

Survey on reporting side effects to medicines

Outcome report for survey of consumers

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Abbreviations

ACC	Accident Compensation Corporation
ADR	adverse drug reaction or suspected adverse drug reaction
CARM	Centre for Adverse Reactions Monitoring
HCP	healthcare professional
HQSC	Health Quality & Safety Commission
IAER	increasing adverse event reporting
ICMRA	International Coalition of Medicines Regulatory Authorities
MARC	Medicines Adverse Reactions Committee

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1) Purpose

Medsafe presented the strategy for promoting reporting of adverse reactions to medicines and medical device incidents to the Medicines Adverse Reactions Committee (MARC) on 13 September 2018. The Committee agreed to the strategy.

One of the projects identified in the strategy was to conduct a survey of healthcare professionals and consumers on adverse drug reaction (ADR) reporting. The strategy recommended that this project be started within the next few months.

The project is being managed in two key stages:

- 1. Survey of healthcare professionals.
- 2. Survey of consumers.

The outcome report for the survey of healthcare professionals was finalised in June 2019. Following this, questions for the survey of consumers were prepared and the survey opened on 31 January 2020 and closed 24 April 2020 – a period of almost three months. This document presents an overview and analysis of responses received to the survey of consumers.

2) Background

The survey of consumers on reporting side effects to medicines aimed to explore:

- How much consumers know about reporting side effects to medicines.
- How consumers find out about how well a medicine works or its side effects.

Medsafe was interested to know how to make it easier for consumers to report side effects to medicines and how to keep them informed about medicines safety.

Information gathered from this survey will help guide future campaigns and promotional activities to promote reporting of side effects. Repeating the survey after these campaigns and activities can be a way of measuring their success and effectiveness.

This survey of consumers used questions from the healthcare professional survey as a starting point. The questions were modified to better suit the audience, and learnings from the healthcare professional survey were applied.

Both surveys of healthcare professionals and consumers will be based on learnings of other regulators that are part of the International Coalition of Medicines Regulatory Authorities (ICMRA) pharmacovigilance subproject on increasing adverse event reporting (IAER).

The survey was initially pushed out through various electronic methods including:

- Emails to various organisations, including patient support organisations.
- A tweet using the Ministry of Health's twitter account on 3 February 2020.
- Using the 'What's New' box on the homepage of Medsafe's website from 31 January 2020 to 16 February 2020.

The plan was to send a reminder to complete the survey four weeks before the survey closed. However, due to the COVID-19 pandemic and the level 4 lockdown restrictions that were in place to support the health response, this reminder was not sent.

3) Survey structure

The overall survey structure is shown in Figure 1. Please refer to Appendix 1 for the full list of questions. The survey was hosted on SurveyMonkey from 31 January 2020 to 24 April 2020.

Figure 1: Structure of the survey for consumers on reporting side effects to medicines



= Part of the survey that wasn't set up correctly, so participants weren't directed to these questions; CARM = Centre for Adverse Reactions Monitoring; Q = question(s)

There were 19 questions included in the survey. The majority were optional questions where participants could skip the question if they didn't want to provide an answer. However, there were some questions that were compulsory and these were marked with an asterisk (*). Compulsory questions were required because this ensures the survey structure works in places where it "splits". An example of this is Q3 where the survey splits into Part 2A and Part 2B as shown in Figure 1. Other questions were made compulsory to gather demographic data and where Medsafe was particularly interested to learn more from participants (eg, Q15 'What is your main reason for not reporting a side effect to the Centre for Adverse Reactions Monitoring (CARM) before?').

4) Survey results

In-built SurveyMonkey tools were used to analyse results and present data.

A total of 1311 participants started the survey, of which 1302 participants were eligible to complete the survey (see Q1 analysis for further information). The weekly response rates were highest during the first three to four weeks of the survey, with a peak of 201 responses received during the week beginning 3 February 2020. The average time participants spent on the survey was 4 minutes.

Compulsory questions are marked with an asterisk (*) throughout. Note that there are space limitations for labels on some of the figures so these have been condensed where applicable. Please refer to Appendix 1 for the full statement.

