

**The Right Drugs, at the Right Times, for the Right Prices:  
Toward a Prescription Drug Policy for Canada**

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CMA Presentation to House of Commons Standing  
Committee on Health

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A healthy population...a vibrant medical profession  
Une population en santé...une profession médicale dynamique

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The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, the CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, of the highest standards of health and health care.

On behalf of its 55,000 members and the Canadian public, CMA performs a wide variety of functions, such as advocating health promotion and disease/accident prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 45 affiliated medical organizations.

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## EXECUTIVE SUMMARY

Every year, three hundred million prescriptions – about 10 for every man, woman and child – are filled in Canada. Prescription drugs have benefited both the health of Canadians, and the health care system itself; they have meant dramatically improved quality of life for many Canadians, and have saved the country a great deal in hospitalization, social benefits and other expenses. However, it could be questioned whether all of Canada’s prescription drug use is appropriate; patients may be receiving too few medications, too many medications or suboptimal medications for their conditions. In addition, prescription drugs carry a price tag of their own. Since 1975, expenditures on prescription medication have risen faster than any other category in the health sector in Canada, and more is now spent on prescription drugs than on physician services.

Governments, health care providers, drug manufacturers and the public must constantly strive to ensure that Canadians receive optimal and appropriate prescription drug therapy: the right drugs, at the right times, for the right prices.

A considered, coherent, comprehensive, “made in Canada” approach to prescription drug policy should:

- Put the health of the patient first;
- Promote and enhance quality prescribing;
- Respect, sustain and enhance the therapeutic relationship between patients and health professionals;
- Promote patient compliance with drug therapy;
- Respect the principles of patient confidentiality and the privacy of patient and prescriber information.

Prescription drug policy in Canada should address:

**Access:** to

- efficacious new drugs within an appropriate time;
- coverage for medically necessary drugs for catastrophic care;
- generic drugs at reasonable prices;
- a patient/physician consultation as part of the prescribing process;
- continued research and development capacity in Canada.

**Information** for health care providers and the public that is balanced and accurate.

**Safety:** through mechanisms for the systematic monitoring of prescription drugs and their effects.

Canada’s doctors are committed to working with others to ensure that Canadians receive the right drugs, at the right times, for the right prices.

### **Summary of CMA Recommendations:**

1. That the federal government implement a timely and efficient drug review process to reduce review times to a level at or better than that in other OECD countries.
2. That the pharmaceutical industry give priority to research and development on drugs and delivery mechanisms that demonstrate a substantial improvement over products already on the market.
3. That Health Canada apply a priority review process to all drugs that demonstrate a substantial improvement over products already on the market.
4. That governments and insurance providers conduct research to identify the current gaps in prescription drug coverage for all Canadians, and develop policy options for providing this coverage, including consideration of the roles of public and private payers.
5. That the federal government monitor and, if necessary, regulate the export of prescription medications to ensure their continued availability to Canadians.
6. That prescribing of medication be done within the context of the therapeutic relationship which exists between the patient and the physician.
7. That brand-specific direct to consumer prescription drug advertising (DTCA) not be permitted in Canada.
8. That the federal government enforce the existing restrictions on DTCA found in the Food and Drug Act to the full extent of the law.
9. That the federal government develop and fund a comprehensive program to provide accurate, unbiased prescription drug information to patients.
10. That all stakeholders join in supporting and encouraging outcome-based research to ascertain best practices in prescribing.
11. That government accelerate activities to establish the Patient Safety Institute using a systems approach to support a culture of safety.
12. That a post-marketing surveillance system be implemented to monitor the ongoing safety of marketed drugs.

### **PURPOSE**

The Canadian Medical Association (CMA) has prepared this submission for the House of Commons Standing Committee on Health's review of prescription drugs in Canada. We applaud this review and welcome the opportunity to present the views of Canada's medical community.

Our vision is simple: that all Canadians should receive, if appropriate, the right drugs for their conditions, at the right times, for the right prices.

Governments, health care providers, drug manufacturers and the public should all work together to develop a “made in Canada” prescription drug policy to realize this vision. This policy must be considered, coherent and comprehensive, and should:

- Put the health of the patient first;
- Promote and enhance quality prescribing;
- Respect, sustain and enhance the therapeutic relationship between patients and health professionals;
- Promote patient compliance with drug therapy;
- Respect the principles of patient confidentiality and the privacy of patient and prescriber information.

In developing this policy we consider it particularly important to address the issues of:

### **Access to quality health care**

In this context, the CMA’s vision of a National Access Strategy includes appropriate access to

- efficacious new drugs within an appropriate time,
  - coverage for medically necessary drugs for catastrophic care,
  - generic drugs at reasonable prices,
  - a patient/physician consultation as part of the prescribing process,
  - continued research and development capacity in Canada.
- **Information** for health care providers and the public that is balanced and accurate.
  - **Safety**: through mechanisms for the systematic monitoring of prescription drugs and their effects.

Canada’s doctors look forward to working with others to realize our vision. In this submission we will discuss the steps that the CMA recommends be taken.

## INTRODUCTION

### The value of prescription medications

Prescription drugs play an important role in preventing and treating health conditions. Every year, three hundred million prescriptions – about 10 for every man, woman and child – are filled in Canada<sup>1</sup>.

In recent years, powerful new medications have meant dramatically improved quality of life, or substantial change in modes and patterns of treatment, for many Canadians. Anti-retroviral treatment has saved thousands of people with HIV infection from rapid, fatal progression to AIDS. Thanks to selective serotonin reuptake inhibitors (SSRIs) millions of people with chronic depression who might otherwise have been incapacitated or institutionalized can lead normal, productive lives in the community. Drugs to treat peptic ulcer disease have changed its treatment profile from one based mainly on surgery to a largely medical one. Though the cumulative savings on hospital care, lost workforce productivity, social benefits and disability insurance payments due to prescription drug use have not been quantified, they have undoubtedly been significant.

### Areas of Concern

In short, prescription drugs have benefited both the health of Canadians, and the health care system itself. However, they have also created concerns that must be addressed.

Utilization: is it Appropriate? Experts have questioned whether all of Canada's prescription drug use is appropriate: are patients receiving too many medications, too few medications, or suboptimal medications for their conditions? Over-utilization of prescription drugs has been a topic of some attention, but under-utilization also exists. For example, as many as 60% of people with high blood pressure may not be receiving treatment; many of these people do not even know they have the condition.<sup>2</sup>

In addition, patient compliance with prescription drug therapy is increasingly recognized as a problem, especially for long-term or chronic conditions. Compliance is a potential issue in all treatments but is of special concern in conditions where few clinical symptoms are present: for example in hypertension, where lack of treatment over the long term may result in kidney damage, vascular and ophthalmological damage, stroke or heart disease. One study found that only 50% of patients comply with long-term drug therapy, and an even smaller percentage comply with lifestyle alterations.<sup>3</sup>

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<sup>1</sup> Romanow R. *Building on Values: the Future of Health Care in Canada*. Report of the Commission on the Future of Health Care in Canada; November 2002.

