Drug Saf
DOI 10.1007/s40264-017-0598-y

LEADING ARTICLE

Overview of Pharmacovigilance System in Vietnam: Lessons Learned in a Resource-Restricted Country

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Abstract Drug safety issues in developing countries are complex and sensitive, and health authorities cannot always simply implement decisions from developed countries because the health system, disease patterns, and lists of marketed drugs all differ. A system for proactive and effective surveillance of drugs in each nation is needed to identify and manage the exact drug-related problems faced by patients in these countries. Vietnam launched its university-based National Drug Information and Adverse Drug Reaction Monitoring Centre (NDIADRMC) in 2009, a significant step towards catching up with international trends. Although the center is still in its infancy and has limited resources, it has attained some achievements and largely met the minimum World Health Organization requirements for a functional pharmacovigilance center. The number of reports has increased rapidly, with some important signals generated from the national database leading to regulatory actions at a national level. In addition, this system can help detect drug-quality problems that are less common in developed countries. The success of the quantity and quality of reporting, risk assessment, and communication is still limited compared with more developed systems. A number of opportunities remain to enhance the system, particularly in risk communication and evaluation of the impact of pharmacovigilance, and to apply reporting outcomes to reduce drug-related risks throughout the country. More internal and external support is needed to develop a stronger and more comprehensive pharmacovigilance system.

Key Points

As an independent university-based center, the National Drug Information and Adverse Drug Reaction Monitoring Centre (NDIADRMC) in Vietnam has benefited from the well-educated human resources and research capacities of the Hanoi University of Pharmacy and close coordination with the drug regulatory authority in managing all pharmacovigilance activities.

With national and international support (from the Global Fund) and increasing participation from clinical pharmacists in reporting adverse drug reactions, the NDIADRMC has been able to solve drug safety problems to some extent, especially the detection of drug-quality signals.

An interactive two-way mechanism between the NDIADRMC and healthcare units has been created to enhance the quality of the pharmacovigilance process, from signal detection to risk management.

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Published online: 03 October 2017

1 Introduction

As the Vietnamese health system operates within a resource-restricted country, protecting public health can be challenging [1]. To enhance both the quality of healthcare and the confidence in the healthcare system, health authorities implemented efficient policies, including rigorous supervision of the entire lifecycle of registered drugs. Recognizing the importance of drug safety, Vietnam officially joined the World Health Organization (WHO) Program for International Drug Monitoring in 1999 and became part of the global flow of postmarketing drug surveillance information. Pharmacovigilance is an indispensable tool in ensuring drug safety for the whole community and can be used to detect, assess, understand, and prevent the adverse drug reactions (ADRs) that can be encountered with pharmaceutical products, including traditional and herbal medicines, vaccines, biological products, and medical devices [2]. Pharmacovigilance also covers medication errors, drug interactions, and quality issues as well as tracing and detecting counterfeit, substandard, or poor-quality medicines, because these undeniably cause harm to patients. Despite the challenges, Vietnam has always endeavored to develop an independent pharmacovigilance system instead of relying solely on information from other international drug administrations. This article aims to provide an overall picture of the Vietnamese pharmacovigilance system since the establishment of the National Drug Information and Adverse Drug Reaction Monitoring Centre (NDIADRMC) and describe lessons learnt in a resource-limited country when dealing with pharmacovigilance issues.

2 Healthcare and Drug Regulatory Systems

Vietnam is classed as a developing country. It is a member of the Association of Southeast Asian Nations and has a population of about 91.7 million. In the space of only a few decades, between the late 1980s and the end of 2015, the Renovation Policy (Doi-moi) and the creation of a socialist-oriented market economy saw Vietnam transition from being one of the poorest countries (per capita yearly income of approximately $US100) to a lower middle-income country (per capita yearly income of approximately $US2100) [3]. To meet the needs of this rapidly changing country, the healthcare system was restructured towards universal health coverage [4]. Limited budgets required the country to mobilize all possible available resources towards healthcare. The operational schedule for the strategy was carried out in stages: user-pays fees for public healthcare services were implemented and doors opened to private healthcare providers in 1989, health insurance was introduced in 1992, and—with the aid of government subsidies—health insurance coverage was increased to 70% of the population in 2015 [4, 5]. These actions improved healthcare services in remote and urban areas and reinforced primary healthcare at the grassroots level. With 13,617 public health establishments, including 1153 public hospitals, 630 regional polyclinics, and 11,113 units in communes or precincts, and 710 medical service units in offices or businesses across the country in 2015, the accessibility of basic healthcare services for Vietnamese people has improved considerably [6].