Part 1: About you

Q1: What region of New Zealand do you live in? *

A total of 1311 participants provided a response. The options provided for this question were according to the geographic regions of New Zealand. Most participants live in Auckland (25.8%) followed by Wellington (16%), Canterbury (12.7%), Waikato (9.7%), Manawatu/Wanganui (6.6%) and Bay of Plenty (6.1%).

There were 9 participants (0.7%) who selected 'I don't live in New Zealand'. These participants were automatically disqualified from completing the survey. Therefore, the remaining 1302 participants were eligible to complete the survey.

Part 2: Reporting side effects

Q2: Who or which organisation would you contact if you wanted to report a side effect? *

Participants could select more than one option for this question. A total of 1280 participants answered this question (Table 1). This was a compulsory question indicating that 1280 participants completed the survey to this point and there were 22 drop-outs. A healthcare professional attracted the most responses (n=1138).

Who or which organisation	Count	Percent
A healthcare professional	1138	88.9
A family member, friend, or work colleague	286	22.3
Centre for Adverse Reactions Monitoring (CARM)	155	12.1
Don't know	132	10.3
Medsafe	127	9.9
Ministry of Health	87	6.8
The pharmaceutical company that makes the medicine	77	6.0
PHARMAC	71	5.6
Health and Disability Commissioner (HDC)	29	2.3
Health Quality & Safety Commission (HQSC)	25	2.0
Accident Compensation Corporation (ACC)	23	1.8

Table 1: Who or which organisation participants would contact to report a side effect

Q3: Have you reported a side effect to the Centre for Adverse Reactions Monitoring (CARM) before? *

A total of 1270 participants responded to this question (Figure 2). Most participants had not reported a side effect to CARM before (92.3%).

Figure 2: Responses to whether participants had reported a side effect to CARM before



Part 2A: Participants who have reported a side effect to CARM

Q4: How many times have you reported a side effect to CARM? *

79 out of the 98 participants that had reported a side effect to CARM before answered this question. Responses to this question are shown in Figure 3. More than half of the responders to this question had reported a side effect to CARM once (55.7%).



Figure 3: The number of times participants had reported a side effect to CARM

Q5: How did you find out about reporting side effects to CARM?

Participants could select more than one option for this question. Of the 98 participants who had reported a side effect to CARM before, 76 answered this question. Responses to this question are shown in Figure 4. The option that attracted the most responses was 'from my healthcare professional' (n=31, 40.8%).



Figure 4: Responses to how participants found out about reporting side effects to CARM

Q6: What are your main reasons for reporting side effects? *

Participants could select more than one option for this question. Of the 98 participants who had reported a side effect to CARM before, 79 answered this question. Responses are shown in Figure 5. Preventing the same thing from happening to someone else (n=50, 63.3%) and contributing to the monitoring of medicines safety (n=45, 57.0%) attracted the most responses.





The full statements for the options were 'To prevent the same thing happening to someone else', 'To make a contribution to the monitoring of medicines safety', 'To tell someone about my experiences', 'To get some advice on what I should do about the side effect' and 'Someone else told me that I should report it'.

Q7: Did you talk to a healthcare professional (eg, doctor, nurse, pharmacist) before reporting the side effect to CARM?

Of the 98 participants who had reported a side effect to CARM before, 78 answered this question. Most participants (83.3%) answered affirmatively (Figure 6).

Figure 6: Responses to whether participants talked to a healthcare professional before reporting to CARM



Q8: Was the report for a side effect you experienced, or were you reporting on behalf of someone else (eg, your child, partner, friend etc.)?

Of the 98 participants who had reported a side effect to CARM before, 79 answered this question. Responses are shown in Figure 7. Most participants reported for a side effect they themselves had experienced (n=47, 59.5%).



Figure 7: Who the report of the side effect was for

Q9: What effect do you think your report should have?

Participants could select more than one option for this question. Of the 98 participants who had reported a side effect to CARM before, 79 answered this question (Figure 8). Additional monitoring of the medicine (n=41, 51.9%), some or all of the above depending on the situation (n=38, 48.1%), a formal benefit risk review takes place (n=28, 35.4%) and information is sent out to the general public warning them about the medicine (n=27, 34.2%) attracted the most responses.



Figure 8: The effect the report should have #

The full statements for the options were 'Additional safety monitoring of the medicine takes place', 'Some or all of the above depending on the situation', 'A formal review of the benefits and risks of the medicine takes place', 'Information is sent out to the general public warning them about the medicine', 'The funded brand of the medicine should change', 'The medicine is taken off the market', 'I don't know' and 'Nothing needs to happen'.

