ANNEX-1: INFORMED CONSENT FOR HCPs

Title of the research: Knowledge and perception of health care professionals for consumer’s pharmacovigilance.

Investigator’s Statement:
Namaste! I am doing a research project for my PhD research work on “Knowledge and perception of health care professionals for consumers pharmacovigilance”. This study has already being approved from Institutional review board of KIST Medical College. If you have any question regarding the research you are invited to ask the researcher. You are free to take part and all the participant data will be used for the study purposes only.

Purpose and benefits: The purpose of this research is to obtain information on consumer’s pharmacovigilance among the health care professionals.

Procedure: Information would be obtained using a questionnaire. The median knowledge, attitude and practice scores and the total score will be calculated. The median scores would be compared among different subgroups of participants. Identity of an individual participant will not be revealed and only the group data would be revealed. We intend to publish the findings in future. If you are interested in obtaining preliminary information then kindly enter your e-mail address in the back side of the informed consent form.

All my questions and doubts have been answered to my satisfaction. I have read and understood the above and consent to participate in the research.

Name of the participant:_________________
Date:_________________
Signature:_________________
ANNEX-2: QUESTIONNAIRE FOR HEALTHCARE PROFESSIONALS

Age: Male/Female
Professional qualification: Date: Length of working experience:

For the following statements score using the following key (1 = strongly disagree with the statement, 2= disagree with the statement, 3= neutral, 4= agree with the statement, 5= strongly agree with the statement.) Use whole numbers only.

1. Pharmacovigilance is very much essential in developing countries like Nepal.
3. Adverse drug reactions are one of the major causes of death in the world.
4. Reporting of ADRs should be made mandatory by the government of Nepal.
5. Consumers pharmacovigilance is already established in Nepal.
6. The Pharmacovigilance program in Nepal is successful.
7. Patients can themselves report ADR to the doctors and other health care professionals.
8. Consumers can report for herbal medicines as equal to allopathic medicines.
9. There is a separate form developed for consumers reporting of ADRs.
10. Consumer’s ADR reporting should be encouraged.
11. The ADR reporting form for consumers should be in a single page.
12. Department of drug administration (DDA) should take steps for strengthening pharmacovigilance in Nepal.
13. DDA should also emphasize for consumers reporting of ADRs.
14. Pharmaceutical Industries should also report ADRs.
15. Nepal Chemists and Druggists Association should be involved more on drug safety issues.
16. Pharmacovigilance should be included in the curriculum of all health care professionals.
17. Over the counter (OTC) medications do not cause any ADRs
18. Remuneration should be given to the health care professionals to report ADRs
19. Many adverse effects are preventable.
20. A good number of adverse drug reactions can be prevented if appropriate measures are taken.
21. The National Pharmacovigilance Center in Nepal is located at Department of Drug Administration.
22. The international center for adverse drug reaction monitoring is located in Sweden.
23. Adverse drug reaction reporting should be made mandatory by consumers as well as health care professionals.
24. Hartwig scale is used to establish the severity of an adverse drug reaction.
25. Reading articles on adverse drug reaction will be beneficial to health care professionals.
26. Consumers are not aware enough of adverse reactions of their own medicines.
27. Consumer can report through their health care providers.
28. You are optimistic about the success of consumer reporting of ADRs in Nepal.
29. Involvement of patients is important as well as health care professionals in reporting of ADRs.
30. The report given by patient can be a good source of information of ADR.
31. Under reporting, the main problem of national program can be solved by consumer reports.
32. Consumer reporting will increase the knowledge about ADR information.
33. Consumer reporting will promote consumer rights in Nepal.
34. Consumer reporting will ensure the safe use of medicines in Nepal.
35. Consumers can write valid ADR reports like health care professionals.
36. The quality of consumer reports will be similar to health care Professionals’ reports.
37. Consumers need more education regarding reporting of adverse drug reactions of their medicines.
38. Media may play a role in the success of consumer reporting in Nepal.
39. Non-governmental organizations (NGOs) in Nepal can help and play important role in the success of consumer reporting programme.

Thank you!
ANNEX-3: INFORMED CONSENT FOR COMMUNITY PHARMACISTS

Title of the research: Knowledge and perception of community pharmacists for consumer’s pharmacovigilance.