Data on file at the Drug Administration of Vietnam (DAV) indicate that, in July 2014, Vietnam was home to more than 2265 national and foreign pharmaceutical manufacturers, with over 40,000 approved products, and drug registrations, especially for generic products, have increased dramatically since then. However, despite many of the products having identical active ingredients, the price, origin, or quality varies widely. Numerous pharmaceutical companies, including nationalized, joint venture, private, and foreign-owned companies, are involved in drug research and development, production, supply-chain management, marketing, and post-marketing surveillance. Despite this complex situation, Vietnam has maintained its objective of developing a domestic pharmaceutical industry as a priority, as stated in Prime Minister's decisions 154/2006/QD-TTg and 68/QD-TTg (2014) [7, 8]. In addition, the Ministry of Health (MOH) implemented five "Good Practice" guidelines for total quality assurance in the healthcare sector (manufacturing, laboratory, storage, delivery, and pharmacy) and maintains close surveillance over their implementation [9]. Other approaches at a national level have included revising and updating the standards of drug quality control in the latest version of the Vietnamese Pharmacopoeia [10] and the second version of the Vietnamese National Drug Formulary [11] to integrate all these aspects regarding registered drugs.

3 Adverse Drug Reaction Monitoring System

3.1 History, Organization, and Regulation

Although pharmacovigilance was introduced in Europe in the 1960s, Vietnam only became aware of it in 1994, when the country launched its first ADR monitoring center—an experimental center inside the National Institute for Drug Quality Control—with financial and technical support from the Swedish International Development Cooperation Agency. In 1999, Vietnam became the 98th member of the WHO Program for International Drug Monitoring, operated by the Uppsala Monitoring Centre (UMC). Unexpectedly, in 2004, soon after the Swedish support ended,

pharmacovigilance activities decreased significantly, and all ADR reports were forwarded to the DAV. From 2004 to 2009, although the DAV strived to maintain basic pharmacovigilance activities, reporting of ADRs resulted in no connection or feedback to reporters or healthcare units, and the DAV faced many difficulties regarding database control and management, especially when the number of reports increased. In March 2009, MoH decision 991/QD-BYT established the NDIADRMC under the management of the Hanoi University of Pharmacy and the direction of the MoH. Six months later, this center was brought into service as an important milestone, creating new opportunities for the development of drug safety surveillance. In addition, decentralization of pharmacovigilance activities was approved, and creation of three regional pharmacovigilance centers was intended, in the north, middle, and south of the country [7]. However, by March 2011, only one regional center had been set up, at Cho Ray hospital, the biggest hospital in Ho Chi Minh City. Since then, only two centers have collected drug safety information across the entire country and assisted DAV in drug regulation activities. Moreover, the Pharmacy Act (2005), which supported pharmacovigilance activities, was strengthened by the revised Pharmacy Act (April 2016), which addressed the specific responsibilities of different stakeholders in the pharmacovigilance system [12].

Regarding the structure of the pharmacovigilance system, the NDIADRMC acts as a technical support unit for the DAV and plays an important role in monitoring, detecting, and reporting information related to ADRs, medication errors, suspected counterfeit drugs, substandard drug quality, and drug-related failure of treatment (Fig. 1). The NDIADRMC

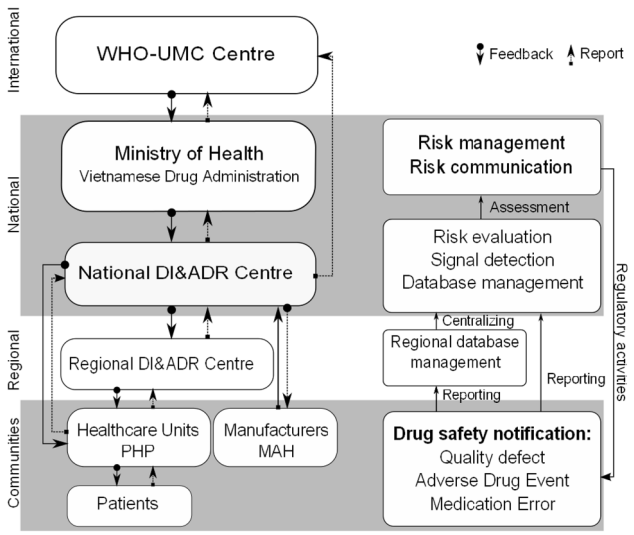

Fig. 1 Structure of the pharmacovigilance system in Vietnam. *DI&ADR* Drug Information and Adverse Drug Reaction Monitoring, *PHP* Public Healthcare Programs, *MAH* Market Authorization Holder, *WHO-UMC* World Health Organization Uppsala Monitoring Centre

