Declarations of interest by members of Health Canada's Special Advisory Committees and Panels: A Descriptive Study

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Abstract:	Background Health Canada supplements its in-house expertise on pharmacotherapy and pharmaceutical policy through the use of Scientific/Expert Advisory Committees (SAC) and Scientific/Expert Advisory Panels (SAP). This study was undertaken to examine the declared interests of Health Canada committee and panel members. Methods Observational study of the financial and intellectual interests of members of SACs and SAPs. The following information was extracted from Health Canada websites: name, name of committee/panel, direct, indirect and intellectual interests. Information extracted about the SAC/SAP included: number of meetings for which record of proceedings was available and topics discussed at meetings. Results There were three SACs and eight SAPs. Out of 99 people making declarations there were only 12 with a direct financial interest on 5 SACs/SAPs. Six of the 11 SACs/SAPs had a majority of members with an indirect financial interest and nine had a majority of members with an intellectual interest. SAC and SAP meetings rarely discussed individual products but recommendations from all but one of the meetings could potentially have affected the sales of medications. Interpretation Only a minority of members of committees and panels have direct financial interests but the majority of members on a majority of committees had indirect financial and intellectual interests. It was not possible to determine if financial or intellectual interests influenced voting patterns.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Location in study
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title, page 1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract, page 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Introduction, page 4
Objectives	3	State specific objectives, including any prespecified hypotheses	Introduction, pages 4
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, pages 5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, pages 5-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Methods, page 5-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, page 5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, pages 5-6
Bias	9	Describe any efforts to address potential sources of bias	Not relevant
Study size	10	Explain how the study size was arrived at	Not relevant
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, page 5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Not relevant
		(*b*) Describe any methods used to examine subgroups and interactions	Methods, page 6

		(*c*) Explain how missing data were addressed	Not relevant
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	Not relevant
		(*e*) Describe any sensitivity analyses	Not relevant
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, page 6-8
		(b) Give reasons for non-participation at each stage	Not relevant
		(c) Consider use of a flow diagram	Not relevant
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Not relevant
		(b) Indicate number of participants with missing data for each variable of interest	Not relevant
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	Not relevant
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Results, page 6-8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	Not relevant
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not relevant
Discussion			
Key results	18	Summarise key results with reference to study objectives	Interpretation, page 8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Limitations, page 10-11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Conclusion, page 11-12

Generalisability	21	Discuss the generalisability (external validity) of the study results	Not relevant
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Declarations of interest by members of Health Canada's Special Advisory Committees and Panels: A Descriptive Study

Joel Lexchin MSc, MD

Professor Emeritus

School of Health Policy and Management

York University

and

Emergency Physician

University Health Network

and

Associate Professor

Faculty of Medicine

University of Toronto

Correspondence:

Joel Lexchin MD

School of Health Policy and Management

York University

4700 Keele St.

Toronto, ON M3J 1P3

Tel: 416-964-7186

Email: jlexchin@yorku.ca

ORCID ID: 0000-0001-5120-8029

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Competing interests:

In 2015-2018, Joel Lexchin was a paid consultant on three projects: one looking at indication-based prescribing (United States Agency for Healthcare Research and Quality), a second to develop principles for conservative diagnosis (Gordon and Betty Moore Foundation) and a third deciding what drugs should be provided free of charge by general practitioners (Government of Canada, Ontario Supporting Patient Oriented Research Support Unit and the St Michael's Hospital Foundation). He also received payments for being on a panel that discussed a pharmacare plan for Canada (Canadian Institute, a for-profit organization), a panel at the American Diabetes Association, a talk at the Toronto Reference Library and writing a brief for a law firm on the effects of promotion on prescribing. He is currently a member of research groups that are receiving money from the Canadian Institutes of Health Research and the Australian National Health and Medical Research Council. He is member of the Foundation Board of Health Action International and the Board of Canadian Doctors for Medicare.

