SUMMARY OF THE BACKGROUND PAPERS

FOR PUBLIC DISCUSSION

DRUG PROGRAMS REFORM SECRETARIAT

ONTARIO MINISTRY OF HEALTH

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INTRODUCTION

Over the past years, there have been major advances in the study of drugs and the use of drugs in the treatment of illness. These changes have led to a number of reviews and studies carried out by the various professions, government and others. These studies indicate a considerable body of opinion that, from the perspective of quality of treatment and cost effectiveness, reforms are required in aspects of prescribing, distribution, pharmaceutical investment and development, and eligibility for drug benefits.

Ministry of Health expenditures for the Ontario Drug Benefit Program are one of the fastest growing components in the health care sector. In 1986-87, the Ministry's expenditures on the ODB Program were $385 million; for 1990-91, the Ministry's expenditures were $685 million. This is in addition to expenditures for ODB by the Ministry of Community and Social Services to cover the costs of those on social assistance; in 1990-91, these expenditures totalled another $156 million. Reform of drug programs thus would affect two major centres of provincial government expenditures.

The Drug Programs Reform Secretariat was established in January 1992 by the Ministry of Health to implement reform of Ontario's drug programs. The Secretariat is working in partnership with all key stakeholders, including consumers and seniors' groups, labour, the insurance industry, physicians, pharmacists and other health professionals, the pharmaceutical industry, and other Ministries and levels of government.

The Secretariat's mission is to ensure reasonable access and affordability of appropriate and effective drug therapy for all Ontario residents through a diversified and integrated provincial system. The reform will be guided by the vision and health goals of the government and the Minister of Health's principles for the reform of the health care system.

The goals of the Drug Programs Reform Secretariat include:

1. Improvements in prescriber education to reduce inappropriate drug use;

2. Empowerment of consumers to engage in meaningful discussion and decisions about their drugs;

3. Cost containment of drug programs, with immediate and sustainable controls to keep the program affordable;

4. A drug program design that achieves equitable protection for Ontarians against unaffordable prescription drug costs;

5. Constructive partnerships with consumers, unions, professionals and industry in the planning, delivery and evaluation of public drug programs; and

6. Ensure that legislation accommodates changing environments, especially with respect to purchasing, payment and delivery mechanisms, as well as the government's right to list or delist products.

The Secretariat is working in an atmosphere of on-going consultation with key stakeholders and groups and the interested public. To this end, the Secretariat has released Background Papers to provide a basis for early discussions on reform: Pharmaceutical Investment and Manufacturing, Prescribing, Equity and Eligibility, and Distribution.

The Papers are intended to provide a common basis for public discussion by setting out a preliminary definition of key issues in the reform of drug programs in Ontario.

The following summaries of the Background Papers are provided for easy reference. The abbreviated format precludes a detailed explanation of the facts presented. The complete Papers are available from the Drug Programs Reform Secretariat, and are recommended for anyone who would like to comment on the issues raised.

BACKGROUND PAPER #1
DISTRIBUTION

Pharmacists are highly trained professionals. The majority of pharmacists practising in Ontario have at least a baccalaureate degree.

The pharmacist's dispensing function involves review of the physician's medication order: the appropriateness of the chemical entity; the required dosage; strength; frequency and route; and duration of administration.

Pharmacists recommend drugs to consumers: usually advising on a suitable over-the-counter product such as a cold remedy. They also use their professional judgement on the prescriptions that physicians write, by (a) selecting a brand from a choice of interchangeable products, (b) recommending specific therapies to prescribers, and (c) selecting or recommending an alternative therapy where the drug prescribed is not listed in either the ODB Formulary or the Formulary of the institution.

In addition, the pharmacist who owns or manages a pharmacy has the added responsibility of ensuring that the pharmacy operates efficiently and makes a profit.

The Ontario College of Pharmacists licenses pharmacists, accredits pharmacies and investigates complaints and does routine inspections of all pharmacies. Increasingly, the OCP has been involved with developing practice guidelines and setting appropriate standards to ensure pharmacists are not only qualified initially, but remain qualified throughout their years of practice.

Drugs move from the manufacturers to retailers (usually a pharmacy) either directly or via a wholesaler. The current method of pharmacy reimbursement (the best available price -- BAP -- plus a 10% upcharge) encourages retail pharmacies to buy directly from pharmaceutical manufacturers. The decision to purchase drugs directly or indirectly may also be based on other factors such as the company's invoicing and payment terms and product availability.

