

Assessment of Country Pharmacovigilance Situation February 2008

Thank you for taking the time to complete this survey which will be invaluable in helping to identify the most urgent pharmacovigilance priorities and funding agendas. We would request return of the questionnaire by **31 March 2008**.

The questionnaire should take approximately 20 minutes to complete; any individual identifying information will be kept confidential. An online version of this survey is accessible through the UMC Web site, www.who-umc.org.

Please tick boxes or write your answers in the given spaces, as appropriate. (The online version must be completed in one go.)

I. Background Information

1. Country
2. Date when completing the survey
3. Name and title of person completing the survey
.....
4. Organization and department
.....
5. Address
.....
6. E-mail @
7. Phone number

II. Overview of Pharmacovigilance Programme

8. Does your country have a designated national centre, department, or unit that conducts pharmacovigilance activities?
 - a) No (*skip to question 55*)
 - b) Yes
9. What is the name of the programme or unit (*if different from question 4 above*) ?
10. In which year was the pharmacovigilance programme created?

11. What organization or agency oversees or is responsible for the pharmacovigilance centre?

12. Name and contact details of the responsible person in the overseeing organisation (*if different from questions 3 – 7 above*)

13. Is pharmacovigilance or adverse drug reaction reporting covered by legislation in your country?

- a) No
- b) Yes
- c) Not sure

14. Is there a budget designated for pharmacovigilance provided by a governmental authority?

- a) No
- b) Yes What is the size of the annual budget?

15. Do any of the following programmes conduct or assist in supporting pharmacovigilance anywhere in your country (*select all that apply*) ?

- a) Global Fund
- b) PEPFAR (*President's Emergency Plan for AIDS Relief*)
- c) PMI (*President's Malaria Initiative*)
- d) Clinton foundation
- e) Bill & Melinda Gates Foundation
- f) MSH (*Management Sciences for Health*)
- g) Universities
- h) Poison centre
- i) Public health programmes
- j) Patient Safety Alliance
- k) Rational Use of Drugs (RUD) networks
- l) Other (*please specify*)

16. How is the pharmacovigilance system organized?

- a) National centre only
- b) Network with national and regional centres or sentinel sites*

**Sentinel sites are usually clinics or hospitals where a pilot programme takes place. Often, a sentinel site is where a particular population is served (i.e., pregnant women) or a particular illness/disease is managed (ie, HIV/AIDS clinics).*

17. How many staff (full-time equivalents) are working with pharmacovigilance in the national programme, including regional centres if available?

- a) Health professionals
- i. Number with some formal pharmacovigilance training
- b) Community workers
- c) Others (e.g. administrative staff)

18. What is the geographical coverage of the pharmacovigilance system?

- a) Information collected from the whole country
- b) Information collected from some region(s) only

19. Is your centre devoted to pharmacovigilance only or is it combined with any of the following services (*please select all that apply*) ?

- a) Drug information
- b) Poison information
- c) Rational use of drugs
- d) Promoting patient safety
- e) Other Please specify?

20. Does your pharmacovigilance centre have access to computer facilities (*please select one of the following*)?

- a) No
- b) Yes
- c) Yes, designated for pharmacovigilance only
- i. Do you consider the capacity adequate?
 - 1. No
 - 2. Yes

21. Which of the following means of communication does your pharmacovigilance centre have direct access to?

- a) Telephone
- b) Facsimile
- c) E-mail
- d) Internet

If possible give communication speed available

22. Does your pharmacovigilance centre have access to a library with basic current reference books on drug safety or access to such sources over internet?

- a) No
- b) Yes

III. Activities within Your Country Related to Pharmacovigilance

23. Is there a pharmacovigilance programme in any organization in your country that focuses on any of the following diseases, populations or areas of work (select all that apply):

- a) Malaria
- b) HIV/AIDS
- c) Tuberculosis
- d) Other tropical diseases
- e) Children
- f) Immunization
- g) Pregnant women
- h) Medication errors
- i) Rational use of drugs
- j) Poison control
- k) Other

24. If there are other focused pharmacovigilance programmes as stated in question 23 above, are they coordinated by or integrated with the national pharmacovigilance system?