<sup>2</sup> Chobanian et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. *JAMA* 2003; 289.

<sup>3</sup> Butler C, Rollnick S, Stott N. The practitioner, the patient and resistance to change. *Recent Ideas on Compliance* 1996;14(9):1357-62.

Partial compliance with antibiotic therapy for infectious diseases is well recognized as one cause of anti-microbial resistance to common infectious pathogens.

Cost: is it too high? More is now spent on prescription medicine than on physician services. Since 1975, expenditures on prescription medication have risen faster than any other category;<sup>4</sup> during the 1990's they rose more than twice as quickly as overall spending on health care.<sup>5</sup> In 2002 retail spending on drugs in Canada (prescribed and non-prescribed) was estimated to be at least 16% of total health care spending. Prescription medication accounts for 80% of this category, up from 70.3% in 1990.

What drives drug expenditure in Canada? There is considerable debate on this subject, but some of the drivers are believed to be:

- Increased utilization: as the population ages there is an increased prevalence of conditions such as hypertension, type 2 diabetes mellitus and osteoarthritis, which often require pharmacological treatment.
- Newer (patented) drugs, which are more expensive than generics, dominate the prescription market. Between 1995 and 2000, five drug categories (including cholesterol lowering agents, high blood pressure drugs, acid-reducing agents and anti-depressants) contributed significantly to the overall rise in drug costs.<sup>5</sup> These categories are dominated by newer, patented drugs, many of which are heavily promoted.
- Prices of generic drugs, though lower than those of patented drugs, are higher in Canada than in some other countries. For example, generic drug prices are 26% lower in Germany and 68% lower in New Zealand.<sup>6</sup>
- Marketing practices such as mass media direct to consumer advertising (DTCA) in the United States, and its attendant “spillover” into the Canadian marketplace, may contribute to increased utilization.

In Canada the Patent Medicine Prices Review Board (PMPRB) maintains price controls on brand-name drugs. Similar price-control mechanisms exist in European Union countries. However, no such controls exist for generic medications in Canada. All in all, prescription medications can be costly for Canadians, especially for those who lack any kind of insurance coverage.

### **The Role of Physicians and the Canadian Medical Association**

Canada's doctors are committed to ensuring that Canadians have access to the right drugs, at the right times, at the right prices, to help them achieve the right results – in other words, the best possible health outcomes.

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<sup>4</sup> Canadian Institute for Health Information. *Health spending to top \$112 billion in 2002, reports CIHI*. Media release. December 18, 2002. [http://secure.cihi.ca/cihiweb/dispPage.jsp?cw\\_page=media\\_18dec2002\\_e](http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_18dec2002_e)

<sup>5</sup> Patent Medicine Prices Review Board. *Pharmaceutical Trends, 1995/96 – 1999/00*. Prepared for the Federal/Provincial/Territorial Working Group on Drug Prices; September 2001.

<sup>6</sup> Patent Medicine Prices Review Board, *A study of the Prices of the Top Selling Multiple Source Medicines in Canada*. November 2002.

The goal of drug therapy is to improve patients' health and quality of life by preventing, eliminating or controlling diseases or symptoms. Patients, physicians and pharmacists must work in collaboration to achieve this goal. The physician's role in drug therapy goes well beyond the act of writing out a prescription; it encompasses:

- Diagnosing diseases, assessing the need for drug therapy and designing the medication regime;
- Working with patients to set treatment goals and monitor progress toward them;
- Monitoring the patient's response to drug therapy, revising the care plan when necessary to support compliance and achieve the best possible health outcomes;
- Sharing with the patient specific information about the diseases and the drug therapy, including its effects and potential side effects (including, in some cases, the potential for prescription drug addiction).<sup>7</sup>

The CMA's activity has been focused on promoting excellence in prescribing, and on disseminating drug information to physicians.<sup>8</sup> In 1999, the CMA worked with Health Canada and the Canadian Pharmacists Association (CPhA) to convene an expert roundtable on the subject of "Best Practices in Prescribing". This was but one effort of the profession to explore why some therapies appear to be under-prescribed, while others may be over-prescribed.

CMA has developed principles on the issues of physician information and of providing information on prescription drugs to consumers; both these documents will be discussed later in this submission. CMA and CPhA have also developed a joint policy statement on approaches to enhancing the quality of drug therapy (attached as Appendix I). In addition CMA is co-funding, with the Canadian Institute of Health Research, an interdisciplinary research team focussed on Drug Policy Futures. The team's identified areas of study include: financing and public expectations; improving quality; health care evaluation and technology assessment; and public advice-seeking in the era of e-health.

The CMA publishes *Drugs of Choice*, a definitive Canadian guide to first- and second-line drug therapies for hundreds of clinical conditions. It is now in its third edition. In addition CMA maintains an extensive database of clinical practice guidelines, including prescribing guidelines, available to physicians and the public through the CMA Web site, and has developed an on line course for physicians on Safe Medication Practices. The cma.ca web site also provides access to a Canadian online drug database that can be downloaded and used with state-of-the-art PDA (personal device) technology at the point of clinical care.

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<sup>7</sup> Approaches to Enhancing the Quality of Drug Therapy." Joint policy of the Canadian Medical Association and Canadian Pharmacists Association.

<sup>8</sup> It should be noted that the CMA does not have the authority to enforce directives on physicians with regard to prescribing. The provincial and Territorial Colleges of Physicians handle licensing and regulatory matters.

## **CMA'S PRIORITIES FOR ACTION**

### **A) Access to quality health care**

CMA's history of advocating for access to needed health care services goes back many years. In 2004, a National Access Strategy will be one of the association's highest-priority activities. With respect to prescription drugs there are several access-related problems: slow approval of new drugs, uneven insurance coverage, and the possible consequences of cross-border shopping on the availability of drugs in Canada.

#### *i) Drug Approvals: The Right Drug at the Right Time*

##### **CMA recommends:**

- 1. That the federal government implement a timely and efficient drug review process to reduce review times to a level at or better than that in other OECD countries.*
- 2. That the pharmaceutical industry give priority to research and development on drugs and delivery mechanisms that demonstrate a substantial improvement over products already on the market.*
- 3. That Health Canada apply a priority review process to drugs that demonstrate a substantial improvement over products already on the market.*

Stakeholders have repeatedly drawn attention to the slowness of Canada's drug review process. Between 1996 and 1998 Canadian approval times (median 518 days) were significantly longer than Sweden (median 371 days), the UK (median 308 days) and the United States (median 369 days). These have not improved significantly even after Health Canada implemented a cost-recovery approach to funding the drug review process.

Delays in the drug review process mean delays in access to new, potentially life-saving medications. For example, 15 other countries approved Singulair, a major breakthrough in asthma therapy, before it was approved in Canada, even though the drug was developed in Montreal! Approximately 10% of children between 5 and 14 years of age have asthma and could have benefited from this relatively safe drug. Intravenous tissue plasminogen activator (tPA), a medication for treatment of acute stroke, was approved for use in the United States in 1996 but was not approved in Canada until 1999.

