4. Roadmap for implementation of Pharmacovigilance for vector-borne diseases

4.1 Introduction

Pharmacovigilance (PV) is the science and activities relating to the detection, monitoring, assessment, understanding and prevention of adverse effects or any other drug-related problem from any pharmaceutical products[1]. The core purpose of pharmacovigilance is to enhance patient care and generate the evidence based information on safety of medicines. It is increasingly gaining significance in pursuit of safe-guarding public health by monitoring and prevention of adverse drug reactions. Adverse drug reactions (ADRs) represent the 3rd leading cause of death after cancer and cardiac disease in USA[2]. In the USA and Canada ADRs account for 4.2-30% of hospital admissions, 5.7-18.8% of admissions in Australia, and 2.5-10.6% of admissions in Europe[3]. A study in India reported overall incidence of 9.8% ADRs including 3.4% of total hospital admissions and 3.7% adverse drug reactions developed during hospital stay[4].

The present roadmap and its implementation at national, state and district levels will provide a crucial opportunity not only in early recognition and management of adverse drug reactions, improved benefit-risk ratio, better patient compliance but also improved treatment outcomes, thus encouraging the safe, rational and more, effective (including cost effective) use of vector borne disease medicines. The Road map has been prepared with clear objectives, outcomes, proposed roles, and responsibilities at national, state and district levels.

Pharmacovigilance of vector-borne disease (VBD) medicines will require effective involvement of state VBD officers, District VBD officers, VBD consultants, medical officers at district and block levels, various partners including PVPI, data entry operators and ASHA at village level for early identification of a suspected adverse drug reaction, reporting the event, assessing causality assessment and uploading the information in the database. Effective management of the data flow will result in success of the pharmacovigilance of vector borne disease programme.

In summary, pharmacovigilance is a branch of patient care and surveillance. It promotes the safe and effective use of medicines, through providing timely information about the safety of medicines to healthcare professionals and patients.

1. *http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/*
2. *Makary Martin A, Daniel Michael. Medical error—the third leading cause of death in the US. BMJ 2016; 353: i2139*
3. *Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol. 2007; 63:136–47.*
4. *Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. Br J Clin Pharmacol. 2008; 65:210–6*

4.2 Organizations involved in pharmacovigilance for vector-borne diseases

Indian Pharmacopoeia Commission (IPC)- Pharmacovigilance Programme of India (PvPI)
IPC is an autonomous institution of the Ministry of Health and Family Welfare, Govt. of India. IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India. IPC also provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP.

IPC is functioning as national coordinating center (NCC) for PvPI since 15th April 2011 to monitor the Adverse Drug Reaction. The mission of PvPI is to safeguard the health and welfare of the Indian population by monitoring drug safety and ensuring the benefits of use of medicine outweigh the risks associated with their use. The vision of PvPI is to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines.

Organization Committees under NCC

Steering Committee

PvPI Working Group

Core Training Panel

Quality Review Panel

Signal Review Panel

Memorandum of Understanding between NVBDCP, IPC-PvPI

NVBDCP and Pharmacovigilance Programme of India (PvPI) have signed a Memorandum of Understanding (MOU) in New Delhi on 3 August 2016 to monitor drug safety in vector-borne diseases and to initiate and promote the process for reporting adverse drug reactions (ADRs) with WHO as the technical partner.

4.3 Adverse drug reaction monitoring and reporting – Definitions and terminologies

Adverse drug reaction: It is a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Serious adverse events: A Serious Adverse events (SAE) based on ICH is any toward medical occurrence that any dose:

- results in death;
- is life-threatening; (the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.)
- requires inpatient hospitalization or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect;
- is a suspected transmission of any infectious agent via a medicinal product;
- is medically important;

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should usually be considered serious.

Non-serious adverse drug reactions (ADR) (associated with the use of the drug): Any untoward medical occurrence that does not meet the above criteria to be serious and also is considered associated with the use of the drug.

Life threatening ADR: Any event in which the patient was at risk of death at the time of the even; it does not refer to an event, which hypothetically might have a caused death if it were more severe.

Severity criteria:
The severity of a specific event describes its intensity, and it is the intensity which is graded. Assessment of severity will be made as per the following general categorical descriptors:

Mild: Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated.

Moderate: Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated.

Severe: Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated.

4.4 Road map for pharmacovigilance in vector-borne diseases

4.4.1 Objectives

The main objective of setting up of pharmacovigilance system in programme is, earliest possible recognition of adverse drug reactions, including interactions. It will also include identification of previously unknown adverse drug reactions and interactions, to assess safety in pregnancy and lactation, quality and cost assessment/economic analysis, evaluate the risk factors that could lead to adverse drug reactions with vector borne disease (VBD) medicines. It will also provide evidence for benefit or harm assessment of different regimens or products leading to evidence based regulatory action. The roadmap also aims to provide training to the VBD key functionaries in all the aspects of pharmacovigilance and patient safety for VBD medicines and to enhance their ability to evaluate and address the problems related to adverse drug reactions (ADRs) in the field.

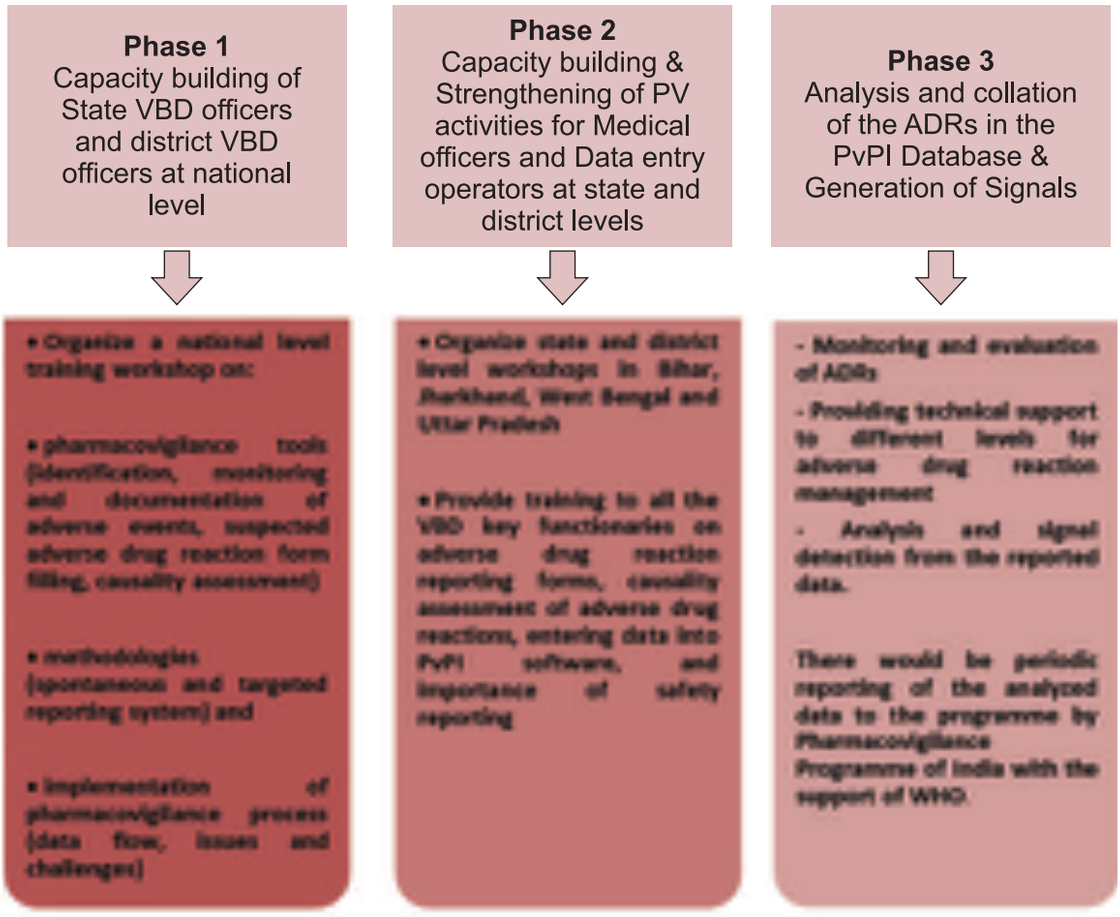
4.4.2 Pharmacovigilance methods

The most common method of pharmacovigilance is 'Spontaneous Reporting'[8]. This method has the potential of early identification of rare & previously unlabeled adverse drug reactions. Targeted spontaneous reporting[9] is useful in focused adverse drug reaction reporting system. It works as an add on to the spontaneous reporting system for a defined medicine and patient group. For the programme, 'Spontaneous reporting' and 'Targeted spontaneous reporting' (for Ambisome) methods will be used.