- a) No
- b) To some extent
- c) Yes
- d) Does not apply

IV. Spontaneous Adverse Drug Reaction Reporting

25. Is there a nationally approved form for reporting suspected adverse reactions to medicinal products?

- a) No
- b) Yes, one national form
- c) Yes, several forms (e.g. for different kind of problems/settings)
(please provide a copy of any of the forms)

26. Is reporting mandatory for healthcare professionals, and if so for whom (please select all that apply)?

- a) No, reporting is voluntary
- b) Yes,

If yes please specify criteria e.g. serious or unlabelled:
.....
.....
.....

27. Is reporting mandatory for marketing authorization holders (manufacturers)?

a) Yes

b) No

If yes please specify e.g expedited individual case reports, Periodic Safety Update Reports (PSUR:s) or risk management plans:

.....

.....

.....

.....

28. What kind of drug related problems does your pharmacovigilance programme cover (*please select all that apply*) ?

- a) Suspected adverse drug reactions
- b) Unexpected lack of efficacy
- c) Quality defects
- d) Drug dependence/abuse
- e) Medication errors
- f) Drug poisoning
- g) Other (*please specify*)

29. Which kind of products are covered by your pharmacovigilance programme (*please select all that apply*) ?

- a) Pharmaceuticals
- b) Traditional/herbal medicines
- c) Biologicals including vaccines
- d) Medical devices
- e) Cosmetics
- f) Other (*please specify*)

30. Which groups in society are encouraged to submit case information to the pharmacovigilance programme (*please select all that apply*) ?

- a) Doctors
- b) Pharmacists
- c) Traditional/herbal therapists
- d) Nurses
- e) Patients
- f) Manufacturers
- g) Other

31. How many individual reports were received in 2007 ?

Total number =

32. How many of these reports (Q31) did you receive from each of the following groups?
- a) Doctors
 - b) Pharmacists
 - c) Traditional/herbal therapists
 - d) Nurses
 - e) Patients
 - f) Manufacturers (domestic cases only)
 - g) Other

33. What is the cumulative number of individual case safety reports received by your pharmacovigilance system since operation started (sum of all systems if separate)?

34. How are reporting forms made available to health care practitioners and other reporters (*select all that apply*)?

- a) Direct mailing to individual health care practitioners
- b) Through health care facilities
- c) From an internet site
- d) Through pharmacies
- e) In drug formularies
- f) In professional bulletins/newsletters
- g) Insert in prescription pad
- h) Provided on demand
- i) Other (*please specify*)

35. What mechanisms are used to return completed forms to the pharmacovigilance programme (*select all that apply*)?

- a) Postal – not prepaid postage
- b) Postal – prepaid postage
- c) Telephone – regular
- d) Telephone – toll-free number
- e) Facsimile
- f) Internet/Web
- g) Transportation system in healthcare used also for other purposes (eg. drug deliveries)
- h) Specific transportation line or pick-up system for pharmacovigilance only
- i) Other (*please specify*)

36. Which system is used for recording the suspected adverse drug reaction reports?
- a) No computerized recording system
 - b) Spreadsheet (e.g. Excel®)
 - c) VigiFlow from the UMC
 - d) Other commercial software
 - e) Software designed in-house
 - f) Other
37. Does anyone from your pharmacovigilance programme ever contact the reporter to validate information or to get further details?
- a) No
 - b) Yes If yes, how?
38. Does the pharmacovigilance programme provide any individual acknowledgement to reporters?
- a) No
 - b) Yes If yes, how?
39. Do you classify reports received according to some causality grading?
- a) No
 - b) Yes, to all cases
 - c) Yes, but only some cases Which?
 - d) Yes, but only when a new signal is suspected
 - e) Other
-
-
40. Is there an established independent committee in your country which advises the drug regulatory agency on drug safety?
41. If yes, how often does it meet?

42. Which activities have been carried out to promote reporting (*select all that apply*) ?
- a) Training and sensitization lectures for healthcare professionals
 - b) Payment for reporters
 - c) Articles in professional journals or newsletters
 - d) Articles or programmes in general media
 - e) Inclusion of pharmacovigilance in professional curricula
 - f) Involvement of organizations/associations of health professionals
 - g) E-mail, internet
 - h) Paid advertisements
 - i) Specific sessions at conferences
 - j) Benefits for reporters e.g. Continuing Education Points
 - k) Other ...

V. Sentinel Sites* and Active Surveillance**

*Sentinel sites are usually clinics or hospitals where a pilot programme takes place. Often, a sentinel site is where a particular population is served (ie, pregnant women) or a particular illness/disease is managed (ie, HIV/AIDS clinics).