Canada's long drug review times are mainly attributed to lack of resources at Health Canada. CMA recommends that Canada implement a timely and efficient drug review process to reduce these times to an appropriate level. The 2003 federal budget announcement of \$190 million over five years to improve the timeliness of the regulatory process was encouraging. We hope that this will soon translate into a significant reduction in drug review times.

Many drugs submitted for approval are not genuinely innovative; some are virtual copies of drugs already on the market. Others, however, could offer substantial improvement over what is currently available. They could be more clinically effective; or they could have fewer side effects; or their mechanism of delivery could increase compliance (for example, medication that can be taken only once a day instead of three or four times a day). CMA recommends that the pharmaceutical industry give priority to research and development on products and delivery mechanisms that offer substantial additional benefit to Canadian patients.

It seems logical that drugs that offer benefits not yet available to Canadians should reach patients who need them more quickly. Recently, Health Canada implemented a priority review process for drugs to treat serious, life threatening or debilitating conditions, for which there is substantial evidence that the drug is a significant improvement over existing therapies. This is a promising step. CMA recommends that Health Canada apply a priority review process to all drugs deemed to offer substantial improvement over what is already on the market. This will also serve as an incentive to the pharmaceutical industry to emphasize drugs that offer substantial benefit in their research and development plans.

ii) *Coverage: Making the System Work*

**CMA recommends:**

- 4. *That governments and insurance providers conduct research to identify the current gaps in prescription drug coverage for Canadians, and develop policy options for providing this coverage, including consideration of the roles of public and private payers.***

Coverage for all Canadians. Prescription drugs are Canada's most notable example of a public/private partnership in health services delivery. Our country's blend of public and private drug insurance coverage has worked reasonably well; but there is room for improvement.

The *Canada Health Act's* mandate covers "drugs, biologicals and related preparations when administered in the hospital". Provincial and territorial drug programs vary with most covering only seniors and people on social assistance.<sup>9</sup> Many Canadians get their drug coverage through private plans offered by their employers. But many people in Canada lack any kind of drug coverage. We do not know exactly how many. According to a report prepared for the Canadian Life and Health Insurance Association, 2% to 4% of Canadians have no coverage, but other reports place the number closer to 10%.<sup>10,11</sup> At a minimum, 1 million to 3 million Canadians are in need of basic prescription drug coverage.

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<sup>9</sup> Manitoba, British Columbia and Saskatchewan provide some coverage to all residents after the co-payments and deductibles are paid. Quebec provides universal coverage to those not in a private plan.

<sup>10</sup> Fraser Group/Tristat Resources. *Drug Expense Coverage in the Canadian Population – Protection from Severe Drug Expenses*. CLHIA. August 2002.

<sup>11</sup> Palmer D'Angelo Consulting Inc. *National Pharmacare Cost Impact Update Study*. Executive Summary. September 4, 2002.

Drug therapy may be more cost-efficient than some forms of hospital care. Is the current health care system promoting inefficiency by covering hospital services more completely than prescription drug therapy?

In 1997 the National Forum on Health recommended that drugs become part of the publicly funded system. However, such a system would be prohibitively expensive; estimates range from \$12.4 billion for a combined public and private model (with co-payments) to \$13.8 billion for fully funded, public only model (no co-payments).<sup>12</sup> The report of the Romanow Commission acknowledged this when it emphasized the need to “move in a gradual but deliberate and dedicated way to integrate prescription drugs more fully into the continuum of care”. For the short term, the report recommended a Catastrophic Drug Transfer to ensure that Canadians who face the greatest financial burden can continue to access the medications they need. The Trillium program in Ontario is an example of such a program.

We need to know more about both the number of people who need drug coverage and the best means of providing them with it. As a first step, CMA recommends that the government, insurance providers and all partners in the public and private sectors conduct research to more accurately identify current gaps in prescription drug coverage, and develop policy options for bridging them.

Given the ever larger role that prescription drug therapy is playing in health care in Canada, governments should consider expanding the current basket of “core services” to include prescription drugs. Under the *Canada Health Act* provinces and territories must ensure that medically necessary physician and hospital services are provided on a first-dollar basis. CMA has recommended that the scope of the basket of core services be updated regularly to reflect the realities of health care delivery and the needs of Canadians. Given the potential of prescription drugs to improve the system’s cost-effectiveness, we believe that Canadian governments must consider whether the concept of “core services” needs to be revised to reflect their importance, *provided that this does not further compromise access to medically necessary hospital and physician services.*

Drug Pricing Policies: Toward a Policy for All Drugs in Canada. As mentioned previously, PMPRB controls the prices of brand-name patent medications in Canada. However, generic drug make up 40% of the drugs prescribed in this country. Canada has no mechanism to control the prices of generic drugs, as do some other countries (France, for example, has a decree stating that the price of a generic product must be at least 30% less than the price of the original patented brand.)<sup>6</sup> Most provinces have policies encouraging substitution of a brand drug by a comparable generic where appropriate. CMA believes it is time for Canadian governments to explore mechanisms for ensuring appropriate pricing of generic medications.

Product Substitution: Making health the first priority. Even under their current system of limited coverage, federal and provincial governments have expressed concern about the cost of their drug programs, and implemented measures to reduce this cost. One of these is drug product substitution. Generic substitution, discussed in the previous section, is now commonplace; British Columbia has taken the concept further with its system of reference-based pricing.

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<sup>12</sup> Ibid

While CMA recognizes the motives behind drug product substitution, we believe that it should only be implemented if it does not jeopardize quality of care or patient confidentiality. Doctors would be happy to participate in discussion of initiatives around drug product substitution, to ensure that the health of the patient continues to be the highest priority to all stakeholders.

*iii) Access and Cross-Border Prescribing*

*CMA recommends:*

- 5. That the federal government monitor and, if necessary, regulate the export of prescription medications to ensure their continued availability to Canadians.*
- 6. That prescribing of medication be done within the context of the therapeutic relationship that exists between the patient and the physician.*

Prices of brand-name prescription drugs are higher in the US, where no price review body exists, than they are in Canada. As a result access to the need for prescription medication can pose considerable financial hardship, particularly for America's elderly and poor.

The rising cost of brand-name medications in the United States has led many Americans to look to Canada for less expensive alternatives. At least one US city, Springfield, Massachusetts, has begun a voluntary program to purchase prescription medication from Canada for its workers and retirees<sup>13</sup> and the State of Illinois is examining the feasibility of following Springfield's lead.<sup>14</sup> US drug costs have also spurred a growth industry in Canada: Internet pharmacies. According to estimates in US media, approximately \$650 million (US) worth of prescriptions are sold online every year.<sup>15</sup> The prospect of accessing cheaper Canadian drugs is particularly appealing to elderly Americans who have turned to the Internet to purchase prescriptions they would be unable to afford at home.