Hospital pharmacies usually acquire drugs through group purchasing programs, notably the Hospital Purchasing Plan of the OHA or Hospitals Purchasing Incorporated, although there are also a few smaller, regional purchasing groups.

The Ontario Government Pharmacy purchases and distributes pharmaceutical products for all psychiatric hospitals, public health units, ambulances and provincial laboratories. On request it will also act for nursing homes, homes for the aged, public hospitals and other agencies and programs funded by the government.

In the mail order drug system the written prescription is sent to a distribution house where the pharmacy fills the order and mails it to the patient. Generally a toll free number is

offered for patients to discuss their prescriptions. Computerized patient profiles can be scanned for drug-related problems.

The physician chooses the most appropriate drug for a patient and is the first to tell the patient about his or her medicine. The community pharmacist dispenses the medication to the patient and frequently gives additional information. It is important that physician and pharmacist collaborate on what is best for the patient. The pharmacist should be an invaluable resource to the physician but barriers to effective communication are frequent.

The pharmacist-patient relationship has two facets. Most obvious is the traditional role of the pharmacist as a dispenser of prescriptions. A second, equally important role is patient counselling. Patient counselling by the pharmacist normally includes reinforcing the physician's directions and providing pertinent information about the medication.

For the pharmacist, poor communication may mean inadequate understanding of the patient's condition, which may translate into flawed decisions and inadequate care by the pharmacist. For the patient, information about the medication, its appropriate use and storage, its side effects, its cost and necessary changes in lifestyles (e.g. diet, driving, smoking) is needed in order to make informed decisions about the prescribed treatment.

Counselling by the pharmacist is hindered by pharmacy design, which allows the patient no privacy and also lets customers purchase over-the-counter drugs without advice.

Drug utilization review (DUR) is a group of techniques for evaluating the appropriateness, effectiveness, costs and quality of drug prescribing. A drug utilization must include information on four interrelated items: the drug (therapy), patient (diagnosis), physician (prescriber) and pharmacy (dispensing record). Pharmacists have an important role to play in DUR, but lack the opportunity and data systems to realize that role.

Over 90% of pharmacies use computer systems to maintain individual patient profiles. Pharmacy computer systems can supply a list of the patient's medications, strengths, dosages, directions, medical conditions and allergies in a wallet card format for the patient's convenience. The Smart Card is a more sophisticated, computer interactive system, allowing pharmacists, physicians and emergency departments to read and record information on the card. The Saskatchewan government operates a computer connection between pharmacies and the public drug plan, to confirm eligibility and the co-payment required while the drug is being dispensed.

Literature suggests improvements in the way pharmacists practise, focusing on the pharmacist-patient relationship. Most pharmacists consider themselves clinical pharmacists, a model that involves maintaining and/or providing patient profiles, monitoring patient incomes, patient counselling, ensuring compliance, reviewing drug utilization and providing pharmacokinetic consultations. The pharmaceutical care model is defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a

patient's quality of life". Pharmaceutical care goes beyond the OCP guidelines, and assigns pharmacists greater responsibility for health outcomes. These outcomes are to ensure that (1) the patient is receiving/taking the appropriate drug and dosage form for each valid indication, (2) the patient has the appropriate amount of each drug and is taking each dose at the appropriate time and interval, and (3) the patient's adverse drug reactions, side effects or drug interactions have been prevented or resolved.

Formularies are lists of drug products reviewed and approved by the funding jurisdiction. They may be restricted or unrestricted, national, provincial, hospital and local. ODB uses a restricted Formulary, as do most provincial drug plans, except British Columbia, Alberta and the Yukon. In a restricted Formulary, provinces select drugs that are considered most useful in patient care, based on therapeutic and pharmacoeconomic judgements.

Many of Ontario's medium to larger hospitals have their own formularies. A drug and therapeutics committee evaluates which drugs should be used in the hospital. Studies have shown that inclusion in or deletion of a particular drug from the hospital Formulary are major influences on the use of drugs in a hospital, but do not always lead to more rational or lower cost drug therapy. Some studies concerning restrictive hospital formularies found that while drug costs fell other related costs rose.

The ODB Formulary is a list of drug products which qualify for payment under the plan. It includes all drugs eligible for reimbursement, available strengths and dosage forms, the drug identification numbers (DINs) and the cost. The provincial Drug Quality and Therapeutics Committee reviews drugs for listing. The DQTC is composed of independent physicians, pharmacists and scientists who have the expertise to review drug product submissions and advise the government as to whether or not a particular drug product should be listed.