[8] *WHO. The SAFETY of MEDICINES IN PUBLIC HEALTH PROGRAMMES: Pharmacovigilance an essential tool: WHO; 1997*
[9] *WHO. A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis. Geneva: WHO; 2012.*

4.4.3 Proposed action plan for implementation at national, state and district levels

The road map will be implemented in a phased manner at national, state and district levels



Detailed action plan of implementation of pharmacovigilance systems at national, state and district Levels

4.4.4 Phase 1 of Implementation of PV activities

Roles and responsibilities of key functionaries in the kala-azar programme under NVBDCP

S.No.	Component	Responsibilities
1.	Pharmacovigilance Programme of India	• Provide support in national, state and district level workshops and to train data entry operators on entering data into PvPI software • To evaluate the data uploaded in PvPI Software and prepare monthly reports • Provide reports for early warnings and signals • Communicate regularly with all the stakeholders (NBVDCP, MoHFW and Partners) about the trends of reporting and new findings • Pharmacovigilance Associates who are working in ADR Monitoring Centres will coordinate district level centres/NVBDCP and Zonal Coordinators

		• Provide support in setting up identified additional Adverse Drug Reaction Monitoring Centers (AMCs) for Kala-azar Program (11 medical colleges from the four endemic states) • Facilitate the access to PvPI Software and provide training
2.	WHO India	• Provide technical support for the implementation of pharmacovigilance systems at national, state and district levels • Periodic analysis of the reported ADRs along with PvPI
3.	State Programme Officer	• Monitor the overall pharmacovigilance process in their State • Jointly review the progress of PV activities along with state level review committees • Conduct regular orientations for Medical officers and other staff in public facilities to maintain a high degree of surveillance on finding adverse drug reaction in kala-azar cases
4.	District Vector Borne Disease Officers	• Monitor the overall pharmacovigilance process in their Districts • Jointly review the progress of PV activities in their districts • Conduct regular orientations at district levels
5.	Vector Borne Disease Consultants	• Follow up with medical officers and nurses for reported adverse drug reactions • Communicate with KTS for follow up cases
6.	Medical officers (District/Block level)	• Early detection of any adverse drug reaction during infusion of AmBisome • Identification of adverse drug reactions from any kala-azar medicine during regular checkup • Identification of any drug interaction due to any concomitant drugs (specifically, in case of co-infections) • Filling of suspected Adverse Drug reaction Form for kala-azar Treatment • Causality assessment of ADRs • Evaluate severity and seriousness of the reaction • Encourage patients to report adverse drug reaction voluntarily • Inform patients about toll-free number (1800-180-3024) of Pharmacovigilance Programme of India to report any adverse drug reaction • Counsel patients on reporting of possible adverse drug reactions after discharge from hospital • Entry of data into PvPI software at district level, where required

7.	Data Entry Operators (District/block level)	• Enter the data from adverse drug reaction forms to the PvPI software • Proper documentation of the adverse drug reaction forms at their centre
8.	Nurses	• Early detection of any adverse event during infusion of AmBisome • Identification of any drug interaction due to any concomitant drugs (specifically, in case of co-infections) • Filling of suspected adverse drug reaction form • Encourage and counsel patients to report adverse drug reaction voluntarily • Inform patients about Pharmacovigilance Programme of India toll-free number to report adverse drug reactions and how to report adverse drug reactions after discharge
9.	Partners	• Help in spreading awareness among kala-azar patients for reporting adverse drug reactions • Assist in entering adverse drug reactions data into the PvPI software • Support to Data Entry Operators • Provide support on training of ASHA facilitators and ANMs on pharmacovigilance process • Work with KTS to identify the follow up cases and fill the follow up adverse drug reaction form
10.	Kala-azar technical supervisors (KTS)	• Provide support on training of ASHA facilitators and ANMs on pharmacovigilance process • Work with ASHA facilitators and ANMs to identify the follow up cases • Help in spreading awareness among kala-azar patients for reporting adverse drug reactions
11.	ASHA / Anganwadi staff	• Encourage and counsel patients to report adverse drug reaction • Talk to patients in every village/ block and identify any adverse drug reactions happened to any patient due to Kala-azar treatment at any point • Detection of adverse drug reaction after discharge from hospital following infusion of Ambisome • Follow Up of patients on adverse drug reactions during routine visits and fill Follow Up form, if any ADRs are reported

4.4.5 Phase 2 of Implementation of pharmacovigilance activities

a) Training Plan and Capacity Building Activities for Pharmacovigilance at State Levels

Activities for Pharmacovigilance at State Levels

- Organize workshops and trainings for VBD officers, district medical officers, zonal officers, medical college HCPs (AMC Coordinator and treating physicians)
- Monitor the pharmacovigilance processes and reporting of VBD medicines
- Field visits to district hospitals and medical colleges, block level hospitals, to monitor the activities related to adverse drug reaction reporting and collect feedback
- Analysis of the monthly collected data from all the districts by Pharmacovigilance Programme of India and monthly reporting to programme and other stakeholders
- Monthly meetings at state levels to review the process at various levels, discuss the issues and challenges, take recommendations and feedbacks

b) Training plan and capacity-building activities for pharmacovigilance at district levels

Activities for pharmacovigilance at district levels

- Organize three workshops in Bihar, Jharkhand and West Bengal for block level medical officers, data entry operators and nurses
- Adverse drug reactions will be entered in PvPI software by data entry operators in every district and block level hospitals or by the nearest Pharmacovigilance Programme of India ADR monitoring centers, on monthly basis
- Conduct review meetings periodically at district and block level for healthcare providers to update them on standard process of adverse drug reaction reporting, assess causality, severity of reaction and take their feedbacks on how to improve the existing program
- Training of Field Monitors, ASHA and KTS supervisors for Identification and filling of follow up forms for follow up of the cases
- Spread awareness by regular workshops at district level for medical officers and VBD officers on any updates, sharing data reports
- Expedited reporting of serious and unexpected adverse drug reaction is required as soon as possible, but in no case later than 15 calendar days.
- Death cases should be reported within 24 hours to the Pharmacovigilance Programme of India

Filling of ADR reporting form and data entry into PvPI software: Roles and responsibilities

State	Level	Responsibilities	
		Form filling	Data entry
Bihar	Block level	Block level physicians providing AmBisome treatment to fill the forms and perform causality assessment	Block level data entry operator will enter the data in PvPI software
West Bengal	District/Block level & Treating medical colleges	Block level physicians providing AmBisome treatment to fill the forms and perform causality assessment	District level data entry operators and medical college associates will enter the data in PvPI software
Uttar Pradesh	District level & Treating medical colleges	District hospital physicans & treating physicians of medical colleges providing AmBisome, will fill adverse drug reaction reporting form and perform causality assessment	District level data entry operators and medical college associates will enter the data in PvPI software
Jharkhand	District level	District hospital physicans providing AmBisome will fill adverse drug reaction reporting form and perform causality assessment	District level data entry operators and medical college associates will enter the data in PvPI software

Capacity-building of functionaries: At a glance

Pharmacovigilance reporting: The process

Detection and reporting of adverse drug reaction at district hospitals, medical colleges, or block level by medical officers

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Data entry into Pharmacovigilance Programme of India (PvPI) software by district medical officers/data entry operators

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Pharmacovigilance Programme of India will analyse the data with WHO Support