The burgeoning cross-border export of pharmaceuticals has had its consequences. Several brand-name multinational pharmaceutical manufacturers have moved to stop or limit supplies to those Canadian pharmacies they believe are selling drugs over the Internet. They must now order directly from the manufacturer instead of from wholesalers.<sup>16</sup> The brand-name companies have also held out the prospect of boycotting Canada in response to legislation passed by the US House of Representatives that would allow the importation of drugs by Americans.<sup>17</sup>

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<sup>13</sup> Tynan T. Cash-strapped Springfield, Mass., begins buying Canadian prescription drugs. *Edmonton Journal* July 29, 2003. <http://www.canada.com/edmonton/story.asp?id=21FB8445-1143-4C13-B282-76F380CB4FE1>

<sup>14</sup> CBSNews.com. Illinois looks to Canada for drugs. *CBS News* September 15, 2003. <http://www.cbsnews.com/stories/2003/07/29/health/main565611.shtml>

<sup>15</sup> Kedrosky P. Dangerous popularity of online pharmacies. *National Post* August 13, 2003.

<sup>16</sup> Harris G. Pfizer moves to stem Canadian drug imports. *New York Times* August 7, 2003. <http://www.nytimes.com/2003/08/07/business/07DRUG.html>

<sup>17</sup> Cusack B., Stinson S. US drug firms set to boycott Canada. *National Post* August 7, 2003. <http://www.nationalpost.com/home/story.html?id=363CC2EA-1832-42F2-954C-0F52D1828E23>

This legislation is now before the US Senate Health, Education, Labor and Pensions Committee. The US Food and Drug Administration has opposed importation on safety grounds.

The CMA shares the increasingly prevalent concern that cross-border export will result in reduced access to prescription drugs in Canada, and damage the research and development capacity of brand-name prescription drug manufacturers in Canada. Therefore the CMA recommends that Canada monitor and, if necessary, regulate the export of brand-name drugs to ensure their continued availability in this country.

Many Internet pharmacies offer the services of physicians who will sign prescriptions without seeing the patient in a consultation. This is not acceptable to the CMA, or to the regulatory Colleges of Physicians and Surgeons or the Canadian Medical Protective Association. It is clear that, in principle, to form an appropriate therapeutic relationship a physician must take a history, perform an appropriate physical examination, and order and interpret appropriate diagnostic tests on her patients. The role of the physician in drug therapy is a complex one; to be most effective it requires a strong ongoing professional relationship between patient and physician. This relationship is the foundation of medical practice; it is key to a prescribing decision and it must be maintained. Our position is discussed in greater detail in CMA's Statement on Internet Prescribing (attached as Appendix II).

**B) Consumer Drug Information: From DTCA to DTCI**

*CMA recommends:*

- 7. That brand-specific direct to consumer prescription drug advertising (DTCA) not be permitted in Canada.*
- 8. That the federal government enforce the existing restrictions on DTCA found in the Food and Drug Act to the full extent of the law.*
- 9. That the federal government develop and fund a comprehensive program to provide accurate, unbiased prescription drug information to patients.*

In the past few years an increasing amount of information on prescription medication has become available to consumers. Much of this reaches Canadians in the form of direct to consumer advertising (DTCA) for specific brands, transmitted across the border from the United States, where it is a billion-dollar-a-year business.

DTCA is not legal in Canada, except for notification of price, quantity and the name of the drug. However, advertisers have taken advantage of loopholes in the law to promote brand-name drugs in this country – for example, the controversial television campaign for Viagra. DTCA is also transmitted by print and TV across the border from the United States, and worldwide through the Internet. There is a strong lobby for a relaxation of the DTCA restrictions in Canada.

DTCA boosts sales of advertised drugs. In 1999, 25 drugs accounted for 40% of that year's increase in retail drug spending in the US; all these drugs were advertised to the public.<sup>18</sup> Further, DTCA adversely affects the patient/physician relationship. Doctors report feeling pressure and ambivalence when patients ask them to prescribe a specific brand-name drug.<sup>19,20</sup> About 20% of respondents to the CMA's 2003 physician survey felt patients' request for advertised drugs had a negative impact on the patient/physician relationship.<sup>21</sup>

Advocates for DTCA maintain that it provides "consumers" with the information they need to become partners in their own health care. They maintain that DTCA does not undermine the patient/physician relationship, because it does not alter the fact that ultimate prescribing authority remains in the hands of the physician.

However, the CMA believes that direct to consumer advertising of prescription drugs is inappropriate. DTCA

- does not communicate risk adequately, or provide enough information to allow the consumer to make appropriate drug selections. Generally it does not provide information about other products or therapies that could be used to treat the same condition,
- stimulates demand by exaggerating the risks of a disease and generating unnecessary fear,
- contributes to a culture of "overmedicalization" by treating normal human conditions such as aging and baldness as diseases, and offering "a pill for every ill".

Brand-specific direct to consumer prescription drug advertising should not be permitted in Canada. CMA calls on the federal government to enforce the existing restrictions on DTCA found in the Food and Drug Act and its regulations to the full extent of the law.

We believe that the public has a right to accurate, unbiased direct to consumer *information* (DTCI) on drugs and other therapies, to enable patients to make decisions regarding their own health care. This information may increase the appropriateness of prescription drug use. For example, it may encourage consumers to get treatment for conditions that are currently under-treated. However, there are more effective ways to provide this information than brand-name advertising. CMA has developed "Principles for Providing Information about Prescription Drugs to Consumers" as an alternative to DTCA; these are attached as Appendix III. We call on Canadian stakeholders, including governments, health professionals, consumer groups and industry, to work together to provide information for the public based on these principles.

Further, the CMA calls on the federal government to develop and fund a comprehensive program to provide accurate, unbiased prescription drug information to patients.

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<sup>18</sup> "Prescription Drugs and Mass Media Advertising." National Institute for Health Care Management Research. Washington, DC, 2001.

<sup>19</sup> Mintzes B, Barer ML, Kravitz RL at al. How does direct to consumer advertising affect prescribing? a survey in primary care environments with and without legal DTCA. *CMAJ* 169 (2003): 405 –412.

<sup>20</sup> Food and Drug Administration. Direct to consumer advertising of prescription drugs: physician survey preliminary results. Accessed at [www.fda.gov/cder/ddmac](http://www.fda.gov/cder/ddmac).

<sup>21</sup> Survey shows strong opposition to direct to consumer advertising. Accessed at <http://www.cma.ca/cma/>

**C) Safety: Ensuring Best Practices in Prescribing**

*CMA recommends:*

- 10. That all stakeholders join in supporting and encouraging outcome-based research to ascertain best practices in prescribing.*
- 11. That government accelerate activities to establish the Patient Safety Institute using a systems approach to support a culture of safety.*
- 12. That a post-marketing surveillance system be implemented to monitor the ongoing safety of marketed drugs.*

The health care system is complex, involving many inter-related and interdependent factors which could influence the frequency and intensity of medication incidents. Such “systems factors” might include

- shortage of qualified health professionals (physicians, nurses and others),
- inappropriate use of new technology,
- unclear labeling or similar-looking drug preparations,
- prescription drug misuse, including over-prescribing or under-prescribing of certain medications.