Since the Formulary has a substantial influence on physician prescribing and on product selection, manufacturers expend considerable efforts to ensure that their products are listed. This applies to new single-source drugs (from one manufacturer) and generic versions seeking interchangeable listing.

The Formulary is important to pharmacists in making up their inventory. It defines the products for which reimbursement is offered and the amount of that reimbursement, and it determines the products that are interchangeable. The Formulary is also a mechanism by which the government can influence the cost of the ODB program and the cost of drugs to consumers who have private or no coverage.

For drugs not listed in the Formulary, retail pharmacies in Ontario will usually base their prices on those published by Drug Trading, the major wholesaler. Some pharmacists add a percentage to these prices, others do not.

Pharmacists are reimbursed by salary (hospital settings), dispensing fees (pharmacist owners), capitation (nursing homes), private service fees (cash customers requesting extra

counselling), contracts for consultation services (with long-term-care facilities), billable hour consultation rates (in the U.S., billed to non-government insurers), fees for medication management (for specific documented changes in patient therapy -- a variation on this model is used in Quebec).

The consultation questions asked in the Background Paper are:

1. How should pharmacists fulfil their professional responsibilities to the physician?
2. How should pharmacists fulfil their professional responsibility to the patient/consumer?
3. What are the most appropriate mechanisms to reimburse pharmacists for their professional services?

BACKGROUND PAPER #2
PRESCRIBING

It has been estimated that on average, physicians write 4,000 - 5,000 prescriptions per year, but the highest average is among family physicians who write 6,000 - 8,000 prescriptions per year, that is 25-30 prescriptions each working day.

Over 17,000 individuals are treated each year in Ontario for problems related to prescription drug use. Most of these problems are minor, a few are serious and a few progress to adverse drug reactions. Adverse drug reactions can be especially problematic for the elderly, pregnant women and the foetus, and children.

Studies suggest that physicians may not be as well educated as they might be fore choosing the most appropriate drug. There are often unknowns about the patient's condition, compliance, and the effects of a drug on a particular patient. Increasing numbers of physicians recognize that decisions on treatment and drug therapy should be a joint process with the patient, and some physicians and patients have difficulty working together toward this goal.

Physicians are influenced in their prescribing habits by: the patient's condition, age, sex, health attributes and likely compliance, experience with similar conditions, the express wishes of the patient, and local opinions about acceptable clinical practice.

Any particular physician uses only a small fraction of the 16,000 products on the market, or the 500 new drugs that are approved each year. The physician's medical education, and the practices, habits and preferences of his or her teachers are long-lasting influences. There is some evidence that medical students are inadequately prepared during their medical school years. Also, the physician may become accustomed to using only those drugs in the local hospital Formulary.

Once out of school, the physician's prescribing practices will be influenced by scientific journals, licensing requirements and medical training, experiences in the local community, professional associations, local and national medical leaders, influentials in the physician's area of specialization, the activities of pharmaceutical companies, pharmacists, nurses and patients, or participation in clinical trials or drug utilization reviews.

Much of the information on prescription drugs that many physicians received comes from the pharmaceutical industry through advertising and sales visits: the combined expenditures of the industry is about $6,000. to $10,000. per physician per year.

Information from pharmaceutical manufacturers will emphasize product suitability, but many not deal with aspects of the drug which might be unfavourable. Physicians require objective, scientifically-based information on suitability, therapeutic interchangeability, cost

effectiveness, new drugs on the market, common doses and suggestions for alternative drug or non-drug strategies.

The most effective way to support physicians must take into account the wide range of influences which affect prescribing behaviour. To produce long-term changes, one has to decide whether the behaviour to be altered concerns the use of a particular drug or family of drugs; therapies for a particular health condition; general prescribing habits in the community or clinical setting; therapies administered to an individual patient or group of patients; or, the practices of a particular physician. A multi-dimensional approach might include academic detailing, peer review, clinical guidelines, continuing feedback, computerized reminder systems, continuing education or activities of professional associations. Because prescribing occurs within the broader scope of clinical activities, quality in prescribing will also require quality in these other areas.

The purpose of a Drug Utilization Review Program (DUR) is to improve the outcome of the patient and to encourage the physician to use efficient and effective drug therapy. Essentially, a DUR program is designed to evaluate the use of medication from the perspective of quality management and costs and benefits.

