

A photograph of the University of Otago's clock tower at dusk. The tower is illuminated from within, showing the clock faces and the intricate Gothic architecture. The sky is a deep blue, and the foreground shows a dark, reflective surface, possibly a fountain or a pool, with the tower's reflection visible. Large trees are silhouetted against the building and the sky.

COMMUNICATING DRUG SAFETY INFORMATION TO HEALTH CARE PROFESSIONALS AND THE PUBLIC

Results from a survey by the University of Otago
Pharmacovigilance Research Team

UNIVERSITY
of
OTAGO



Te Whare Wānanga o Ōtāgo

NEW ZEALAND

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Medsafe, New Zealand

Norwegian Medicines Agency, Norway

Health Sciences Authority, Singapore

Medical Products Agency, Sweden

Medicines and Healthcare products Regulatory Agency, UK

Food and Drug Administration, USA

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Executive Summary

In 2010, the University of Otago initiated a three-year project, which aims to develop an interdisciplinary approach to pharmacovigilance to enable timely identification and investigation of medicine safety issues and effective communication of that information to health practitioners and the public. The project is jointly funded by the Health Research Council of New Zealand and the New Zealand medicines regulator, Medsafe.

A key aspect of the project is the exploration of possible strategies to increase public awareness of, and engagement in, medicines safety issues. As part of this communication research, an online survey was undertaken with a small number of international medicines regulators to investigate current practices in drug safety communication with health care professionals (HCP) and the public. The results from the survey are presented in this report and are primarily descriptive in nature. Detailed analyses and conclusions from the study will be presented in a scientific paper for publication, and a full assessment report on medicines risk communication with the New Zealand public will be delivered to the New Zealand Ministry of Health at the end of the project in 2012.

Twelve out of 14 invited countries agreed to participate in the online survey, which consists of four sections: Target Groups, Communication Channels, Measuring the Effectiveness of Drug Safety Communications, and Organisation and Resources. The results are presented in the same order as the questions appeared in the online questionnaire.

A. Target Groups

Among the twelve participating agencies, the five most frequently selected target groups for drug safety communications were doctors, pharmacists, HCP/medical organizations, the public and mass media.

Drug safety communications for the public were adapted to different numeracy or literacy levels by five of the agencies, while two agencies adapted their communications for the needs of people with certain disabilities.

Pre-testing drug safety communications on members of the target groups was reserved for very select cases, if any.

Agencies were generally more confident about their knowledge of the amount and type of risk-benefit information required by HCP to make informed decisions about the use of therapeutic products than they were about the needs of the public.

Six agencies had a defined strategy to raise public drug safety awareness in their countries.

Nine of the agencies reported having implemented strategies to improve drug safety coverage in the mass media, often with positive results. Most frequently, these strategies involved developing relationships with the media, educating the media, and media training for agency staff.

The agencies' most important partners in communicating drug safety messages to HCP and the public were the mass media, professional organisations, governmental agencies, the pharmaceutical industry, HCP and patient organisations.

B. Communication Channels

The four most commonly selected channels for drug safety communication with HCP were the agency website, mass media coverage, electronic newsletter and print bulletin/newsletter. The top selected channels for communicating with the public were the agency website, mass media coverage, print bulletin/newsletter, Facebook, electronic newsletter, and print brochures. Five agencies used new social media on the Internet (Facebook, Twitter, YouTube) and nine used some form of print media. In general, more channels were used for communicating with the public than with HCP.

The agency website was by far the most popular communication channel for both urgent and non-urgent drug safety messages.

C. Measuring Effectiveness of Drug Safety Communications

Measurements of the effectiveness of drug safety communications were not done routinely at any of the agencies, and predetermined goals were seldom set. There was, however, a general positive notion among many agencies that their drug safety communication efforts did reach their goals.

D. Organisation and Resources

The task of drug safety communication was shared between different departments/units in the majority of the agencies. Drug safety communication is a cross-disciplinary task, which was illustrated by the number of skills/roles involved in these activities at the agencies. Pharmaceutical, medical, communications/journalism and epidemiological skills were the most commonly involved skills/roles in the creation of drug safety communications.

Throughout the questionnaire, generous comments from the participants provided interesting insights into the context in which the agencies work, and rationales for different strategies or choices. They also highlighted the challenges and the dynamic nature of communicating drug safety messages in today's global, fast-changing and around-the-clock information society.

Introduction

In 2010, the University of Otago initiated a three-year project, which aims to develop an interdisciplinary approach to pharmacovigilance to enable timely identification and investigation of medicine safety issues and effective communication of that information to health practitioners and the public. The project is jointly funded by the Health Research Council of New Zealand and the New Zealand medicines regulator, Medsafe.

A key aspect of the project is the exploration of possible strategies to increase public awareness of, and engagement in, medicines safety issues in New Zealand. As part of this communication research, an online survey was undertaken with a small number of international medicines regulators to investigate current practices in drug safety communication with health care professionals (HCP) and the public.

Twelve out of 14 invited countries agreed to participate in the online survey. The results presented in this report are primarily descriptive in nature. Detailed analyses and conclusions from the study will be presented in a scientific paper for publication, and a full assessment report on medicines risk communication with the New Zealand public will be delivered to the New Zealand Ministry of Health at the end of the project in 2012.

Results

The online survey consists of four sections: Target Groups, Communication Channels, Measuring the Effectiveness of Drug Safety Communications, and Organisation and Resources. The results in this report are presented in the same order as the questions appeared in the online questionnaire.

In the interests of providing us with a complete picture, the participating agencies had the option of checking a “confidentiality box” at the end of each question. Comments given under this condition are displayed as “anonymous”.

A. Target Groups

In the first section of the questionnaire, we wanted to ascertain which target groups agencies had identified for their drug safety communications, and if/how they adapted their communications to the needs of these target groups. We also wanted to explore the extent to which methods such as pre-testing communications on members of the target group were used and how well the agencies felt they knew the needs and preferences of health care professionals (HCP) and the public, with regards to the amount and type of risk-benefit information they need to make informed choices about the use of medicinal products.

From an organisational point of view, we were interested in which skills/roles were involved at the agencies in creating drug safety communications for the different audiences.

The mass media plays an important part in drug safety communications, as drug safety news is very newsworthy and often makes the headlines. From this perspective, we wanted to learn about the agencies' work with the media to improve the coverage of drug safety related issues.

1. Below is a list of possible target groups for drug safety communications. Please select which groups your agency has identified as target groups for ANY of its drug safety communications.

(Answer alternatives: Doctors, Pharmacists, Health Professional/Medical Organisations, The Public, Mass Media, Nurses, Patient Organisations, Politicians/Policy Makers, Drug Retailers, Other)

Doctors, pharmacists, HCP/medical organisations were identified as target groups by all participating agencies. The public and mass media were selected by all but one agency, while nurses and patient organisations were target groups for ten and eight agencies, respectively. Only five agencies considered politicians and policy makers to be a target group for drug safety communications, and drug retailers were at the bottom of the list, with four agencies considering them to be a target group.

Table 1. Target groups identified by the agencies for ANY of their drug safety communications.