collects and analyzes ADR reports from various sources, assesses the benefit–risk balance, and manages and communicates drug-related risks. The NDIADRMC has also organized many pharmacovigilance training courses for healthcare practitioners (HCPs), provided drug safety information to DAV, contributed to the international individual case safety report (ICSR) database, and operated as a drug information center. Until recently, ADR reports were sent to the pharmacovigilance centers by post, fax, telephone, or email. However, a new web-based notification system has now been deployed, with access controlled and validated by the NDIADRMC. As of January 2014, ADR reports can be submitted via the official NDIADRMC website (http://canhgiacduoc.org.vn/), which has helped reduce the time for data to be recorded and encoded and has facilitated reporting activities, especially for remote provinces. To maintain the quality of reporting using both the website portal and other reporting channels, an interactive two-way information exchange between the NDIADRMC and healthcare units and/or reporters has been established. The NDIADRMC has supplied up-to-date, practical, and useful drug information via feedback letters, or via telephone in urgent cases. Risk-minimization information has also been widely disseminated. This information has helped HCPs better understand drug-related issues.

Thus far, the reporting system has focused mainly on HCPs in healthcare units, national public health programs (PHPs), and pharmaceutical companies but not community pharmacies and customers because of the fear of these sources submitting misleading information. As an important stakeholder in the pharmacovigilance system, pharmaceutical companies seeking a new valid registration or renewal are required to supply safety and efficacy documents related to their products. After companies commence marketing of their registered products, they are required to take primary responsibility for monitoring ADRs and reporting serious or unknown ADRs involving their drug in Vietnamese territory to the pharmacovigilance center, using either the official national reporting form or the Council for International Organizations of Medical Sciences (CIOMS) form [13]. In the case of life-threatening or fatal ADRs, companies must send the primary report no later than 7 days after receiving an initial report; any follow-up reports must be sent within 15 days after receiving the additional information. Reports of other serious domestic cases must be sent no later than 15 days. In addition, companies are required to submit a Periodic Safety Update Report, a Periodic Benefit Risk Evaluation Report, or a Safety Report (defined by the revised drug registration regulations) accompanied by a summary safety report in the Vietnamese language that includes details of both foreign and domestic ICSRs within 90 days of the last day of the period covered by the report. If a company

receives new safety information from anywhere in the world about drugs registered in Vietnam, they are also required to submit updated information to the NDIADRMC or the DAV. Risk management plans are encouraged but not mandatory unless the DAV requests them, usually for high-risk medicines.

3.2 Management Process

For each ICSR received, NDIADRMC staff thoroughly review the administrative and medical information then code and record it on the national pharmacovigilance database. A management process is then selected according to the seriousness of the ICSR and the potential public health impact (Fig. 2). According to the WHO, the criteria for serious ICSRs includes death, life-threatening reaction, required or prolonged hospitalization, resulting in a congenital anomaly, or resulting in persistent or significant disability or incapacity. To identify early drug-quality signals, in which case it is important to activate an appropriate management plan, the NDIADRMC extends this definition using "case series of ADRs related to a specific product." An urgent management scheme (UMS) applies to reports of death (including death and prognosis of eventual death after administration of suspected drug) and "case series of ADRs related to a specific product." The requirements for case series of ADRs suspected of being related to drug quality are pre-defined in the internal NDIADRMC procedure database management according to two criteria: the seriousness and frequency of reporting of the ADR related to a specific drug within a short time. For example, a UMS is considered to be activated in case series with at least two serious ADR reports or at least five non-serious ADR reports for the same suspected drug lot number within 7 working days in the same healthcare unit. The UMS has helped both to overcome the limited human resources available to manage ICSRs and to identify and manage important risks as well as early signals generated about drug quality. In the UMS, two independent expert evaluations from the technical expert committee (TEC) are obtained within 2 weeks. These evaluations assess causality and, where necessary, communicate the risks through the NDIADRMC via official letters to the DAV. At the same time, a feedback letter and an acknowledgment letter are sent directly to the reporter and/or the healthcare unit. Basic information about and assessments of ADR case series are updated weekly on the official NDIADRMC website to provide information for the public. The UMS has made pharmacovigilance management more flexible, confident, and efficient by establishing early signals for drug safety as well as triggering intervention by the DAV when further action is necessary.

