UKaid from the British people

ASCEND
Accelerating Sustainable Control and Elimination of Neglected Tropical Diseases

Ascend learning brief:

INVOLVING THE ZAMBIA MEDICINES REGULATORY AUTHORITY IN PHARMACOVIGILANCE TRAINING

Author: E. Kleipool, 9 Aug 2021

Acknowledgement

We are very thankful to Namuchile Kaonga (ASCEND supply chain technical officer), Mwewa Monda Siame (Head of ZAMRA), Grace Hameja (MoH NTD department, schistosomiasis focal point) and Tendai Munthal (MoH NTD department, infectious diseases) whose contributions were vital in the development of this case learning.

We also gratefully acknowledge the financial support provided by the UK Foreign Commonwealth and Development Office (FCDO) and the Ascend programme.

Licence

This work is licensed under the Creative Commons Attribution-Non-commercial-ShareAlike 4.0 license. This license allows reusers to copy and distribute the material in any medium or format in unadapted form only, for noncommercial purposes only, and only so long as attribution is given to the creator. If you remix, adapt, or build upon the material, you must license the modified material under identical terms. For further information, please see: About CC Licenses - Creative Commons.

1. Introduction

In Zambia, the Accelerate the Sustainable Control and Elimination of Neglected Tropical Diseases (ASCEND) programme is supporting the Neglected Tropical Diseases (NTD) programme, including the implementation of Mass Drug Administration Campaigns (MDAs).

Prior to the MDA campaign, trainings are conducted to educate Community Medicine Distributors (CDDs) on how to administering the drugs. Generally, this training is conducted by the Ministry of Health Department for Neglected Tropical Diseases (MoH NTD), and is preceded by a training of trainers (TOT) on central or regional levels, with support from the concerned sponsor of the MDA and ASCEND staff. Since MDAs involve medicines, part of the training is to teach CDDs on pharmacovigilance, or, adverse side effects (ASE) that can occur upon administering the medicines.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems[1]. The occurrence of Serious Adverse Events (SAEs) of medicines are inevitable in MDA, and are most often outweighed by the benefits of administering the medicines[2]. However, it is important that medicine recipients and their caretakers are well informed about potential side effects, and about the benefits of taking the medicines. This way, medicine recipients and health workers can respond accurately when noticing side effects, which can contribute to preventing serious medical adversity, as well as help identifying rare side effects.

In Zambia, the Zambia Medicines Regulatory Authority (ZAMRA) is the Statutory National Medicines Regulatory body, responsible for the availability of medicines that meet the set quality, efficacy, and safety standards, but also with specific mandates related to pharmacovigilance[3]. The structure of the pharmacovigilance system around ZAMRA is presented in figure 1.

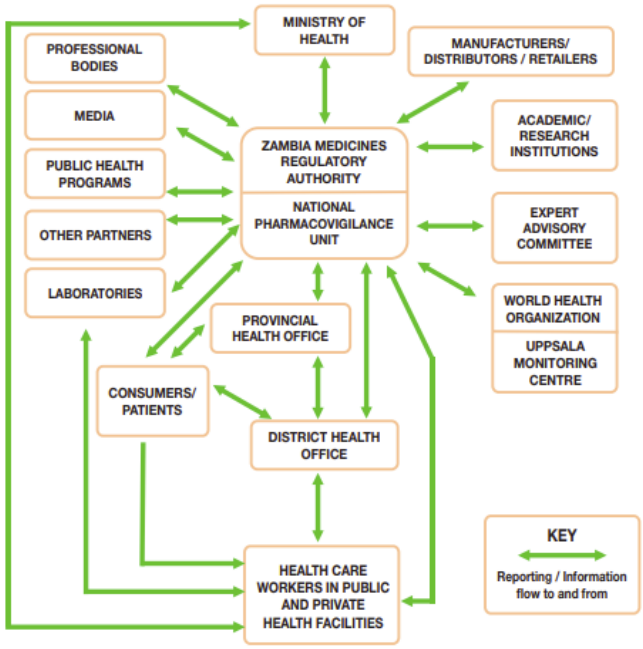

Figure 1 Organisation of the pharmacovigilance system in Zambia [3]

2. Involving ZAMRA

ASCEND in Zambia initiated the engagement of ZAMRA to ensure an accurate and up to date TOT for staff of the MoH NTD department. Recently, new SAEs of Praziquantel – the medicine to administer in the Schistosiomasis MDA) – had been reported in Eritrea, including blurred vision, visual impairment, and increased lacrimation[4].

Following its mandate, ZAMRA works with programs such as the national TB program, HIV program, and immunization program. It was therefore in ZAMRAs interest to engage also with the ASCEND program. Because it is ZAMRA's role to be part of any activities related to pharmacovigilance in Zambia, it was not needed to formalize the collaboration with a contract, and no costs were required. It is the responsibility of

[1] World Health Organization. (2002). The importance of pharmacovigilance. World Health Organization. https://apps.who.int/iris/handle/10665/42493
[2] Zambia Medicines Regulatory Authority Pharmacovigilance Orientation for health workers presentation 2018.
[3] Zambia Medicines Regulatory Authority Pharmacovigilance Handbook 2020. https://www.zamra.co.zm/wp-content/uploads/2021/02/ZAMBIA-PHARMACOVIGILANCE-Handbook-March-2020.pdf
[4] Debesai, M., & Russom, M. (2020). Praziquantel and risk of visual disorders: Case series assessment. PLoS neglected tropical diseases, 14(4), e0008198. https://doi.org/10.1371/journal.pntd.0008198

the MoH/NTD department to engage ZAMRA. On this occasion, ASCEND facilitated this engagement in the interest of all parties. As an important stakeholder, ASCEND also engaged ZAMRA at an earlier stage of its activities, with the review of the draft guidelines for supply chain management on the sections of health waste and importing medicines.