Canada’s doctors are working to promote drug safety on a number of fronts. For example, CMA is working with governments at all levels to ensure that we do not “enrich the nation’s urine” through unnecessary prescribing. The *Canadian Medical Association Journal* regularly publishes research on prescribing practices. CMA also publishes *Safe Medication Practices*, a physician guide to patient safety; a companion online course is available on the [cma.ca](http://cma.ca) web site.

We propose that the health care system work to create a culture that promotes optimal prescribing, by fostering outcomes research, creating supportive infrastructures, strengthening the capacity for post-marketing surveillance, and making the best possible use of technology. Our suggestions are discussed below.

Closing the Care Gap.

Given our present knowledge base, it is often difficult to ascertain whether current drug utilization patterns lead to improvements in health. For example, research on compliance with drug therapy, and the factors that improve it, is in its infancy and though we know that direct-to-consumer advertising affects drug sales we have yet to determine whether it affects health outcomes. A commitment to outcome-based research on drug utilization would help us find the answers to these and other questions. Research on prescribing patterns should respect the conditions outlined in CMA’s “Principles Concerning Physician Information” (attached as Appendix IV).

The CMA calls on all stakeholders (governments, health professionals and the private sector) to join in supporting and encouraging outcome-based research to ascertain best practices in drug utilization and prescribing, and close care gaps when they are identified.

### Creating an infrastructure for safety.

The CMA has no doubt of the overall quality of the prescription medications approved for use in Canada. However, the more drugs are used, the greater their potential for unintended harm. Studies in the United States have found that almost 2% of patients admitted to hospitals experienced a significant adverse drug event, and that the number of deaths due to medications increased over 200% over five years.<sup>22</sup> Though studies are still in progress in Canada, we assume that rates of adverse medication events are similar in the two countries.

The 2003 federal budget committed \$10 million per year to establish a Patient Safety Institute to monitor and prevent medical incidents. This is an important step toward building a safer health care system, and Canada's doctors are committed to moving this initiative forward. The CMA, with 11 other health care organizations, is a member of the Canadian Coalition on Medication Incident Reporting and Prevention. This initiative is led by Health Canada and has recently been funded through the Patient Safety Initiative. The federal government has also recently funded the Canadian Medication Incident Reporting and Prevention System to collect data on medication incidents and disseminate information designed to reduce their risk.

The CMA believes that to be effective a patient safety initiative must

- be voluntary,
- be non-punitive; and
- protect the privacy and confidentiality of physicians and patients.

Further, efforts towards ensuring patient safety should address in a timely manner the “systems” issues referred to above, supporting and fostering a culture of safety. CMA is calling on governments to accelerate activities to establish the Patient Safety Institute using a “systems” approach.

### Strengthening Post-Marketing Surveillance.

No matter how rigorous the drug approval and review process, it cannot identify all of a medication's effects; many of these are only identified once the drug is in widespread use in the general population. A strong post-marketing surveillance system is needed to gather this knowledge and ensure patient safety. A post marketing surveillance system should include timely collection of data related to

- adverse drug reactions,
- medication incidents,
- targeted drug effectiveness studies,
- optimal utilization of medications.

The goal of an enhanced post-marketing surveillance system is to monitor the ongoing safety and risk/benefit ratio of medications once they have been approved and are being used in the broad population. An ideal surveillance system would go beyond collecting and collating data, to analyze it and produce information that health care professionals and policy makers can use in decision-making at the population level.

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<sup>22</sup> Canadian Coalition on Medication Incident Reporting and Prevention. A medication incident reporting and prevention system for Canada: business Plan. March 2002.

For example, data could be used to

- communicate product related risks to health professionals and patients,
- determine the incidence of adverse drug reactions and medication incidents in the Canadian population as a whole and various subgroups over time, as well as their health and economic impact.

Currently post-marketing surveillance of drugs in Canada is inadequate, relying on reporting which is often erratic and inconsistent, and for which reporters are not compensated. Canada needs a coordinated post-marketing surveillance system to monitor the ongoing safety of marketed drugs. Surveillance should include medication incidents and adverse drug reactions, and should document and consider the effect of the “systems factors” contributing to these events.

#### Making use of supportive technology.

We mentioned that the current reporting system is erratic and inconsistent. An investment in supportive technology would reduce inconsistencies by increasing physicians’ capacity to report and even prevent medication incidents.

Under the September 2000 federal/provincial Health Accord, the Government of Canada announced \$500 million to expand the use of health information and communications technologies, including the adoption of electronic health records (EHRs). One of the advantages cited for a pan-Canadian EHR is that it could reduce the occurrence of adverse drug events – for example, handwritten prescription and interpretation errors. Progress has been slow, but CMA will follow with interest the pilot EHR program just announced in Alberta. While we expect improvement in prescribing practices and outcomes under such programs, we expect them to respect the principles of patient confidentiality and the right of prescribers to the privacy of their prescribing information.

Technology can also make real-time communication within the health care system much easier. and CMA strongly recommends an investment in systems that can link physicians to one another and to the rest of the health care system. In its 2003 brief to the Finance Committee’s pre budget hearings, CMA recommended that the federal government immediately fund dedicated Internet connectivity for all physicians in Canada. CMA has also repeatedly called for sustained and substantial investment in a “REAL” (rapid, effective, accessible and linked) Health Communications and Coordination Initiative to improve technical capacity to communicate with front-line health providers in real time. Real-time information is essential for effective day-to-day health care and will form the cornerstone of an adverse drug reaction communication program for the 21<sup>st</sup> century.

## **Conclusion**

It is vital to Canada's physicians that our patients receive the right medications for their condition, at the right times, at the right prices. CMA calls on the federal government and all other stakeholders to work together to develop a comprehensive "made in Canada" prescription drug policy to realize this vision – one that promotes optimal prescribing, puts the health of patients first, respects the relationships of patient and physician and of patient and pharmacist, and honours the principle of patient confidentiality and the privacy of patient and prescriber information.

The reports of the Romanow Commission on the Future of Health Care in Canada and the Senate Standing Committee on Science, Social Affairs and Technology review discussed issues surrounding prescription drug policy in Canada. We hope that the review by this parliamentary committee will lead to prompt and decisive action.

## **APPROACHES TO ENHANCING THE QUALITY OF DRUG THERAPY A JOINT STATEMENT BY THE CMA AND THE CANADIAN PHARMACEUTICAL ASSOCIATION**

*This joint statement was developed by the CMA and the Canadian Pharmaceutical Association, a national association of pharmacists, and includes the goal of drug therapy, strategies for collaboration to optimize drug therapy and physicians' and pharmacists' responsibilities in drug therapy. The statement recognizes the importance of patients, physicians and pharmacists working in close collaboration and partnership to achieve optimal outcomes from drug therapy.*

### **Goal of This Joint Statement**

The goal of this joint statement is to promote optimal drug therapy by enhancing communication and working relationships among patients, physicians and pharmacists. It is also meant to serve as an educational resource for pharmacists and physicians so that they will have a clearer understanding of each other's responsibilities in drug therapy. In the context of this statement, a "patient" may include a designated patient representative, such as a parent, spouse, other family member, patient advocate or health care provider.