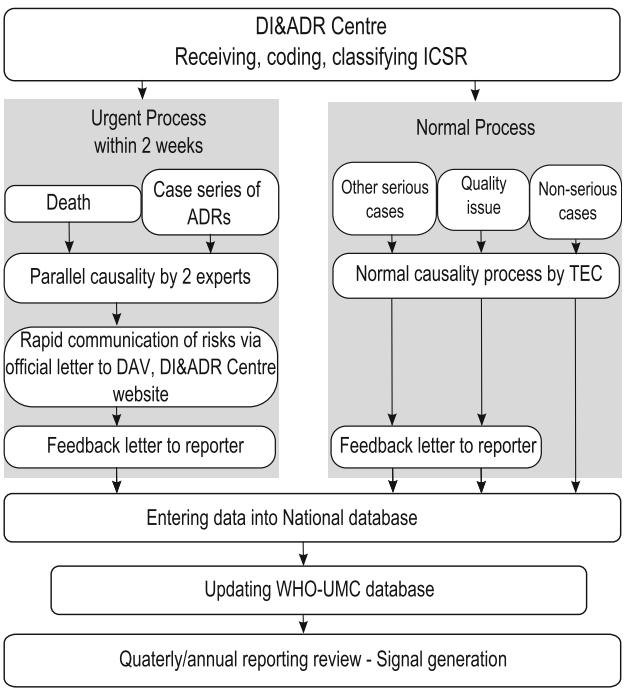

Fig. 2 Internal process of individual case safety report management in the National Drug Information and Adverse Drug Reaction Monitoring Centre. *ADR* adverse drug reaction, *DAV* Drug Administration of Vietnam, *DI&ADR* Drug Information and Adverse Drug Reaction Monitoring, *ICSR* individual case safety report, *WHO-UMC* *World* Health Organization Uppsala Monitoring Centre, TEC Technical Expert Committee

Unlike the UMS, the routine scheme has no precise time constraints, and the causality of cases is assessed by TEC members. The TEC comprises a number of experts, such as pharmacists or medical specialists, with a minimum of 5 years' experience in clinical practice. TEC members meet with NDIADRMC representatives monthly or bimonthly to discuss, evaluate, and deal with important pharmacovigilance issues. The committee has played an important role in judging the risk communication that should follow its assessments, especially after reviewing UMS cases. The TEC is also responsible for evaluating the circumstances of notable cases and coordinating with the NDIADRMC the conduct of further investigations or studies in the national database. The NDIADRMC sends advice letters to the DAV for further decision making, such as issuing drug safety warnings for HCPs and requiring labelling changes, recalls, or withdrawals. Information in these advice letters includes TEC advice, outcomes of individual matters, notable signals from the national database, and drug safety information from international authorities. Not all letters conveying information from the NDIADRMC have resulted in regulatory actions (Fig. 3).

To enhance the quality of information for data analysis, the NDIADRMC uses the VigiGrade tool developed by WHO–UMC to score the completeness of every ICSR received [14]. When important data are omitted, especially relating to a UMS, the reporter/healthcare unit is contacted directly to verify the cases and add supplementary information to the report. The national database is revised periodically, and duplicate reports with identical patient name, sex, age, drug, ADR, and onset date are removed. Quarterly/annual reviews include summaries of reporting rates, statistics regarding serious ADRs, and contributions from classes of reporters. However, further data-mining using disproportional criteria (reporting odds ratio [ROR] or the proportional reporting ratio [PRR]) and the other statistical signal-generation methods are only conducted in the context of university research and not in routine practice.

4 Some Initial Achievements

Within 7 years of the NDIADRMC being established, both the quality and the quantity of ADR reporting in Vietnam increased considerably. In the period 2010–2016, the NDIADRMC officially received 40,031 ADR reports from various sources, including healthcare units, PHPs, and marketing authorization holders (MAHs) (reports from MAHs have been accepted since 2011 and included in the database since 2012) (Fig. 4). The number of reports has increased rapidly. In particular, reports received in the last 3 years have accounted for over 70% of the total reports received in the past 7 years. This increase indicates that attitudes about and knowledge and acceptance of pharmacovigilance among HCPs has improved considerably. In terms of quality, the completeness score for reports from HCPs in the period 2010–2014 was >0.8, relatively better than the international average score [14].