3. Pharmacovigilance training

The TOT was conducted online for ten to twelve participants and took one hour. The participants were from the central level, meaning this was staff from the MoH NTD department. These trainees were then passing on the training to the provincial and district government levels, who in turn trained the CDDs, health facility staff, and schoolteachers involved in the MDA. In these lower level trainings, as well as during MDAs, NTD and ASCEND staff was present as supervisors and monitors. The TOT on the central level was reported to be very comprehensive and detailed, while the trainings on lower levels focused on passing on the key points.

The content of the training was two-fold. Firstly, to make CDDs and the community aware of SAEs as a part of the social mobilization to attend the MDA, thereby training CDDs to answer worries of the community about SAEs, how to recognize SAEs and know in which case to return to the medicine administering site or go to a health facility; and secondly, to explain to CDDs how they can use the reporting forms for ASE. The forms for reporting were handed out by ZAMRA to the TOT participants, who distributed them to the lower levels.

Apart from the purpose of the TOT to prepare for the MDA, it had an additional benefit that it served as a technical refresher course for the NTD staff for them to have up to date knowledge on pharmacovigilance. ZAMRA works with focal points on the provincial and district levels in the country to act as pharmacovigilance experts who are able to conduct trainings on the topic for health facility staff or in the context of a public health program. TOTs such as this one increase capacity of people also outside of ZAMRA to conduct trainings on pharmacovigilance. This is of added value especially for occasions where ZAMRA is not in the capacity to conduct trainings on sub-national level.

4. Reporting of SAE

The forms from ZAMRA are the official mean to report SAE in Zambia. ASCEND and the NTD department distributed ZAMRAs forms, and explained and encouraged the use of the forms as part of the trainings. In addition to the reporting to ZAMRA by health facility staff, public health programs, such as the NTD program, are also obligated to report SAE encountered by their program's participants[5]. The NTD programs in turn are expected to report SAE to the WHO. In Zambia, the NTD program is also expected to report SAE to ZAMRA. In case of MDAs, the NTD program is collecting the information on SAE. Their general reporting of the schistosomiasis MDA showed the occurrence of common side effects such as nausea and headache, but no reporting of SAE.[6] Through the forms reporting system ZAMRA did not receive any reporting of SAEs following the schistosomiasis MDA. Also NTD and ASCEND staff mention that they did not see any reporting happening in the field during or after the MDA.

5. Discussion

When it comes to the reporting of SAE, in ZAMRA's experience, receiving forms often happens in delay because there are different routes of sending the reports to ZAMRA, which is the professional responsibility of health workers at health facilities. However, it can also be that the CDDs had reasons not to report the SAEs, for instance due to a lack of understanding in why or how to do the reporting and use the forms. There can also be obstacles in reporting SAEs from the side of the medicine recipients or communities who received the medicines, although it is likely that in case of SAE patients would return to the drug administration site or to a

[5] Zambia Medicines Regulatory Authority pharmacovigliance reference manual second edition 2020: https://www.zamra.co.zm/wp-content/uploads/2021/02/ZAMBIA-PHARMACOVIGILANCE-Reference-Manual-March-2020.pdf

[6] A handbook for managing adverse events following mass drug administration (AEs-f-MDA) and serious adverse events (SAEs). ENVISION 2015: https://www.ntdtoolbox.org/toolbox-search/sae-handbook-handbook-managing-adverse-events-following-mass-drug-administration-and

health facility. ASCEND did not do a formal evaluation of the training for this WHO funded MDA, so this is as this point in time not known if there were any issues with reporting SAE to the NTD program, or referring patients with SAE to health facilities.

It is the intention of the NTD department and ASCEND to again collaborate with ZAMRA in upcoming MDAs and to make the inclusion of ZAMRA part of the norm in such activities. Collaboration is relevant if activities involve medicines that are typically prone to side effects, such as for schistosomiasis, but also trachoma. When medicines are part of the program, it is intended to check with ZAMRA prior to the start to hear if any new information or warnings about the use of the medicines exists that the program should be aware of. ZAMRA is open for collaboration with different programs in different ways, either on the central or on regional levels. It is up to the MoH NTD department to initiate the collaboration.

6. Opportunities

It is useful to know whether CDDs are able to apply what they learned on the pharmacovigilance training to their job. Therefore it can be considered to **add the element of knowledge about pharmacovigilance to the evaluation of the MDA**. This way it can be assessed if the training is sufficient for the CDDs to be confident in explaining SAEs to the community and medicine recipients, but also if there is enough knowledge and confidence to appropriately report SAE to the NTD program, or refer patients to health facilities who in turn can treat the patients and report the case formally to ZAMRA. This can provide important information in for instance knowing whether SAEs did not occur or were not reported. In addition, **assessing the knowledge on SAEs among the community**, or asking for their feedback on the community awareness training can also provide insights in the effectiveness of the training for CDDs.

One way to improve the likelihood of reporting is **to practice with filling in the forms during the training**. Furthermore, ZAMRA recently adopted a new reporting mechanism for SAEs through a phone-based app. Once developed for MDA medicines, this should be part of the next trainings. **For reporting through the NTD program, a similar app could be developed to improve user-friendliness and speed of reporting.**

Involving the pharmacovigilance department is an opportunity for NTD activities that involve medicines that are typically prone to side effects, such as for schistosomiasis, but also trachoma. It can be considered **to include the pharmacovigilance authority also in the provincial and regional level trainings and perhaps in the community awareness training that is part of MDAs**.

Finally, it is ideal **to establish a standard in which the pharmacovigilance authority is continuously informed about and where needed included in NTD activities** to ensure up to date and accurate guidance in relation to medicine administration.