DUR components include quality, medical necessity, clinical outcome, cost effectiveness and optimal drug therapy standards. To be effective, DUR programs require the cooperation of physicians, pharmacists and, depending upon conditions, the hospital or clinic and the government.

Rational pharmacotherapy is a model for decision-making that gives physicians a step by step process when writing a prescription. For example, after deciding that a drug is necessary, it proposes asking questions about whether a more effective drug is available, what change is desired and how will it be demonstrated, is an equally effective but less expensive product available, what are the possible side effects, are the benefits greater than the risks, and so on. The process encourages physicians to involve the patient in shared decision-making and informed consent. Using a continuous quality improvement approach, reviewing and monitoring the quality of the service provided to the patient would occur on a continual basis.

Much of the time, the patient expects and the physician provides a prescription for a drug as one of the major therapeutic activities performed. Patients are often dependent on the physician for information; it is important to improve the ability and willingness of the patient to participate more effectively with the physician in the decisions around treatment and drug therapy.

There is some evidence that the patient's participation in decision-making can have a bearing on the patient's compliance. To participate in an informed an effective manner, the patient must also know the kinds of questions to ask and be willing to ask them.

Consumers are besieged with random, unorganized, often inconsistent information on drugs from friends and family, television, radio and newspaper stories and advertising. The physician thus has the task of transferring objective information to the patient, and then using that information as a basis for discussing the options and clarifying the patient's preferences.

Patients sometimes complain that the doctor or pharmacist gave incomplete or confusing instructions. Physicians complain that their instructions are ignored or that the patient is simply behaving in a contrary way.

The relationship between the individual pharmacist and physician is not well defined and is often not active. There is evidence that when physicians in the community make use of clinical pharmacy services, choice of drug and drug dose both improved.

Improvements are needed in the way in which physicians, pharmacists and consumers interact and evaluate the drug treatment choices that have been made. The optimal level of clinically appropriate medication must be available in a manner consistent with the highest quality that is possible.

The consultation questions asked in the Background Paper are:

1. How does the physician ensure optimal drug prescribing?
2. How can the patient participate more effectively with the physician in the decisions pertaining to the patient's drug therapy?
3. How can the physician make the best use of the professional knowledge of the pharmacist to enhance the quality of treatment to the consumer?

BACKGROUND PAPER #3
EQUITY AND ELIGIBILITY

Ontario announced its publicly funded prescription drug plan in 1974. The new Ontario Drug Benefit Plan (ODB) covered 100% of prescription drug costs for seniors who were receiving Old Age Security, the Guaranteed Income Supplement, and provincial Guaranteed Annual Income Supplement, and all residents receiving Family Benefits Allowance. At that time, recipients of General Welfare Assistance had prescription support directly from their municipalities, and they were not included under ODB until 1975.

Initially, eligibility for ODB was tied to financial need. In 1975, the program was expanded to include all seniors, regardless of their income. During the 1980s, people with rare or devastating illnesses began to receive their drugs under government plans. The high cost of those drugs was an important reason for offering assistance. In the 1990s, prescription costs are still a burden to 20% of Ontarians.

Over 2700 products are now listed as ODB benefits, including over-the-counter drugs that are benefits when prescribed.

Special funding to hospitals and clinics is in addition to listed Formulary benefits that ODB covers, and people become eligible for this coverage by meeting clinical criteria, regardless of their age or financial status.

Programs in this category are for people with extraordinary drug costs, or those who need life-saving drugs not required by the general population; they include: AZT, pentamadine, cystic fibrosis, thalassemia, cancer, human growth hormone, recipients of organ transplants, end stage renal disease, nursing homes, homes for the aged and homes for special care.

Most private insurance plans in Ontario that offer health insurance packages only offer them to groups, not individuals. Prescription drug plans are not available separately, in any form, from private firms. The two largest insurers, Ontario Blue Cross and Green Shield Prepaid Services Inc., sell insurance packages that include drugs. Premiums may range from $200. to $2,000. per year, with a variety of arrangements for deductibles and co-payments.

Group insurance plans through employment account for approximately 60% of the people in Ontario who have prescription drug coverage. Eighty-eight percent of the smallest companies offer a benefits package that includes prescription drugs, and in the larger companies up to 99% of employees are covered. Of the 363 companies that offer such benefits to their employees, more than 80% require no cost-sharing from the consumer. Civil servants' plans, and those offered by manufacturing firms, consistently have some co-payment required of the consumer.