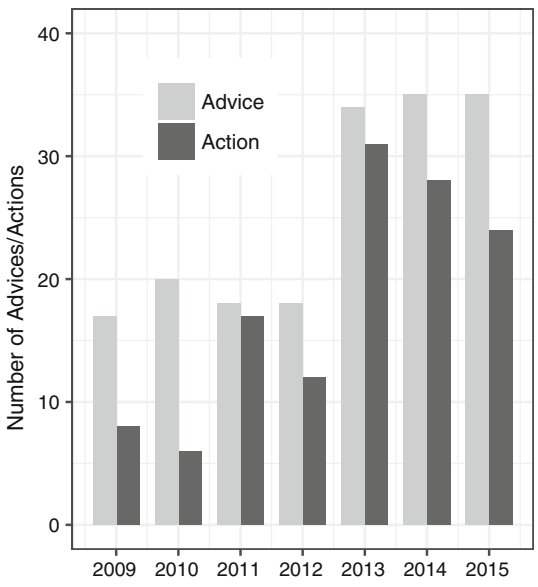

Fig. 3 Number of advice letters from the Drug Information and Adverse Drug Reaction Monitoring Centre and subsequent regulatory actions by the Drug Administration of Vietnam (2009–2015)

Between 2010 and 2015, the MoH issued a number of legal documents related to pharmacovigilance: the *National Guideline on Pharmacovigilance* [15], a specific guidance on reporting ADRs in healthcare facilities [16], and a series of technical guidelines on ADR reporting in national targeted PHPs (HIV/AIDS, tuberculosis, and malaria) [17]. In addition, the MoH issued a series of circulars emphasizing pharmacovigilance activities related to registration, drug labeling, drug advertising, herbal and traditional medicines, biosimilars, clinical trials, and biological products. The legal framework strengthened the pharmacovigilance network throughout the country and created a culture of co-operation among all stakeholders, from the grassroots to a national level. This reflects a strong commitment from the MoH and the NDIADRMC to promote the performance of the pharmacovigilance system, thus contributing to improvements in the quality, efficacy, and safety of drugs for the general public. In particular, a productive working environment has been built in which hospital pharmacists monitor safety issues. The contribution from clinical pharmacists, in terms of both the quantity and the quality of ICSRs, has been remarkable. According to data on file at the NDIADRMC, from 2010 to 2016, more than 30% of ICSRs have come from pharmacists and this rate has increased annually [18].

In addition, linkages between pharmacovigilance activities and targeted PHPs have been established and improved over time. For example, a large-scale cohort–event monitoring (CEM) program implemented in 2011–2013 enrolled 645 HIV/AIDS patients [19]. Another CEM in the tuberculosis program, which was launched in 2014, is about to be completed and published [20]. The number of ADR reports from these programs has increased annually, and ADR reporting has been integrated into PHPs' routine practice.

Since the establishment of the NDIADRMC, the pharmacovigilance system development strategy has also focused on educating all HCPs about their role and the importance of reporting. Virtually all reports are accepted and recorded in the national database, and up to 50% of reporters receive feedback letters. The NDIADRMC frequently queries specific ADR–drug pairs from the database, not only to provide additional information in feedback letters but also to contribute somewhat to active signal detection. The pharmacovigilance procedures have operated well, from signal detection and evaluation to risk

