INTERVIEW PLAN – PHARMACISTS

Part 1: Experience with Reporting Systems

The aim of the first part is to share your experience reporting ADRs and dealing with the systems in place.

1) Are you familiar with Health Canada's Canadian Adverse Drug Reaction Monitoring Program?

a. What do you think of the system?

b. How were you put in touch with it?

2) Have you ever had an occasion to report any ADRs to Health Canada?

a. How did it go?

b. Did you have any problems?

c. Do you feel that the system is too bureaucratic (that there is too much red tape)?

3) What do you think that Health Canada does with the data you report?

a. Do you feel that these data are adequately interpreted?

b. Do you believe that Health Canada makes the right decisions ?

4) What do you think about taking drugs off the market due to rare, isolated or one-time ADRs?

a. Have you experienced this situation in practice? If so, how ?

b. Do you have any examples in mind?

c. What impact did they have on your practice?

5) What kind of feedback do you receive from these systems?

a. Does the feedback have an impact on your practice?

b. What kind of feedback would seem pertinent to you ?

6) Are you bothered by the confidentiality of the data you send?

a. Do you feel that your confidentiality is compromised?

7) In your opinion, what purpose does pharmacovigilance serve?

a. What leads you to this conclusion?

b. What examples come to mind?

8) Are these goals currently being met?

a. What leads you to this conclusion?

9) Do you think pharmacovigilance can have a concrete impact on your practice?

a. Why?

b. What impact does ADR reporting have on your practice?

10) What, in your opinion, is the importance of pharmacovigilance in a mother-child hospital setting?

Part 2 : Practice and Drug Risk

The second part refers to your practice and drug-related risk.

11) Are you exposed to ADRs in your practice ?

a. Can you give me a few sample situations?

12) Under what circumstances do you think that a potentially hazardous treatment can be used?

a. Can you provide a few examples?

b. How do you weigh one vs. the other?

13) Do you see a risk in using drugs for an unapproved indication?

a. Can you describe some typical situations?

b. Do you feel that the industry is shirking its responsibilities?

14) Do you think that the pharmaceutical industry takes risks?

a. To what extent?

b. What situations do you have in mind?

c. How do you feel about new drugs on the market in terms of safety?

d. How do you feel about new drugs on the market in terms of efficacy?

15) If the only option is a potentially hazardous treatment, do you think that your patients should assume the risks?

a. Do you think your patients (or their families) are ready to take risks (feel concerned about risk)?

b. Can you provide a few sample situations?

16) When you encounter a patient who is experiencing an ADR, how do you feel?

a. Do you feel responsible for the occurrence of the ADR ?

b. Do you have any precise examples in mind?

17) Do you feel that the ADRs you detect in your practice are manageable?

a. What do you base your point of view on?

b. Can you describe some sample situations (with ADRs under control/out of control)?

c. Do you feel that the ADRs you manage to control warrant being reported?

Part 3: Views on ADRs in Practice

In the third part, we will discuss what you think about ADRs and the impact that they may have in your practice.

18) In your personal opinion, who should be responsible for reporting ADRs?

a. Why?

b. What role do the other caregivers play? Why?

19) When do you feel certain that a drug is the cause of an ADR?

20) Just how certain must you be to think an ADR warrants being reported?

a. Do you have any examples in mind?

21) What do you consider a serious ADR?

a. What examples can you provide?

22) Just how certain must you be to think an ADR warrants being reported?

a. What examples can you think of?

23) Do you think that reporting should be limited to serious ADRs?

a. What leads you to this conclusion?

b. What examples do you have in mind?

24) What incentives would you recommend to get health care professionals to report ADRs?

a. What leads you to this conclusion?

25) What can you suggest to improve the system in place?

Last Point before Concluding the Interview

In order to be sure that I have not left out any issues that you consider to be important:

26) Are there any issues that we have not addressed that you would like to talk about?

INTERVIEW PLAN – PHYSICIANS

Part 1: Practice and Drug Risk

The first part refers to your practice and drug-related risk.

1) In your practice, do you often detect serious ADRs (the question does not refer to drug errors, but rather unexpected ADRs)

a. How often does this type of event occur?

b. Can you give me an example?

