Task Force on High Cost Drugs

Final Report
July 1998

Members of the Task Force

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Ms Tenny Carter, Assistant Vice President, Blue Cross

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Assistance to the Task Force has been provided by Ms Barb Shea and Mr. Kevin Wilson of the Saskatchewan Prescription Drug Plan.

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July 1998

Honourable Clay Serby
Minister of Health
346 Legislative Building
REGINA, Saskatchewan
S4S 0B3

Dear Mr. Serby:

On behalf of the Task Force on High Cost Drugs, I am pleased to submit the attached report. The Task Force report and its recommendations represent the completion of our deliberations. We believe we have fulfilled our mandate, and in doing so, the Task Force will now be disbanded.

On behalf of the Task Force members, I want to thank you for this opportunity to serve the residents of Saskatchewan.

Sincerely,

Dr. Stewart McMillan
Chairman

A. Executive Summary

The Task Force on High Cost Drugs was appointed by the Minister of Health in December 1997, following the debate and controversy over Betaseron and Copaxone. The two drugs to treat Multiple Sclerosis were eventually covered under the province's Drug Plan. But this brought to light an emerging challenge—how can Saskatchewan manage a growing list of new, high-cost drugs?

Many of these drugs are not only extremely expensive but they may have questionable or unproven benefits. Taken together, they represent a growing challenge to the future of our Saskatchewan Prescription Drug Plan (S.P.D.P.).

The Task Force was asked to study how Saskatchewan can better evaluate new high-cost drugs, what implications these drugs may have for our Drug Plan and what action Saskatchewan may take on the national stage.

The Task Force found that Saskatchewan is well served by the current review process. The work done by the province's two review committees has been very thorough. But it is felt the province could do a better job of explaining the process and in outlining the clinical and economic information considered in reviews of specific drugs. As well, residents or groups who disagree with decisions should be able to appeal in writing to the province's Formulary Committee if they feel vital scientific information was missed.

The Task Force also considers sharing research with other provinces on the costs and benefits of selected drugs to be a valuable practice.

In all, the Task Force makes seven recommendations. They are listed throughout this report and presented in summary form on the final page.

B. The Mandate of the Task Force

The Task Force was given three specific areas to review:

1. What improvements might be appropriate to the way government evaluates new pharmaceuticals, including bringing greater transparency to the process.

2. The implications of providing new drugs on the scope of the Saskatchewan Prescription Drug Plan.

3. What action Saskatchewan should take in the months to come at the federal, provincial and territorial level, including approaches to a National Pharmacare Program.

C. Methods

The Task Force carefully examined how drugs are currently reviewed before they are added to the Saskatchewan Formulary. To do that, we met with members of the Drug Quality Assessment Committee (D.Q.A.C.) and the Saskatchewan Formulary Committee (S.F.C.).

We learned about how other provinces review new drugs and have discussed the process used in British Columbia and Alberta with representatives of the Pharmaceutical Evaluation Committees in these provinces. We also met with and had a very interesting presentation from Dr. Nick Otten of the Canadian Coordinating Office for Health Technology Assessment (C.C.O.H.T.A.) on the topic of pharmaco-economics.

The Task Force met with various stakeholders to ask their opinions on the process in Saskatchewan. In particular, we asked for their suggestions on how the transparency of the process could be improved. A listing of those consulted appears at the conclusion of this report as Appendix I.

D. Findings and Recommendations: The Saskatchewan Approval Process

The first term of reference of the Task Force was **"To review what improvements might be appropriate to the way government evaluates new pharmaceuticals, including bringing greater transparency to the process."**

When a pharmaceutical company applies to have a particular drug listed on the Saskatchewan Formulary, a standard review process is followed.

To address our first term of reference and look at bringing greater transparency to the process, we decided to assess how well the current process works.

A diagram of the current process is in Appendix II. Terms of reference for the D.Q.A.C. and the S.F.C. are listed as Appendix III and Appendix IV respectively.