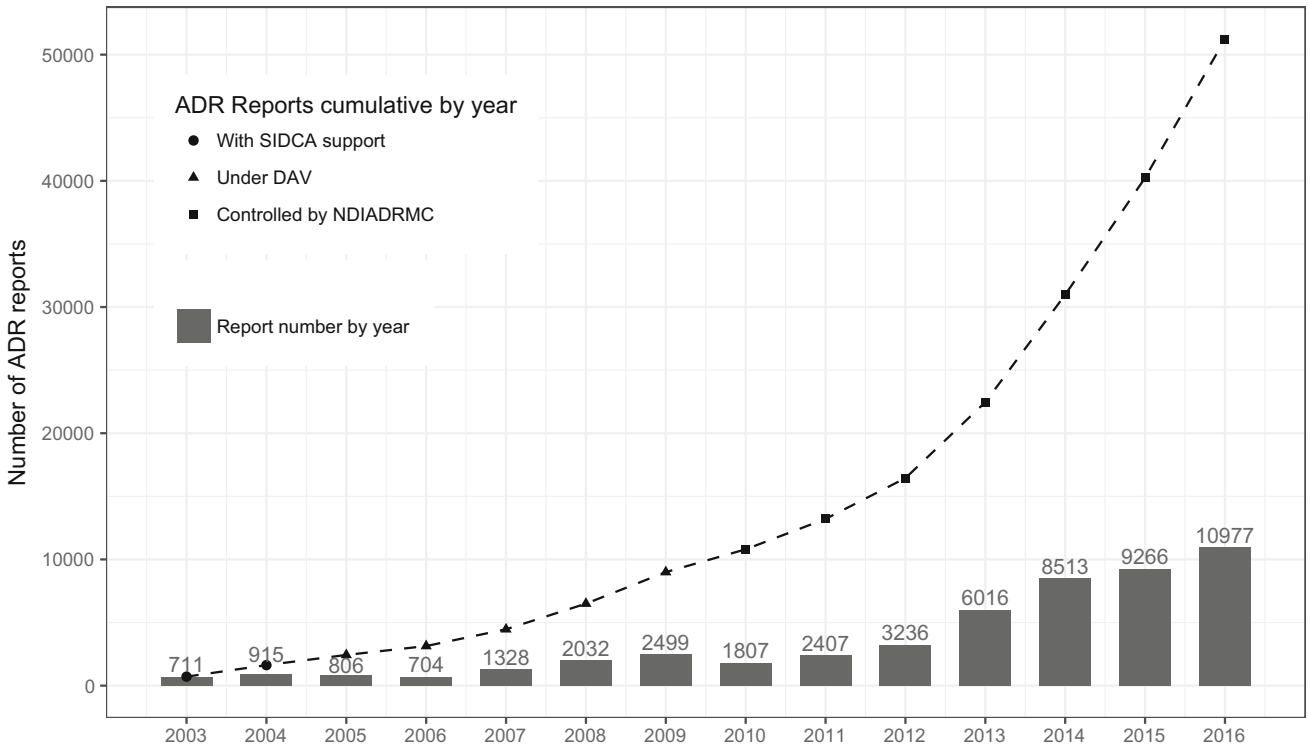

Fig. 4 Number of adverse drug reaction reports in the Vietnamese database. *ADR* adverse drug reaction, *DAV* Drug Administration of Vietnam, *NDIADRMC* National Drug Information and Adverse Drug Reaction Monitoring Centre, *SIDCA* Swedish International Development Cooperation Agency

management and communication. As a result, UMSs have detected a number of important signals from local resources, leading to the investigation of the quality of relevant lots, warning pharmaceutical companies, or even suspending/recalling drug products [e.g., Relab® (albumin 20%) after it failed to meet quality standard requirements] [21]. Other examples have included strong signals relating to medication errors in real practice, such as anaphylactic shock due to the lack of sufficient prophylaxis, failure of recognition and management when using iodinated contrast media, or severe cutaneous adverse reactions related to the irrational use of allopurinol for hyperuricemia [22, 23]. The pharmacovigilance system has also provided important evidence about high-risk medicines, such as the signal that arose from a case series of 21 ADR reports (rigors accompanied by fever or even anaphylactic shock) related to the same lot number of Levelamy® (L-ornithine-L-aspartate) and led to the company voluntarily withdrawing the drug [24]. These outcomes have confirmed the capacity of the NDIADRMC and its communication strategies, notwithstanding that it is a university-based center, unlike other NDIADRMC, which are located within national drug regulatory authorities. Vietnam has met almost all of the minimum requirements for a functional pharmacovigilance system [25, 26].

5 Challenges

5.1 Inequitability in Quality and Quantity of Individual Case Safety Reports

The main obstacle faced by the Vietnamese pharmacovigilance system is the remarkable variation in the quality and quantity of reports between regions, hospitals, and even subgroups of HCPs (i.e., physicians, pharmacists, nurses). Until 2016, only 805 of 13,617 health establishments (fewer than 6%) participated in reporting activities. This imbalance is worse in remote areas because of a lack of highly qualified HCPs. Furthermore, the burden of work in healthcare centers and differences in knowledge, attitude, and practice have led to under-reporting. Pharmacovigilance might still be unfamiliar to the majority of healthcare workers despite the official *National Pharmacovigilance Guideline* promulgated in June 2015. Submission time (i.e., from initial detection to completing the form) has been relatively long, impacting on follow-up and information updates. Although the quality of reports is generally relatively good, some inaccuracies in important fields, such as date of onset, indications, and dosage, still exist. Completeness scores vary between areas, and the areas reporting most frequently have worse scores than

those reporting less frequently. As such, the NDIADRMC needs to rebalance the situation in the next development period.