Abstract

Background

Health Canada supplements its in-house expertise on pharmacotherapy and pharmaceutical policy through the use of Scientific/Expert Advisory Committees (SAC) and Scientific/Expert Advisory Panels (SAP). This study was undertaken to examine the declared interests of Health Canada committee and panel members.

Methods

Observational study of the financial and intellectual interests of members of SACs and SAPs. The following information was extracted from Health Canada websites: name, name of committee/panel, direct, indirect and intellectual interests. Information extracted about the SAC/SAP included: number of meetings for which record of proceedings was available and topics discussed at meetings.

Results

There were three SACs and eight SAPs. Out of 99 people making declarations there were only 12 with a direct financial interest on 5 SACs/SAPs. Six of the 11 SACs/SAPs had a majority of members with an indirect financial interest and nine had a majority of members with an intellectual interest. SAC and SAP meetings rarely discussed individual products but recommendations from all but one of the meetings could potentially have affected the sales of medications.

Interpretation

Only a minority of members of committees and panels have direct financial interests but the majority of members on a majority of committees had indirect financial and intellectual interests. It was not possible to determine if financial or intellectual interests influenced voting patterns.

Introduction

Health Canada supplements its in-house expertise on pharmacotherapy and pharmaceutical policy through the use of Scientific/Expert Advisory Committees (SAC) and Scientific/Expert Advisory Panels (SAP). SACs "are standing committees that provide on-going medical/technical/scientific advice and recommendations on regulatory issues for drugs and medical devices in specific therapeutic areas or classes" (1). Health Canada uses ad hoc SAPs "to provide medical/technical/scientific advice and recommendations on specific drug and medical device issues" (2). People interested in serving on a committee or a panel fill out an on-line application form listing their qualifications and expertise (3) and Health Canada chooses members from this list for its various committees and panels.

In order for individuals to be considered for appointment to committees or panels, Health Canada requires them to complete the *Affiliations and Interests Declaration Form for Advisory Body Members* and disclose all affiliations and interests, including any direct financial interest of relevance to the mandate of the committee or panel. People with a direct financial interest in the outcome of a review of a product cannot be a committee or panel member when its mandate is solely to provide advice on specific matters relating to the review, but can be members if the broader mandate encompasses matters of policy, management or program development. In addition to direct financial interests, potential committee and panel members have to disclose indirect financial interests, intellectual interests and "other" interests (4).

In the United States, conflicts of interest are associated with the voting patterns of members of Food and Drug Administration (FDA) advisory committees (5). Whether the same applies

to Canada is not known. This study was undertaken to examine the declared interests of Health Canada committee and panel members.

Methods

Source of data

Health Canada treats completed *Affiliation and Interest Declaration Form for Advisory Body Members* (6) as confidential, but does make public a *Summary of Expertise, Experience, and Affiliations and Interests* for individual members of currently active SACs and SAPs (7). Questions about direct financial interests on the *Affiliation and Interest Declaration Form for Advisory Body Members* ask the respondent to name the company and the type of interest but not the monetary value. Questions about indirect financial interests on the same form ask the respondent to name the company and the approximate amount of money received. Information about company names, the type of interest and its monetary value are not reported in the *Summary of Expertise, Experience, and Affiliations and Interests*.

For each active SAC and SAP, the following information was extracted for each member: name, name of committee/panel, perspective/sector, declaration of interests in each of the four categories listed in Table 1. Information extracted about the SAC/SAP included: name of chair, date of terms of reference, number of meetings, number and date of meetings for which a record of proceedings was available, topics discussed at meetings and recommendations from the SAC/SAP. A second person, CO, a retired family physician, verified the extracted data and differences were resolved by discussion. Information was current as of December 15, 2018 the date of data collection.

