt of submission, Sr. Pharmacist will determine if there is a need for DBC and/or TI review for certain drugs.
B. Based on Sr. Pharmacist determination, TI review will be initiated earlier in the review process.
C. Formulary Management will distribute PLA related submissions to Policy Development & Management (PDM).
D. PharmaCare will send drug manufacturers a letter confirming receipt of the submission and provide an estimated timeframe when the submission will be scheduled for review by the DBC.

Potential Benefits

- Speed up review of certain submissions such as Line-Extensions.
- Minimize TI assessment time.
- More comprehensive and predictable communication about drug submissions will increase the transparency of the review process and minimize the number of requests for status updates.

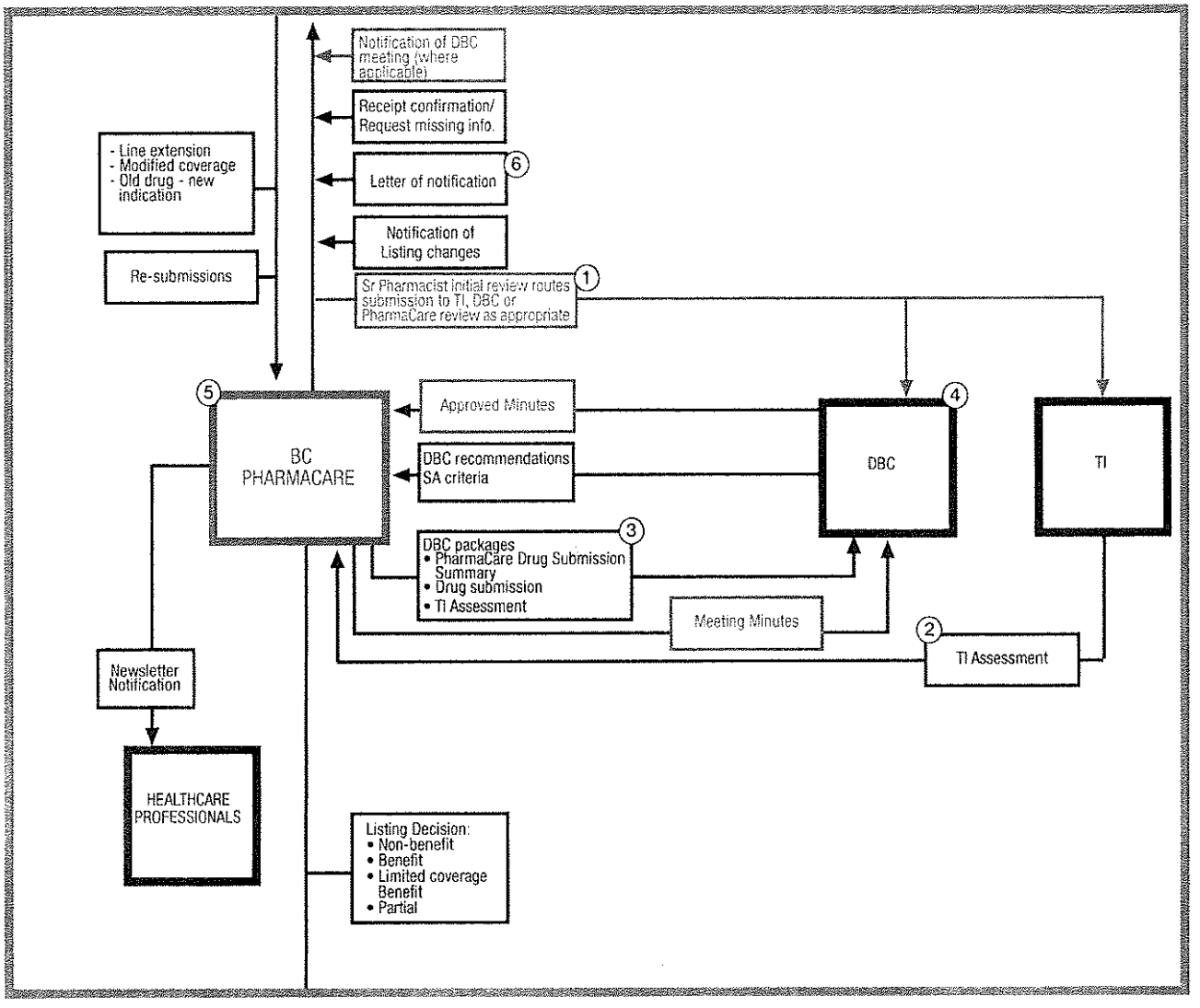
Process Steps

1. Drug manufacturers forward their submissions for line extensions and old drugs with new indications directly to PharmaCare for Formulary Management (FM) review. Drug manufacturers may also send drug resubmissions and modified coverage requests directly to PharmaCare.