Q10: How did you report the side effect to CARM? *

Of the 98 participants who had reported a side effect to CARM before, 79 answered this question. Responses are shown in Figure 9. Most participants reported using the online form (n=42).



Figure 9: The method participants used to report to CARM

Q11 to Q14: Questions on the online reporting form

It was intended that participants who had used the online reporting form would be directed to questions asking about the ease of using the form, fields that may have been missing or unnecessary on the form, and anything that would make it easier to report a side effect. However, the survey wasn't set up correctly and therefore these questions were never asked (ie, responses to these questions were all zero).

Although it would have been desirable to find out how the online reporting from could be improved, there are similar questions at the end of the online reporting form on CARM's website (<u>https://nzphvc.otago.ac.nz/consumer-reporting/</u>) and Medsafe has not been informed of any issues with the form.

Please see Appendix 1 for the full wording of these questions.

Part 2B: Participants who have never reported a side effect to CARM

Q15: What is your main reason for not reporting a side effect to the Centre for Adverse Reactions Monitoring (CARM) before? Please select the option that is the most relevant to you. *

1172 participants indicated in Q3 that they had never reported a side effect to CARM before. Of these 1172 participants, 1141 answered this question the majority of whom didn't report because they didn't know they could (n=641, 56.2%). There were two participants who selected 'I don't understand what a side effect is'. Responses are shown in Figure 10.

Figure 10: Participants' main reason for not reporting a side effect to the Centre for Adverse Reactions Monitoring (CARM)



The full statements for the options were 'I didn't know I could report side effects to medicines', 'I've never had a side effect before', 'I wasn't sure that it was a side effect to a medicine I was taking', 'I don't know how to report', 'My healthcare professional (eg, doctor, nurse, pharmacist) reported it for me', 'No reason in particular', 'I don't see the point in reporting', 'The reporting process was too difficult', 'I have concerns about the privacy of my information' and 'I don't understand what a side effect is'.

Part 3: Medicines information

Q16: How do you find information about medicines?

Participants could select more than one option. 1183 of the 1131 survey participants answered this question (Table 2). Healthcare professionals (n=797), a search on the internet (n=747), and consumer medicine information or patient information leaflets (n=646) were the top three options.

Of the 103 participants who selected 'Other (please specify)', the following sources were commonly mentioned:

- e health-related website (eg, Health Navigator, Mayo Clinic)
- C New Zealand Formulary or New Zealand Formulary for Children
- Sooks and journals.

Table 2: How participants find information about medicines

Source	Count	Percent
Healthcare professionals (eg, doctor, nurse, pharmacist)		67.4
Search on the internet (eg, through Google or another search engine)		63.1
Consumer medicine information or patient information leaflets	646	54.6
Medicine data sheets	505	42.7
Medsafe website		40.2
Scientific literature	197	16.7
General media (eg, newspapers, online news website, radio, TV etc.)	169	14.3
A family member, friend, or work colleague	161	13.6
Information from pharmaceutical companies	138	11.7
Ministry of Health		10.5
Other (please specify)		8.7
PHARMAC		7.6
Patient organisations or consumer groups		7.5
Social media (eg, Facebook, Twitter)		4.5
I don't search for information about my medicines		1.4
Health Quality & Safety Commission (HQSC)		1.3
l don't know		0.8

Q17: How would you like to receive new information on medicines safety from Medsafe?

Participants could select more than one option. 1106 of the 1131 survey participants answered this question (Figure 11). Being able to choose the type of alerts that are subscribed to attracted the most responses (n=658, 59.5%).

The top three methods that participants that selected 'Other (please specify)' suggested were:

- e being notified by a healthcare professional (eg, doctor, prescriber, nurse, pharmacist)
- Inot receiving any emails or alerts and/or looking for information as needed
- Seing able to receive information or alerts on the specific medicines they are taking.

Other suggestions included receiving information on paper (eg, patient information leaflet), disseminated through general media or social media, looking on the Medsafe website which could be more user friendly, through their mobile phone (eg, text message, app), and having information in braille.