Data analysis

For the purposes of analysis, the three different types of indirect financial interests were combined into one category as were the three different types of intellectual interests. Descriptive data is reported as counts: the number of individual committee and panel members, the number of SACs/SAPs, the number and types of interests of each of the members on individual SACs/SAPs and their perspective/sector. Because the chairs of SACs/SAPs may have more influence than regular panel members the number and type of their interest declarations were analyzed separately. The topics discussed in the SAC/SAP meetings and the recommendations from the SACs/SAPs about those topics are also reported.

Ethics approval

All data was publicly available and no patients were involved, therefore ethics approval was not sought.

Results

There were three active SACs and eight active SAPs. Information about all four types of interests (direct and indirect financial, intellectual and other) was available for all 81 unique individuals who were members of these SACs and SAPs as of December 15, 2018. Sixty-nine sat on a single SAC/SAP, seven on two, four on three and one on four SACs/SAPs. In total there were 99 unique declarations of interests. There were also seven inactive SACs – four had completed their mandate and three had been cancelled (8) and 10 SAPs that had completed their mandate (9).) Health Canada does not provide a list of the membership of these inactive committees and panels. People who sat on more than one SAC/SAP sometimes made different declarations of interest. Health Canada does not give the dates when the declarations were made. (Supplementary File 1 available on request from the author contains the complete dataset for this study.)

SACs and SAPs had between 4 and 21 members. Out of 99 declarations there were only 12 for direct financial interest on 5 SACs/SAPs. The maximum percent of members on a SAC/SAP with a direct financial interest was 30.8%, while six SACs/SAPs had no members with a direct financial interest. In contrast, six of the 11 SACs/SAPs had a majority of members with an indirect financial interest and nine had a majority of members with an intellectual interest. Six SACs/SAPs had more members with an intellectual interest than with an indirect financial interest and two had an equal number of people with both. Five SACs/SAPs had a minority of members with either a direct or indirect financial interest, but none had an entire membership that was free of any type of financial interest. Only one SAC/SAP had a minority of members with intellectual interests. There was a total of six "other" interests declared (Table 2). The exact nature of these interests was not clear.

Forty-one of the 53 declarations from SAC members listed their sector/perspective as academia alone or academia with an additional sector. Seven of the remaining 12 listed health professional. Declarations from SAP members listed academia alone or academia with an additional sector 26 out of 46 times and health professional only was listed 10 times. There were only 5 members in total who were from the public/consumer/patient sector and only 2 solely from industry (Table 3).

Only one chair had a direct financial interest whereas eight out of 11 had an indirect financial interest and a similar number had an intellectual interest (data not shown).

Health Canada does not require the disclosure of the names of companies that members have interests with, the amount of money that they received from companies, nor the undertakings

that they have with particular companies. The one partial exception is that members have to declare the value of materials, discounted products, gifts, or other benefits, or travel and accommodation costs if the amount exceeds $1,000.

The 11 SACs/SAPs had a total of 30 meetings (range 1 to 11) but a record of proceedings is only available for 10 meetings. These meetings only discussed two specific products (Diclectin and isotretinoin). Table 4 presents the recommendations from the committees and panels. Some recommendations, such as the one not to change the labelling for Diclectin, could have had a positive effect on sales whereas others, such as adding warnings about fluoroquinolones, could have had a negative effect. The votes of individual members are not recorded so it is not possible to determine how members with and without different types of conflicts voted.

Interpretation

Only a minority of members of committees and panels have direct financial interests. Indirect financial interests are much more prevalent than direct interests on SACs/SAPs and the majority of committees and panels had a majority of members with indirect interests. Similarly, only a minority of chairs had a direct financial interest, but the majority had indirect financial interests. Individuals with intellectual interests were more common than individuals with financial interests on most committees and panels. Differences in declarations by people serving on multiple committees might be a consequence of making declarations at different times but since Health Canada does not give the dates of the declarations this hypothesis cannot be further investigated.