** Active surveillance is the regular periodic follow-up of patients undergoing drug treatment where the number of persons exposed to a medication is known and recorded (ie, known denominator for estimation of rates of adverse events).

43. Are there **sentinel** pharmacovigilance sites in your country?
- a) No (*proceed to question 45*)
 - b) Yes
44. If yes, is there any particular **population** targeted for monitoring through a **sentinel** site programme?
- a) No
 - b) Yes Which **populations**?
45. If a **sentinel** site programme exists, are particular **medicines** targeted for monitoring?
- a) No
 - b) Yes Which ones?
46. Is there an **active** surveillance system for identifying and reporting adverse drug reactions?
- a) No
 - b) Yes Please describe e.g. setting (hospital or community) and method used.
47. If **active** surveillance exists, are particular medicines targeted for monitoring?
- a) No
 - b) Yes Which ones?

VI. Registries for Pharmacovigilance

48. Do any pregnancy exposure registries exist in your country that are designed to study the safety of medication use during pregnancy?
- a) No
- b) Yes Which medicines are the focus of the registry(ies).....
49. If no, are there any plans to implement pregnancy exposure registries in the next two years?
- a) No
- b) Yes
50. Are there any registries for other populations or patient groups that either exist or are being planned for your country for the purpose of studying the safety of medications?
- a) No
- b) Yes Please specify
.....
.....
51. Are there any sources for drug utilization statistics in your country?
- a) No
- b) Do not know
- c) Yes Which?.....
.....
.....

VII. Use of Information from Pharmacovigilance Activities

52. How is information from pharmacovigilance activities utilized? (*select all that apply*)
- a) For drug regulatory activities
- b) Shared with managers of Public Health Programmes
(*e.g. immunization, HIV/AIDS etc*)
- c) Shared with pharmaceutical manufacturers
- d) Available to drug information/poison information centres
- e) Actively disseminated to health professionals/Drug and Therapeutics Committees
- f) Advice to consumer groups or general public
- g) As background for development of national Essential Drugs List
- h) In development of national drug therapeutic guidelines
- i) Other Please specify.....

53. If information is disseminated, by what means (*select all that apply*)?

- a) Newsletter or information bulletins
- b) Articles in professional journals
- c) Conferences
- d) Mass media
- e) Targeted messages for consumers (*eg. in retail pharmacies*)
- f) Internet web site
- g) Information is not disseminated
- h) Other Please specify.....

54. Have any of the following occurred as a result of information from pharmacovigilance activities in your country (*select all that apply*)?

- a) Changes of product information
Number of times in 2007
- b) Safety warnings
Number of times in 2007
- c) Suspension/withdrawal of drug product licence
Number of times in 2007
- d) None of the above
- e) Other Please specify.....

VIII. Challenges and Future Activities

55. What are the challenges in implementation, or if a programme is implemented, further development of pharmacovigilance?
56. What would you suggest for implementing, improving or scaling up pharmacovigilance in Public Health Programmes e.g in the treatment of:
- a) Malaria

 - b) HIV/AIDS

 - c) Tuberculosis

 - d) Other diseases
57. What assistance (technical/financial/training) would be needed to establish an efficient and effective pharmacovigilance programme in your country? Please list in order of priority:

58. What pharmacovigilance activities are you planning to conduct in the immediate future (1–2 years)?

IX. Pharmaceutical Market

59. To what extent do you estimate that drugs are sold in your country through the informal sector (unlicensed vendors and unlicensed internet sales)?

- | | |
|------------------|--------------------------|
| a) Not at all | <input type="checkbox"/> |
| b) 0 – 10% | <input type="checkbox"/> |
| c) 11 – 30% | <input type="checkbox"/> |
| d) 31 – 50% | <input type="checkbox"/> |
| e) More than 50% | <input type="checkbox"/> |

Additional information to provide, if available:

60. URL for pharmacovigilance website (*if any*) :

Reporting Form(s) for suspected adverse effects of drugs (*attach*) :

Please return this form to

Assessment of Country Pharmacovigilance Situation
Sten Olsson
The Uppsala Monitoring Centre
Box 1051
SE-751 40 UPPSALA
Sweden

or fax it to:
Fax: +46 18 656080

**There is an online version accessible via the UMC website.
Go to www.who-umc.org > WHO Programme**