Investigator’s Statement:

Namaste! I am doing a research project for my PhD research work on “Knowledge and perception of community pharmacists for consumers pharmacovigilance”. This study has already being approved from Institutional review board of KIST Medical College. If you have any question regarding the research you are invited to ask the researcher. You are free to take part and all the participant data will be used for the study purposes only.

Purpose and benefits: The purpose of this research is to obtain information on consumer’s pharmacovigilance among the community pharmacists at Lalitpur.

Procedure: Information would be obtained using a questionnaire. The median knowledge, attitude and practice scores and the total score will be calculated. The median scores would be compared among different subgroups of participants. Identity of an individual participant will not be revealed and only the group data would be revealed. We intend to publish the findings in future. If you are interested in obtaining preliminary information then kindly enter your e-mail address in the back side of the informed consent form.

All my questions and doubts have been answered to my satisfaction. I have read and understood the above and consent to participate in the research.

Name of the participant:-________________
Date:-________________________
Signature:-____________________
ANNEX-4: QUESTIONNAIRE USED FOR HEALTHCARE PROFESSIONALS

The knowledge, attitude and practice (KAP) questionnaire on consumer’s pharmacovigilance and adverse drug reactions among community pharmacists in Lalitpur

Details of the responder and the pharmacy

<table>
<thead>
<tr>
<th>Name:</th>
<th>Age:</th>
<th>Gender: Male/Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional qualification:</td>
<td>Pharmacy Name:</td>
<td>Date:</td>
</tr>
<tr>
<td>Length of experience:</td>
<td>Number of pharmacists working:</td>
<td></td>
</tr>
<tr>
<td>Average No. of patients per day:</td>
<td>Year of starting the Pharmacy:</td>
<td></td>
</tr>
<tr>
<td>No. of persons involved dispensing:</td>
<td>Location of the Pharmacy:</td>
<td></td>
</tr>
<tr>
<td>Available source for information:</td>
<td>Total number of preparations:</td>
<td></td>
</tr>
</tbody>
</table>

For the following statements score using the following key (1 = strongly disagree with the statement, 2= disagree with the statement, 3= neutral, 4= agree with the statement, 5= strongly agree with the statement.) Use whole numbers only.

1) A drug may take more than 12 months to reach the market.
2) The international center for adverse drug reaction monitoring is located in Unites States of America.
3) Department of Drug Administration (DDA) is the organization in Nepal which is involved in drug safety issues.
4) Adverse drug reactions are one of the major causes of death in the world.
5) Reporting of ADRs should be made mandatory by the government of Nepal.
6) Consumers pharmacovigilance is already established in Nepal.
7) Patients can themselves report ADR to the doctors and other health care professionals.
8) Consumers can report for herbal medicines as equal to allopathic medicines.
9) There should be a form developed for consumers to report ADRs.
10) Consumer’s ADR reporting should be encouraged.
11) ADR reporting will waste my useful time.
12) Department of drug administration should take steps for reporting ADRs by consumers in Nepal.
13) Pharmaceutical Industries should also report ADRs.
14) Nepal Chemists and Druggists Association should be involved more on drug safety issues.
15) Over the counter (OTC) medications do not cause any ADRs.
16) Remuneration should be given to the health care professionals to report ADRs.
17) The National Pharmacovigilance Center in Nepal is located at Department of Drug Administration.
18) Adverse drug reaction reporting should be made mandatory by consumers as well as health care professionals.
19) Hartwig scale is used to establish the severity of an adverse drug reaction.
20) Reading articles on adverse drug reaction will be beneficial to you as a community pharmacist.
21) Consumers are not aware enough of adverse reactions of their own medicines.
22) Consumer can report through you as a health care service provider.
23) You are optimistic about the success of consumer reporting of ADRs in Nepal.
24) Involvement of patients is important as well as health care professionals in reporting of ADRs.
25) Community pharmacists should know about side effects of medicines.
26) The report given by patient can be a good source of information of ADR.
27) Consumer reporting will increase the knowledge about ADR information.
28) Consumer reporting will promote consumer rights in Nepal.
29) Consumer reporting will ensure the safe use of medicines in Nepal.

30) Consumers need more education regarding reporting of adverse drug reactions of their medicines.

31) You have seen any patient experiencing an adverse drug reaction.

32) Patient cooperation is important factor necessary to report an adverse drug reaction by community pharmacists.

33) Media may play a role in the success of consumer reporting in Nepal.