Physicians and pharmacists have a responsibility to work with their patients to achieve optimal outcomes by providing high-quality drug therapy. The important contribution of all members of the health care team and the need for cooperative working relationships are recognized; however, this statement focuses on the specific relationships among pharmacists, physicians and patients with respect to drug therapy.

This statement is a general guide and is not intended to describe all aspects of physicians' or pharmacists' activities. It is not intended to be restrictive, nor should it inhibit positive developments in pharmacist-physician relationships or in their respective practices that contribute to optimal drug therapy. Furthermore, this statement should be used and interpreted in accordance with applicable legislation and other legal requirements.

This statement will be reviewed and assessed regularly to ensure its continuing applicability to medical and pharmacy practices.

### **Goal of Drug Therapy**

The goal of drug therapy is to improve patients' health and quality of life by preventing, eliminating or controlling diseases or symptoms. Optimal drug therapy is safe, effective, appropriate, affordable, cost-effective and tailored to meet the needs of patients, who participate, to the best of their ability, in making informed decisions about their therapy. Patients require access to necessary drug therapy and specific, unbiased drug information to meet their individual needs. Providing optimal drug therapy also requires a valid and accessible information base generated by basic, clinical, pharmaceutical and other scientific research.

### **Working Together for Optimal Drug Therapy**

Physicians and pharmacists have complementary and supportive responsibilities in providing optimal drug therapy. To achieve this goal, and to ensure that patients receive consistent information, patients, pharmacists and physicians must work cooperatively and in partnership. This requires effective communication, respect, trust, and mutual recognition and understanding of each other's complementary responsibilities. The role of each profession in drug therapy depends on numerous factors, including the specific patient and his or her drug therapy, the prescription status of the drug concerned, the setting and the patient physician pharmacist relationship. However, it is recognized that, in general, each profession may focus on certain areas more than others.

For example, when counselling patients on their drug therapy, a physician may focus on disease-specific counselling, goals of therapy, risks and benefits and rare side effects, whereas a pharmacist may focus on correct usage, treatment adherence, dosage, precautions, dietary restrictions and storage. Areas of overlap may include purpose, common side effects and their management and warnings regarding drug interactions and lifestyle concerns. Similarly, when monitoring drug therapy, a physician would focus on clinical progress toward treatment goals, whereas a pharmacist may focus on drug effects, interactions and treatment adherence; both would monitor adverse effects.

Both professions should tailor drug therapy, including education, to meet the needs of individual patients. To provide continuity of care and to promote consistency in the information being provided, it is important that both pharmacists and physicians assess the patients' knowledge and identify and reinforce the educational component provided by the other.

### ***Strategies for Collaborating to Optimize Drug Therapy***

Patients, physicians and pharmacists need to work in close collaboration and partnership to achieve optimal drug therapy. Strategies to facilitate such teamwork include the following.

Respecting and supporting patients' rights to make informed decisions regarding their drug therapy.

Promoting knowledge, understanding and acceptance by physicians and pharmacists of their responsibilities in drug therapy and fostering widespread communication of these responsibilities so they are clearly understood by all.

Supporting both professions' relationship with patients, and promoting a collaborative approach to drug therapy within the health care team. Care must be taken to maintain patients' trust and their relationship with other caregivers.

Sharing relevant patient information for the enhancement of patient care, in accordance and compliance with all of the following: ethical standards to protect patient privacy, accepted medical and pharmacy practice, and the law. Patients should inform their physician and pharmacist of any information that may assist in providing optimal drug therapy.

Increasing physicians' and pharmacists' awareness that it is important to make themselves readily available to each other to communicate about a patient for whom they are both providing care.

Enhancing documentation (e.g., clearly written prescriptions and communication forms) and optimizing the use of technology (e.g., e-mail, voice mail and fax) in individual practices to enhance communication, improve efficiency and support consistency in information provided to patients.

Developing effective communication and administrative procedures between health care institutions and community-based pharmacists and physicians to support continuity of care.

Developing local communication channels and encouraging dialogue between the professions (e.g., through joint continuing education programs and local meetings) to promote a peer-review-based approach to local prescribing and drug-use issues.

Teaching a collaborative approach to patient care as early as possible in the training of pharmacists and physicians.

Developing effective communication channels and encouraging dialogue among patients, physicians and pharmacists at the regional, provincial, territorial and national levels to address issues such as drug-use policy, prescribing guidelines and continuing professional education.

Collaborating in the development of technology to enhance communication in practices (e.g., shared patient databases relevant to drug therapy).

Working jointly on committees and projects concerned with issues in drug therapy such as patient education, treatment adherence, formularies and practice guidelines, hospital-to-community care, cost-control strategies, sampling and other relevant policy issues concerning drug therapy.

Fostering the development and utilization of a high-quality clinical and scientific information base to support evidence-based decision making.

## ***The Physician's Responsibilities***

Physicians and pharmacists recognize the following responsibilities in drug therapy as being within the scope of physicians' practice, on the basis of such factors as physicians' education and specialized skills, relationship with patients and practice environment. Some responsibilities may overlap with those of pharmacists (see *The Pharmacist's Responsibilities*). In addition, it is recognized that practice environments within medicine may differ and may affect the physician's role.

Assessing health status, diagnosing diseases, assessing the need for drug therapy and providing curative, preventive, palliative and rehabilitative drug therapy in consultation with patients and in collaboration with caregivers, pharmacists and other health care professionals, when appropriate.

Working with patients to set therapeutic goals and monitor progress toward such goals in consultation with caregivers, pharmacists and other health care providers, when appropriate.

Monitoring and assessing response to drug therapy, progress toward therapeutic goals and patient adherence to the therapeutic plan; when necessary, revising the plan on the basis of outcomes of current therapy and progress toward goals of therapy, in consultation with patients and in collaboration with caregivers, pharmacists and other health care providers, when appropriate.

Carrying out surveillance of and assessing patients for adverse reactions to drugs and other unanticipated problems related to drug therapy, revising therapy and, when appropriate, reporting adverse reactions and other complications to health authorities.

Providing specific information to patients and caregivers about diagnosis, indications and treatment goals, and the action, benefits, risks and potential side effects of drug therapy.

Providing and sharing general and specific information and advice about disease and drugs with patients, caregivers, health care providers and the public.