The Present Evaluation Process

The D.Q.A.C. is a committee of scientists that advises the S.F.C. on products for which coverage has been requested.

In its deliberations, the D.Q.A.C. ascertains the therapeutic value of a specific drug. If the new drug is the only drug available to treat a particular condition, its absolute value is assessed. If the drug will be used to treat a condition for which there is already a recognized medical treatment, then the D.Q.A.C. determines the incremental value the new drug may have over existing treatments.

The D.Q.A.C. looks at all available scientific evidence to guide its recommendation to the S.F.C. This can include scientific publications and information submitted by the manufacturers.

As with all scientific review, some information sources carry more weight than others. The D.Q.A.C. places a higher value on good randomized control trials than any other form of evidence. A good randomized control trial is considered to be Level 1 evidence (the best information possible). This is appropriate, as these trials are the most rigorous means of assessing, scientifically, the efficacy of a particular drug.

Often, particularly with new drugs, randomized controlled trials are not available and the committee has to rely on lesser levels of evidence. In these cases, the committee will often supplement the information they have with the opinion of respected specialists in the area of practice in which the new medicine would be used.

The D.Q.A.C. is not made aware of any costing information in its deliberations. It merely makes recommendations to the S.F.C. on the therapeutic merits (or lack thereof) of a particular drug.

The S.F.C. is made up of health care professionals. Once it has the review from the D.Q.A.C., it begins the next step of the review process—considering economic information relative to the drug.

This information includes cost, potential numbers of beneficiaries and the impact that coverage may have on other segments of the health system. With certain high cost products, the S.F.C. may refer to a pharmaco-economic study performed by Canadian Coordinating Office for Health Technology (C.C.O.H.T.A.) to further guide a decision.

The S.F.C. does not feel restrained by a budgetary ceiling. Its recommendation is based on the merits and value for money of the particular product.

By law, the Minister of Health is responsible for decisions regarding drug coverage. Thus, the findings of these two expert committees are passed to the Minister for his decision.

The groups that we met with were clearly aware that the Minister of Health makes the final decisions about what medications are covered under the Saskatchewan Prescription Drug Plan. The expressed wish of these groups was that every effort be made to ensure that the process leading up to the recommendation to the Minister was understandable and fair.

The Present Review Process – Limitations

The Task Force wishes to recognize the thoroughness of the work done by both the D.Q.A.C. and the S.F.C. to date. The task that both committees face is time consuming and formidable. We have been impressed by the dedication of the members of both committees to their mission and to ensuring that their evaluation of new drugs is as complete as possible.

There are some limitations to the process, however, that should be noted. The Task Force wishes to stress that the limitations are related to the information which is available at the time of considering a product for inclusion in the formulary and are not related to the skill, dedication or thoroughness of the committees. The same limitations are experienced by the formulary committees everywhere.

In the area of pharmaceutical review, especially when a new drug becomes available, there may be few, or even no, good randomized controlled clinical trials (Level 1 evidence). As a consequence, the committees may often have to rely on lesser evidence.

Often clinical trials and evaluation of new drugs are undertaken over relatively short periods of time. This makes it difficult to assess the benefit of new drugs for chronic conditions, as often patients will expect to use the drug for much longer than the period of clinical trial.

At this time, the process assesses what impact adding the new drug may have on other segments of the health care system. For example, will a drug result in less hospitalization, fewer physician visits, more lab tests or reduced surgery? Such assessments are complemented at times by pharmaco-economic evaluations done by C.C.O.H.T.A. or other provinces, most notably Ontario, Alberta and B.C.

Pharmaco-economics is still a fairly new science and full pharmaco-economic reviews are often expensive. They are useful adjuncts to the present process but could not be used in the case of all new drugs or to replace the present process.

We heard from some stakeholders that the drug review process is not well understood. This leads to concern about transparency and fairness. It is clear from experience that when a recommendation is made not to include a medication on the Formulary, those affected would like to know what information was used in arriving at that decision.