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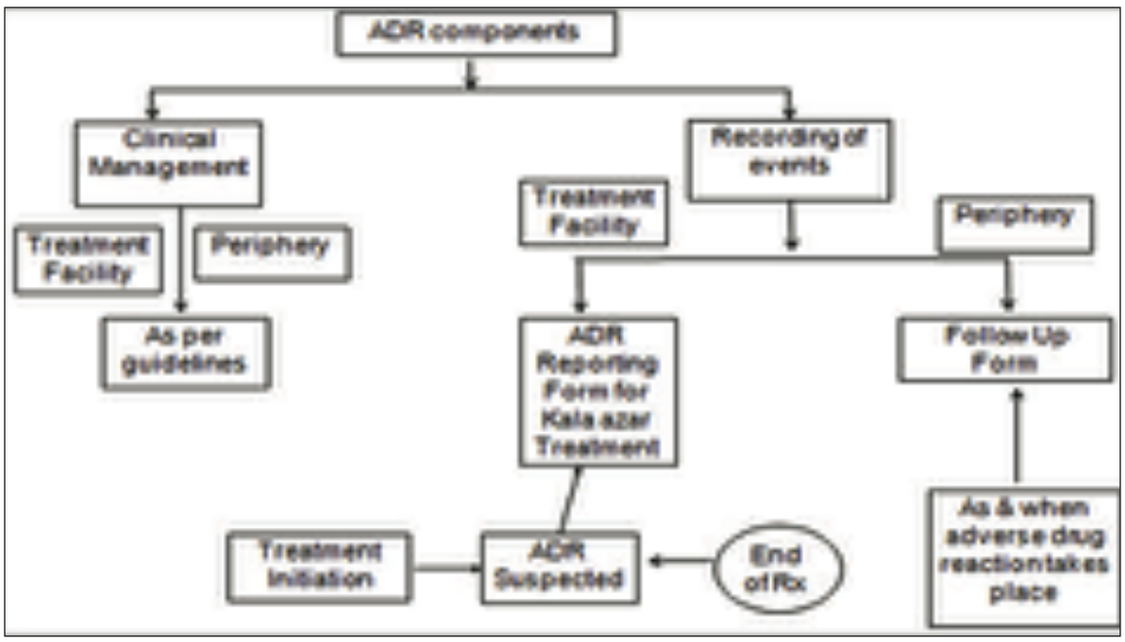
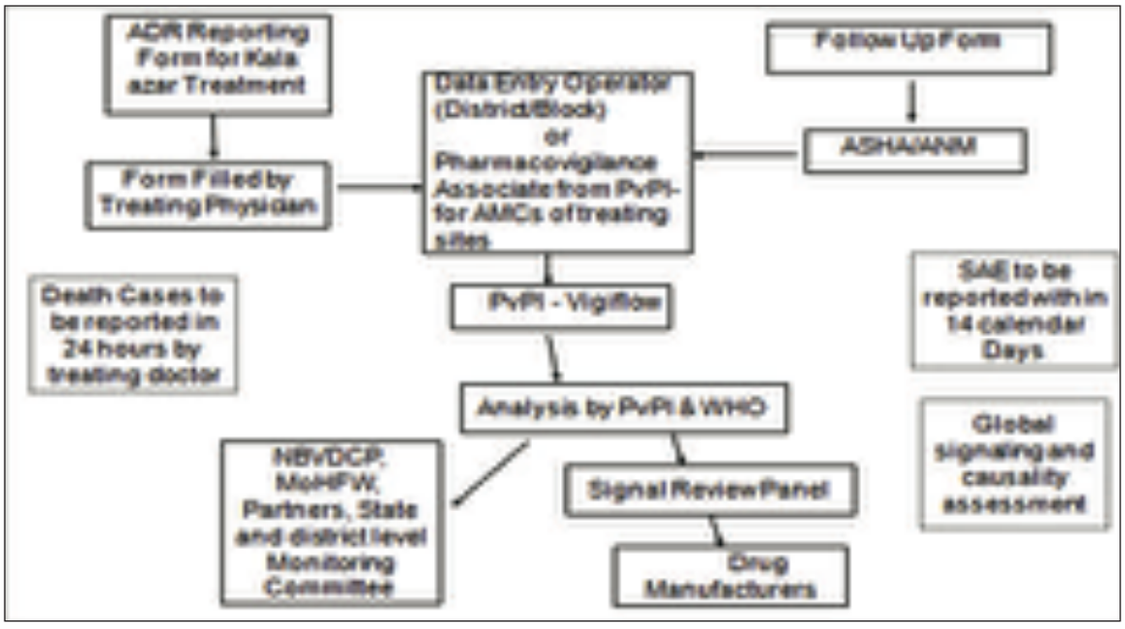
Pharmacovigilance Programme of India will communicate the outcomes (early trends, warnings, signals) to all the stakeholders including NBVDCP, MoHFW, WHO, PvPI, States and Districts

Flowchart 1: ADR management and data capturing related to pharmacovigilance



Flowchart 2: Protocol on data entry, sharing of data and analysis



4.4.6 Phase 3: Outcome phase

Outcome phase will have a major focus on analysis and collation of the ADRs in the PvPI database & generation of signals. There would be periodic reporting of the analyzed data to the programme by Pharmacovigilance Programme of India with the support of WHO.

Technical support will be provided to different levels for:

- Monitoring and evaluation of ADRs
- Analysis and signal detection from the reported data
- Designation of new ADR Monitoring Centres by PVPI to enable scale up PV activities in endemic states
- Facilitate the access to PvPI Software and provide training
- Providing technical support to different levels for adverse drug reaction management

4.5 Frequently asked questions on pharmacovigilance

Q 1. What is Pharmacovigilance?

Pharmacovigilance, as defined by the World Health Organization, is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other possible drug-related problems. Recent inclusions to this definition are: herbals, traditional and complementary medicines, blood products, biologicals, medical devices and vaccines.

Q 2. What is Pharmacovigilance Programme of India (PvPI)?

The Central Drugs Standard Control Organisation (CDSCO), New Delhi has initiated a nation-wide pharmacovigilance programme under the aegis of Ministry of Health & Family Welfare, Government of India. The programme is coordinated by The Indian Pharmacopoeia Commission (IPC) located at Ghaziabad. The National Coordinating Centre (NCC) is operating under the supervision of Steering Committee to recommend procedures and guidelines for regulatory interventions in India.

Q 3. What is an Adverse Drug Reaction (ADR)?

It is a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Q 4. What is Serious Adverse Event (SAE)?

A serious adverse event or adverse reaction is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity or
- Is a congenital anomaly or birth defect

Q 5. What is the difference between side-effect and Adverse Drug Reaction?

A side effect is any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug.

An adverse drug reactiont or experience is defined as a noxious response to a drug which is unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Q 6. Why to report ADR?

As a healthcare professional and citizen of India its moral responsibility to report adverse reaction associated with pharmaceutical products to safeguard public health and help in improving patient safety.

Q 7. Who can report Adverse Drug Reaction?

All healthcare professionals including Clinicians, Dentists, Pharmacists, Nurses and Non-healthcare professionals (patients, consumers) can report ADRs.

Q 8. What type of Adverse Drug Reactions should be reported?

All types of suspected adverse drug reactions irrespective of whether they are known or unknown, serious or non-serious and frequent or rare should be reported.

Q 9. How do we report ADRs through PvPI?

The health care professional attending to the patient, can:

- fill up the suspected ADR form for ADR can report to the nearest ADRs Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI). The details of AMCs are given in the website of IPC i.e. www.ipc.gov.in
- Toll free helpline (1800-180-3024) number on all working days (Mon-Fri) from 9:00 am-5.30 pm. If a call is not responded then one can drop a voice message on voice recording system.
- Email the form directly to: pvpi@ipcindia.net or ipclab@vsnl.net.
- Android Mobile App: adr (ADR Reporting) PvPI

Q 10. What will happen after submitting the ADR?

There will be monthly reporting for trends of ADRs by PvPI, with technical support of WHO, to NVBDCP and MoHFW. The ADRs will be sent to PvPI software/database for analysis and signal detection. ADRs will be evaluated and the inferences will be used to recommend regulatory body i.e. CDSCO to take necessary regulatory interventions, besides communicating risks to healthcare professionals and the public.

Q11. Terminologies used in ADR Reporting Form

Causality

The evaluation of the likelihood that a particular medicine was the cause of an observed adverse reaction is known as Causality. Causality assessment is done according to established WHO-UMC algorithm (as given below):

Table: WHO-UMC Causality Categories

Causality term	Assessment criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an bjective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary

Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified
* All points should be reasonably complied with	

Causal relationship

A relationship between one phenomenon or event (A) and another (B) in which A precedes and causes B. In pharmacovigilance; a medicine causing an adverse reaction.

Congenital anomalies

Morphological, functional and/or biochemical developmental disturbance in the embryo or foetus whether detected at birth or not. The term congenital anomaly is broad and includes congenital abnormalities, foetopathies, genetic diseases with early onset, developmental delay, etc.

Dechallenge

The withdrawal of a drug from a patient; the point at which the continuity, reduction or disappearance of adverse effects may be observed.

Expectedness

Expectedness means the adverse event/ side effect is expected or has been previously documented as adverse drug reaction with the use of the drug as per the reference safety information.

Outcome

An outcome is one of the possible results or effect of an event.

Rechallenge

The point at which a drug is again given to a patient after its previous withdrawal (see dechallenge).

Severity

The severity of a specific event describes its intensity, and it is the intensity which is graded.