Maintaining adequate records of drug therapy for each patient, including, when applicable, goals of therapy, therapy prescribed, progress toward goals, revisions of therapy, a list of drugs (both prescription and over-the-counter drugs) currently taken, adverse reactions to therapy, history of known drug allergies, smoking history, occupational exposure or risk, known patterns of alcohol or substance use that may influence response to drugs, history of treatment adherence and attitudes toward drugs. Records should also document patient counselling and advice given, when appropriate.

Ensuring safe procurement, storage, handling, preparation, distribution, dispensing and record keeping of drugs (in keeping with federal and provincial regulations and the CMA policy summary "Physicians and the Pharmaceutical Industry (Update 1994)" (Can Med Assoc J 1994;150:256A-C.) when the patient cannot reasonably receive such services from a pharmacist.

Maintaining a high level of knowledge about drug therapy through critical appraisal of the literature and continuing professional development.

Care must be provided in accordance with legislation and in an atmosphere of privacy, and patient confidentiality must be maintained. Care also should be provided in accordance with accepted scientific and ethical standards and procedures.

## ***The Pharmacist's Responsibilities***

Pharmacists and physicians recognize the following responsibilities as being within the scope of pharmacists' practice, on the basis of such factors as pharmacists' education and specialized skills, relationship with patients and practice environment. Some responsibilities may overlap with those of physicians (see *The Physician's Responsibilities*). In addition, it is recognized that, in selected practice environments, the pharmacists' role may differ considerably.

Evaluating the patients' drug-therapy record ("drug profile") and reviewing prescription orders to ensure that a prescribed therapy is safe and to identify, solve or prevent actual or potential drug-related problems or concerns. Examples include possible contraindications, drug interactions or therapeutic duplication, allergic reactions and patient nonadherence to treatment.

Significant concerns should be discussed with the prescriber.

Ensuring safe procurement, storage, preparation, distribution and dispensing of pharmaceutical products (in keeping with federal, provincial and other applicable regulations).

Discussing actual or potential drug-related problems or concerns and the purpose of drug therapy with patients, in consultation with caregivers, physicians and health care providers, when appropriate.

Monitoring drug therapy to identify drug-related problems or concerns, such as lack of symptomatic response, lack of adherence to treatment plans and suspected adverse effects. Significant concerns should be discussed with the physician.

Advising patients and caregivers on the selection and use of nonprescription drugs and the management of minor symptoms or ailments.

Directing patients to consult their physician for diagnosis and treatment when required. Pharmacists may be the first contact for health advice. Through basic patient assessment (i.e., observation and interview) they should identify the need for referral to a physician or an emergency department.

Notifying physicians of actual or suspected adverse reactions to drugs and, when appropriate, reporting such reactions to health authorities.

Providing specific information to patients and caregivers about drug therapy, taking into account patients' existing knowledge about their drug therapy. This information may include the name of the drug, its purpose, potential interactions or side effects, precautions, correct usage, methods to promote adherence to the treatment plan and any other health information appropriate to the needs of the patient.

Providing and sharing general and specific drug-related information and advice with patients, caregivers, physicians, health care providers and the public.

Maintaining adequate records of drug therapy to facilitate the prevention, identification and management of drug-related problems or concerns. These records should contain, but are not limited to, each patient's current and past drug therapy (including both prescribed and selected over-the-counter drugs), drug-allergy history, appropriate demographic data

and, if known, the purpose of therapy and progress toward treatment goals, adverse reactions to therapy, the patient's history of adherence to treatment, attitudes toward drugs, smoking history, occupational exposure or risk, and known patterns of alcohol or substance use that may influence his or her response to drugs. Records should also document patient counselling and advice given, when appropriate.

Maintaining a high level of knowledge about drug therapy through critical appraisal of the literature and continuing professional development.

Care must be provided in accordance with legislation and in an atmosphere of privacy, and patient confidentiality must be maintained. Products and services should be provided in accordance with accepted scientific and ethical standards and procedures.

## Statement on Internet Prescribing

The act of prescribing medication is a medical act carried out in the context of a patient-physician relationship. As such, it is subject to the clinical standards of practice, as well as the ethical guidelines of the medical profession and applicable law. Physicians should be aware of and comply with the legal requirements in their province or territory.

If a physician wishes to sign a prescription for an individual who has not previously been his/her patient or a patient of his/her group practice or shared call group, basic principles of assessment and diagnosis must be applied. It is incumbent upon the

physician to obtain an adequate history and perform an appropriate physical examination to reach a diagnosis which will ensure that the prescribed medications are appropriate. The physician should be expected to provide advice about any prescribed medication, and, where appropriate, would be expected to provide advice about appropriate monitoring requirements. The physician is advised to fully document the encounter.

It is not acceptable for a physician to sign a prescription without properly assessing the patient.

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## Principles for Providing Information about Prescription Drugs to Consumers

*Approved by the CMA Board of Directors, March 2003*

Since the late 1990's expenditures on direct to consumer advertising (DTCA) of prescription drugs in the United States have increased many-fold. Though U.S.-style DTCA is not legal in Canada<sup>23</sup>, it-reaches Canadians through cross-border transmission of print and broadcast media, and through the Internet. It is believed to have affected drug sales and patient behaviour in Canada. Other therapeutic products, such as vaccines and diagnostic tests, are also being marketed directly to the public.

Proponents of DTCA argue that they are providing consumers with much-needed information on drugs and the conditions they treat. Others argue that the underlying intent of such advertising is to increase revenue or market share, and that it therefore cannot be interpreted as unbiased information.

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<sup>23</sup> DTCA is not legal in Canada, except for notification of price, quantity and the name of the drug. However, "information-seeking" advertisements for prescription drugs, which may provide the name of the drug without mentioning its indications, or announce that treatments are available for specific indications without mentioning drugs by name, have appeared in Canadian mass media.

The CMA believes that consumers have a right to accurate information on prescription medications and other therapeutic interventions, to enable them to make informed decisions about their own health.

This information is especially necessary as more and more Canadians live with chronic conditions, and as we anticipate the availability of new products that may accompany the "biological revolution", e.g. gene therapies.

The CMA recommends a review of current mechanisms, including mass media communications, for providing this information to the public. CMA believes that consumer information on prescription drugs should be provided according to the following principles.<sup>24</sup>

### **Principle #1: The Goal is Good Health**

The ultimate measure of the effectiveness of consumer drug information should be its impact on the health and well-being of Canadians and the quality of health care.

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<sup>24</sup> Though the paper applies primarily to prescription drug information, its principles are also applicable to health information in general.

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**Principle #2: Ready Access**

Canadians should have ready access to credible, high-quality information about prescription drugs. The primary purpose of this information should be education; sales of drugs must not be a concern to the originator.

**Principle #3: Patient Involvement**

Consumer drug information should help Canadians make informed decisions regarding management of their health, and facilitate informed discussion with their physicians and other health professionals. CMA encourages Canadians to become educated about their own health and health care, and to appraise health information critically.

**Principle #4: Evidence-Based Content**

Consumer drug information should be evidence based, using generally accepted prescribing guidelines as a source where available.