Part 4: Medicines regulation

Q18: Who or which organisation do you think regulates medicines to make sure they work and are safe enough to use? *

1163 of the 1311 participants responded to this question. Responses are shown in Figure 12. The top two responses were Medsafe (n=421; 36.2%) and PHARMAC (n=271; 23.3%).



Figure 12: Responses to who or which organisation regulates medicines

Q19: Please select to what extent you agree or disagree with each of the following statements

Responses to the statements in this question are shown in Figure 13:

- A total of 458 participants (39.6%) either strongly disagreed (n=179) or tended to disagree (n=279) with the statement 'I know how medicines are regulated in New Zealand'. An additional 252 participants (21.8%) neither agreed nor disagreed with this statement. This indicates the potential for Medsafe to improve the public's awareness of who we are and what we do.
- The majority of participants (n=645; 55.9%) tended to agree or strongly agreed with the statement 'Pharmaceutical companies have too much influence over the way medicines are regulated'.
- Participants appeared to want more communication the risks of medicines rather than the benefits (789 tended to agree or strongly agreed for communication on risks vs. 582 for communication on benefits).



Figure 13: The extent participants agreed or disagreed with four statements #

The full statements were 'I know how medicines are regulated in New Zealand', 'Pharmaceutical companies have too much influence over the way medicines are regulated', 'I'd like to receive more communication on the benefits of medicines', 'I'd like to receive more communication on the risks of medicines'.

Summary of results

The denominator of the percentages shown in this section is the total number of participants that provided a response to that particular question. Participants could also select more than one option for some questions.

- I311 participants started the survey. Of these, 9 were disqualified from completing the survey because they didn't live in New Zealand, leaving a total of 1302 participants that were eligible to complete the survey.
- Approximately 1150 responses were received for the final question indicating there may have been about 150 dropouts.
- Most participants (88.9%) would contact their healthcare professional if they wanted to report a side effect.
- C There were 98 participants (7.7%) who had reported a side effect to CARM before. Of these:
 - More than half had reported once (55.7%).
 - Most participants found out about reporting to CARM through a healthcare professional (40.8%).
 - The top two reasons for reporting side effects were to prevent it happening to someone else (63.3%) and to contribute to the monitoring of medicines safety (57%).
 - 83.3% talked to a healthcare professional before reporting the side effect to CARM.
 - The top two effects participants thought their report should have was additional safety monitoring of the medicine (51.9%) and some or all of the above depending on the situation (48.1%).
 - Reporting to CARM using an online form was the most popular (53.2%).
 - Questions on the online form were never asked because the survey wasn't set up correctly.
- Most participants had never reported a side effect to CARM before (n=1172, 92.3%). Of these, 56.2% didn't know they could report a side effect to CARM.
- C The top three ways that participants obtain information about medicines were through healthcare professionals (67.4%), searching the internet (63.1%) and through consumer medicine information or patient information leaflets (54.6%).
- Most participants wanted to be able to choose the type of Medsafe alerts that they can subscribe to (59.5%).
- Most participants identified Medsafe as the organisation that regulates medicines (36.2%); however, there were 23.3% who selected PHARMAC as the medicines regulator.
- C There were 39.6% of participants who either strongly disagreed or tended to disagree with the statement 'I know how medicines are regulated in New Zealand', and an additional 21.8% of participants neither agreed nor disagreed with this statement. This indicates the potential for Medsafe to improve the public's awareness of who we are and what we do.

5) Discussion

We pushed this survey out through various electronic methods. This included emails to various organisations, including patient support organisations, to ask if they could help us publicise the survey to their service users. The 'What's New' box on the homepage of Medsafe's website also featured the survey for the first two weeks and a tweet was posted from the Ministry of Health's twitter account. It is possible participants in the survey aren't a representative cross-section of New Zealand's population based on the electronic methods used to push out the survey and the need to complete the survey online.

We planned to send a reminder to complete the survey four weeks before the survey was due to close. However, this was during COVID-19 alert level 4 so the reminder wasn't sent during this unprecedented time.

A total of 1311 participants started the survey of which 1302 participants were eligible to complete the survey because they live in New Zealand. A peak of 201 responses were received during the week beginning 3 February 2020. It is difficult to know how many participants completed the survey due to the way it was structured.