Prescription drug plans are not routinely offered in agriculture, the retail trade, seasonal or part-time employees. The largest group of vulnerable individuals are those whose full-time working income is less than $15,000. per year. An estimated 138,000 households are in that category, and are not receiving social assistance, and are not over 65.

Another vulnerable group are the disabled and those with chronic diseases who are employed but are disqualified from part or all of their group insurance plan because of their health status. Almost half of the 691,590 disabled persons in Ontario between 15 and 64 years of age do not qualify for drug plans through social assistance and there is no reliable estimate of the numbers who are facing prohibitive drug costs.

Eligibility, meaning who is entitled to receive benefits, and what is the range of benefits provided, is only part of the question. The goal of equity also includes "appropriate allocation" of those benefits and financing of the program -- are the right people getting the right amount of help. Equitable eligibility in most parts of Canada, means that people eligible for provincial drug coverage also pay a portion of the cost for their drugs.

Only Ontario, the Yukon and the Northwest Territories have no consumer cost-sharing. Several provinces have instituted a deductible for drugs, whereby consumers pay the full cost of their prescriptions up to a defined maximum, before the government plan starts to contribute. After the deductible Manitoba and Saskatchewan require a continuing share of the cost to be paid by the beneficiary.

Co-payments have been designed to apply to: the fee, the ingredient, some specific drugs, drugs at a certain cost, or categories of drugs (assessed as essential or non-essential).

There are positive and negative incentives caused by co-payment: the types of co-payment that make consumers cost-sensitive have the strongest impact on promoting generic substitution. These are fixed per-prescription co-payments. Cost sharing that requires the consumer to pay the dispensing fee, on the other hand, promotes comparison shopping for the pharmacy with the lowest fee. Deductibles might have a behaviour-changing effect on consumers who know that their annual drug costs will be lower than that amount, but cannot be expected to change utilization among people who know that their annual costs will exceed the deductible. The clearest impact of co-payment is that people will become more selective about when to spend the money, and will sometimes make inappropriate treatment decisions based solely on the cost of, rather than on the need for, the service.

Cost-sharing policies throughout Canada exempt any groups whose income is already low, and people receiving social assistance. For Ontario that would mean at least 11% - 12% of seniors who receive Drug Benefit would have to be considered low-income individuals, and exempt from a co-payment for drugs.

Consumer cost-sharing can reduce utilization by 20-30%, and therefore reduce expenditures for the insurer. This may produce financial equality in the sense that a co-payment would be

on equal terms for everyone, but it does not improve access to necessary drugs for people who cannot afford them now.

Cost-sharing also has an effect on utilization. The higher the direct price, the less often consumers will use the plan. The variation in the number of people who use the drug insurance plans of their respective provinces shows that sometimes the type of coverage has a definite effect on whether the plan is used. The effect is uneven: Saskatchewan, with one of the highest rates of cost-sharing, has virtually the same rate of seniors using the plan as Ontario.

Provinces have developed a variety of mechanisms for program administration, eligibility terms, drugs to be covered, and financing of their plans. British Columbia, Alberta, Saskatchewan and Manitoba offer universal eligibility to their residents.

Alberta and New Brunswick have arrangements with Blue Cross for the administration of their programs. Prince Edward Island distributes all the prescriptions for social assistance and disease-related programs through their provincial pharmacy. Most provinces have tied coverage for their disease-related programs to hospitals, clinics or other agencies for distribution.

The *Pharmaceutical Inquiry of Ontario*, in describing the "catastrophic" costs of prescription drugs faced by the uninsured, concluded that governments have an obligation to honour the spirit of the Canada Health Act by providing necessary pharmacotherapy as well as other health services. The Inquiry found it unacceptable that some Ontarians cannot afford essential treatment, while others who could afford to buy their own drugs or insurance are covered by ODB.

Equitable eligibility therefore needs to answer these access problems, and do so within the context of "appropriate allocation of resources".

The consultation questions asked the in the Background Paper are:

1. Who should be eligible for benefits, and should ability to pay be a consideration?
2. Which is more fair, to limit the number of people who can receive benefits, or the limit the benefits available?
3. Should the government administer its own drug programs, or work with the private sector? What other types of partnerships are possible in prescription drug plans?
4. Should the government be the "first payer" or the "payer of last resort" for prescription drugs.