Mild	Moderate	Severe
Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated

* *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0; Accessed from: http://rsc.tech-res.com/docs/default-source/safety/daids_ae_grading_table_v2_nov2014.pdf*

Seriousness vs. severity

- Severity is the intensity of a specific event (mild, moderate and severe); the event however may be of relatively minor medical significance (eg: severe headache)

- Seriousness is based on patient event/outcome or action criteria which may serve as regulatory reporting obligation[10]

[10]http://ipc.nic.in/index2.asp?slid=466&sublinkid=371&lang=1&EncHid=; https://www.who-umc.org/graphics/25301.pdf

Annexure 1 (adopted from TRS 949)

Performance of the rK39 rapid diagnostic test

The utility of a rapid diagnostic test for visceral leishmaniasis lies in its simplicity.
Several brands of test with rK39 antigen are available. Operators should always read the package insert carefully, and follow the manufacturer's instructions. This is especially important with regard to the type of specimen used: serum or whole blood. Some brands can be used only with serum, while others can be used with whole blood collected by finger prick.

Test procedure

Refer always to the specifications given by the manufacturer.

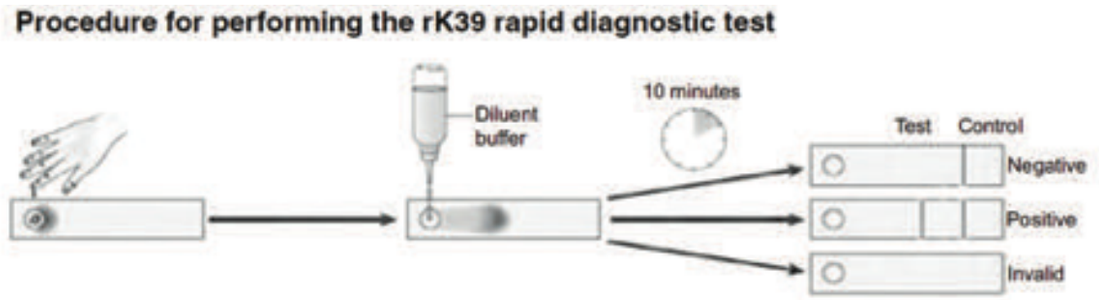
In general, the test procedure is as follows (Figure A5.1):

1. Remove the test strip from the pouch and place it on a flat surface
2. Place a specified amount of patient specimen (serum or finger-prick blood) on the absorbent pad on the bottom of the strip
3. Add the specified amount of buffer provided
4. Read the result after 10–20 min, according to the manufacturer's instructions

Figure A5.1.

Some brands require a slightly different procedure, for example:

1. Take a test tube or a U-bottom microtitre plate
2. Add a specified amount of buffer to the tube or well
3. Add a specified amount of specimen (blood or serum) to the tube or well and mix
4. Immerse the test strip into the buffer–specimen mixture
5. Read the result after 10–20 min, according to the manufacturer's instructions



Points to consider for optimizing use of rapid diagnostic tests:

- Have a clear management plan to deal with·
- positive and negative results
- Follow biosafety standards and precautions for handling blood and other body fluids
- Ensure proper storage conditions
- Do not use damaged or expired tests
- Adhere strictly to the manufacturer's instructions
- Use test kits within 1 h of removal from pouch
- Read the results within the time specified by the manufacturer
- Do not reuse a test

Interpretation of the test

Positive result: When both control and test lines appear, the sample tested has antibodies against recombinant K39 antigen of Leishmania. Even a faint line should be considered positive.

Negative result: When only the control line appears, there are no antibodies against recombinant K39 antigen of Leishmania present in the patient's sample.

Invalid result: When no control line appears, a fresh patient sample should be tested with a new strip.

Advantages and disadvantages of the rK39 test

Advantages

- Simple to perform with minimal training.
- Does not require a laboratory.
- Can be performed with finger-prick whole blood, serum or plasma.
- Kits can be transported and stored at ambient temperature (up to 30°C).
- Results are available within 10–20 min.

Disadvantages

- Cannot distinguish between active cases and relapse in previously treated cases. Therefore, interpretation must always be accompanied by clinical case definition.

In patients with advanced HIV infection, a negative result does not rule out a diagnosis of visceral leishmaniasis.

Annexure 2 (adopted from WHO TRS 949)

Procedures for splenic aspiration and grading of parasites

Splenic aspiration should be performed only if the following conditions are met:

- absence of clinical contraindication(s):
    - o signs of active bleeding (e.g. epistaxis, rectal bleeding, skin bruises)
    - o jaundice (a potential marker of liver dysfunction)
    - o pregnancy
    - o spleen barely palpable
    - o bad general condition (e.g. cardiovascular shock, altered consciousness)
- absence of biological contraindication(s):
    - o severe anaemia (haemoglobin count <5 g/l)
    - o difference in prothrombin time between patient and control > 5 s
    - o platelet count < 40 000/ml
- rapid access to blood transfusion in case of bleeding

The two important prerequisites for the safety of the procedure are rapidity, so that the needle remains within the spleen for less than l s; and precision, so that the entry and exit axes of the aspirating needle are identical to avoid tearing the splenic capsule.

The procedure is as follows:

1. Clean three glass slides and label them with patient´s name, date and the words ‘splenic aspirate’. Have culture medium ready (if available) and labelled in the same way as the slides. Attach a 11/4 -inch × 21-gauge (32 × 0.8-mm) needle to a 5-ml syringe. Place all items on a table at the bedside.

2. Inform the patient about the procedure. Check all clinical and biological contraindications again. Palpate the spleen and outline its margins on the patient´s abdomen with a pen. For safety, the spleen should be palpable at least 3 cm below the costal margin on expiration. Use an alcohol swab to clean the skin at the site of aspiration, and allow the skin to dry.

3. With the 21-gauge (0.8-mm) needle attached to the 5-ml syringe, just penetrate the skin, midway between the edges of the spleen, 2–4 cm below the costal margin. Aim the needle cranially at an angle of 45° to the abdominal wall. The actual aspiration is done as follows: pull the syringe plunger back to approximately the 1- ml mark to apply suction, and with a quick in-and-out movement push the needle into the spleen to the full needle depth and then withdraw it completely, maintaining suction throughout.

4. For young, restless children, have two assistants hold the child (arms folded across the chest, with shirt raised to obstruct the line of vision, and pelvis held firmly). Carry out the aspiration as a single-stage procedure, using the same landmarks, angles and suction as in step 3, all in one quick motion. The insertion should be timed with the patient´s breathing so that the diaphragm is not moving; this should be done during fixed expiration if the child is crying. Only a minute amount of splenic material is obtained, but this is sufficient for culture and smear.

5. If culture is available: slowly pull the plunger back to the 2–3-ml mark, and, using sterile techniques, insert the needle into a tube containing culture medium and briskly push the plunger into the barrel to expel the contents of the needle onto the side walls of the tube. If necessary, repeat once or twice until splenic material is visible in the tube. Replace the cap on the tube and invert to wash splenic material on the side of the tube. Repeat the procedure for the second tube of culture medium. Sterile techniques are essential throughout.

6. Expel material (or additional material if culture is available) gently onto glass slides, holding the needle tip on the surface of the slide. Immediately spread evenly with the needle, using a linear (not circular) motion. The smear should be slightly thinner than a thick blood film for malaria. Remove the needle, and use the end of it to obtain additional material from the tip of the syringe and spread it on slides. Further material found on the end of the plunger may be dabbed directly onto a slide and spread. Allow the slides to dry.

7. Write the time of aspiration on the patient's chart, with the instructions: "Record pulse and blood pressure every half hour for 4 h, then every hour for 6 h. Patient must remain in bed for 12 h." Ensure that the patient understands the instructions. Enter the procedure in the notes, and sign.

8. Take the slides (and medium) to the laboratory. Slides are stained with Giemsa as for a thin malaria film and examined under oil immersion.