Recommendation #1

Task Force members have been impressed by the work of the two present committees. In all cases they have rigorously held to the principles of scientific review in assessing new drugs for coverage.

The Task Force spent considerable time discussing the possible merits of combining the D.Q.A.C. and the S.F.C. We have noted that some provinces have changed to a single committee format, while others have favoured the two-committee model.

It was postulated that there might be some efficiency in having one committee. We concluded that while this might improve the efficiency of the review process, it would not improve the rigour of the evaluations. We were also concerned that the very important, more general clinical perspective brought to the review by the S.F.C. could be diminished.

The Task Force therefore recommends that the present two-committee structure for the assessment of pharmaceuticals for inclusion on the Saskatchewan Prescription Drug Plan (S.P.D.P.) continue unchanged.

Recommendation #2

As mentioned in the body of the report, the S.F.C. uses economic information in reaching a recommendation. It has been practice to sometimes use the offices of the C.C.O.H.T.A. to undertake a complex pharmaco-economic study. We do not think that it should be necessary to use C.C.O.H.T.A. in all assessments but recognize that this independent body may be able to provide valuable supplementary information in some reviews. Additional information may also be obtained from other jurisdictions.

The Task Force recommends that the S.P.D.P. continue to use scientific appraisal from other expert bodies, especially where the potential for individual or overall population benefit may be small but the cost high.

Recommendation #3

We recognize that not all drugs being reviewed will have the same profile. It is likely that drugs for conditions that heretofore have had no pharmaceutical treatments will be the focus of much attention outside the committees. In these cases, public expectation that such drugs will be covered is likely to be high. The same is true of drugs for conditions that are chronic, disabling or in which a treatment offers faint hope of cure or of some small improvement.

The Task Force is of the opinion that nearly all of the information received by the committees will be in the public domain. However, it is possible that the committees may receive information on a confidential basis (e.g. from the manufacturer). To ensure that the committees have as much information as possible, it will be important to respect information given on the understanding of confidentiality.

The Task Force therefore recommends that when a negative recommendation is made, the committee compile a short report indicating the information that they have received and used in their deliberations. When confidential information is received, reference may be made to the nature of the information without specifically detailing it.

Recommendation #4

As mentioned earlier in the report, the drug approval process appears not to be well understood. It is important to reassure the public that in the opinion of the Task Force, the present process is very credible and reliable.

The Task Force recommends that Saskatchewan Health prepare an informational pamphlet outlining the drug approval process and the structure and Terms of Reference of D.Q.A.C. and the S.F.C.

Recommendation #5

In the case of some drug reviews, individuals, specific disease advocacy groups or other stakeholders are likely to have a keen interest. As such, they may wish to ensure that the committees consider as much relevant information as possible before making a recommendation to the Minister of Health. It is important that in such cases, those affected feel assured that all relevant scientific information is considered by the committees. The Task Force considered suggesting that at the start of a drug review, special interest groups be invited to submit any scientific information that they may have to the committees.

We concluded that this was fraught with many difficulties. How would special interest groups be identified? What if a group was missed and later indicated that they believed they had a significant stake or opinion? We were also concerned that the process could be dominated by "lobbying" rather than evidence-based scientific review.

After much discussion, we concluded that it was better to ensure that those with an interest could receive a report of the deliberations of the committees, as recommended earlier. If they have further scientific information, they may then submit the information in writing to the S.P.D.P. requesting that the committees review it. It must be understood, however, that committee members will have to consider what level of evidence is contained in the submission. They must be satisfied that the information is of a high quality that would cause them to change their opinion and recommendations.

The Task Force recommends that if any person or groups wishes to request reconsideration of a recommendation of the S.F.C., that they may submit in writing scientific information that the committee has not considered.

The above steps can ensure that the public has access to the information used by the committees before a recommendation is made to the Minister of Health.