Target group	Agencies (N=12)
Doctors	12
Pharmacists	12
Health Professional/Medical Organisations	12
The Public	11
Mass Media	11
Nurses	10
Patient Organisations	8
Politicians/Policy Makers	5
Drug retailers	4
Other	3 ¹

Agency comments:

SWEDEN

"Mass media is not looked upon as a target group, more as a tool to spread information to the public."

GERMANY

"As risk communication is mainly done via the Agency's website, all information is accessible to everybody. However, style and content is adapted to the needs and understanding of 'informed lay persons'."

¹ Pharmaceutical companies, Industry associations, Naturopaths.

MOROCCO:

"All the staff members are implicated in communication with the public. The leader of the unit is in charge of communicating with the media in case of an alert."

ANONYMOUS

"All of these groups could be targeted. How and which group is targeted depends on the particular issue. For instance, information about a product recall could include supermarkets, health food stores and pharmacists as well as health professionals, whereas distribution of a 'Dear Health Care Professional Letter' is limited to prescribers and/or dispensers."

2. Below are the groups that you selected as target groups in the previous question. Please select the groups for which your agency specifically tailors its drug safety communications (e.g. through the use of different wording, key messages or communication channels).

(Answer alternatives as selected in the first question)

As would be expected, the top five identified target groups from the first question (doctors, pharmacists, HCP/medical organisations, the public, mass media) were still the top five when it came to tailored drug safety communications, although now in a slightly different order. The public was the only target group for which all agencies (who had selected the public as a target group in the previous question) tailored their drug safety communications. Politicians/policy makers and drug retailers were recognized by few as target groups for drug safety communications, and received tailored drug safety communications from even fewer.

Table 2. Target groups for which the agencies tailor their drug safety communications.

Target group	Number of agencies (N=12)
The Public	11
Doctors	10
Mass Media	10
Pharmacists	9
Health Professional/Medical Organisations	8
Patient Organisations	7
Nurses	7
Politicians/Policy Makers	2
Drug retailers	1
Other	2 ²

Agency comments:

SINGAPORE

"We usually group healthcare professionals as one category for messaging. This group will include the doctors, pharmacists and dentists."

2 Pharmaceutical companies, Industry associations.

SWEDEN

"Our web page has three different target groups, the public, healthcare professionals and the pharmaceutical industry. In select cases, depending on the nature of the information, the message regarding safety issues is targeted for patients and consumers. Patient organisations are on a case by case basis contacted individually to raise awareness of the issue and to assist in spreading the message."

DENMARK

"Ad hoc website publications are written in lay language; the monthly newsletter is more directed to health professionals."

NORWAY

"We strive to keep the language in our communications as simple as possible. This is of course to make it readable for the public, but feedback from health professionals indicate that they too appreciate short, precise information in a simplified language. We'll normally include advice for patients and health professionals in all our communications (whenever it's found relevant). Patient organisations are included as a communication channel based on case by case evaluation of the usefulness."

GERMANY

"For information directed to health care professionals (doctors, pharmacists etc.) language, style and structure is adapted accordingly. The agency issues press releases containing simple, easily understandable messages which are the most important in an actual situation."

CANADA

"The agency's risk communications related to marketed health products have two main target groups. The public audience includes patients, consumers, consumer groups, the media and the general public. The health professional audience includes, but is not limited to, physicians, dentists, naturopaths, pharmacists, nurses, hospitals, registered dieticians and other medical and support personnel involved in the delivery of health care. The mass media receive information through Notice to Editors and Newswire."

UK

"In general information to healthcare professionals is provided via a regular bulletin or urgent communications. For these methods the messages are usually not tailored between the specialities or professional groups."

3. When designing drug safety communications for THE PUBLIC (patients/consumers), does your agency typically adapt communications to meet the needs of different audiences?

(Answer alternatives: Different literacy or numeracy levels, Different languages, Disabilities, Other)

Three agencies adapted drug safety communications to different literacy or numeracy levels and different languages, one adapted to different languages and disabilities. One agency adapted communications for people with disabilities and two agencies adapted to different literacy or numeracy levels. The Other option was ticked by two agencies to describe a general adaptation of communications to a style easy to understand by lay persons.

Table 3. Target group needs for which agencies adapt their drug safety communications.

Needs of different audiences within the public	Agencies (N=10 ³)
Different literacy or numeracy levels	5
Different languages	4
Disabilities	2
Other	2

Agency comments:

SINGAPORE

"We only adapt to different languages when using printed materials such as brochures and patient information leaflets and in very important situations (such as the H1N1 pandemic). Our Branch currently does not have the capability to do translations of languages so it is quite challenging to translate every piece of communication unless we seek help from another department (e.g. the Chinese Proprietary Medicines unit). There are a few official languages used in Singapore – English, Mandarin, Tamil, Malay, so to translate to all these languages is quite a challenge. Currently, the drug safety information carried on our HSA website is in English."

ANONYMOUS

"The communications are tailored to the low end of range of adult health literacy."

USA

"We attempt to define or explain regulatory terms of art and to simplify complex medical or statistical terms, where possible. For select communications (crisis or emergency situations or safety issues affecting very large numbers of people) we translate from English to other languages commonly used in the United States."

3 Two agencies chose not to answer the question.

DENMARK

"Lay language is used to facilitate communication to the public in general; all website messages are translated to English."

NORWAY

"Except for keeping the language as simple as possible, other adaptations are – as of now – not made."

GERMANY

"According to national law information from official institutions (e.g. our agency), electronic communications on the agency website must be provided 'barrier free', which means the user must get additional information (e.g. explanations of acronyms) via internal links in the text."

ANONYMOUS

"Messages would be customised as per the generally accepted levels of literacy and numeracy for consumer messages. Additionally, use of different languages via the foreign language news media (print/radio/TV) may be considered particularly where a specific ethnic group may be at a higher risk. This is also the situation where a message about say, a mass vaccination program is to be communicated. Having persons presenting sign language in parallel during media conferences about important public issue is becoming more widespread."

CANADA

"Health Canada communications are available in both official languages, English and French. Health Canada is committed to providing Canadians with accurate, reliable, clear and relevant information that enables them to make informed decisions about their health. Evaluations are underway to assess the literacy levels required to read and comprehend Health Canada's Public Advisories. Some Health Canada Public Advisories may be in other specific languages – Chinese, Arabic – depending on issue to target population most likely to use health product."

4. In your agency, what different skills/roles are typically involved in designing a drug safety communication from the agency to HEALTHCARE PROFESSIONALS (doctors, nurses, pharmacists)?

(Answer alternatives: Medical, Pharmaceutical, Communications/Journalism, Epidemiology, Risk and Decision Expertise, Legal Advisor/Attorney, Communications Systems Expertise, Target Audience Pre-testers, Behavioural Science Expertise, Other)

The number of skills/roles involved ranged from one (pharmaceutical) in one agency, to six skills/roles (medical, pharmaceutical, epidemiology, communications/journalism, risk and decision analysis expertise, legal advisor/attorney) in two agencies. Medical, pharmaceutical, communications/journalism and epidemiology were the four most commonly involved skills/roles. The mean number of skills/roles involved was 3.8. This illustrates the cross-disciplinary nature of drug safety communication.