BACKGROUND PAPER #4
PHARMACEUTICAL INVESTMENT AND DEVELOPMENT

This Background Paper was developed to help form the agenda for the Working Group on Pharmaceutical Investment and Development.

The pharmaceutical industry is a valued contributor to the provincial economy. The Patented Medicine Prices Review Board (PMPRB) recently published data showing that current R&D expenditures by the pharmaceutical industry amounted to $156.5 million in 1991. A publication released by the Ministries of Health and Industry, Trade and Technology -- the *Pharmaceutical Industry Study* -- noted the industry's long-term market potential and, as a result, the scope for expansion of knowledge-based employment. Opportunities for growth exist for all sectors of the industry: original brand, generic, fine chemical, over-the-counter, biological and veterinary products.

The working relationship that government seeks with industry and other stakeholders will address this complex challenge: to implement a balanced package of measures that work together to preserve the affordability, accessibility and quality of Ontario's important drug programs, while ensuring that Canadians participate in a fair share of the industry's global research and manufacturing activities.

Ontario's changed fiscal situation has forced adjustments to many provincially-funded institutions and programs, including payments to hospitals and physicians. It is clear that the design of provincial drug programs will also have to adjust so that the programs continue to meet their objectives within available resources.

From 1981/82 to 1991/92, Ministry of Health spending grew by an average of 11.2% annually, while growth in ODB expenditures for the same period averaged 17.4%. Drug costs are 75% of the total ODB program expenditures: within that, 65% is for single source products and 35% for multiple source products.

Paul Gorecki of the Economic Council of Canada found that the total number of claims had risen 93.7% in an eight-year period ending in 1987/88, or an average of 8.6% per year. Drug costs per claim over that period grew 57% faster than inflation.

Increases in drug cost are not strictly equivalent to increases in drug price, even when look at on a per claim basis. The cost of reimbursements per claim is growing many times faster among single-source drugs than among multiple-source drugs, suggesting that higher prices of new, single-source drugs is a major cost-driver. However, this would be considered a price increase only if the new product were identical to the product it replaced.

The methodology to compare the effectiveness of the "basket" of drug products consumed today with products ten years earlier simply does not exist. The data allow us to conclude only that within the 5.8% real increase in drug cost per claim from 1979/80 to 1987/88, above the rather rapid growth of inflation, many effects are happening simultaneously: prices of existing drugs are rising and some are falling, and substitution towards new more expensive therapies is occurring at the same time as less expensive generic substitutes

displace some other products where patent protection is expiring. There is little consensus on the relative size of these effects, in Canada or elsewhere.

A significant share of total prescription drugs in Ontario is paid by the ODB program. Even for the non-ODB cash market, the Formulary's price for an interchangeable product becomes a benchmark that manufacturers have difficulty exceeding. Along with the influence that Ontario's Formulary can have on other provinces' reimbursement decisions, the DQTC's recommendation on listing a product in the ODB Formulary has become a critical marketing hurdle for manufacturers to reach insured and cash customers across Canada.

The terms of reference for the DQTC currently focus on the quality and therapeutic value of drug products. The *Pharmaceutical Inquiry of Ontario* recommended that its mandate "be expanded to authorize a more effective evaluation of drug product cost factors:. The Inquiry argued that this change was necessary in order for the Province to be able to assess the cost-effectiveness of new products before they were admitted to the Formulary. This recommendation, however, is among those that have yet to be implemented.

Drug reimbursement systems in other jurisdictions were examined. In the British example, the "rate of return regulation", firms are permitted to set their own prices for new and existing products, but these are subject to downward adjustment in subsequent years if the firm exceeds its target profit rate in relation to capital employed. Within the system, controls are designed to limit spending by firms on promotional activities to 9% of sales, and allowances are made to take into account expenditures on research.

Several European countries have "detailed reimbursement lists", such as Italy and France. In France, prices have been set by a negotiation process which permitted higher prices for firms with domestic manufacturing. The French government has recently proposed to replace the current structure with a system of pricing envelopes, where companies would set their prices in view of sales forecasts in order to stay within the envelope. Italy has also recently introduced a plan to control expenditures, and proposed an across-the-board price cut, delistings of drugs, and a sharp increase in consumer co-payments.

Another system is called "reference pricing" and is used by Germany and the Netherlands -- instead of separate reimbursements being set for each product, rates are set at the same level for products falling within one therapeutic category or sub-category. This system has been accepted by the World Health Organization.