The average amastigote density is graded as follows:

6+: > 100 parasites per field (viewed with a 10× eyepiece and 100×oil- immersion lens)

5+: 10–100 parasites per field

4+: 1–10 parasites per field

3+: 1–10 parasites per 10 fields

2+: 1–10 parasites per 100 fields

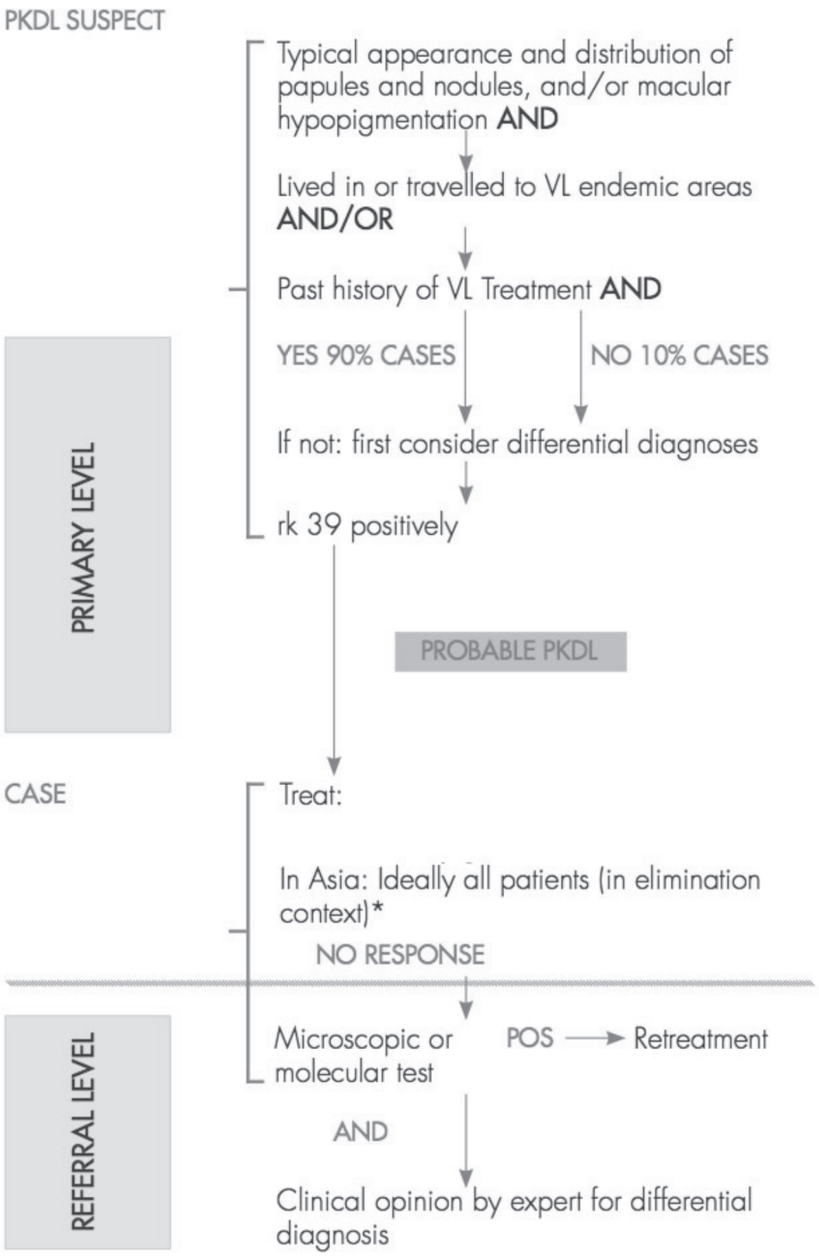
1+: 1–10 parasites per 1000 fields

0: 0 parasite per 1000 fields

Parasite grading has several uses. It increases the sensitivity of parasite detection, provides an objective measure of the speed of response to treatment, distinguishes quickly between slow responders and non responders, and provides an indication of parasite load that is useful in research.

Annexure 3

Algorithm for diagnosing and treating post-kala-azar dermal leishmaniasis (PKDL)



Annexure 4

Dose calculation of insecticide for IRS

Flow rate from a pump (stirrup/hand compression):

Please note that a spray operator should spray a 2 metre (6 ft) high wall with 0.75 m swathe in 5 seconds, i.e. speed = 24 m/min.

Discharge rate:

1. If hand compression pump with CFV is used- 550 mL liquid per minute
2. If hand compression pump without CFV is used- 650-750 mL liquid per minute (average 700 mL)
3. If stirrup pump with CFV is used- 550 mL liquid per minute
4. If stirrup pump without CFV is used- 650-750 mL liquid per minute (average 700 mL)

Example- Taking that nozzle of a compression sprayer with CFV emits a fixed 550 mL liquid per minute, it will deposit 30mL per square metre on wall surface, as calculated under. Following is the formula

$$\textbf{Spray deposit rate} = \frac{\textbf{Volume of suspension (in mL per minute)}}{\textbf{Swath width (in metre) X Operator's speed (in metre per min)}}$$

$$= \frac{505}{0.75 \times 24} = 30\text{mL/m}^2$$

Now, when a stirrup pump is used, normal discharge rate can be 650-750 mL per minute. Taking 700 mL mean value, the discharge from above formula comes to about 40 mL per square metre (actually 38.9mL).

Calculation of dose of insecticide for making solutions: what is happening in different states

Example of dose calculation:
Alphacypermethrin 5% WP applied at 0.025g/m^2 (25 mg/m^2) on walls

(use of CFV with compression sprayers)

Bihar: preparing 7.5 L solution using 125 g 5% (WP) alpha-cypermethrin using hand compression pump with CFV	A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	0.025
	B	Percentage of the insecticide formulation being used	5
	C	Amount of water in the sprayer tank in milli litre (mL) i.e., 7.5 L = 7500 mL	7500
	D	Amount of liquid suspension applied per m2 of wall using a CFV (i.e. 30 mL/m^2)	30
	E	Surface to be treated with one tank load of 7.5 L = C÷ D = 7500 ÷ 30 = 250 m^2	250
	F	Quantity of active ingredient needed to cover 250 m2 wall area = A x E gram	6.25
	G	Quantity in gram of formulation needed per tank load to cover 250 m^2 area = F x 100/B	125

Example of dose calculation: Alphacypermethrin 5% WP applied at 0.025g/m^2 (25 mg/m^2) on walls

(use of stirrup pump with no CFV with 700mL per minute discharge)

Bihar: preparing 15 L solution in bucket using stirrup pump without CFV with a discharge rate of 700 mL per minute)	A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	0.025
	B	Percentage of the insecticide formulation being used	5
	C	Amount of water in the sprayer tank (bucket) in milli litre (mL) i.e., 15 L = 15000 mL	15000
	D	Amount of liquid suspension applied per m^2 of wall without using a CFV (i.e. flow rate/m^2)	40
	E	Surface to be treated with one tank load of 15 L = C÷ D (in m^2)	375
	F	Quantity of active ingredient needed to cover 375 m^2 wall area =A x E gram	9
	G	Quantity in gram of formulation needed per 15L bucket load to cover 375 m^2 area = F x 100/B	188

Example of dose calculation: Alphacypermethrin 5% WP applied at 0.025g/m^2 (25 mg/m^2) on walls

(use of stirrup pump with no CFV with 700mL per minute discharge)

Jharkhand: preparing 10 L solution in bucket using stirrup pump without CFV with a discharge rate of 700 mL per minute)	A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	0.025
	B	Percentage of the insecticide formulation being used	5
	C	Amount of water in the sprayer tank (bucket) in milliliter (mL) i.e., 10 L = 10000 mL	10000
	D	Amount of liquid suspension applied per m2 of wall using a CFV (i.e. flow rate/m^2)	40
	E	Surface to be treated with one tank load of 10 L = C÷ D (in m^2)	250
	F	Quantity of active ingredient needed per tank load to cover 250m^2 area =A x E gram	6.25
	G	Quantity in gram of formulation needed per tank load to cover 250 m2 area = F x 100/B	215

Note: doses in decimal have been rounded off

Note: If the discharge rate is 650mL the WP quantity will be about 140g; if it 750 mL (i.e. when more water is emitted), the WP quantity will be lower, i.e. 120g. Same calculation can be done for DDT as below.

Example of dose calculation: DDT 50% applied at 1g/m2 on walls

A	Dose of the insecticide active ingredient to be applied on walls in gram per square metre	1
B	Percentage of the insecticide formulation being used	50
C	Amount of water in the sprayer tank in milliliter (mL) i.e., 7.5 L = 7500 mL	7500
D	Amount of liquid suspension applied per m2 of wall using a CFV (i.e. 30 mL/m^2)	30
E	Surface to be treated with one tank load of 7.5 L = C÷ D = 7500 ÷ 30 = 250 m^2	250
F	Quantity of active ingredient needed to cover 250 m^2 wall area = A x E = 1 x 250 = 250g	250
G	Quantity of formulation needed per tank load to cover 250 m2 area = F x 100/B = 250 x 100/50 = 500g	500