Associated Tasks

Initial Processing of Drug Manufacturer Submission by PharmaCare

2. The Sr. Pharmacist conducts a preliminary assessment of each drug submission to determine what review processes are required. Only submissions that require DBC and/or TI review will be forwarded to those groups. Drug reviews and listing decision recommendations that do not require TI or DBC review will be done internally by PharmaCare. 3. PharmaCare sends a receipt confirmation to the drug manufacturers to acknowledge the receipt of a submission. If a submission is incomplete, the drug manufacturer is responsible for ensuring that all of the requirements are met. Review does not proceed until the submission is complete. See Website: www.healthservices.gov.bc.ca/pharme/drugsub.html 4. When applicable, PharmaCare estimates the schedule for DBC to review each drug submission and provides this estimate to the drug manufacturer.	



CHANGES

A. Immediately upon receipt, relevant submission information will be prepared into DBC packages including PharmaCare Drug Submission Summary and uploaded to a secure website, accessible only by Formulary Management and the DBC.

B. A PharmaCare pharmacist will take the minutes of the DBC meetings.

C. DBC meeting minutes will be completed within 5 business days and DBC will approve minutes within 5 days of receiving them

D. FM will consult PDM on PLAs earlier and throughout the review process

Potential Benefits

- Reduces time required to seek clarification from DBC members.
- Ensures that DBC recommendations are made official within 2 weeks of DBC meetings.
- Speeds internal processes related to PLAs and ensures that critical clinical aspects of the agreements are addressed.
- Improves structure of TI and aligns processes with FM requirements

E. Draft new Terms of Reference for the TI including performance targets related to the timeliness of drug submission review. F. At the discretion of PharmaCare, drug manufacturers may be invited to submit proposals for PLAs. This will only occur after a "YES - with conditions" listing decision has been communicated to the manufacturer.	• Enhances the clarity of the listing decisions and allows for performance management of PLA negotiation process.

Process

1. If the senior pharmacist determines the need for an expert review, PharmaCare will ask the Therapeutics Initiative (TI) for an expert review.

2. Once the TI has conducted its expert review, if required, the resulting assessment is sent to PharmaCare.

3. Upon receiving the TI assessment, PharmaCare prepares a PharmaCare Drug Submission summary that is included within the DBC Package. The DBC package is made available to DBC through a secure website.

4. The DBC receives the expert review assessment and incorporates the information into their review process.

5. PharmaCare considers the DBC listing recommendation in the context of existing PharmaCare policies, programs, priorities and resources. Based on these factors, a decision is then made to list the drug as a full benefit, limited coverage benefit, partial benefit, or non-benefit.

6. At the end of this stage of the FM review process, a Letter of Notification is issued to the drug manufacturer to advise of the listing decision.

7. At the discretion of PharmaCare, drug manufacturers may be invited to submit proposals for PLAs. This will only occur after a "YES - with conditions" listing decision has been communicated to the manufacturer.

Associated Tasks

Initial Processing of Drug Manufacturer Submission by PharmaCare

PharmaCare FM review of Drug Manufacturer Submission

- *Submission is prepared for DBC to conduct review*
- *Coordination is provided to facilitate DBC meeting*

DBC Review Process Pre DBC Meeting:

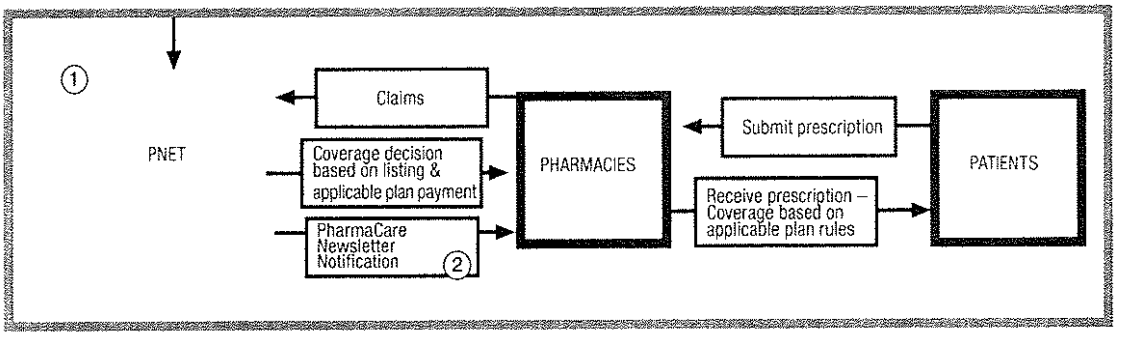
- *Submission is received and arrangements are made to facilitate DBC meeting: location and communication logistics*
- *Expert review may be requested (TI review)*
- *Action items and meeting minutes are recorded*

Post DBC Meeting:

- *Further review assessment may be required*
- *DBC meeting action items and minutes are provided to PharmaCare*
- *DBC listing recommendation is provided to PharmaCare*

PharmaCare Listing Decision

- *PharmaCare receives listing recommendation from DBC*
- *Executive Director provides final approval of listing decision. Depending on issues associated with a listing decison, approval may be required from the ADM or DM as well.*
- *Drug Submission Status Document is updated to reflect listing decision*
- *Listing decision information is sent to PharmaCare Information Support – HIBC for for entering into PharmaNet*



CHANGES – no changes proposed

Process

1. The PharmaNet data system is updated to reflect new FM decisions. Products and their associated listing and benefit status are reflected in the system, including price changes, modifications, and deletions.

2. PharmaCare provides a notification in the PharmaCare Newsletter to health care professionals and pharmacies to advise them of the listing decisions including new entries in the PharmaNet system.

Associated Tasks

PharmaNet System Updated
- *PharmaCare Information Support - HIBC enters Listing Decision into PharmaNet*
- *PharmaNet is updated to reflect addition listing decisions for claims adjudication processing*

PharmaNet System Updated
- *PharmaCare Information Support - HIBC enters Listing Decision into PharmaNet*
- *PharmaNet is updated to reflect additional listing decisions for claims adjudication processing*