Health Canada collects information about the names of companies that committee and panel members have direct and indirect interests with and, in the case of indirect financial interests, the approximate monetary value of the interest in the *Affiliation and Interest Declaration Form for Advisory Body Members*. However, it does not disclose this information in the *Summary of Expertise, Experience, and Affiliations and Interests* that appears on its website. Nor does Health Canada publicly record the votes of individual members. As a result, it is not possible to determine if direct or indirect financial interests influence voting patterns. Similarly, intellectual interests cannot be linked with voting patterns.

By asking for a declaration of financial and intellectual interests Health Canada seems to be equating the importance of the two different types. However, their equivalence has been contested. Bero and Grundy (10) state that there is substantial evidence that financial conflicts of interest "lead to systematic biases in scientific research at all stages of the research process" and that focusing on "interests such as personal beliefs, experience, or intellectual commitments can divert attention from financial conflicts." In contrast to financial interests, the training that researchers receive, their institutional setting and prior or current membership in particular organizations could influence their views about a particular topic, but as Bero asks "are these really conflicts of interest…or innate characteristics of the researcher? These…are an inextricable part of the primary interest of conducting research. Science is not value free and it makes sense to assume that a researcher's personal characteristics and experience will influence judgments that must be made in the course of research" (11). Scientific experts can decline financial interests, but that is not possible with interests that form part of their personalities. Finally, individual interests can influence views in multiple directions whereas financial interests exert influence in only a single direction, in favour of the party that is providing the money.

Even the receipt of small amounts of money or the equivalent can affect behaviour. Meals valued at less than US $20 are associated with higher prescribing rates for drugs made by the companies providing the meals (12). Research on voting patterns of people serving on FDA advisory committees shows an association between having financial ties solely to the firm sponsoring the drug under question or serving on advisory boards for sponsoring companies and pro-sponsor bias (5).

Experts may not participate on FDA advisory committees if their financial conflict of interest (COI) is in excess of $50,000 USD but the FDA grants waivers under one of three conditions: (i) the COI is unlikely to "affect the integrity of the services," (ii) the "need for the individual's services outweighs the potential for a COI," or (iii) they will contribute "essential expertise." The number of waivers granted has been increasing (13). COI declarations and waivers are publicly available on the FDA website and financial COI is reported in dollar ranges (e.g., $0-5,000, $5,001-10,000) (14). The FDA can also exclude people from serving on committees for intellectual conflicts (15). The chair, members and expert advisors of the Commission on Human Medicines (CHM) of the United Kingdom's Medicines and Healthcare products Regulatory Agency are governed by a 2006 Code of Practice which requires each member to make an annual declaration of interests in the pharmaceutical industry and the declarations are published annually (16). In Canada, the Canadian Agency for Drugs and Technology in Health (CADTH) requires expert committee and panel members to declare direct and indirect financial interests and intellectual interests. A summary of the member's expertise, experience, affiliations and conflict of interest declarations is posted and publicly available on the CADTH website. The declaration form asks members for the name of the party that they have a conflict with and for the monetary

value of the benefit in dollar ranges (e.g., $0-5,000, $5,001-10,000) (17). Company names are disclosed on the website but not the monetary value of the benefits.

Limitations

The committees and panels that were examined are only a minority of the ones that Health Canada has used and whether the results of this study can be applied to inactive SACs/SAPs is unknown. The interests that were declared by individual members and reported in the *Summary of Expertise, Experience, and Affiliations and Interests* could not verified by independent searching since not enough detail was provided in the declarations on the Health Canada web site. Some members may have undeclared direct and indirect financial interests (18).

The three types of indirect financial interests were combined into a single category since it was not possible to link interests with particular companies to individual members' voting patterns. Different types of intellectual interests were combined for a similar reason. Disaggregating indirect financial interests and intellectual interests could provide important information about individuals voting patterns once the disaggregated information is available.