Annexures 5

WHO Pesticide Evaluation Scheme recommended insecticide formulations

Insecticide compounds and formulations[1]	Class group[2]	Dosage (g a.i./m^2)	Mode of action	Duration of effective action (months)
DDT WP	OC	1-2	contact	>6
Malathion WP	OP	2	contact	2–3
Fenitrothion WP	OP	2	contact & airborne	3–6
Pirimiphos-methyl WP & EC	OP	1-2	contact & airborne	2–3
Pirimiphos-methyl CS	OP	1	contact & airborne	4–6
Bendiocarb WP	C	0.1–0.4	contact & airborne	2–6
Propoxur WP	C	1–2	contact & airborne	3–6
Alpha-cypermethrin WP, SC	PY	0.02–0.03	contact	4–6
Alpha-cypermethrin WG-SB	PY	0.02–0.03	contact	up to 4
Bifenthrin WP	PY	0.025–0.05	contact	3–6
Cyfluthrin WP	PY	0.02–0.05	contact	3–6
Deltamethrin SC-PE	PY	0.02–0.025	contact	6
Deltamethrin WP, WG, WG-SB	PY	0.02–0.025	contact	3–6
Etofenprox WP	PY	0.1–0.3	contact	3–6
Lambda-cyhalothrin WP, CS	PY	0.02–0.03	contact	3–6

Annexure 6

Adverse Drug Reaction Reporting Form For Kala Azar Drugs

ADVERSE DRUG REACTION REPORTING FORM FOR KALA-AZAR (KA) TREATMENT

Annexure 7

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

दवाओं से दुष्प्रभाव सूचना फॉर्म (उपभोक्ताओं के लिए)

Annexure 8

List of adverse drug reactions from Kala-azar drugs

Medicine	Common ADR	Other ADRs	
Liposome Amphotericin B (LAMB) / Ambisome	• Rigors/chills • Pyrexia • Back pain • Rash • Hypokalemia • Hyponatremia • Hypocalcemia • Hypomagnesaemia • Hyperglycemia • Headache • Tachycardia • Vasodilatation • Flushing • Hypotension • Nausea • Vomiting • Abdominal Pain • Diarrhea • Dyspnea • Liver function tests abnormal • Hyperbilirubinemia • ALP increased • BUN increased • Creatinine increased • Chest pain	• Asthenia • Pruritus • Sepsis • Thrombocytopenia • Anaphylactoid reaction • Anaphylactic reactions • Hypersensitivity • ALT/SGPT increased • AST/SGOT increased • Edema • Hypervolemia • Peripheral edema • Convulsion • Anxiety • Insomnia • Renal insufficiency	• Cardiac arrest • Arrhythmia • Cough increased • Epistaxis • Hypoxia • Lung disorder • Pleural effusion • Rhinitis • Gastrointestinal hemorrhage • Sweating • Rhabdomyolysis (associated with hypokalemia) • musculoskeletal pain (arthralgia or bone pain) • Renal failure • Hypertension • Hematuria
Source: http://www.who.int/neglected_diseases/resources/AmBisomeReport.pdf; https://www.medicines.org.uk/emc/medicine/1236			
Miltefosine	• Abdominal Pain • Diarrhea • Nausea • Vomiting • Malaise • Pyrexia • Headache • Pruritus • Increased billirubin • Pregnancy Category D	• Motion Sickness • Melena • Dyspepsia • Asthenia • Pain at lesion • Dizziness • Somnolence • Seizure • Parasitic Infections • Absent ejaculation • Epistaxis • Jaundice	• Infestations Lymphangitis • Lesion Infection • Generalized edema • Peripheral edema • Decreased Appetite • Thrombocytopenia • Agranulocytosis • Lymphadenopathy • Scrotal pain • Decreased ejaculate volume

http://www.who.int/selection_medicines/committees/expert/18/applications/Miltefosine_application.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204684s000lbl.pdf			
Paramomycin	• Mild injection site pain • Nausea • Vomiting • Fever • Rigors • Malaise • Liver toxicity • Ototoxicity • Nephrotoxicity	• Transient AST and ALT elevation • Reversible abnormal audiogram • ALP elevation • Ear buzzing • Blood bilirubin elevation • Albuminuria	• Injection site swelling • Abscess • Conductive deafness • Proteinuria • Hepatotoxic jaundice • Bilateral partial deafness
Source:http://archives.who.int/eml/expcom/expcom15/applications/newmed/paromomycin/paromomycin.pdf			
Amphotericin B deoxycholate	• Diarrhea • Nausea • Vomiting • Abdominal pain • Nephrotoxicity • Rigors/chills • Pyrexia • Hypokalemia • Hyponatremia • Hypocalcemia • Hypomagnesaemia • Hyperglycemia • Myalgia • Headache • Dyspnea • Chest pain • BUN increased • Creatinine increased • Liver enzymes elevated • Back pain • Rashes • Pruritis	• Anxiety • Confusion • Insomnia • Hypoxia • Wheezing • Hypotension • Tachycardia • Edema • Hypertension • Hyperbilirubinemia • Hematuria • ALP increased • ALT (SGPT) increased • AST (SGOT) increased • Bilirubinemia	• Edema • Hypervolemia • Peripheral edema • Anemia • Leukopenia • Thrombocytopenia • Phlebitis • Rhabdomyolysis (associated with hypokalemia) • musculoskeletal pain (arthralgia or bone pain) • Asthenia • Sepsis • Acute infusion reactions • Hypersensitivity reaction
Source: http://www.cdsco.nic.in/writereaddata/NFI_2011%20(1).pdf			
SAG/SSG	• Cardiac toxicity • Arthralgia • Hepato and renal toxicity • Sudden death syndrome	• Anorexia, • Nausea, • Vomiting, • Abdominal pain • ECG changes • Headache • Lethargy • Myalgia • Raised liver enzymes • Renal function impairment • Coughing • Bleeding from nose or gum • Metallic taste in mouth Dizziness	• Substernal pain • Anaphylaxis • Fever • Sweating • Flushing • Vertigo • Jaundice • Thrombosis on intravenous administration • Pain on intramuscular injection • Phlebotoxicity
Source:http://www.cdsco.nic.in/writereaddata/NFI_2011%20(1).pdf			

Annexure 9

List of Adverse Event Reporting Medical Colleges in 4 endemic Kala-azar states[11]

Bihar				
1	Indira Gandhi Institute of Medical Sciences, Bailey Road, Sheikhpura, Patna-800014	Prof. (Dr.) Harihar Dikshit	dikshithariharpatna@yahoo.co.in amcigims2015@gmail.com	0933410638
2	All India Institute of Medical Sciences, Phulwari Sharif, Patna-801505	Prof. P.P. Gupta	drprempgupta@gmail.com	07763800139 09415210579
3	Lord Buddha Koshi Medical College & Hospital, NH 107, Baijnathpur, Saharsa-852201	Dr. Akhilesh Kumar	sykalabs@yahoo.co.in	09431243204
4	Katihar Medical College, post box No. 23, Karimbagh, Katihar, Bihar-854105	Dr. C. B Choudhary	drcb_choudhary@yahoo.co.uk	09431025891
5	M. G memorial medical college, Purabbali, Dinajpur Road, Kishanganj, Bihar-855107	-	-	-
6	Sri Krishna Memorial Medical College & Hospital. Muzaffarpur	In Pipeline		
7	Darbhanga medical College & Hospital, Darbhanga	In Pipeline		
8	Government Medical College & hospital, Betiya, West Champaran	In Pipeline		
9	Narayan Medical College, Rohtas	In Pipeline		
10	Anugrah Narayan Medical College & Hospital, Gaya	In Pipeline		
11	Patna Medical college & Hospital, Patna	In Pipeline		
Jharkhand				
1	Rajendra Institute of Medical Sciences (RIMS), Bariatu, Ranchi-834009	Dr. Janardan Sharma	drsharmaj@gmail.com amcrims@gmail.com	09431175014
2	MGM Medical College, Dimna Roand, Jamshedpur, Jharkhand-831001	In Pipeline		
3	Patliputra Medical College & Hospital (B.C.C.L. Township, Koyla Nagar, Dhanbad - 826005, Jharkhand)	In Pipeline		