Table 4. Skills/roles typically involved in designing drug safety communications from the agencies to HCP.

Skill/Role	Agencies (N=12)
Medical	11
Pharmaceutical	11
Communications/Journalism	8
Epidemiology	7
Risk and Decision Expertise	4
Legal Advisor/Attorney	2
Communications Systems Expertise	1
Target Audience Pre-testers	1
Behavioural Science Expertise	0
Other	0

Agency comments:

SINGAPORE

"To further define our selection of 'Pharmaceutical', it means officers with pharmacy training and relevant working experience in hospitals or clinical-related setting, who are familiar with communicating with doctors and other healthcare professionals."

USA

"Occasionally we consult our behavioural scientists and conduct pre-testing with non-scientific staff and it is our goal to more formally institutionalize such a social science approach to our drug safety communications. However, we are not presently organized in such a way nor do we have sufficient staff expertise to do this on a systematic basis. Generally, we also do not have available risk and decision analysis expertise outside of our external risk communications advisory committee."

ANONYMOUS

"Drug safety messages from the agency generally relate to a sub-acute/acute situation. However, for a communication campaign about vaccine programs, more broad based communications expertise and/or road testing may be employed. Sponsors may be required to utilise this sort of expertise/undertake these processes for educational programs which are additional risk minimisation activities required for/included in a risk management plan for, say, a newly marketed drug or extension of indications for an existing drug where there are particular safety considerations such as use in specific patient populations. It could also apply to consumer medicine information or other material given to patients when receiving prescribed medications."

5. In your agency, what different skills/roles are typically involved in designing a drug safety communication from the agency to THE PUBLIC (patients/consumers)?

(Answer alternatives: Medical, Pharmaceutical, Communications/Journalism, Epidemiology, Risk and Decision Expertise, Legal Advisor/Attorney, Communications Systems Expertise, Target Audience Pre-testers, Behavioural Science Expertise)

For drug safety communications to the public, the number of skills/roles involved ranged from two (pharmaceutical, communications/journalism) in one agency, to six skills/roles in two agencies (medical, pharmaceutical, epidemiology, communications/journalism, risk and decision analysis expertise, legal advisor/attorney). Largely, the same core skills/roles were involved for communicating both with the public and HCP. Communications/journalism and communications systems expertise were more commonly involved when communicating with the public, whereas epidemiology skills were slightly less present. The mean number of skills involved was 4.2.

Table 5. Skills/roles typically involved in designing drug safety communications from the agencies to the public.

Skill/Role	Agencies (N=11) ⁴
Pharmaceutical	11
Medical	10
Communications/Journalism	10
Epidemiology	5
Risk and Decision Expertise	4
Communications Systems Expertise	3
Legal Advisor/Attorney	2
Target Audience Pre-testers	1
Behavioural Science Expertise	0
Other	0

Agency comments:

USA:

"We try to summarize and simplify complex information for consumers. However, we have not been able to test or evaluate reader comprehension or the effect of our communications in any systematic way. Plans are in progress to attempt to identify tools to measure comprehension and impact."

4 One agency had not included the public as a target group and was automatically redirected to skip this question.

ANONYMOUS

"Drug safety messages from the agency generally relate to a sub-acute / acute situation. However, for a communication campaign about vaccine programs, more broad based communications expertise and/or road testing may be employed. Sponsors may be required to utilise this sort of expertise/undertake these processes for educational programs which are additional risk minimisation activities required for/included in a risk management plan for, say, a newly marketed drug or extension of indications for an existing drug where there are particular safety considerations such as use in specific patient populations. It could also apply to consumer medicine information or other material given to patients when receiving prescribed medications."

6. Does your agency pre-test its drug safety communications on members of THE PUBLIC (patients/consumers)?

(Answer alternatives: Always, Often, Sometimes, Never)

Pre-testing a communication on members of a target group can, for example, be used to assess perception, comprehension and attitudes regarding the communicated message. As can be seen from the responses, pre-testing drug safety communications on members of the public was not regularly practised in any of the agencies.

Table 6. Frequency with which the agencies pre-test their drug safety communications on members of the public.

Frequency	Always	Often	Sometimes	Never
Agencies (N=12)	0	0	6	6

Agency comments:

SWEDEN

"In very select cases this is an option."

CANADA

"Rarely, would be an exceptional situation."

ANONYMOUS

"Use of pre-testing is issue- and time-dependent. Media statements use communications staff to pre-test. Development of website resources aimed at consumers would generally be pre-tested."

USA

"We occasionally conduct pre-testing on non-scientific FDA staff. Federal laws place limitations on our ability to test or survey the public in a systematic and ongoing way. We also occasionally seek input from patient and consumer organisations that help us develop messages that are most likely to be understood by patients and consumers. Federal law and regulations regarding disclosure of industry confidential information make such efforts challenging."

ANONYMOUS

"Broad based communication campaigns for non acute issues (e.g. a vaccine program) maybe road tested prior to implementation. Also, sponsors may be required to do this for educational programs which are additional risk minimisation activities required for / included in a risk management plan for, say, a newly marketed drug or extension of indications for an existing drug where there are particular safety considerations such as use in specific patient populations. It could also apply to consumer medicine information or other material given to patients when receiving prescribed medications."

7. Does your agency pre-test its drug safety communications on health care professionals (doctors, nurses, pharmacists)?

(Answer alternatives: Always, Often, Sometimes, Never)

One agency reported it always pre-tested its drug safety communications on HCP, however this pre-testing appears to have involved the agency's own staff rather than any external health care professionals. When adjusting this answer to a "Sometimes" instead, the comparative figures in questions 6 and (7) read as follows: Always 0 (0), Often 0 (1), Sometimes 6 (4), Never 6 (7).

In summary, for the majority of the participating agencies, pre-testing drug safety communications on HCP or members of the public is reserved for very select cases, if any.

Table 7. Frequency with which the agencies pre-test their drug safety communications on HCP.

Frequency	Always	Often	Sometimes	Never
Agencies (N=12)	1	1	3	7

Agency comments:

ANONYMOUS

"Sometimes communications are reviewed by doctors or pharmacists in an expert advisory committee."

USA

"We have a Drug Safety Oversight Board made up of FDA staff and health professionals (mostly physicians and pharmacists) from 12 U.S. federal agencies, several of which have large patient populations such as the Veterans Administration and the Department of Defence. We often share our draft drug safety communications with the Board and find this input valuable in identifying target audiences, crafting the message, and predicting impact on patient populations. We also occasionally seek input from medical professional organisations to help us determine whether our messages will have the desired impact. However, as with similar efforts directed to patient and consumer organisations we must observe legal and regulatory limits on pre-disclosure of industry confidential information and other information that is protected or as a matter of policy cannot be disclosed to select groups."

CANADA

"Rarely, would be an exceptional situation."

ANONYMOUS

"As the employees involved in writing and commenting on texts for publications mostly are doctors and pharmacists, you can say that we do pre-test, but we seldom use external health professionals for this purpose."