The Minister has a very difficult task thereafter. He has to balance the interests of the population at large with the desires and aspirations of individuals. However, the Task Force can assure the Minister that the review process in Saskatchewan is scientifically and methodologically sound.

We have noted that often, while a drug is still under review, expectations are raised in both the public and professional domains. The benefits of the drug are often touted, and there can be a wide belief that it will soon be covered under the Drug Plan. We would strongly encourage that the Minister act quickly after receiving a recommendation from the committees. Delays in acting on these recommendations have the potential to reflect negatively on the process.

E. Findings and Recommendations: Implications of New Drugs

The second term of reference of the Task Force was **"To review the implications of providing new drugs on the scope of the Saskatchewan Prescription Drug Plan."**

There have been substantial advances made in all areas of health care over the last decade or so. These advances can be seen in the medicines used to treat patients. We have more effective drugs and a wider range of pharmaceutical agents. Some of the advances offer hope for sufferers of diseases who until now have had little if any hope or prospect of cure. Other advances allow us to treat patients in their homes rather than admitting them to hospitals.

Such advances, however, are not inexpensive. The process of researching, developing and making new drugs is expensive. Practitioners will often observe to patients that there are "no new cheap drugs."

Total drug costs in Saskatchewan (both consumer and government share) for drugs covered by the S.P.D.P. have risen from $22 million in 1976 to $162 million in 1997. A continuing upward spiral in the cost of drugs to both the patient and the Saskatchewan Prescription Drug Plan is expected. In 1997, prescription drug sales in Canada grew by nearly 10% over 1996 ($6.63 billion in 1997, $6.03 billion in 1996). In addition, there are numerous biotechnology products currently under development. Many of these drugs are similar to the biotechnology products Betaseron and Copaxone in that they are expected to benefit small numbers of patients at a very high cost.

It is the view of the Task Force that the S.P.D.P. should continue to maintain a Saskatchewan Formulary. In addition, the Formulary should continue to review medications proposed for coverage, considering what benefits the newer drugs may have over the older drugs. The Formulary should continue to be considered as a means of informing good health care practices.

It was not within the scope of our terms of reference to recommend any changes specifically in the drug plan. However, we made the following observations, which the S.P.D.P. and its committees may wish to consider the implications of in the future.

1. It is unusual to delete a medication from the formulary. Once a drug becomes listed as a benefit, it remains on the formulary and is only replaced by newer drugs with the passage of time and changes in physicians' practice, rather than by an active process of review.

2. We heard on a number of occasions that there is not much review of drug utilization practices. It was postulated that some of the spiralling costs could be curtailed by more actively managing drug use. The Task Force did not study this particular issue and has no data to directly support or refute this opinion. It was, however, a recurrent theme during presentations to us. Intuitively, it makes sense to ensure that the resources of the drug plan are used as effectively as possible.

3. We noted on a number of occasions that improvements in drug treatment might reduce hospital stays. This directly transfers costs to the S.P.D.P. that would otherwise be borne by another health care sector. It is hoped that the trend of caring for patients in the community will continue. However, there are obvious implications for the S.P.D.P. budget that must be recognized or its ability to provide benefits in other areas of community care may be impeded. The Advisory Committee on Institutional Pharmacy Practice (A.C.I.P.P.) makes recommendations as to which drugs will be covered in hospitals in Saskatchewan.

Recommendation #6

The Task Force recommends that as there is now considerable overlap between community and institutional practice that care be taken to ensure very close linkage between the D.Q.A.C. and the A.C.I.P.P.

F. Review and Recommendations: The Federal, Provincial, and Territorial Strategy

The third term of reference of the Task Force was **"To review what action Saskatchewan should take in the months to come at the federal, provincial and territorial level, including approaches to a National Pharmacare program."**

In the past, there has been much hoopla and hype about the concept of a national pharmacare program. While not discussing the pros and cons of such a program, the Task Force believes that it may be some time (if ever) before such a vision is realized. We feel it is more important to look at how Saskatchewan can address common challenges with other jurisdictions.