34) Non-governmental organizations (NGOs) in Nepal can help and play important role in the success of consumer reporting programme.

Thank you for your valuable time and kind support!
ANNEX-5: INFORMED CONSENT USED FOR CONSUMERS

Title of the research: Knowledge and perception of consumers for consumer’s pharmacovigilance.

Investigator’s Statement:

Namaste! I am doing a research project for my PhD research work on “Knowledge and perception of consumers for consumers pharmacovigilance”. This study has already being approved from Institutional review board of KIST Medical College. If you have any question regarding the research you are invited to ask the researcher. You are free to take part and all the participant data will be used for the study purposes only.

Purpose and benefits: The purpose of this research is to obtain information on consumer’s pharmacovigilance among the consumers.

Procedure: Information would be obtained using a questionnaire. The median knowledge, attitude and practice scores and the total score will be calculated. The median scores would be compared among different subgroups of respondents. Identity of an individual participant will not be revealed and only the group data would be revealed. We intend to publish the findings in future. If you are interested in obtaining preliminary information then kindly enter your e-mail address in the back side of the informed consent form.

All my questions and doubts have been answered to my satisfaction. I have read and understood the above and consent to participate in the research.

Name of the participant: - ______________________
Date: - ________________________________
Signature: - __________________________

Initiating Consumers Pharmacovigilance in Lalitpur District
ANNEX-6: QUESTIONNAIRE USED FOR CONSUMERS

Gender: M / F  Age: ____  Occupation: _______  Ethnic caste: _________  Education: ________  Current illness: _________  Date: ____________  Rural / Urban

Instruction: Please (✓) only once for each question at the appropriate response and fill in the lines below accordingly.

1. What do you understand about an adverse drug reaction?
   a. Harmful and unpredicted response that we experience after taking a medicine at normal doses. ( )
   b. Side effects that you have experienced after taking medication ( )
   c. Any desired effects that you experience after taking a medicine ( )
   d) Don’t know ( )

2. Is there any difference between side effects and adverse drug reactions?
   Yes (  )  No (  )
   If yes, please state: ____________________________________________

3. Based on your knowledge, which one of these can be considered as an adverse drug reaction?
   a) You experience sleepiness after taking cough syrup (  )
   b) You develop diarrhea after taking penicillin (antibiotic) (  )
   c) You can meet an accident after taking cough syrup (  )
   d) Your fever relieved after taking paracetamol (cetamol) (  )
   e) Not sure (  )

4. Which group of the people can develop adverse drug reaction?
   a) Children (  )
   b) Adults (  )
   c) Elderly (  )
   d) Anyone (  )
   e) Don’t know (  )
5. Do you think collecting information on adverse drug reaction is important?
   Yes ( ) No ( )
   If YES, why?____________________________________________________________________
   If NO, why?____________________________________________________________________

6. What is the purpose of adverse drug reaction reporting?
   a) To enable safe drug to be used ( )
   b) To prevent recurrent of adverse drug reaction to other people ( )
   c) Just to fulfill the requirement ( )
   d) To make the doctor easily diagnose the illness ( )
   e) Do not know ( )

7. What will you do if you experience any strange or unintended response after taking a certain medicine?
   (a) Stop taking the medicine ( )
   (b) Go to the doctor ( )
   (c) Report the adverse drug reaction ( )
   (d) Continuing taking the medicine ( )
   (e) Others: Please state__________________________________________

8. Do you know to whom you can report an adverse drug reaction?
   Yes ( ) No ( )
   If yes, to whom?
   a) Doctor ( )
   b) Pharmacist ( )
   c) Nurses ( )
   d) Department of drug administration ( )
   e) All the above ( )
9. In case you are interested in reporting the adverse drug reaction, which method do you prefer the most?
   a) Computerized ( )
   b) Filling in the form manually ( )
   c) Orally reporting to the physician ( )
   d) Face to face reporting at the adverse drug reaction reporting center ( )
   e) Do not know ( )

10. Nepal has developed a system for evaluating adverse drug reaction. Which one of these centers is involving in the system?
    a) World Health Organization (WHO) ( )
    b) Uppsala Monitoring Center (UMC) ( )
    c) Ministry of Health and Population ( )
    d) Department of drug administration (DDA) ( )
    e) Don’t know ( )

11. If your neighbor is suspected with an adverse drug reaction, could you advice your neighbor to report the adverse drug reaction?
    Yes ( )  No ( )
    If YES, why?________________________________________________
    If NO, why?____________________________________________