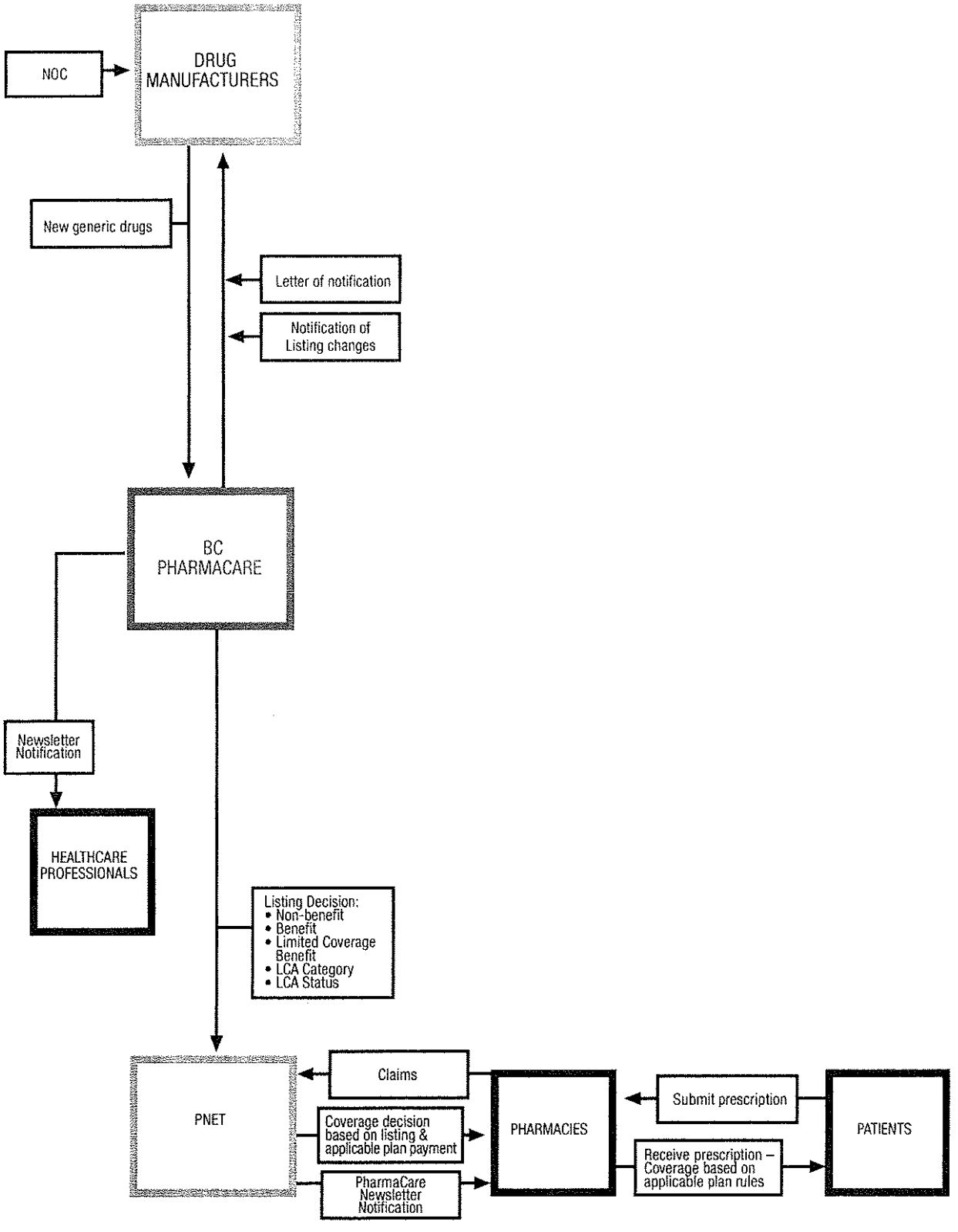
PharmaCare Newsletter
- *New listing decisions are included in PharmaCare Newsletter*

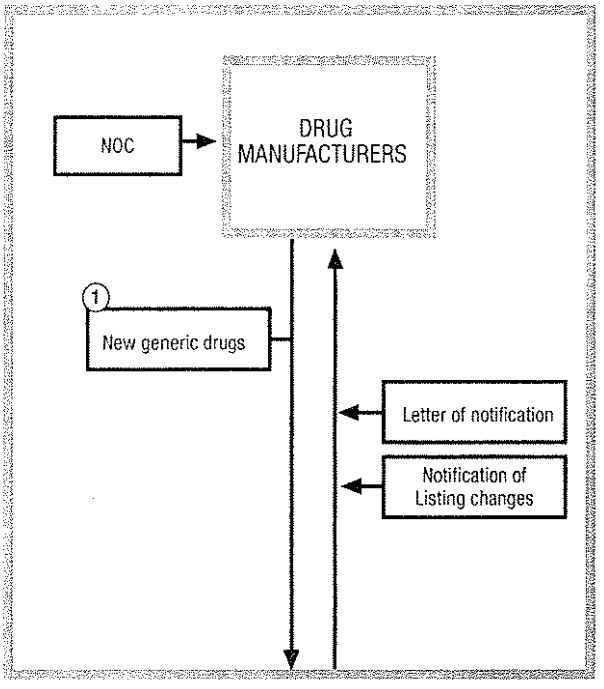
PharmaCare Formulary Management Process:

Generics

PharmaCare Formulary Management: Generics Process

Changes in process are indicated in red





CHANGES – no changes proposed

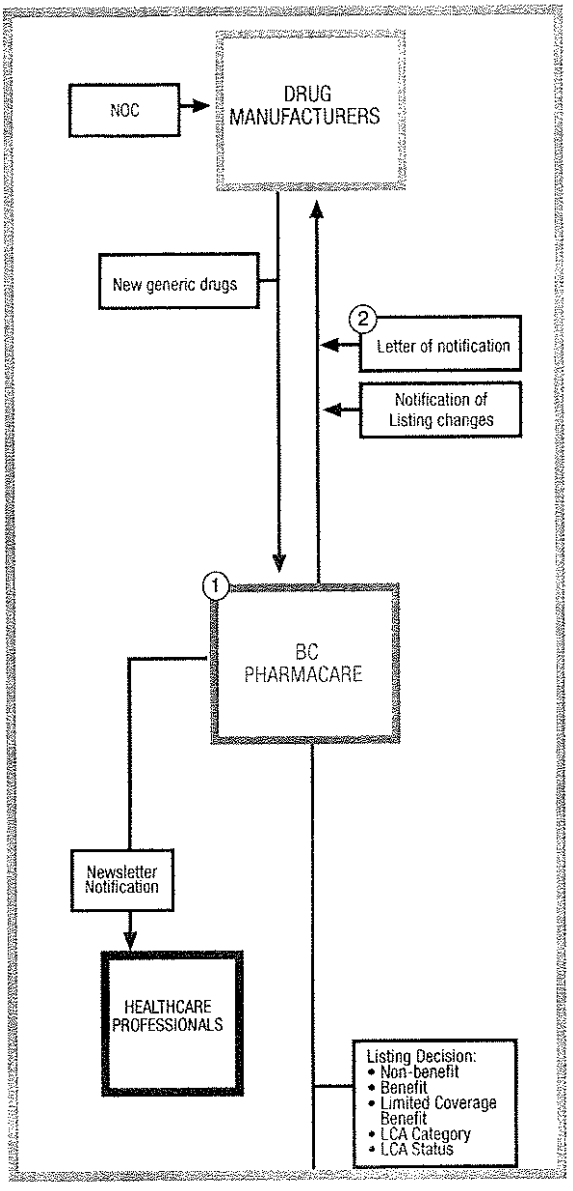
Process

1. Drug manufacturers forward their submissions for new generic drugs directly to the PharmaCare for Formulary Management (FM) review.

Associated Tasks

Receipt of Drug Manufacturer Submission:

- *New generic drug Submission is date stamped*
- *Submission is accepted by PharmaCare for review*



CHANGES

A. Sr Pharmacist will be responsible for making all listing decisions regarding generic pharmaceuticals.

POTENTIAL BENEFITS

- Speeds up approval and listing proccesses.

Process

1. As a result of processing, the Sr. Pharmacist in PharmaCare FM determines Listing Decision and generic drugs are listed as benefits, non-benefits, limited coverage benefits or LCA.

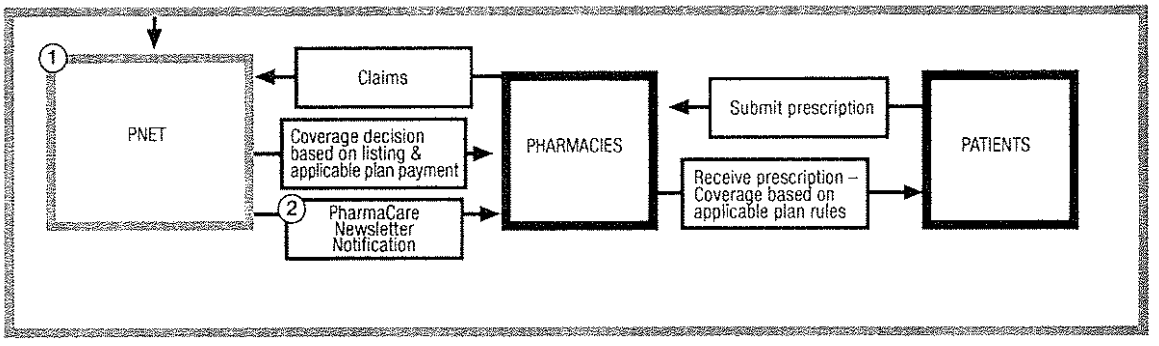
2. Letter of Notification is sent to the drug manufacturer to advise of the listing decision.

Associated Tasks

Initial Processing of Drug Manufacturer Submission by PharmaCare

Drug Submission Status Document (MS Excel) is updated

Letter of Notification is sent to health professionals



CHANGES – no changes proposed

Process

1. The PharmaNet data system is updated to reflect new FM decisions. Products and their associated listing and benefit status are reflected in the system, including price changes, modifications, and deletions.

2. PharmaCare provides a notification in the PharmaCare Newsletter to health care professionals and pharmacies to advise them of the listing decision including new entries in the PharmaNet system.