8. How would you rate your agency's knowledge of the amount and type of risk-benefit information required by THE PUBLIC (patients/consumers) to enable them to make informed decisions about the use of therapeutic products?

(Answer alternatives: 1 (Poor), 2, 3, 4, 5 (Excellent))

The mean score on the question was 2.5. According to some of the received comments, this is an area for improvement in drug safety communication with the public. Please see the next question for a comparison with the corresponding mean score for HCP.

Table 8. Self-ratings of the agencies' knowledge of the public's needs for risk-benefit information on medicines.

Rating	1 (Poor)	2	3	4	5 (Excellent)
Agencies (N=11 ⁵)	0	6	5	0	0

Agency comments:

SWEDEN

"We have good knowledge of different sources of information available for patients, e.g. SmPC/ PL and treatment guidelines in lay language on our web pages. We also have regular contacts with patient/consumer representatives."

ANONYMOUS

"Would be better informed by better knowledge of health literacy levels, especially for groups in which health inequalities are known to exist e.g. minority ethnic groups. General lack of feedback from the public makes this difficult to assess."

MOROCCO

"Among the priorities of the centre in 2011 is one day for the mass media for the sensitizing of the public on the safety of medicines."

CANADA

"By regularly engaging stakeholders and expert groups through consultations as well as public surveys, Health Canada has been able to collect important data to inform the Department on the needs and expectations of the public regarding the amount and type of information they require."

USA

"We need to do a lot more work in this area to better understand what patients and consumers need and in what form and through what venue."

⁵ One agency chose not to answer the question.

9. How would you rate your agency's knowledge of the amount and type of risk-benefit information required by HEALTHCARE PROFESSIONALS (doctors, nurses, pharmacists) to enable them to make informed decisions about the use of therapeutic products?

(Answer alternatives: 1 (Poor), 2, 3, 4, 5 (Excellent))

The mean score on the question was 3.8. The ratings of the agencies knowledge on the amount and type of risk-benefit information needed by HCPs was thus higher than the corresponding number for the public/patients (2.5) – see previous question. From comments provided, possible reasons for this may include better feedback mechanisms from HCPs as well as a general "feel" for the needs and preferences of HCP from a drug safety communication staff consisting partly of target group peers.

Table 9. Self-ratings of the agencies' knowledge of HCP's needs for risk-benefit information on medicines.

Rating	1 (Poor)	2	3	4	5 (Excellent)
Agencies (N=11 ⁶)	0	2	6	3	0

Agency comments:

SWEDEN

"We have regular contacts with HCP through the work with treatment guidelines and through the scientific committee."

ANONYMOUS

"This view is reinforced by positive feedback from target audience."

USA

"Without post evaluation of our drug safety communications it is difficult to know if we are meeting the needs of the target audiences. We rely primarily on anecdotal feedback at this time."

CANADA

"By regularly engaging stakeholders and expert groups through consultations as well as health professional surveys, Health Canada has been able to collect important data to inform the Department on the needs and expectations of the health professionals regarding the amount and type of information they require."

ANONYMOUS

"We have many healthcare professionals on our staff and we have carried out some surveys with healthcare professionals."

6 One agency chose not to answer the question.

10. Does your agency have a defined strategy to raise public awareness of drug safety issues in your country?

(Answer alternatives: Yes, No)

One important aim of the current communication project is to explore possible strategies to increase public awareness and engagement in medicines safety issues in New Zealand. From this perspective, we were interested to hear about similar national strategies used by the participating agencies. Six out of eleven agencies reported having a defined strategy to raise public awareness of drug safety issues in their respective countries.

Agency comments:

CANADA

"No. Health Canada provides information on health products to both health care professionals and the public through a variety of risk communication tools. See Guidance Document – Description of Current Risk Communication Documents for Marketed Health Products for Human Use. Working on an internal policy Public Access to Health Risk Information – to apply consistently for all product lines, ie drugs, cosmetics, consumer products, food etc. Working on a Performance Measurement Evaluation Plan for specific risk communications. The MedEffect Canada initiative, established in 2005, provides a centralized access to new safety information on marketed health products both from industry and health Canada to inform and educate Canadians about new health risks associated with marketed health products. The Consumer Information Strategy and Portal was launched in the fall of 2009, with a goal to provide authoritative, credible and balanced product information for Canadians, which is easily accessible and reflects Canadian knowledge and circumstances. Other initiatives to make use of social media and outreach to consumers through Canadians Health Living Web site in development."

ANONYMOUS

"Yes. We are still working with our communications department on the strategy to educate our public about drug safety. One of the strategies includes enhancing the public information component of our website and promoting it to the members of the public."

SWEDEN

"Yes. From the agency's instruction it is clear that we have a responsibility to inform the public about drugs, which includes drug safety."

ANONYMOUS

"No. A pharmacovigilance strategy is in development, which will have a communication strand."

USA

"Yes. Refine the criteria and triggers we use to decide to issue a drug safety communication. Develop a social science research base to develop our drug safety communications. Identify and utilize best practices in risk communications. Strengthen relationships with patient, consumer and healthcare professional groups to better identify their information needs and preferred formats and methods of dissemination. Develop mechanisms to measure effectiveness and impact of our drug safety communications. Employ state of the art tools to track and measure message diffusion."

DENMARK

"Yes. Through a national action plan involving all stakeholders the agency consistently tries to raise awareness; more information can be provided if necessary. During the H1N1 pandemic and prior to introduction of the HPV vaccine in the publicly funded vaccination programme extraordinary effort was put into projects aiming at raising awareness; in cooperation with other institutions."

GERMANY

"Yes. The strategy includes early, but not premature, information to a variety of audiences (doctors, patients, industry, media). If possible, communication should be proactive, i.e. when the agency has safety information not freely accessible, has assessed the issue and is of the opinion that this information should be released together with concrete advice for patients how to behave, if possible. We try to avoid reactive communication (not always possible)."

MOROCCO

"No there is no defined strategy, but we communicate case by case regularly with some media in order to enhance patient awareness or to disseminate information related to drug alert"

11. Has your agency implemented any strategies to improve the quality of drug safety coverage in the mass media (e.g. developing relationships with the media, educational texts for the media on the agency website, media seminars, media training for agency employees)?

(Answer alternatives: Yes, No)

Drug safety news often makes the headlines, which makes the mass media a very important agent in drug safety communications. For this reason, we wanted to learn more about the agencies' work with the mass media, for example if they had used any specific strategies to improve drug safety coverage, and with what results.

Nine out of eleven agencies had implemented strategies to improve the quality of drug safety coverage in the mass media. Three main themes emerged from the comments: (1) Developing relationships with the media, (2) Educating the media and (3) Media training for agency staff. These strategies aimed to bring journalists and experts closer together by teaching the media how to read and interpret the agencies' reports and publications, and teaching the agency experts how to better communicate their knowledge with the media.

Agency comments:

24

SWEDEN

"Yes. Educational text regarding how to interpret adverse drug reaction (ADR) reports. Media training for agency employees. In general the Swedish mass media correctly reflects information on drug safety. The information about how to interpret ADRs, which is always attached when ADR listings are provided has been used and referred to by journalists."