Conclusion

Indirect financial interests and intellectual interests are widespread on SACs and SAPs. Biases in voting as a result of interests could influence sales of products. The Institute of Medicine (now the National Academy of Medicine) in its report on conflict of interest in guidelines recommends that the chair of any panel should be free of all conflicts as should the majority of members on the panel (19). There are differences between clinical practice guideline committees and SACs/SAPs, but they are both expected to produce unbiased

information. Health Canada should follow the IOM recommendations in constituting its SACs/SAPs. Health Canada should also publicly release all of the information about direct and indirect financial interests that is on the *Affiliation and Interest Declaration Form for Advisory Body Members* along with the date when the declarations were made.

In addition, the Canadian government could supplement the information that individual experts report by emulating the United States and requiring companies to report all transfers of value to doctors (20) and other regulated healthcare professionals. This change would help to ensure that all financial conflicts are disclosed. (Some of the committee and panel members are not regulated healthcare professionals and therefore this reporting requirement would not cover their interactions with industry.)

In order to be able to see if there are changing patterns in the declarations of experts, Health Canada should make available lists of the membership of inactive committees and panels and their declarations on a publicly available web site.

Finally, Health Canada should record the votes of individual committee and panel members so that voting patterns can be linked to different types of financial interests with particular companies and with different types of intellectual interests.

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Table 1: Description of conflicts of interest

Type of conflict	Description
Direct financial interests	Current employment, investments in companies, partnerships, equity, royalties, joint ventures, trusts, real property, stocks, shares or bonds, with the regulated industry
Indirect financial interests	Within the past five years, payment from regulated industry for work done or being done, including past employment, contracts or consulting; or financial support including research support, personal education grants, contributions, fellowships, sponsorships, and honoraria
	Within the past five years, materials, discounted products, gifts, or other benefits, or attendance at meetings where all or part of the travel and accommodation costs were provided by the regulated industry
	Within the last three years, grants or other funding from the regulated industry to any of the organizations where you are currently employed or participate in internal decision making
Intellectual interests	Within the last five years, any formal advice or opinion to industry, a government organization or a non-government organization on a matter of relevance to the Scientific Advisory Committee or Scientific Advisory Panel
	Within the last five years, any published or publicly stated point of view on issues of relevance to the Scientific Advisory Committee or Scientific Advisory Panel mandate
	Current professional or volunteer affiliations such as membership of professional societies, lobbying, public interest or advocacy groups, of relevance to the Scientific Advisory Committee or Scientific Advisory Panel
Other interests	Any other affiliations and interests or potential circumstances that might give a well-informed member of the public reasonable grounds for concern regarding the integrity and objectivity of your participation

Table 2: Number (percent) of committee/panel members with various types of interest

Title	Committee/ Panel	Total number of members	Direct financial interest	Indirect financial interest	Direct or indirect financial interest	Intellectual interest	Other interests
Oncology Therapies	Committee	21	3 (14.3)	18 (85.7)	18 (85.7)	16 (76.2)	2 (9.5)
Pharmaceutical Sciences and Clinical Pharmacology	Committee	13	4 (30.8)	9 (69.2)	10 (76.9)	12 (92.3)	0 (0)
Respiratory and Allergy Therapies	Committee	19	3 (15.8)	14 (73.7)	14 (73.7)	16 (84.2)	0 (0)
Anti-infective Therapies	Panel	6	1 (16.7)	2 (33.3)	2 (33.3)	6 (100)	0 (0)
Bioequivalence Requirements for Gender-Specific Drug Products	Panel	7	0 (0)	4 (57.1)	4 (57.1)	6 (85.7)	0 (0)
Bioequivalence Requirements for Modified-Release Dosage Forms	Panel	6	0 (0)	5 (83.3)	5 (83.3)	5 (83.3)	0 (0)
Diclectin	Panel	4	0 (0)	1 (25.0)	1 (25.0)	1 (25.0)	0 (0)
Opioid Analgesic Abuse	Panel	6	1 (16.7)	4 (66.7)	4 (66.7)	4 (66.7)	0 (0)
Opioid Use and Contraindications	Panel	6	0 (0)	1 (16.7)	1 (16.7)	6 (100)	2 (33.3)
Opioids	Panel	6	0 (0)	2 (33.3)	2 (33.3)	6 (100)	2 (33.3)