Associated Tasks

PharmaNet System Updated

- *PharmaCare Information Support - HIBC enters Listing Decision into PharmaNet*
- *PharmaNet is updated to reflect additional listing decisions for claims adjudication processing*

PharmaNet System Updated

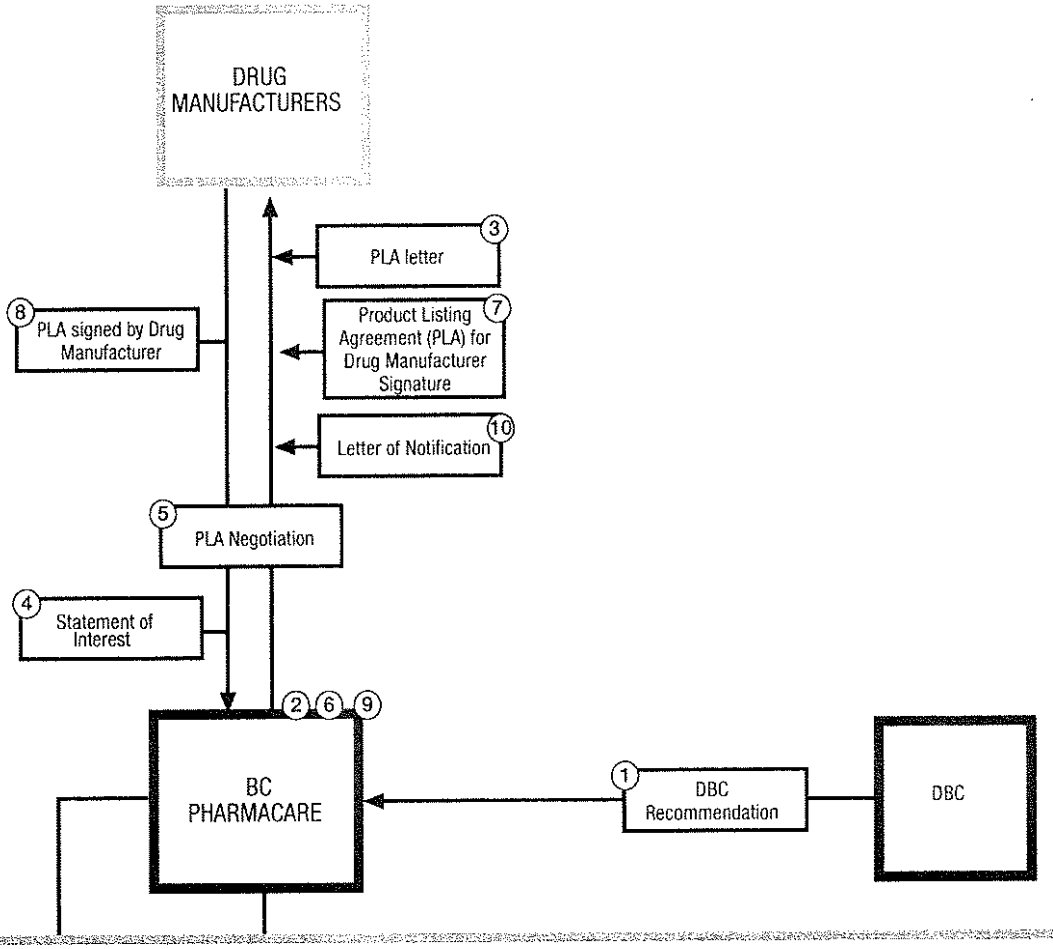
- *PharmaCare Information Support - HIBC enters Listing Decision into PharmaNet*
- *PharmaNet is updated to reflect additional listing decisions for claims adjudication processing*

PharmaCare Newsletter

- *New listing decisions are included in PharmaCare Newsletter*

PLA Process

Product Listing Agreement



Process

1. The Drug Benefit Committee (DBC) makes a "YES - with conditions" recommendation.

2. Taking into account the DBC recommendation, the Business Impact Assessment, and existing PharmaCare policies, programs, priorities and resources, PharmaCare may identify that a drug that has potential for a PLA. PharmaCare then determines the needs/ expectations that must be accommodated through a possible PLA.

3. PharmaCare sends a letter to the drug manufacturer identifying the opportunity for a PLA and requesting a formal response within 30 days. If no response is received within 30 days then the FM Review process is considered complete and the drug will be listed as a non-benefit.