[11]http://ipc.nic.in/showfile.asp?lid=514&EncHid=

Uttar Pradesh				
1	B.R.D Medical College & Nehru Hospital, Gorakhpur-273013	Dr. Jamal Haider	jamal001@gmail.com	09839828358
2	GSVM Medical College, Swaroop Nagar, Kanpur-208001	Dr. S.P. Singh	singhdrsp@gmail.com	09415154744
3	Institute of Medical Sciences Banaras Hindu University, Varanasi-221005	Dr. B.L. Pandey	blp53@rediffmail.com	09451964917 09451440039
4	JN Medical College, Aligarh Muslim University, Aligarh-202002	Dr. Mohammad Nasiruddin	naseer_bettiah@yahoo.co.in	09412596898
5	M.L.B. Medical College, Jhansi- 284128	Dr. Sadhna Kaushik	kaushiksadhna55@gmail.com	07897038922
6	M.L.N Medical College, Darbhanga Colony, George Town, Allahabad- 211002	Dr. Rakesh Chandra Chaurasia	drrakesh65@rediffmail.com	09415615064
7	Santosh Medical University, Santosh Nagar, Ghaziabad-201001	Dr. V. S. Chopra	vipen.chopra@gmail.com jjhingran@yahoo.co.in	07838961411 09868579737
8	U.P Rural Institute of Medical Sciences and Research, Safai, Etawah-206130	Dr. Asha Pathak	drasha_pathak@yahoo.co.in	09451021779
9	Muzaffarnagar Medical College & Hospital, opp. Begrajpur Industrial Area, Ghasipur, Muzaffarnagar-251201	Dr. Suman Lata	dr.sumanlata@yahoo.com	09897878728
10	School of Medical Sciences & Research, Sharda University, Greater Noida-201306	Prof. Qazi M. Ahmed Dr. Ashok K Dubey	qma49@yahoo.co.in drakd1105@yahoo.co.in	09313766906
11	Subharati Medical College, Subharti Puram, NH-58, Delhi-Haridwar By Pass Road, Meerut-250005	Dr. Prem Prakash Khosla Dr. Ruchi Choudhary (dy. coordinator)	khoslapp@yahoo.com ruchi.upmanyu@gmail.com	08909654319 09410866646
12	Era's Lucknow Medical College & Hospital, Sarfazganj, Moosa Bagh picnic Spot, Hardoi Road, Lucknow-226003	Dr. Afroz Abidi	afrozabidi@gmail.com	09794979717
13	Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow-226010	Dr. Mukul Mishra	mukul_rk_misra1@yahoo.com	09450959088

14	Sarojini Naidu (S. N) Medical College, Moti Katra, Agra-282002	Dr. Mona Verma	dpsupagr@tbcindia.nic.in dpsupagr@rntcp.org pvpi.snmc@gmail.com	09997024763
15	Teerthanker Mahaveer Medical College and Research Centre, N.H-24,Bagarpur, Delhi Road, Moradabad, U.P-244001	Dr. Farhan Ahmad Khan	dr.farhan.k@gmail.com	09759468300
16	Yashoda Super Speciality Hospital, H-1, Kaushambi, Ghaziabad-201010	Dr. G. J Singh	dr.sunil@yashodahospital.org	09891957745
17	National Drug Dependence treatment centre, sector-19, Kamla Nehru Nagar, C. G. O Complex, Ghaziabad-201002	Dr. Sudhir K. Khandelwal	sudhir_aiims@yahoo.co.uk	011-26593675
West Bengal				
1	School of Tropical Medicine, 108, Medical College Campus Chittaranjan Avenue, Kolkata- 700073	Dr. Santanu Tripathi	stm.pvpi@gmail.com	09230566771
2	R.G. Kar Medical College, 1, Kshudiram Bose Sarani Kolkata-700073	Dr. Anjan Adhikari	adr.rgk.pharma@gmail.com	09831012503
3	Calcutta National Medical College, Dr Sundari Mohan Ave, Beniapukur, Kolkata-700014	Dr. Sushobhan Pramanik	sushobhan.pramanik@gmail.com	09831155886
4	Institute of Postgraduate Medical Education & Research, 244B, A.J.C Bose Road, Kolkata-700020	Dr. Suparna Chatterjee	drsupchat@gmail.com	09831130980 033- 22041428
5	Burdwan Medical college, Baburbag, P.O. Rajbati-Burdwan-713104	Dr. Mithilesh Haldar	amc.pvpibmc@gmail.com	09733106803
6	Bankura Sammilani Medical College, kenduadihi, Bankura 722101	Dr. Ananya Mandal	drananyamandal@gmail.com	09674446226
7	Nilratan Sircar Medical College, Acharya Jagdish Chandra Bose Road, Kolkata-700014	Prof. Nina Das	drninadas@yahoo.com	09433165691
8	College of Medicine & J.N.M. Hospital, Kalyani, Nadia-741235	Dr. Abhishek Ghosh	drghosh.new@gmail.com principal.comjnmh.kalyani@gmail.com	09836557042
9	North Bengal Medical College, PO Sushrutanagar, Siliguri, Distt. Darjeeling-734012	Dr. Anupam Gupta	nathguptadranupam@yahoo.com	09434686320

10	Murshidabad Medical College & Hospital, Berhampore-742101	Dr. Mainak Ghosh	docmainak@gmail.com	09007924708
11	Midnapore Medical College & Hospital, Vidyasagar Road, Paschim Medinipur-721101	Dr. Balaram Ghosh	drbrghosh@gmail.com amc.mmch@gmail.com	09800442964 0322-2222411
12	ICARE institute of medical Sciences & research and Dr. Bidhan chandra roy hospital, Banbishnupur, Balughata, Haldia, Dist.-Purba, Medinipur, W.B-721645	Dr. Sukanta Sen	drsukant@gmail.com	08420532336
13	Malda Medical College, Dist & PO-Malda, PS-English Bazar,Pin-732101	In Pipeline		

Annexure 10

List of villages where five or more than five VL cases have been reported (Nov) in 2016 Jharkhand, West Bengal and Bihar

Name of Villages with 5 or >5 VL Case till Nov 2016				
S.No.	**District**	**CHC**	**Village**	**VL**
1	**Dumka**	Kathikund	Kolha	6
2		Kathikund	Bhandaro	5
3		Kathikund	Nayadih	5
Total				**16**
4	**Godda**	Poraiyahat	Gumma	21
5		Boarijore	Ramkol	8
6		Boarijore	Ithari	5
Total				**34**
7	**Pakur**	Amrapara	Piparjori	9
8		Maheshpur	Barmasia	8
9		Maheshpur	Narayangarh	7
10		Pakur	Shyampur	6
11		Pakur	Dharsundri	7
12		Pakur	Kalidaspur	7
13		Maheshpur	Rolagram	5
14		Maheshpur	Mahadevnagar	5
15		Maheshpur	Datiarpokhar	5
16		Maheshpur	Kutubpur	5
Total				**64**
17	**Sahibganj**	(blank)*	(blank)*	14
18		Barhait	Pahadpur	7
Total				**21**
Grand Total				**135**

* Missing information in line list till Nov 2016. Any mismatch in name of the CHC/village is due to issue in line list entries.

West Bengal Villages with 5 or >5 VL case till Nov 2016	
Darjeeling District – Naxulbari Block – Tirhana Tea Estate	7

Name of villages with 3 or >3 PKDL case till Nov 2016				
S.No.	**District**	**Name of the Block/CHC**	**Village**	**PKDL**
1	**Dumka**	**Gopikander**	Gopikander	3
2		**Kathikund**	Bhitra	4
3			Jangala	4
4			Madhuban	9
5			Pipra	3
6		**Shikaripara**	Balijor	3

Dumka Total				**26**
7	**Godda**	**Boarijore**	Baghmara	4
8			Boarijore	4
9			Dahwa	4
10			Dumariya	4
11			Litti	3
12			Rajabhitta	4
13		**Mahagama**	Bhagan	4
14			Gaurikitta	3
15			Kittapathar	3
16		**Pathargama**	Teteriya Tikar	3
17		**Poraiyahat**	Amuwar	5
18			Bankatti	3
19			Siktia	3
20			Sugabathan	3
21		**Sadar Prakhand**	Dullu	4
22		**Sunderpahari**	Bansjori	3
23		**Thakurgangti**	Budhwachak	4
24			Gajhanda	4
25			Gopalpur	5
26			Navadih	4
27			Raidih	4
Godda Total				**78**
28	**Pakur**	**Amrapara**	Borandiha	3
29			Jamkanali	3
30			Jamugaria	3
31			Pachuwara	5
32			Paderkola	4
33		**Hiranpur**	Binjhamara	3
34			Gamharia	3
35			Hathkathi	4
36		**Maheshpur**	Bhimpur	3
37			Gaibathan	3
38			Kharutola	3
39		**Pakur**	Kalidaspur	3
40			Sonajori	5
41		**Pakuria**	Dholkatta	3
Pakur Total				**48**

42	Sahibganj	Mandrio	Bachha	3
43			Dokuti	3
44			Hatamari	3
45			Randhi	3
46		Pathana	Kesro	4
47			Rangatola	4
48		Rajmahal	Beldharcheak	3
49		Taljhari	(blank)	5
Sahibganj Total				**28**
Grand Total				**180**