SINGAPORE

"Yes. Develop media relationships, providing exclusives, engaging the media in specific media interviews, media training for agency employees. Interaction with the media and media strategies are under the purview of the agency's corporate communications department."

USA

"Yes. All of the above. Further, we have been using social media and networking tools to enhance our ability to reach both mainstream and non-mainstream media."

ANONYMOUS

"No. Lack of resources to undertake such activities without impacting significantly on core business. Also, all communications with media are managed through a centralised communications unit outside of the agency therefore opportunities to foster relationships with the media are limited."

DENMARK

"Yes. Examples are meetings with journalists where the agency provides general information on drug safety."

ANONYMOUS

"Yes. Developing relationships with key media, one-to-one briefings, general press releases and media seminars."

MOROCCO

"Yes. Through our toxicological review (dedicated for HCP and the public) and our website."

CANADA

"Yes. Some technical briefings with media, media training for staff. Enhanced linkages with media relations and communications staff with the program expert staff."

AUSTRALIA

"Yes. Media training for agency employees."

GERMANY

"No. More broad training and other activities to improve the quality of safety coverage in the mass media is in preparation. Media training for some agency employees has been done."

UK

"Yes. We have developed a media strategy to develop better working relations with the mass media."

12. Have any of the strategies implemented by your agency to improve the quality of drug safety coverage in the mass media been successful in your agency's opinion? Please briefly describe what you regard as some of the success stories.

Agency comments:

SINGAPORE

"Some of the strategies have achieved good results. Our best example is that of the illegal health product- "Power I Walnut" which was very well covered by the media and followed through for quite a long period of time. As the media was the most important tool of communications to the mass public (and we did not know which man on the street was actually consuming this product), it was critical that they co-operated with us to send constant reminders to the public about the dangers of illegal health products so as to curb the demand for it. Without a demand for the product, illegal supply will cease. The media also carried some of our drug safety pieces very well and factually, such as those of product withdrawals from the market and more recently our regulatory positions on certain drugs such as rosiglitazone and sibutramine."

SWEDEN

"In general our national mass media correctly reflects information on drug safety. The information about how to interpret ADRs, which is always attached when ADR listings are provided has been used and referred to by journalists."

USA

"Yes, investing in our relationships with mass media and being timely and transparent with them and providing them with not only our decisions but the rationale behind those decisions has resulted in a more informed cadre of reporters and more balanced and nuanced reporting."

DENMARK

"Transparency is an international community trend with significant impact on the way we work at the agency with communication."

ANONYMOUS

"Strategies to highlight dangers of online and counterfeit medicines highly successful including significant national TV, radio and online coverage. Strategy to communicate regular safety updates re H1N1 vaccine also well received in the media. Specific key journalists have also endorsed our approach to mass media communications."

CANADA

"When the labelling for cough and cold remedies was updated, consultations with organisations to release same messaging and development of short videos for news was successful but resource intensive. Such a strategy could not be used systematically for all risk communications."

13. Please list your agency's most important partners (e.g. other governmental agencies/authorities, pharmaceutical companies, professional organisations, patient organisations, mass media collaborations in communicating drug safety messages to healthcare professionals and the public.

(Fields for free text for Partner 1, Partner 2 and Partner 3)

Communication never takes place in a vacuum – most often there are several parties who alternate between the roles of senders and recipients in the communication process. To put the agencies' drug safety communication work in context, we wanted to identify their main partners in drug safety communication.

The most commonly mentioned partners in communicating drug safety messages to HCP and the public are shown in the table below.

Table 10. The most important drug safety communication partners, as selected by the agencies.

Communication partner	Agencies (N=117)
Mass media	6
Professional organisations	6
Governmental agencies/departments	5
Pharmaceutical industry	4
HCP	4
Patient organisations	3

Agency comments:

ANONYMOUS

"It is important to reach professional organisations and patient organisations but we also rely much on mass media to spread the message."

ANONYMOUS

"We currently use the mass media to communicate to the public but are looking at developing links to patient organisations in the future."

ANONYMOUS

"The agency participates in ongoing meetings with other regulatory agencies and shares some risk communications through various memorandums of understanding – but each regulatory agency takes its own actions. Through our electronic listservs, health professional organisations such as medical and pharmacy licensing bodies distribute drug safety information to their members on a regular basis."

7 One agency chose not to answer the question.

B. Communication Channels

In the second part of the questionnaire, we aimed to explore the agencies' use of communication channels to reach their target groups with drug safety messages. We were particularly interested to find out if, and how, different types of channels, for example new social media on the Internet and print media were used for different types of communications and to reach different target groups.

1. A communication channel is the medium through which a message is transmitted to its intended audience. What channels does your agency use when communicating with THE PUBLIC (patients/consumers) about drug safety issues?

(Answer alternatives: Agency website, Electronic newsletter, Facebook, Twitter, Other social media, Internet forums, Internet blogs, Internet advertising on other web pages, Mobile phone messages, Podcasts, Other electronic media, Print bulletin/newsletter, Print brochures, Print books, Other print media, Mass media advertising, Mass media coverage (via press releases), Media especially designed for people with disabilities, Other)

The number of communication channels used to communicate drug safety messages with the public ranged from three (two agencies) to ten (two agencies). The mean number of channels used was 5.7.

Five agencies used new social media on the Internet (Facebook, Twitter, YouTube), while nine agencies used some form of print media (brochures, books, bulletin/newsletter). The two by far most commonly used channels were the agency's website and mass media coverage via press releases.

Table 11. Communication channels used by the agencies for drug safety communication with the public.

Channel	Agencies (N=11 ⁸)
Agency website	11
Mass media coverage	10
Print bulletin/newsletter	5
Facebook	5
Electronic newsletter	5
Print brochures	5
Twitter	4
Mass media advertising	4
YouTube	3
Print books	1
Podcasts	1
Patient groups	1
Internet blogs	1
Internet advertising on other web pages	1

8 One agency had not selected the public as a target group.

Agency comments:

DENMARK

"We are in the early phase of utilising the new social media; recently we placed a video on YouTube where employees told about their experiences at the agency, the agency tasks etc."

SWEDEN

"Mass media advertising – an option in very select cases."

2. What channels does your agency use when communicating with HEALTHCARE PROFESSIONALS (doctors, nurses, pharmacists) about drug safety issues?

(Answer alternatives: Agency website, Electronic newsletter, Facebook, Twitter, Other social media, Internet forums, Internet blogs, Internet advertising on other web pages, Mobile phone messages, Podcasts, Other electronic media, Print bulletin/newsletter, Print brochures, Print books, Other print media, Mass media advertising, Mass media coverage (via press releases), Media especially designed for people with disabilities, Other)

The mean number of channels used was 4.1 for doctors and pharmacists and 3.7 for nurses, thus slightly lower than for the public (5.7 channels). This difference could be explained by the much higher diversity of the public, where different channels can be needed to reach different segments, for example younger/older age groups.