12. After taking an antibiotic, you developed rashes on your skin. What action will you take?
    a) Consult the doctor immediately ( )
    b) Wait for a few days until the rashes get worsen ( )
    c) Buy some medicine from the pharmacy to treat the rashes ( )
    d) Ignore the rashes ( )
    e) Stop taking the medication ( )

13. Have your physician ever told you about adverse drug reactions of the medications that you are taking?
    Yes ( )  No ( )
    If YES, please state ________________________________
14. Have you ever asked your doctor about the possible adverse drug reaction of the medication that you will take?
   Yes (  )       No (  )

15. During consultation with your doctor, if the doctor tells you to report directly to him and if any adverse drug reaction appears, then what would be your plan of action?
   a) Follow the suggestion given by the doctor (  )
   b) Just ignore it because it is only a mild rash (  )
   c) Want to report it but did not know how and where to report (  )
   d) Continue taking the medication (  )
   e) Do not know (  )

16. If you have any idea about adverse drug reaction, what had been your source of information regarding the adverse drug reaction?
   a) Doctor (  )
   b) Pharmacist (  )
   c) Health related magazines/ books (  )
   d) None (  )
   e) Others: Please state___________________________________________

17. Who is responsible to report adverse drug reaction?
   a) Doctor (  )
   b) Pharmacist (  )
   c) Consumer (  )
   d) All the above (  )
   e) Do not know (  )

18. If an adverse drug reaction is not dangerous, do you still want to report it?
   Yes (  )       No (  )
   If YES, why?

Initiating Consumers Pharmacovigilance in Lalitpur District
19. In your opinion, educating the consumer on adverse drug reaction is beneficial or not?

Yes ( )  No ( )

If YES, how?

If NO, how?

20. What would be the most effective way to educate the consumer regarding adverse drug reaction reporting?

   a) Consultation by the pharmacist ( )
   b) Label on medication: ‘Please consult your physician immediately once you experiencing any adverse drug reaction’ ( )
   c) Awareness campaign ( )
   d) Publish articles on adverse drug reaction in the newspaper ( )
   e) Any

others:___________________________

21. Do you think that the adverse drug reaction reporting system is beneficial to the public?

Yes ( )  No ( )

If YES, why?

If NO, why?

22. Do you think is it necessary to set up an adverse drug reaction reporting system in KIST Medical College, Imadol?

Yes ( )  No ( )

If YES, why?

If NO, why?

23. If we develop an adverse drug reaction reporting center at KIST Medical College, would you like to report by coming there?

Yes ( )  No ( )
24. Are you keen to know more possible adverse drug reaction that may be due to the medicine that you consume?

Yes (    ) No (    )

If YES, why?

No, why?

Thank you for your support.
ANNEX-7: SECOND QUESTIONNAIRE USED FOR CONSUMERS FOR DESIGNING AN ADR REPORTING FORM

Gender: M / F  Age: ___  Occupation: _______
Ethnic caste: _______  Education : ____  Rural / Urban

1. Do you think collecting information on adverse drug reaction should be reported?
   Yes (    )  No (    )
   If YES, why?_______________________________
   If NO, why?

2. What should be the language of the adverse drug reaction reporting form?

3. Where should be the form for adverse drug reaction reporting form be placed?

4. What will be your preferred way of reporting any adverse drug reactions?

5. Whom will you report adverse drug reactions?

6. Where will you report any adverse drug reactions?

7. What type of adverse drug reactions are known to you?

8. How will you report any adverse drug reactions?

9. What information will you need for reporting any adverse drug reaction?

10. How many medicines can be reported in a single form for adverse drug reaction?
ANNEX-8: SOME GLIMPLES FROM THE RESEARCH WORK

Photo 8.1. Participants responding to pre-test session

Photo 8.2 Participants doing group work
Photo 8.3 Participants presenting about their views for ADR reporting forms

Photo 8.4 Participants discussing their views for ADR reporting forms
Photo 8.5 Researcher interacting with the participants during educational intervention session

Photo 8.6 Participants doing their post-test after the educational intervention
Photo 8.7 HCPs doing their post-test after the educational intervention
Photo 8.8 Participants doing their post-test after the educational intervention

Photo 8.9 Participants doing their post-test after the educational intervention
Photo 8.10 Educational session prepared for the research work