The difficulty of getting any interjurisdictional agreement will be obvious to any dispassionate observer who has watched the debate over compensation for sufferers of Hepatitis C. The different stance taken by provincial governments over the coverage of Betaseron and Copaxone is yet another example of different reactions to the same information.

Notwithstanding this, the Task Force feels that there is considerable opportunity to work collaboratively with other provinces. We would encourage Saskatchewan to share information, look at a common submission process and priorize sharing of pharmaco-economic studies.

The Task Force encourages the province to remain active in other federal/provincial activities that positively impact residents' access to cost-effective drugs. The recent appearance by the Minister of Health before the Patented Medicine Prices Review Board is an example of this type of activity.

Recommendation #7

We would recommend that the Minister of Health, Saskatchewan and the S.P.D.P. encourage continuing dialogue to ensure that the provinces collectively establish a list of priority areas requiring pharmaco-economic study that they could collectively embark upon or more likely contract for (e.g. with C.C.O.H.T.A).

This would not necessarily mean that all provinces would reach the same conclusion on a particular drug, as science and evidence may not solely govern decisions in various jurisdictions. It would ensure, however, that the scarce resources available to do pharmaco-economic review are carefully and cost effectively deployed. And, it will further encourage the use of good quality evidence in the decision-making process.

G. Summary of Recommendations

1. The Task Force therefore recommends that the present two-committee structure for the assessment of pharmaceuticals for inclusion on the Saskatchewan Prescription Drug Plan (S.P.D.P.) continue unchanged.

2. The Task Force recommends that the S.P.D.P. continue to use scientific appraisal from other expert bodies, especially where the potential for individual or overall population benefit may be small but the cost high.

3. The Task Force therefore recommends that when a negative recommendation is made, the committee compile a short report indicating the information that they have received and used in their deliberations. When confidential information is received, reference may be made to the nature of the information without specifically detailing it.

4. The Task Force recommends that Saskatchewan Health prepare an informational pamphlet outlining the drug approval process and the structure and Terms of Reference of D.Q.A.C. and the S.F.C.

5. The Task Force recommends that if any person or groups wishes to request reconsideration of a recommendation of the S.F.C., that they may submit in writing scientific information that the committee has not considered.

6. The Task Force recommends that as there is now considerable overlap between community and institutional practice that care be taken to ensure very close linkage between the D.Q.A.C. and the Advisory Committee on Institutional Pharmacy Practice.

7. We would recommend that the Minister of Health, Saskatchewan and the S.P.D.P. encourage continuing dialogue to ensure that the provinces collectively establish a list of priority areas requiring pharmaco-economic study that they could collectively embark upon or more likely contract for (e.g. with C.C.O.H.T.A).

ACRONYMS

A.C.I.P.P.	Advisory Committee on Institutional Pharmacy Practice
C.C.O.H.T.A.	Canadian Coordinating Office for Health Technology Assessment
D.Q.A.C.	Drug Quality Assessment Committee
S.F.C.	Saskatchewan Formulary Committee
S.P.D.P.	Saskatchewan Prescription Drug Plan

Appendix I

Listing of Stakeholders

Advisory Committee on Institutional Pharmacy Practice (Presentation)

Canadian Drug Manufacturers Association (Presentation)

Canadian Life and Health Insurance Association (Verbal Response)

College of Medicine (Unable to Attend)

College of Pharmacy (Written Response)

College of Physicians and Surgeons (Presentation)

Community Clinics (Presentation)

Consumers Association of Canada (Written Response)

Pharmaceutical Manufacturers Association of Canada (Presentation)

Regina District Health Board (Presentation)

Rural Health District Board (No Response)

Saskatchewan Medical Association (Presentation)