The range of communication channels used to reach doctors and pharmacists was between two (one agency) and nine (two agencies), and between one (one agency) and nine (one agency) for nurses. The four by far most commonly used channels were the agency's website, mass media coverage, electronic newsletter and print bulletin/newsletter. Nine agencies used some form of print media to communicate with HCP. Social media (Facebook, Twitter and YouTube) were not as frequently used for communicating with HCPs as with the public.

Table 12. Communication channels used by the agencies for drug safety communication with HCP.

Channels	Agencies (N=12)		
	Doctors	Pharmacists	Nurses
Agency website	12	12	12
Mass media coverage	9	9	9
Electronic newsletter	8	8	7
Print bulletin/newsletter	8	8	5
Facebook	2	2	2
Twitter	2	2	2
Print books	2	2	2
Print brochures	2	2	2
Mass media advertising	2	2	2
Mobile phone messages	1	1	1
Podcasts	1	1	1
YouTube	1	1	1
Internet advertising on other web pages	1	1	0

Agency comments:

SINGAPORE

"We also have dentists as one of our target groups. We use emails or faxes to disseminate our Dear Healthcare Professional Letters (DHCPL) riding on a software/system developed by the Ministry of Health, called MOHAlert. The system has the ability to send out mobile phone messages, but we are currently not using this channel. We also consider package inserts as one of our communication channels as there are important safety updates carried in the PI."

SWEDEN

"Personal information (telephone) on upcoming information on webpage followed by e-mail contact with relevant documents/links."

ANONYMOUS

"Use of relevant professional bodies' communication channels, Dear Healthcare Professional Letters."

USA

"Electronic distribution lists. We publish in medical journals."

NORWAY

"One page advertisements in the national, biweekly journal for doctors."

ANONYMOUS

"Email alerts, distribution of key communications through professional and regulatory bodies (via their online channels)."

MOROCCO

"The centre has several means of communication: the Web site, publication of the articles and the bulletins, Annual congress of the National society of pharmacovigilance."

3. Does your agency have a consistent threshold for when to communicate emerging drug safety information?

(Answer alternatives: Yes, No)

With this question we wanted to find out how the agencies decided when to communicate information that has the potential to alter the benefit-risk ratio of a drug but has not yet been fully analysed and evaluated. Criteria for such a threshold may include reliability of the data, extent of patient exposure, or seriousness of the event relative to the indication for treatment. Five out of ten agencies reported having such a consistent threshold.

Agency comments:

SINGAPORE

"Yes. We have developed a Standard Operating Procedure for when to communicate and which channel to use to communicate."

SWEDEN

"No. Information on ongoing evaluations are common within the EU-system."

ANONYMOUS

"No. Emerging drug safety information is usually discussed and coordinated through Europe."

GERMANY

"We make case by case decisions. However, the concept includes early, but not premature, information to a variety of audiences (doctors, patients, industry, media). If possible, communication should be proactive, i.e. when the agency has safety information not freely accessible, has assessed the issue and is of the opinion that this information should be released together with concrete advice for patients how to behave, if possible."

CANADA

"Health Canada is working to finalize a departmental policy on Public Access to Health Risk Information to have a consistent approach for risk communications for all product lines in the Department. Health Canada has developed guidance for industry on issuance of risk communications. Health Canada also published a quarterly newsletter (Canadian Adverse Reaction Newsletter) that is an early-stage risk communication (i.e. before comprehensive benefit-risk evaluation has been undertaken). Specific criteria exist for the selection of topics in the Newsletter. Signal prioritization methods exist for causality assessments of benefit/risk."

NEW ZEALAND

"Yes. Threshold is relatively consistent but decision is made on a case by case basis rather than a defined algorithm. Knowledge of concerns/uncertainty about interpretation of data may trigger communication in some cases."

MOROCCO

"Yes. We communicate validated drug safety information concerning Medication error; misuse, Drug abuse, International or national alert related to serious ADR."

4. Which are your agency's two most important channels for reaching HEALTHCARE PROFESSIONALS (doctors, nurses, pharmacists) and THE PUBLIC with urgent and non-urgent drug safety communications, respectively?

(Answer alternatives for HCP and the public: Agency website, Electronic newsletter, Facebook, Twitter, Other social media, Internet forums, Internet blogs, Internet advertising on other web pages, Mobile phone messages, Podcasts, Other electronic media, Print bulletin/newsletter, Print brochures, Print books, Other print media, Mass media advertising, Mass media coverage (via press releases), Media especially designed for people with disabilities, Other)

This question was designed to provide more information about how the different communication channels were used in urgent and non-urgent communications. Overall, nine different channels were used for urgent communications with doctors, as compared to four different channels for urgent communications with the public. The agency website was by far the most popular communication channel for urgent messages.

Eight different channels were used for non-urgent communications with doctors, and seven different channels were used for non-urgent communications with the public. The agency website was still the most commonly selected communication channel for non-urgent communications, followed by different forms of print media.

Table 13. Channels used by the agencies for urgent drug safety communications to doctors.

Agency	Channel 1	Channel 2 ⁹
1	Emails	Agency website
2	Agency website	Electronic newsletter
3	Mass media coverage	DHCPL ¹⁰
4	Mass media advertising	Agency website
5	Agency website	Agency website
6	Agency website	Ad in national doctors' journal
7	Agency website	Print bulletin newsletter
8	Mass media coverage	Mass media coverage
9	Mass media coverage	Agency website
10	Agency website	Fax out/Mail out
11 ¹¹	Fax/email cascade	Agency website

⁹ Agencies 5 and 8 identified the same channel for both Channel 1 and Channel 2.

¹⁰ Dear Health Care Professional Letter.

¹¹ One agency chose not to answer the question.

Table 14. Channels used by the agencies for urgent drug safety communications to the public.

Agency	Channel 1	Channel 2 ¹²
1	Mass media coverage	Agency website
2	Agency website	Mass media coverage
3	Mass media coverage	Agency website
4	Mass media advertising	Agency website
5	Agency website	Agency website
6	Agency website	Facebook
7	Mass media coverage	Agency website
8	Mass media coverage	Did not identify a second channel
9	Mass media coverage	Agency website
10	Agency website	Mass media coverage
11 ¹³	Agency website	Mass media coverage

Table 15. Channels used by the agencies for non-urgent drug safety communications to doctors.

Agency	Channel 1	Channel 2 ¹⁴
1	Agency website	Print bulletin/newsletter
2	Agency website	Print bulletin/newsletter
3	Print bulletin/newsletter	Agency website
4	Other print media	Other electronic media
5	Agency website	Did not identify a second channel.
6	Agency website	Ad in national doctors' journal
7	Agency website	Agency website
8	Agency website	Electronic newsletter
9	Agency website	Did not identify a second channel.
10	Print bulletin/newsletter	Print brochures
11 ¹⁵	Electronic newsletter	Print books

12 Agency 5 identified the same channel for both Channel 1 and Channel 2.

13 One agency chose not to answer the question.

14 Agency 7 identified the same channel for both Channel 1 and Channel 2.

15 One agency chose not to answer the question.

Table 16. Channels used by the agencies for non-urgent drug safety communications to the public.