There was a technical glitch in the way the survey was set up. Questions to participants who had reported to CARM using the online form were never asked. Although these questions were never asked due to the glitch, there are similar questions at the end of the online reporting form on CARM's website and Medsafe has not been informed of any issues with the form.

Three questions included an 'Other (please specify)' or 'Other (please tell us more)' field where participants could insert their own text, while the other questions had prespecified options for participants to select. This made analysis of the responses more straightforward, but at the expense of data that is not as rich or detailed. Striking the balance between providing prespecified options and free text fields is always challenging and it is not known if this balance was struck.

The proportion of participants who have never reported a side effect to CARM before was high (1172 of 1270 participants, 92.3%). Of these 1172 participants, a high number didn't know they could report a side effects to medicines. These results indicate there is potential for Medsafe and CARM to improve the public's knowledge of reporting side effects to medicines. In addition, although the number of reports from consumers has increased over time with a peak of 532 reports during 2018, this number dropped to 268 reports during 2019 (see <u>Prescriber</u> <u>Update article on adverse reaction reporting in New Zealand – 2019</u>). Consumer reporting of side effects to medicines is important for patient-centred care. The impact that side effects can have on quality of life and daily activities are aspects that aren't generally reported by healthcare professionals. Therefore, consumer reporting of medicine side effects should be encouraged.

Participants appeared to have a high level of trust in their healthcare professionals. Healthcare professionals was the option that attracted the most responses for how participants find information about medicines, and participants commonly talked to a healthcare professional before reporting a side effect to CARM. There was also a sense that participants want information on medicines that are relevant to them (ie, medicines that they are taking) rather than being inundated with information or alerts on all medicines.

Next steps

There are two areas identified from the survey responses that Medsafe could address:

- Improve awareness amongst consumers of reporting side effects to medicines, including how to report.
- Provide information to consumers on the impact their report can have on the use of medicines in the general population.

Appendix 1 – Survey questions

Questions marked with an asterisk (*) were compulsory.

- 1. What region of New Zealand do you live in? *
 - a. Northland
 - b. Auckland
 - c. Waikato
 - d. Bay of Plenty
 - e. Gisborne
 - f. Hawkes Bay
 - g. Taranaki
 - h. Manawatu/Wanganui
 - i. Wellington
 - j. Nelson/Tasman
 - k. Marlborough
 - I. West Coast
 - m. Canterbury
 - n. Otago
 - o. Southland
 - p. I don't live in New Zealand
- 2. Who or which organisation would you contact if you wanted to report a side effect? You can select more than one option. *
 - a. Centre for Adverse Reactions Monitoring (CARM)
 - b. Medsafe
 - c. Ministry of Health
 - d. PHARMAC
 - e. Health Quality & Safety Commission (HQSC)
 - f. Accident Compensation Corporation (ACC)
 - g. Health and Disability Commissioner (HDC)
 - h. The pharmaceutical company that makes the medicine
 - i. A healthcare professional (eg, doctor, nurse, pharmacist)
 - j. A family member, friend, or work colleague
 - k. Don't know
- 3. Have you reported a side effect to the Centre for Adverse Reactions Monitoring (CARM) before? *
 - a. Yes
 - b. No
- 4. How many times have you reported a side effect to CARM? *
 - a. Once
 - b. 2 to 5 times
 - c. More than 5 times
 - d. Can't remember

- 5. How did you find out about reporting side effects to CARM? You can select more than one option.
 - a. General media (eg, newspaper, online news website, radio, TV etc.)
 - b. Search on the internet (eg, through Google or another search engine)
 - c. Social media (eg, Facebook, Twitter)
 - d. From my healthcare professional (eg, doctor, nurse, pharmacist)
 - e. From a family member, friend, work colleague
 - f. A patient/consumer support group
 - g. I can't remember
- 6. What are your main reasons for reporting side effects? You can select more than one option. *
 - a. To tell someone about my experiences
 - b. To prevent the same thing happening to someone else
 - c. To make a contribution to the monitoring of medicines safety
 - d. To get some advice on what I should do about the side effect
 - e. Someone else told me that I should report it
- 7. Did you talk to a healthcare professional (eg, doctor, nurse, pharmacist) before reporting the side effect to CARM?
 - a. Yes
 - b. No
- 8. Was the report for a side effect you experienced, or were you reporting on behalf of someone else (eg, your child, partner, friend etc.)?
 - a. A side effect I experienced
 - b. On behalf of someone else
 - c. Both I have reported a side effect I experienced as well as a side effect someone else had
- 9. What effect do you think your report should have? You can select more than one option.
 - a. Nothing needs to happen
 - b. The medicine is taken off the market
 - c. The funded brand of the medicine should change
 - d. Additional safety monitoring of the medicine takes place
 - e. A formal review of the benefits and risks of the medicine takes place
 - f. Information is sent out to the general public warning them about the medicine
 - g. Some or all of the above depending on the situation
 - h. I don't know
- 10. How did you report the side effect to CARM? *
 - a. Online form
 - b. Paper form
 - c. Email
 - d. Phone
 - e. I can't remember