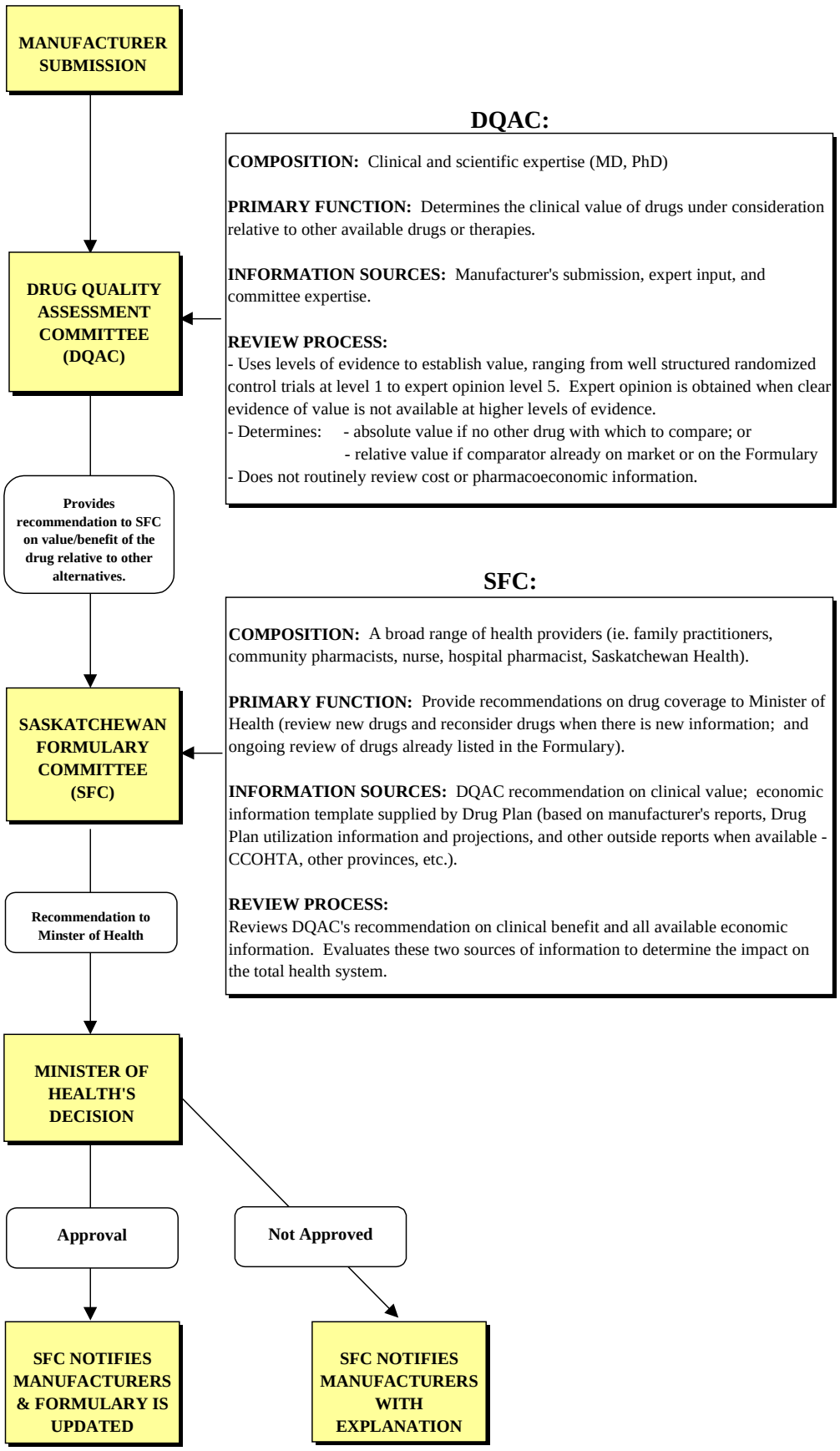
Saskatchewan Pharmaceutical Association (Presentation)

Saskatchewan Registered Nurses Association (Unable to Attend)