4. Drug Manufacturer submits a "Statement of Interest" letter to FM (for tracking purposes). This concludes the FM Review Process and initiates PLA negotiations between PharmaCare and the drug manufacturer.

5. PharmaCare works with the drug manufacturer to negotiate the terms of the PLA. The target for completing this process is 6 months.

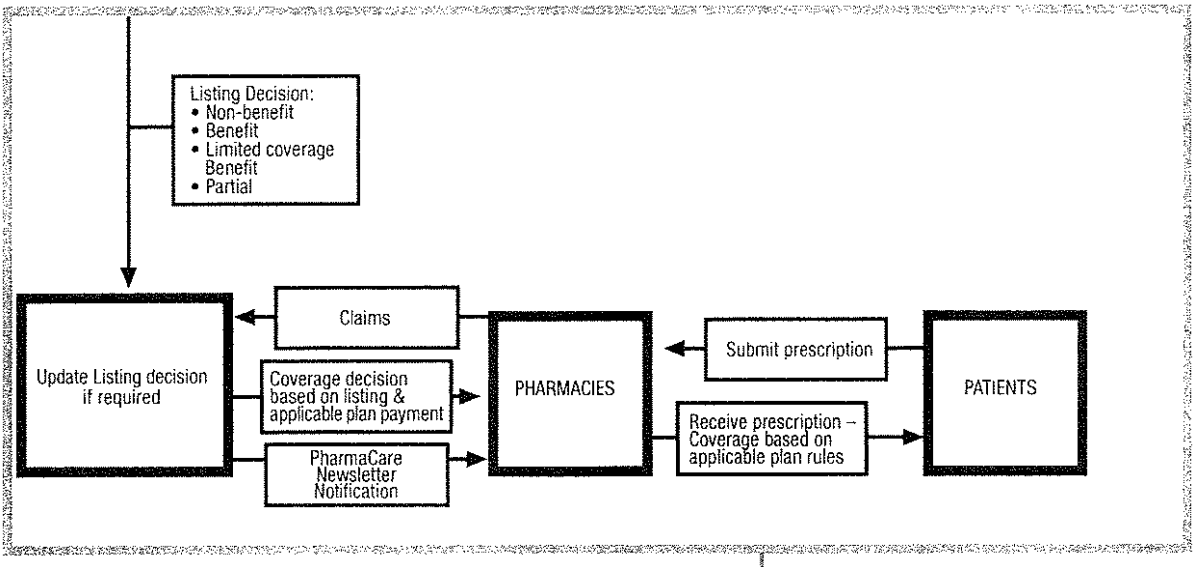
6. Upon completion of the negotiations the PharmaCare ED or ADM (as appropriate) must approve the agreement. a PLA briefing note is prepared by PharmaCare and signed off by either the ED or ADM).

6. The Product Listing Agreement is sent to the drug manufacturer for signature.

7. The drug manufacturer signs and returns the Product Listing Agreement to PharmaCare.

8. The Product Listing Agreement is signed by the ED.

9. PharmaCare sends a Letter of Notification to the drug manufacturer and publishes the Listing Decision on the PharmaCare Website (Newsletter). Information is also provided directly to health care professionals.



Process

1. The PharmaNet data system is updated to reflect new FM decisions. Products and their associated listing and benefit status are reflected in the system, including price changes, modifications, and deletions.

2. PharmaCare provides a notification in the PharmaCare Newsletter to health care professionals and pharmacies to advise them of the listing decision including new entries in the PharmaNet system.

Associated Tasks

PharmaNet System Updated

- *PharmaCare Information Support - HIBC enters Listing Decision into PharmaNet*
- *PharmaNet is updated to reflect additional listing decisions for claims adjudication processing*

PharmaNet System Updated

- *PharmaCare Information Support - HIBC enters Listing Decision into PharmaNet*
- *PharmaNet is updated to reflect additional listing decisions for claims adjudication processing*

PharmaCare Newsletter

- *New listing decisions are included in PharmaCare Newsletter*
- *Newsletter information (based on a template) is sent to PharmaCare Operations*
- *PharmaCare Operations sends Newsletter draft for review and signoff*
- *PharmaCare Newsletter is published on the PharmaCare web site*