Agency	Channel 1	Channel 2 ¹⁶
1	Agency website	Did not identify a second channel.
2	Did not identify a first channel.	Did not identify a second channel.
3	Agency website	Agency website
4	Other social media	Other electronic media
5	Agency website	Did not identify a second channel.
6	Agency website	Facebook
7	Agency website	Agency website
8	Mass media coverage	Did not identify a second channel.
9	Agency website	Did not identify a second channel.
10	Print brochures	Other print media
11 ¹⁷	Agency website	Mass media coverage

Agency comments:

DENMARK

"Scientific societies and patient organisations are contacted and informed in addition to the website publication; press releases may be issued."

UK

"For urgent communications to healthcare professionals we use a fax and email cascade"

ANONYMOUS

"Also, urgent messages for doctors, nurses and pharmacists are provided to regional authorities and professional associations to distribute via their channels."

SWEDEN

"We try to use several channels to reach the target. Regarding the public – the agency's web page is checked by mass media regularly; press releases are seldomly needed to get a message out."

¹⁶ Agencies 3 and 7 identified the same channel for Channel 1 and Channel 2.

¹⁷ One agency chose not to answer the question.

5. Has your agency had any particularly good experiences where use of certain channels has been successful in achieving your communications objectives? If so, please specify which channel(s) and the communication type(s).

(Field for free text)

Agency comments:

USA

"Medical journal articles to reach physicians. Mass media to reach all audiences in urgent situations. Professional medical and healthcare associations to reach medical and healthcare professionals."

SINGAPORE

"The MOHAAlert, the system/software owned by our Ministry of Health contains the database of all the registered doctors, pharmacists and dentists and is a comprehensive channel to use. This software can send out emails or faxes, depending on the choice of the healthcare professional. HSA additionally sends out a separate email to the Chairmen of Medical Boards of public and private institutions as well as professional boards and private pharmacies to enhance the coverage of the message. Our ADR News Bulletin is also well read by the healthcare professionals locally and has received more attention since it was accredited for Continuing Medical Education (CME) and Continuing Professional Education Points (CPE) by the Singapore Medical Council, Singapore Pharmacy Council and Singapore Dental Council."

SWEDEN

"The agency had an information campaign 2008-2010 on counterfeit drugs on the internet, using print and television, advertising, social media with a huge interest and impact. Further, to spread the message of a treatment guideline regarding urinary tract infections in women with the goal of informing on correct use of antibiotics to avoid microbial resistance, we used search engine optimization, add words, to reach the public."

DENMARK

"Facebook in relation to new formulation of an elthyroxin product (same experience as in New Zealand)."

GERMANY

"In general press releases are broadly and rapidly circulated and cited by news papers and journals. Instant radio or TV statements in case of urgency seem to be very effective."

CANADA

"In December 2009, Health Canada issued a Public Advisory to announce the outcome of its review of cough and cold medicines for children. The communication plan for this issue included the use of a variety of risk communication tools and mechanisms, including posters and tear sheets targeted at health professionals and consumers, video clips, and the use of social media, collaboration with paediatric organisations, as well as the standard posting on Health Canada website and media release."

UK

"We have surveyed uses of our drug safety bulletin with positive feedback. It is accredited by an independent national authority."

ANONYMOUS

"Use of a professional fax service to rapidly disseminate urgent communications as many GPs do not have email. Fax company ensures delivery within 30 minutes of receipt from authority."

ANONYMOUS

"Contact personnel in local and regional departments are particularly useful in ensuring urgent messages are relayed to relevant stakeholder groups in the event of an urgent matter such as a recall."

ANONYMOUS

"Media to communicate important medicine safety messages relating adulterated medicines. Use of a pharmaceutical society to communicate and reinforce important safety messages to pharmacists e.g. electronic distribution of agency-issued DHCPL down their channels, responding to pharmacist queries."

MOROCCO

"The Website is a very interesting channel for disseminating drug safety information. In Morocco, we have a successful experience with a site for pharmacists (15000 visitors/day)."

C. Measuring Effectiveness of Drug Safety Communications

The most basic model of a communication loop consists of a sender and a recipient. The sender sends a message and the recipient receives the message, and lets the sender know that he or she has received the message, understood its contents and acted upon it accordingly (or not). Without the feedback from the recipient, the sender will never know whether the communication was successful or not. For regulatory agencies dealing with drug safety communication, such feedback may include assessing and evaluating whether information necessary for informed decision-making has been received and understood by the target group. However, in reality – which can be seen from the following responses – measuring the effectiveness of drug safety communications is a resource-demanding and rare activity at the agencies.

Regardless of the extent to which the agencies measured the effectiveness of the communications, we were also interested in knowing if they felt that, in general, their communication efforts reached their goals.

1. To what extent does your agency measure the effectiveness of its drug safety communications? This may include assessing and evaluating whether information necessary for informed decision-making has been received and understood.

(Answer alternatives: 1 (Always), 2 (Often), 3 (Sometimes), 4 (Rarely), 5 (Never))

As discussed in the introduction to this section of the questionnaire, to be sure that a message has been communicated effectively it is necessary for the sender to actively seek feedback that the message has been received, understood and acted upon by the recipient. In reality, for most agencies this is a time- and resource-consuming activity that is not integrated into everyday communication work. However, as can be seen from the comments, there are many ways in which an agency can gauge the effectiveness of a drug safety communication, for instance by surveying prescription rates and/or sales figures, seeking feedback from HCPs, and through public consultations and surveys.

Table 17. Frequency with which the agencies measure the effectiveness of their drug safety communications.

Frequency	1 (Always)	2 (Often)	3 (Sometimes)	4 (Rarely)	5 (Never)
Agencies (N=10 ¹⁸)	0	0	4	5	1

Agency comments:

GERMANY

"Some, but very few systematic reviews on effectiveness have been done, more or less quantitatively (number of clicks etc.). No evaluation has been done so far in respect to any effect on decision making by doctors or patients or on understanding the messages."

SWEDEN

"We combine several different methods to get a picture of the effectiveness, e.g. web page visitors, questionnaires on prescribing, sales figures etc."

USA

"At the moment our primary means (not necessarily preferred means) are accuracy of media coverage, political commentary, anecdotal feedback from physicians and thought leaders, and calls to our drug information hotline."

ANONYMOUS

"Ad hoc feedback sought and received."

¹⁸ Two agencies chose not to answer the question.

CANADA

"To measure the effectiveness of its risk communications, Health Canada engages stakeholders through its periodic use of public consultations and surveys. The Department also works with expert groups such as the Expert Advisory Committee on the Vigilance of Health Products to examine the effectiveness of specific health product risk communication tools. Currently working on a performance measurement and evaluation plan."

UK

"Measuring receipts and click through rates. We are developing more regular measurement of outcomes in public health terms."

SINGAPORE

"By soliciting for feedback from healthcare professionals. A survey is in the pipeline."