5.2 Limited Communication, Training, and Information Sharing

Within the developing framework, the knowledge, attitudes, and practices of most healthcare workers relating to drug safety are still generally limited. They consider ADR reporting in practice to be difficult and very time-consuming and that it brings more trouble than benefit, especially when working in a stressful environment [27]. These preconceived ideas, together with the very real overload situation in hospitals, constitute a considerable barrier between HCPs and pharmacovigilance. To increase the overall awareness of pharmacovigilance, the DAV and the NDIADRMC should organize training classes, seminars, meetings, and workshops throughout the country. There is also a need to encourage and support research work related to pharmacovigilance within hospitals as well as to encourage publications to disseminate valuable experience among healthcare units [28]. Furthermore, an efficient mechanism for exchanging ideas between stakeholders is needed for the sustainable development of pharmacovigilance.

The spreading of awareness of pharmacovigilance among HCPs via systematic training classes organized by the NDIADRMC, with domestic and international support, is necessary to promote the early detection and reporting of ADRs and to build a sustainable system. Through the knowledge and information gained in these classes, the drug-related risks in actual practice would be communicated and minimized among hospitals and HCPs. Learning from other developed systems by regularly attending international training sections or workshops is also needed to better understand new methods and improve knowledge in pharmacovigilance.

Some important public health data sources, such as health insurance records, the national health registry, or computerized patient record databases, currently have not shared or connected with pharmacovigilance activities for technical or administrative reasons. The NDIADRMC has made some initial attempts to approach and utilize these resources in the context of university research, but it needs more time and resources to achieve usable linkages. Cross-referencing data should be encouraged and used as a valuable source for future research.

Since 2012, the NDIADRMC has issued the *Bulletin of Pharmacovigilance*—a quarterly publication providing up-to-date national and international information about pharmacovigilance [29]. In total, 2500 printed bulletins are freely distributed to 1154 healthcare units across the country every 3 months. This initiative has had a considerable impact on interactions and information sharing between pharmacovigilance centers and pharmacists and other HCPs. The bulletin is also available online (http://magazine.canhgiacduoc.org.vn/) and attracts more than 10,000 visits per month. Nonetheless, the impact of the publication needs to be fully assessed, and the means of dissemination needs improvement.

5.3 Divisions Between Activities Coordinating Public Health

Reporting activities were considered routine practice in HIV/AIDS, tuberculosis, and malaria programs, but this integration was difficult to maintain because of a lack of direct government support and clear institutional instructions. In other healthcare areas, physicians' activities and the establishment of treatment guidelines are under the direction of the Medical Services Administration (another administrative unit in the MoH), whereas ADR monitoring is under the direction of the DAV. Vaccines and herbal medicines are registered by the DAV, but the supervision of vaccines in the community is mainly under the Department of Preventive Medicine (another administrative unit in the MoH), and control of herbal medicines is under the Traditional Medicine Administration (yet another administrative unit in the MoH). Lack of effective communication between these units has sometimes proven a barrier to pharmacovigilance. Safety issues related to vaccines may lead to rumors, possibly damaging overall confidence in vaccination and dramatically affecting immunization coverage and disease incidence.

To prevent adverse consequences on public health, stakeholders in the pharmacovigilance system should coordinate and harmonize their activities with the global aim of strengthening postmarketing drug surveillance. Although the *National Pharmacovigilance Guideline* clearly describes the risk communication strategy, more direct and clear government instructions are also required to coordinate activities between the various authorities in Vietnam.

5.4 Lack of Involvement from Private Drug Retailers, Customers, and Public Media

In Vietnam, patients can easily obtain medicines at most community pharmacies, even without a prescription [30]. They can medicate themselves by buying medicines on the advice of pharmacy staff who may have had only 2 or 3 years of pharmacy education or may even be untrained [31]. These entry-to-practice health workers with limited education have had a hugely negative impact on the rational use of medicines. They do not seem to be involved in any specific pharmacovigilance activities, which is a

significant barrier to perfecting the pharmacovigilance system. Drug safety is the responsibility of not only the pharmacovigilance centers and the MoH but also the community as a whole. Reporting by private pharmacies and patients should be considered appropriate parts of the pharmacovigilance system. Support and a clear strategy from the national authority are needed to deal with this issue. Risk communication via the public media, with information available to the entire population, is still in disarray. Medical safety information for the general audience is not well written, is often not based on evidence, and may even be inaccurate because of the limited healthcare knowledge of unqualified writers.