Saskatoon District Health Board (Written Response)

DRUG APPROVAL PROCESS
DRAFT

Appendix II



FACT SHEET

Title of Request: **Saskatchewan Drug Quality Assessment Committee**

Title of Act: **The Health Services Act**

Purpose, Summary and Background

The Drug Quality Assessment Committee (D.Q.A.C.) is appointed by the Minister of Health to advise the Saskatchewan Formulary Committee in compiling and maintaining of the Saskatchewan Formulary. It reviews scientific reports about new drugs to determine their safety, effectiveness and quality in relation to therapeutic alternatives. It also evaluates reports of comparative bioavailability studies to determine the compliance of different brands of drugs with standards for bioequivalence. It also reviews new chemical agents and existing products to determine their appropriate role, if any, in drug therapy in Saskatchewan.

The Committee was first constituted in 1974 and has operated continuously since that time. The seven members of this committee are selected on the basis of recognized expertise in clinical use of drugs, pharmacology and drug manufacturing. The chairperson of the Saskatchewan Committee is an ex-officio member of this Committee.

Each year, the Committee evaluates between 200 and 300 drug products as part of its ongoing work. As well from time to time Special Review Committees are formed to review entire groups of therapeutic agents. These consist of the members of the Drug Quality Assessment Committee supplemented by specialists and/or family practitioners with interest in the field under review.

DRAFT TERMS OF REFERENCE

SASKATCHEWAN FORMULARY COMMITTEE

Duties

The Saskatchewan Formulary Committee is a professional committee which provides technical assistance to the provincial government. It acts in an advisory capacity in the selection of drugs to be covered by the Saskatchewan Prescription Drug Plan, in the on-going review of existing products currently covered by the Plan, and the development of appropriate drug education materials for consumers and health professionals.

The Committee will be guided by the objectives of the Drug Plan, and by the policies for inclusion of products in and deletion of products from the Saskatchewan Formulary. (See Saskatchewan Formulary, pages v-ix.)

The selection of products for listing in the Saskatchewan Formulary will include the evaluation of bioequivalence and the assignment of interchangeable status where appropriate.

Additionally the Committee will provide technical assistance in the preparation of separate formularies for the specific use of Saskatchewan hospitals and other government health agencies.

Composition

The Chairperson of the Committee shall be a person with good administrative skills and a background in medicine, pharmacy, or health care administration. He/she shall be appointed by the Minister of Health for a three-year term, renewable without limitation.

The Secretary of the Committee shall be a member of the Pharmaceutical Services Division of the Drug Plan. He/she will not be a voting member of the Committee. Other staff of the Drug Plan who will act as liaison and support staff for the Committee include:

Executive Director

Pharmacologist, Pharmaceutical Services Division

Director, Pharmaceutical Services Division

Pharmaceutical Services personnel as requested.

Members of the Committee shall represent the special interest groups as shown below. The term of appointment will be three years, (from July 1 of the first year to June 30 of the third year) with the dates of re-appointment as shown:

College of Medicine	'90/93/96/99
College of Pharmacy	'90/93/96/99
Saskatchewan College of Physicians & Surgeons	'90/93/96/99
Saskatchewan Medical Association	'92/95/98/01
Saskatchewan Pharmaceutical Association	'91/94/97/00
Saskatchewan Association of Health Organizations	'91/94/97/00
Saskatchewan Registered Nurses' Association	'92/95/98/01
Saskatchewan Health	'92/95/98/01
Saskatchewan Health	'90/93/96/99
Member at Large (2)	'90/93/96/99

There will be no limit on the number of terms that may be served by an individual. Appointment will be made by the Minister of Health, in consultation with the executive management of the respective special interest groups.

Confidentiality

Members of the Committee will be required to complete an Oath of Confidentiality.

Reimbursement

Members will receive an honorarium, and coverage of out-of-pocket expenses incurred on Committee business, at current approved rates.