**Principle #5: Appropriate Information**

Consumer drug information should be based as much as possible on drug classes and use of generic names; if discussing brand-name drugs the discussion should not be limited to a single specific brand, and brand names should always be preceded by generic names. It should provide information on the following:

- indications for use of the drug
- contraindications
- side effects
- relative cost.

In addition, consumer drug information should discuss the drug in the context of overall management of the condition for which it is indicated (for example, information about other therapies, lifestyle management and coping strategies).

**Principle #6: Objectivity of Information Sources**

Consumer drug information should be provided in such a way as to minimize the impact of vested commercial interests on the information content. Possible sources include health care

providers, or independent research agencies. Pharmaceutical manufacturers and patient or consumer groups can be valuable partners in this process but must not be the sole providers of information. Federal and provincial/territorial governments should provide appropriate sustaining support for the development and maintenance of up-to-date consumer drug information.

**Principle #7: Endorsement/ Accreditation**

Consumer drug information should be endorsed or accredited by a reputable and unbiased body. Information that is provided to the public through mass media channels should be pre-cleared by an independent board.

**Principle #8: Monitoring and Revision**

Consumer drug information should be continually monitored to ensure that it correctly reflects current evidence, and updated when research findings dictate.

**Principle #9: Physicians as Partners**

Consumer drug information should support and encourage open patient-physician communication, so that the resulting plan of care, including drug therapy, is mutually satisfactory.

Physicians play a vital role in working with patients and other health-care providers to achieve optimal drug therapy, not only through writing prescriptions but through discussing proposed drugs and their use in the context of the overall management of the patient's condition. In addition, physicians and other health care providers, and their associations, can play a valuable part in disseminating drug and other health information to the public.

**Principle #10: Research and Evaluation**

Ongoing research should be conducted into the impact of drug information and DTCA on the health care system, with particular emphasis on its effect on appropriateness of prescribing, and on health outcomes.

## PRINCIPLES CONCERNING PHYSICIAN INFORMATION

In an environment in which the capacity to capture, link and transmit information is growing and the need for fuller accountability is being created, the demand for physician information, and the number of people and organizations seeking to collect it, is increasing.

Physician information, that is, information that includes personal health information about and information that relates or may relate to the professional activity of an identifiable physician or group of physicians, is valuable for a variety of purposes. The legitimacy and importance of these purposes varies a great deal, and therefore the rationale and rules related to the collection, use, access and disclosure of physician information also varies. The Canadian Medical Association (CMA) developed this policy to provide guiding principles to those who collect, use, have access to or disclose physician information. Such people are termed “custodians,” and they should be held publicly accountable. These principles complement and act in concert with the CMA Health Information Privacy Code,<sup>25</sup> which holds patient health information sacrosanct.

Physicians have legitimate interests in what information about them is collected, on what authority, by whom and for what purposes it is collected, and what safeguards and controls are in place. These interests include privacy and the right to exercise some control over the information; protection from the possibility that information will cause unwarranted harm, either at the individual or the group level; and assurance that interpretation of the information is accurate and unbiased. These legitimate interests extend to information about physicians that has been rendered in non-identifiable or aggregate format (e.g., to protect against the possibility of individual physicians being identified

or of physician groups being unjustly stigmatized). Information in these formats, however, may be less sensitive than information from which an individual physician can be readily identified and, therefore, may warrant less protection.

The purposes for the use of physician information may be more or less compelling. One compelling use is related to the fact that physicians, as members of a self-regulating profession, are professionally accountable to their patients, their profession and society. Physicians support this professional accountability purpose through the legislated mandate of their regulatory colleges. Physicians also recognize the importance of peer review in the context of professional development and maintenance of competence.

**The CMA supports the collection, use, access and disclosure of physician information subject to the conditions outlined below.**

1. Purpose(s): The purpose(s) for the collection of physician information, and any other purpose(s) for which physician information may be subsequently used, accessed or disclosed, should be precisely specified at or before the collection. There should be a reasonable expectation that the information will achieve the stated purpose(s). The policy does not prevent the use of information for purposes that were not intended and not reasonably anticipated if principles 3 and 4 of this policy are met.
2. Consent: As a rule, information should be collected directly from the physician. Subject to principle 4, consent should be sought from the physician for the collection, use, access or disclosure of physician information. The physician should be informed about all

<sup>25</sup> Canadian Medical Association. Health Information Privacy Code. *CMAJ* 1998;159(8):997-1016.

intended and anticipated uses, accesses or disclosures of the information.

3. *Conditions for collection, use, access and disclosure:*

The information should:

- be limited to the minimum necessary to carry out the stated purpose(s),
- be in the least intrusive format required for the stated purpose(s), and its collection, use, access and disclosure should not infringe on the physician's duty of confidentiality with respect to that information.

4. *Use of information without consent:* There may be justification for the collection, use, access or disclosure of physician information without the physician's consent if, in addition to the conditions in principle 3 being met, the custodian publicly demonstrates with respect to the purpose(s), generically construed, that:

- the stated purpose(s) could not be met or would be seriously compromised if consent were required,
- the stated purpose(s) is(are) of sufficient importance that the public interest outweighs to a substantial degree the physician's right to privacy and right of consent in a free and democratic society, and
- that the collection, use, access or disclosure of physician information with respect to the stated purpose(s) always ensures justice and fairness to the physician by being consistent with principle 6 of this policy.

5. *Physician's access to his or her own information:* Physicians have a right to view and ensure, in a timely manner, the accuracy of the information collected about them. This principle does not apply if there is reason to believe that the disclosure to the physician will cause substantial adverse effect to others. The onus is on the custodian to justify a denial of access.

6. *Information quality and interpretation:* Custodians must take reasonable steps to ensure that the information they collect, use, gain access to or disclose is accurate, complete and

correct. Custodians must use valid and reliable collection methods and, as appropriate, involve physicians to interpret the information; these physicians must have practice characteristics and credentials similar to those of the physician whose information is being interpreted.

7. *Security:* Physical and human safeguards must exist to ensure the integrity and reliability of physician information and to protect against unauthorized collection, use, access or disclosure of physician information.

8. *Retention and destruction:* Physician information should be retained only for the length of time necessary to fulfill the specified purpose(s), after which time it should be destroyed.

9. *Inquiries and complaints:* Custodians must have in place a process whereby inquiries and complaints can be received, processed and adjudicated in a fair and timely way. The complaint process, including how to initiate a complaint, must be made known to physicians.

10. *Openness and transparency:* Custodians must have transparent and explicit record-keeping or database management policies, practices and systems that are open to public scrutiny, including the purpose(s) for the collection, use, access and disclosure of physician information. The existence of any physician information record-keeping systems or database systems must be made known and available upon request to physicians.

11. *Accountability:* Custodians of physician information must ensure that they have proper authority and mandate to collect, use, gain access to or disclose physician information. Custodians must have policies and procedures in place that give effect to the principles in this document. Custodians must have a designated person who is responsible for monitoring practices and ensuring compliance with the policies and procedures.