West Bengal Villages with 3 or >3 PKDL Case till Nov 2016	
Darjeeling – Phasidewa Block- Paharghumia Tea Estate	7
Malda – Chanchol-II Block - Binodpur	3
Malda – Chanchol-II Block - Gopalpur	3
Malda – Habibpur - Haripur	6
Malda – Habibpur - Kharibari	5
Uttar Dinajpur – Bansihari - Kamardanga	4
Uttar Dinajpur – Kushmandi - Deulabari	4

VL Cases in Bihar

District	Block	Village	2014	2015	Total	Average
Araria	Araria	Araria Basti	8	11	19	10
Araria	Araria	Rampur Mohanpur	4	6	10	5
Araria	Bhargama	Raharia	9	4	13	7
Araria	Forbesganj	Haldiya	13	5	18	9
Araria	Forbesganj	Jhiruwa	8	11	19	10
Araria	Forbesganj	Jhirwa East	6	15	21	11
Araria	Kursakanta	Chikni	6	9	15	8
Araria	Raniganj	Bausi	6	12	18	9
Araria	Raniganj	Gopalpur	6	5	11	6
Araria	Raniganj	Kalabaluwa	4	19	23	12
Araria	Raniganj	Parmanadpur	12		12	6
Darbhanga	Goura Bouraam	Bath mushari tola	7	4	11	6
Darbhanga	Hayaghat	Bilaspur(W)	5	5	10	5
Darbhanga	Kusheshwar Asthan Purbi	Tilkeswar	8	715	8	
East Champaran	Adapur	Nayak Tola	9	3	12	6

East Champaran	Areraj Bajar	Sareya	10	2	12	6
East Champaran	Kalyanpur	Shambhuchak	14	1	15	8
East Champaran	Kesaria	North Hussaini	5	5	10	5
East Champaran	Kesaria	West Sunderapur	7	4	11	6
East Champaran	Kotwa	Bairia	21	1	22	11
East Champaran	Madhuban	Kauriya	9	9	18	9
East Champaran	Turkaulia	Jaisinghpur	26	7	33	17
East Champaran	Turkaulia	Madhopur	5	5	10	5
East Champaran	Turkaulia	Shankar Saraya	6	4	10	5
Gopalganj	Gopalganj Sadar	Hirapaakar		11	11	6
Gopalganj	Manjha	Bathuwa Mauze	9	3	12	6
Katihar	Dandkhora	Kadam Tola	10	1	11	6
Katihar	Sameli	Raksa Rahi	13		13	7
Khagaria	Alauli	Dahma Kharai	8	3	11	6
Khagaria	Alauli	Meghauna	11	3	14	7
Khagaria	Beldaur	Pachath	91	35	126	63
Kishanganj	Bahadurganj	Dhimtola	6	4	10	5
Madhepura	Alamnagar	Bhagipur	2	12	14	7
Madhepura	Ghailar	Bhathrandha	6	7	13	7
Madhepura	Ghailar	Chitty	8	4	12	6
Madhepura	Ghailar	Ghailadh	10	2	12	6
Madhepura	Kumarkhand	Belari	7	7	14	7
Madhepura	Kumarkhand	Gadhiya	13	9	22	11
Madhepura	Madhepura Rural (Murho)	Mathai	6	6	12	6
Madhepura	Madhepura Rural (Murho)	Sahugadh	10	1	11	6
Madhubani	Basopatti	Kauaha	11	2	13	7
Madhubani	Bisfi	Bhataura	4	15	19	10
Madhubani	Khajauli	Chatra	11	6	17	9
Madhubani	Madhepur	Bhargawan	9	1	10	5
Madhubani	Pandaul	Mohanpur	14	2	16	8
Munger	Bariarpur	Hanshu Singh Tola	23	7	30	15
Muzaffarpur	Kurhani	Chajan Dubiyahe	21	10	31	16
Muzaffarpur	Minapur	Minapur	9	3	12	6
Muzaffarpur	Minapur	Tengrari	11	3	14	7
Muzaffarpur	Musahari	Mushari Urf Radhanagar	10	4	14	7

Muzaffarpur	Paroo	Bada Daud	4	13	17	9
Muzaffarpur	Paroo	Deoria	11	5	16	8
Muzaffarpur	Paroo	Dharphari	9	7	16	8
Muzaffarpur	Paroo	Hirapur	11	7	18	9
Muzaffarpur	Paroo	Mohjawa	11	5	16	8
Muzaffarpur	Paroo	Usti	9	1	10	5
Muzaffarpur	Sahebganj	Bangra Nizamat	13	4	17	9
Muzaffarpur	Sahebganj	Madhopur	1	11	12	6
Muzaffarpur	Sahebganj	Madhopur Hazari	14	8	22	11
Nalanda	Islampur	Mohidhin Nagar		20	20	10
Purnea	Dhamdaha	Bishanpur	10	4	14	7
Purnea	Dhamdaha	Jamuniya	8	2	10	5
Purnea	Jalalgarh	Dansar	8	3	11	6
Purnea	Purnea East	Mahrajpur	7	9	16	8
Purnea	Rupauli	Maini Santhal	16	3	19	10
Saharsa	Banma Itahri	Ghourdour	10	2	12	6
Saharsa	Banma Itahri	Murli	7	4	11	6
Saharsa	Banma Itahri	Sarbela	4	6	10	5
Saharsa	Maheshi	Kundah	6	4	10	5
Saharsa	Patarghat	Bishanpur	6	4	10	5
Saharsa	Sattar Katya	Bara	7	5	12	6
Saharsa	Sattar Katya	Bihra	8	6	14	7
Saharsa	Saurbazar	Dhanchhoha	1	11	12	6
Saharsa	Saurbazar	Samada	9	8	17	9
Saharsa	Saurbazar	Saure	17	3	20	10
Saharsa	Simri Bakhtiarpur	Khamothi	11	3	14	7
Saharsa	Simri Bakhtiarpur	Simri	10	7	17	9
Saharsa	Sonbarsa	Sonbarsa	12	2	14	7
Samastipur	Singhia	Akouna	3	7	10	5
Samastipur	Warisnagar	Sathmalpur	16	6	22	11
Saran	Baniapur	Manopali	6	6	12	6
Saran	Dariapur	Banwaripur	7	7	14	7
Saran	Dariapur	Kamalpur	7	13	20	10
Saran	Dariapur	Sutihar	9	5	14	7
Saran	Dighwara	Jhawa	5	6	11	6

Saran	Dighwara	Saidpur	7	4	11	6
Saran	Garkha	Kothia	22	11	33	17
Saran	Garkha	Madanpur	8	5	13	7
Saran	Garkha	Ramgarha	8	2	10	5
Saran	Garkha	Sargatti	10	5	15	8
Saran	Marhaura	Marhaura(Np)	6	5	11	6
Saran	Marhaura	Mothaha	12	4	16	8
Saran	Sonepur	Naya Gaon	5	7	12	6
Sheohar	Dumri Katsari	Rampur Kesho	19	7	26	13
Sheohar	Purnahiya	Adauri	2	16	18	9
Sheohar	Sheohar	Rasidpur	11	2	13	7
Sitamarhi	Bathnaha	Bathnaha	5	5	10	5
Sitamarhi	Bathnaha	Chakwa	8	5	13	7
Sitamarhi	Bathnaha	Godhiya	7	4	11	6
Sitamarhi	Dumra	Khairwa	3	19	22	11
Sitamarhi	Dumra	Punaura	7	9	16	8
Sitamarhi	Parsauni	Parshurampur	10	3	13	7
Sitamarhi	Parsauni	Raja Parsauni	11	4	15	8
Sitamarhi	Pupri	Awapur Utri	7	6	13	7
Sitamarhi	Pupri	Pupri	10	3	13	7
Sitamarhi	Sursand	Sunderpur	11	3	14	7
Siwan	Barharia	Surahiya	4	7	11	6
Siwan	Basantpur	Sipah	18	7	25	13
Siwan	Goriakothi	Agya	9	6	15	8
Supaul	Raghopur	Dhararaha	10	3	13	7
Supaul	Raghopur	Raghopur	11	8	19	10
Supaul	Supaul	Amha	8	9	17	9
Supaul	Supaul	Bairo	9	6	15	8
Vaishali	Patepur	Sakrauli	13	3	16	8
Vaishali	Raghopur	Chandpura Idrak	9	7	16	8
Vaishali	Raghopur	Jurawanpur Barari	9	2	11	6
Vaishali	Raghopur	Paharpur	13	2	15	8
Vaishali	Raghopur	Saidabad	20	8	28	14
Vaishali	Raghopur	Virpur	9	2	11	6
Vaishali	Sahdei Buzurg	Sahdai Buzurg	9	3	12	6

This Accelerated Plan for Kala-azar Elimination 2017 was prepared with the help from WHO Country Office for India, stakeholders and states.