2. Does your agency set predetermined goals for its drug safety communications?

(Answer alternatives: 1 (Always), 2 (Often), 3 (Sometimes), 4 (Rarely), 5 (Never))

Setting predetermined goals for communications provides a means to measure whether a communication has been successful or not, by comparing the predetermined goal to the measured effects of the communication. It can also be a useful way to quantify and frame the purpose of the communication. According to the comments below, goals for drug safety communications can, for example, be related to the transmission of the message, a change in prescription patterns, or an increase in HCP reporting of adverse drug reactions (ADRs) to the agency.

Table 18. Frequency with which the agencies set predetermined goals for their drug safety communications.

Frequency	1 (Always)	2 (Often)	3 (Sometimes)	4 (Rarely)	5 (Never)
Agencies (N=11 ¹⁹)	1	0	3	4	3

Agency comments:

SWEDEN

"Stop prescribing. Public awareness of risks with counterfeit drugs measured before and two times after campaign."

CANADA

"One of the goals of the Canadian Adverse Reaction Newsletter is to stimulate reporting but a quantifiable % of increase has not been pre-determined. We also monitor the number of subscribers to the electronic mailing list - MedEffect e-Notice."

ANONYMOUS

"A more measurable goal would perhaps be those issues with restriction programmes, where we can see if the physician has received and understood our communications. Also, we may be able to assess if a drug usage pattern has changed based on certain communication pieces we published (e.g. discouraging off label use due to safety concerns etc)."

ANONYMOUS

"All urgent communications delivered to professional and regulatory bodies within 12 hours. Adverse reaction reporting trends monitored to identify indications of practice changes following communications of regulatory recommendations."

¹⁹ One agency chose not to answer the question.

3. In general, do you feel that your agency's drug safety communication efforts achieve their goals?

(Answer alternatives: 1 (Always), 2 (Often), 3 (Sometimes), 4 (Rarely), 5 (Never))

Generally, there seemed to be a positive notion that communication efforts did reach their goals. Table 20 summarises the responses received for three questions on measuring effectiveness, the setting of predetermined goals and the general feeling of the success of the communication efforts. It is interesting to note that the five agencies who in question C3 felt that their communication efforts often reached their goals all ranged between the 'sometimes'–'never' answer alternatives in both of the two previous questions.

Table 19. Self-rating of how often the agency's drug safety communications achieve their goals.

Frequency	1 (Always)	2 (Often)	3 (Sometimes)	4 (Rarely)	5 (Never)
Agencies (N=9 ²⁰)	0	5	4	0	0

Table 20. Summary of questions C1-C3.

Measure effectiveness	Set predetermined goals	Feel communication efforts reach goals
Sometimes	Rarely	Often
Sometimes	Sometimes	Sometimes
Rarely	Rarely	Often
Rarely	Sometimes	Sometimes
Never	Never	Sometimes
Did not answer	Did not answer	Did not answer
Rarely	Never	Often
Rarely	Sometimes	Did not answer
Did not answer	Always	Did not answer
Rarely	Rarely	Often
Sometimes	Rarely	Often
Sometimes	Never	Sometimes

20 Three agencies chose not to answer the question.

Agency comments:

ANONYMOUS

"We get feedback from healthcare professionals on our communications pieces, sometimes agreeing with our actions, and sometimes voicing their own opinions about our pieces."

ANONYMOUS

"Our goal is to increase the number of evaluations of communication results."

ANONYMOUS

"Feedback from healthcare professionals is generally positive. Negative feedback is used to inform future communications. Public/patient feedback often indicative of extremely low level of health literacy, lack of basic knowledge of medicine safety systems (including roles of the agency), and 'brand confusion' between the medicines funding and approval systems."

ANONYMOUS

"Unfortunately some information via media are distorted."

D. Organisation and Resources

As is seen in the findings from the first section of this questionnaire, drug safety communication is a task that involves several different skills – from epidemiology to journalism, from risk and decision expertise to communication systems expertise. With the final section of the questionnaire we hoped to learn more about how these skills and processes were organized within the agencies.

1. In your agency, is external drug safety communication managed by:

- A dedicated Communications Unit
- Staff within another unit
- Staff across different units
- Other

Most commonly, the task of drug safety communication was shared between pharmacovigilance and communications units.

Table 21. How external drug safety communication is managed at the agencies.

Responsible unit/department	Dedicated Communications Unit	Staff within another unit	Staff across different units
Agencies (N=12)	3	1	8

2. In your agency, what different skills do those actively involved in the process of drug safety communication have?

(Answer alternatives: Pharmaceutical, Medical, Communications/Journalism, Epidemiology, Risk and Decision Expertise, Communication Systems Expertise, Legal Advisor, Behavioural Science Expertise, Other)

The number of skill sets involved in the process of drug safety communications ranged from two (one agency) to seven (one agency). The mean number of skills was 4.5 per agency; again illustrating the cross-disciplinary nature of drug safety communication.

Two agencies regularly contracted out some of the agency's drug safety communications work; the work that was contracted out was related to media relations and campaigns for increased reporting of adverse drug reactions by HCPs, respectively.

Table 22. Skills of those actively involved in the process of drug safety communication.

Skill/Role	Agencies (N=12)
Pharmaceutical	12
Medical	11
Communications/Journalism	10
Epidemiology	8
Risk and Decision Expertise	6
Communication Systems Expertise	3
Legal Advisor	3
Other (Biostatistics)	1
Behavioural Science Expertise	0
Other	0

3. Does your agency have someone responsible for external communications (e.g., spokesperson/authorised person/PR officer) to speak to the media?

(Answer alternatives: Yes, No)

Eleven out of twelve agencies had someone responsible for external communications, to speak to the media.

Agency comments:

GERMANY

"Yes. The agency's press officer is mainly responsible for developing communication tools and an overall communication concept including public relations to news agencies and journalists. Specific communications, especially on risks and safety issues, are done by trained internal specialists in close co-operation with the press office."

ANONYMOUS

"Yes. Potential to use more than one spokesperson i.e. on an issue-dependent basis. Trained media spokespersons only."

CANADA

"Yes. The Public Affairs, Consultation and Communications Branch at Health Canada is responsible for external communications, including media relations."

USA

"Yes. We have designated press officers and designated subject matter spokespersons."

DENMARK

"Yes. Primary contact by chief press officer (journalist), who finds the person with relevant knowledge for the interview."

SWEDEN

"No. The agency's policy is to use different experts depending on issue."

ANONYMOUS

"Yes. External agency supported by relevant spokespeople such as chief executive plus other directors."

ANONYMOUS

"Yes. The department has spokespersons for external communications. However, the spokesperson for external communications on a drug safety issue may come from the agency depending on the nature of the issue."

Final Comment

Throughout the questionnaire, generous comments from the participants provided interesting insights into the context in which the agencies work, and rationales for different strategies or choices. They also highlighted the challenges and the dynamic nature of communicating drug safety messages in today's global, fast-changing and around-the-clock information society.

The University of Otago Pharmacovigilance Research Team is very grateful to the participating agencies. The results from the survey will be most valuable to the full assessment report on medicines risk communication with the New Zealand public, which will be delivered to the New Zealand Ministry of Health at the end of the project in 2012.