Isotretinoin Risk Management	Panel	5	0 (0)	2 (40.0)	2 (40.0)	3 (60.0)	0 (0)

Table 3: Sector/perspective of Special Advisory Committee/Special Advisory Panel members*

	Academia					Health professional		Industry	Infectious disease	Pharmacy	Public/ consumer/ patient
	Academia only	**+ Health professional**	**+ Health professional + Research**	**+Industry**	**+Research**	**Health professional only**	**+Research**				
Special Advisory Committee	11	17	6	1	6	7	0	2	0	0	3
Special Advisory Panel	10	7	4		5	10	2	0	5	1	2

*Some people were on more than one committee and/or panel

Table 4: Topics discussed at committee/panel meetings

Committee/ panel	Number of meetings	Number of meetings where record of proceedings available	Date of meeting(s) where record of proceedings available†	Summary of topic(s) discussed	Summary of recommendation(s) from SAC* or SAP‡
Oncology therapies SAC	7	1	August/September 2011	• Regulations prohibiting the use of arsenic as an ingredient in drugs sold for human use	• The section of the Food and Drugs Act that prohibits the sale of drugs containing arsenic should be revoked
Respiratory and allergy therapies SAC	11	3	2012-03-14 2013-10-26 2018-02-23	• Data requirements for safety and effectiveness of subsequent market entry inhaled products for use in the treatment of asthma	• An in vitro data package is adequate in lieu of clinical data to demonstrate bioequivalence of a subsequent market entry budesonide suspension for inhalation using a suitable nebulizer • Depending on the type of product clinical outcome studies using FEV1 are acceptable as long as a difference in the mean of at least 12% is demonstrated
Anti-infective Therapies SAP	1	1	2016-10-06	• Issues around the safety and efficacy of fluoroquinolones for different indications	• The Product Monograph for fluoroquinolones should include a statement about disabling and potentially irreversible persistent adverse reactions

					• Fluoroquinolones should not be used for acute sinusitis of less than 7 days duration
Bioequivalence requirements for gender-specific drug products SAP	1	1	2011-06-22	• Requirements for market authorization of a second entry or subsequent entry gender-specific drug product	• The current practice of using only males, males and females or only females for bioequivalence studies should be continued
Diclectin SAP	1	1	2016-06-02	• Data from study of Diclectin	• The panel would not recommend any changes to the current labelling of Diclectin for the management of nausea and vomiting of pregnancy
Opioid use and contraindications SAP	1	1	2017-03-24	• Information about opioids that should be included in Product Monograph • Should low dose codeine products be made prescription-only	• Information about a threshold dose for chronic non-cancer pain should be in the Dosing and Administration section of the Product Monograph in such a way as to draw the attention of the prescriber • The indication for extended/long-acting opioids should be changed to say that patients should first have tried a non-opioid medication

					• Prescriptions for opioids for acute pain should be limited to 3 days • No changes should be made to the non-prescription status of low dose codeine products at present
Opioids SAP	1	1	2016-11-15 & 2016-11-16	• Public information about opioid overdose and addiction • Risk Management Plan for opioids	• A warning sticker should be placed on prescriptions for opioids to highlight the issues of physical dependence, addiction and overdose • Industry involvement in Risk Management Plans and educational programs should be monitored and limited
Isotretinoin risk management SAP	1	1	2017-11-17	• Pregnancy prevention program for isotretinoin	• While there is no evidence to show that the Canadian pregnancy prevention program is not ineffective improvements should be made

†Record of proceedings of meeting of Respiratory and Allergy Therapies SAC on 2018-11-02 not available at time of writing
*Scientific Advisory Committee
‡Scientific Advisory Panel