2) When this type of event occurs, we always weigh the benefits and the risks. How did you weigh the pros and cons?

3) Do you sometimes have to use a drug for an unapproved indication?

a. Do you have an example?

b. In this example, in your opinion, was there a particular risk in using the drug?

c. In this type of situation, do you feel that the industry is shirking its drug-related responsibilities (by not obtaining regulatory approval for the indication)?

4) Have you ever had to face a situation where the sole option available was a potentially hazardous treatment?

a. Can you provide a particular example?

b. In cases such as the one you described, do you think that your patients should assume the risks?

c. Do you think your patients and their families are ready to take these risks (or feel concerned by the risks)?

5) Do you feel that the ADRs you detect in your practice are manageable?

a. What do you base your point of view on?

b. Can you provide a few sample situations (with ADRs under control/out of control)?

c. How do you feel in such situations?

d. Do you feel that the ADRs you manage to control warrant being reported?

e. When an ADR occurs, who in your opinion should be responsible for reporting it: the industry, Health Canada, the attending physician, the pharmacist, the team?

f. Do you believe that a fear of legal liability may prevent physicians from reporting ADRs?

6) Besides clinicians, who must take risks, do you think that the pharmaceutical industry assumes its proper share of the risks?

a. To what extent (investment vs. fear of lawsuits)?

b. What situations do you have in mind?

c. How do you feel about new drugs on the market in terms of safety?

d. How do you feel about new drugs on the market in terms of efficacy?

Part 2: Views of ADRs in Practice

In the second part, we will discuss your views of ADRs and the impact they may have in your practice.

7) Can you give me a sample situation where you were sure that a drug caused an ADR?

a. What was it that made you sure?

b. Were you able to report it?

c. What motivated your choice?

d. Just how certain must you be to think an ADR warrants being reported?

e. Why?

8) Do you have an example of an ADR that you consider serious?

a. What made you think it was serious?

b. Did you have an opportunity to report it?

c. Why?

d. Just how serious does an ADR have to be to warrant reporting?

e. Why?

9) Do you have any examples of known or more common ADRs that you detect in your practice?

a. Do you think they warrant reporting?

b. Why?

10) In your personal opinion, who should be responsible for reporting ADRs?

a. Why?

b. How do you see the role of physicians, pharmacists, nurses, patients? Why?

Part 4: Experience with Reporting Systems

The aim of the third and last part is to share your experiences reporting ADRs and dealing with the systems in place.

11) In your case, how do you go about reporting an ADR? (department meeting, local authorities, industry, Health Canada, publication)

12) Are you familiar with Health Canada's Canadian Adverse Drug Reaction Monitoring Program?

a. What do you think of the system?

b. How were you put in touch with it?

13) Have you ever had an occasion to report ADRs to Health Canada? If so,

a. How did it go?

b. Did you have any trouble?

c. Do you feel that the system is overly bureaucratic (has too much red tape)?

14) What do you think Health Canada does with the data that are reported?

a. Do you feel that these data are adequately interpreted?

b. Do you believe that Health Canada makes the right decisions?

15) Have you ever had a drug taken off the market due to a rare ADR in your practice?

a. What example can you provide?

b. What impact did it have on your practice?

c. What do you think about these drug withdrawals?

16) Have you ever received the Canadian Adverse Reaction Newsletter from Health Canada?

a. Does this feedback have an impact on your practice?

b. Do you receive other types of feedback from Health Canada?

c. What type of feedback seems pertinent to you?

17) Are you concerned about the confidentiality of the data you send?

a. Do you feel that your confidentiality is compromised?

18) Can you provide an example where pharmacovigilance was useful to your practice?

a. What exactly did you find useful?

b. If NOT, in your opinion, what use does pharmacovigilance have in your practice?

c. Do you see a special importance for it in a mother-child hospital setting?

19) In your opinion, are the aims of the reporting system currently being achieved?

a. Why?

b. In your opinion, has Health Canada's Canadian Adverse Drug Reaction Monitoring Program had any accomplishments of note over the last few years?

20) What can you suggest to improve the system in place?