- 11. How easy was it to fill in the form? *
 - a. Extremely easy
 - b. Moderately easy
 - c. Not at all easy
- 12. Was there information you wanted to add but there was no space/opportunity to do so?
 - a. No
 - b. Yes (please tell us more):
- 13. Did the form ask for information that wasn't needed?
 - a. No
 - b. Yes (please tell us more):
- 14. Would any of the following make it easier for you to report a side effect? You can select more than one option. *
 - a. Drop down lists to select the medicine name
 - b. Drop down lists to select the side effect
 - c. More free text space to include all the information I want to tell you about
 - d. More tick boxes so I don't have to type or write as much
 - e. Being able to select dates from an in-built calendar
 - f. Being able to report anonymously (ie, the person who had the side effect is NOT identifiable)
 - g. Don't know
- 15. What is your main reason for not reporting a side effect to the Centre for Adverse Reactions Monitoring (CARM) before? Please select the option that is most relevant to you. *
 - a. I've never had a side effect before
 - b. I didn't know that I could report side effects to medicines
 - c. I don't know how to report
 - d. My healthcare professional (eg, doctor, nurse, pharmacist) reported it for me
 - e. I don't see the point in reporting
 - f. I have concerns about the privacy of my information
 - g. I wasn't sure that it was a side effect to a medicine I was taking
 - h. No reason in particular
 - i. The reporting process was too difficult
 - j. I don't understand what a side effect is
- 16. How do you find information about medicines? You can select more than one.
 - a. Consumer medicine information or patient information leaflets
 - b. General media (eg, newspapers, online news website, radio, TV etc.)
 - c. Health Quality & Safety Commission (HQSC)
 - d. Information from pharmaceutical companies
 - e. Medicine data sheets
 - f. Medsafe website
 - g. Ministry of Health

- h. Healthcare professionals (eg, doctor, nurse, pharmacist)
- i. Patient organisations or consumer groups
- j. PHARMAC
- k. Scientific literature
- I. Search on the internet (eg, through Google or another search engine)
- m. Social media (eg, Facebook, Twitter)
- n. A family member, friend, or work colleague
- o. I don't search for information about my medicines
- p. I don't know
- q. Other (please specify)
- 17. How would you like to receive *new* information on medicines safety from Medsafe? You can select more than one.
 - a. Email when new information is added to the Medsafe website
 - b. Weekly email on additions to the Medsafe website
 - c. I would like to be able to choose which types of alerts I subscribe to
 - d. Social media (eg, Twistter)
 - e. Other (please specify):
- 18. Who or which organisation do you think regulates medicines to make sure they work and are safe enough to use? *
 - a. Centre for Adverse Reactions Monitoring (CARM)
 - b. Health Quality & Safety Commission (HQSC)
 - c. Accident Compensation Corporation (ACC)
 - d. Health and Disability Commissioner (HDC)
 - e. Government
 - f. PHARMAC
 - g. Medsafe
 - h. Ministry of Health
 - i. Healthcare professionals (eg, doctors, nurses, pharmacists)
 - j. Pharmaceutical companies
 - k. Don't know
- 19. Please select to what extent you agree or disagree (strongly disagree, tend to disagree, neither agree nor disagree, tend to agree, strongly agree, no opinion) with each of the following statements.
 - a. I know how medicines are regulated in New Zealand
 - b. Pharmaceutical companies have too much influence over the way medicines are regulated
 - c. I'd like to receive more communication on the benefits of medicines
 - d. I'd like to receive more communication on the risks of medicines