Holland seeks to create clusters of drugs with similar therapeutic activity. Reimbursement is made using the average price within that group: new drugs with therapeutic advantages are priced separately.

"Buyer discount" is the reimbursement model used in Saskatchewan, where the government tenders for the best price to supply the province completely for a particular drug product for six months. In the United States, manufacturers paid reimbursements to the Medicaid program, in effect lowering prices. Industry was free however, to adjust its prices elsewhere to offset this law's impact, and several did so -- bills were then introduced to roll back drug prices for the Department of Veterans Affairs and publicly-funded health clinics.

To guide the debate on cost-containment, four approaches are proposed.

1. Full discussion with stakeholders.
2. A package of cost-containment initiatives designed to address the full range of sources of spending growth: utilization, distribution and drug cost.
3. Simplified regulation, by greater harmonization with drug pricing and evaluation decisions at the federal level.
4. Leadership role for Ontario with respect to cost-effectiveness guidelines.

The industry's importance extends beyond its size, in 1988 contributing $377 million in wages and salaries, which represents 1.25% of Ontario's total manufacturing wages. These jobs are well-paid and knowledge-based. A high proportion of the estimated 12,000 Ontarians currently employed have university level education. This industry employs 7% of all engineers and scientists. Salaries increased at an annual average rate of 11.1% from 1983 to 1988 in Ontario, higher than the national rate of 10.8%. Brand name firms reported R&D expenditures grew by 15.8% in 1991 from the previous year.

Ontario's share of the prescription drug market is more than 46% of Canada's total, compared to 19.4% for Quebec. Ontario had 44.1% of Canada's R&D expenditures in 1991, a share which exceeds Ontario's proportion of population or GDP.

Generic manufacturers have become established and widespread around the world, providing price competition when patents expire. The generic manufacturing industry, with its provision of lower-priced alternatives to consumers, is here to stay.

At the same time there is an international movement to strengthen intellectual property laws so that discoverers receive adequate incentive to continue research that offers the promise of improved productivity and quality of life. In the pharmaceutical industry, the result has been a movement to lengthen periods of patent exclusivity, in Canada and elsewhere.

The following is a sampling of the issues which have been raised publicly or in other jurisdictions, and could be considered by the Working Group.

1. Taking industrial development factors into consideration in ODB decision-making. The Ontario Drug Benefit Act does not allow the government to enter industrial or investment criteria into its pricing and listing decisions. Since expenditures are a form of public procurement, the issue has been raised as to whether Ontario can use these expenditures strategically to encourage a higher level of industry investment.

In Australia, firms can apply for rebates (effectively an increase in prices reimbursed) if they meet targets for increased R&D spending, heavy capital investment and/or exports. In France, the complex system of price negotiations is said to favour firms investing there and exporting from a French base, by providing higher reimbursement levels and faster product approval.

American R&D-to-sales ratios generally exceed 15%. In Canada the average in 1991 was 9.7%, with a wide range of commitment: a few firms have a ratio close to 20% while there are several at near zero.

Strategic investments could address the different types of R&D that Ontario wants to support. Basic a research is generally regarded as the most valuable; clinical trials leave fewer enduring benefits; and early stage marketing activities should not be included within the definition of R&D.

2. Predictability. A decision whether or not to list a product on the ODB Formulary has a dominant influence on sales the product will generate in Ontario, even in the cash market, and to some extent in the rest of the country. Uncertainty about the direction of drug programs reform has been cited as a reason for delaying investments in Ontario.

Greater predictability might be achieved through a process that has the following principles:

- a transparent decision-making process;
- decision-making criteria are well understood;
- appropriate mechanisms for participation of stakeholders; and
- understanding of the impact on industry.

3. Policies and programs to encourage investment and innovation in Ontario. There may be specific policies and programs that could encourage domestic investment and development. For example, would it be a meaningful encouragement of innovation if steps were taken to fast-track the introduction of breakthrough products into the Formulary, and discouraging "me-too" products.

There are a range of policy and program levers available to the government: the package of investment and innovation policies would need to be balanced, and encourage growth in any sector where expansion is feasible. For example, generic firms have opportunities for export, research and diversification to other health care industries. Over-the-counter manufacturers could adopt product mandates with export potential. Brand-name firms have the potential for increased sourcing of research and development in Ontario. Small science firms and biotechnology enterprises represent tremendous potential for new employment.