Some obstacles also exist for information sharing and communication of risk, such as the amount of time required for administrative procedures, and disagreements between different administrative units, albeit these actions are considered extremely important. Furthermore, conflicts of interest still exist in drug information between pharmaceutical companies and the mass media. As a result, community rumors about healthcare matters easily get out of control and decrease confidence in the domestic health system. Thus, the pharmacovigilance system should establish an efficient mechanism to coordinate and harmonize with the mass media to ensure the quality of drug safety information. More specific information aimed at patients and the media should also be developed. Pharmacovigilance activities also need re-organizing to be more transparent, reliable, and effective. Future development of the system should be geared towards patients and consider the various media sources as primary communication sources about pharmacovigilance activities.

6 Conclusions

Despite initial achievements, there remains considerable room for improvement in such a young pharmacovigilance system. Pharmacovigilance activities in Vietnam have been well conducted by the NDIADRMC under instruction from the MoH and have—to some extent—ensured the benefits of drug safety for Vietnamese patients. In the coming years, the mission of the NDIADRMC will focus on maintaining development, diversifying reporting sources, and organizing more frequent training for HCPs. Private pharmacies, drug retailers, herbal and traditional practitioners, and consumers should be encouraged to report ADRs and be involved directly in the pharmacovigilance system. Comprehensive international and domestic support is also required to develop a better-functioning pharmacovigilance system.

Compliance with Ethical Standards

Funding Nguyen K.-D. acknowledges the French Embassy in Hanoi and the Pierre Fabre Foundation for their financial support of his doctoral studies in the UMR 1027 INSERM-Université Toulouse III, France, in close collaboration with the National Centre of Drug Information and Adverse Drug Reaction Monitoring, Hanoi University of Pharmacy, Hanoi, Vietnam. No other sources of funding were used to assist in the preparation of this article.

Conflict of interest Khac-Dung Nguyen, Phuong-Thuy Nguyen, Hoang-Anh Nguyen, Anne Roussin, Jean-Louis Montastruc, Haleh Bagheri, and Sten Olsson have no conflicts of interest that are directly relevant to the content of this manuscript.

References

1. Ministry of Health of Vietnam and Health Partnership Group. The joint annual health review 2015 (JAHR 2015). http://jahr.org.vn/index.php?option=com_content&view=frontpage&lang=en. Accessed 01 July 2016.
2. World Health Organization. The importance of pharmacovigilance—safety monitoring of medicinal products. 2002. http://apps.who.int/medicinedocs/en/d/Js4893e/. Accessed 19 Dec 2016.
3. World Bank. Vietnam overview. 2016. http://www.worldbank.org/en/country/vietnam/overview#1. Accessed 19 Dec 2016.
4. Ha BTT, Frizen S, Thi LM, Duong DTT, Duc DM. Policy processes underpinning universal health insurance in Vietnam. Glob Health Action. 2014;7:24928. doi:10.3402/gha.v7.24928.
5. World Health Organization. A health financing review of Vietnam with a focus on social health insurance. Geneva: WHO: 2011. http://www.who.int/health_financing/documents/cov-oasis_e_11-vietnam/en/. Accessed 19 Dec 2016.
6. General Statistics Office. Health, culture, sport and living standards social order, safety and environment. In: Statistics yearbook. Vietnam 2015. Statistical Publishing House; 2016. p. 740. https://www.gso.gov.vn/default.aspx?tabid=512&idmid=5&ItemID=16051. Accessed 15 Dec 2016.
7. Decision 154/2006/QD-TTg approved Scheme on state management of pharmaceuticals, food hygiene and safety and cosmetics. Issued 30 June 2006. http://vbpl.vn/TW/pages/vbpqen-toanvan.aspx?ItemID=5319. Accessed 15 Dec 2016.
8. Decision No. 68/QD-TTg. The national strategy on development of the Vietnam pharmaceutical industry up to 2020. Issued 10 Jan 2014. http://www.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban?mode=detail&document_id=171793. Accessed 15 Dec 2016.
9. Drug Administration of Vietnam. The Good Practices (GPs) documents [Internet]. 2017. Available from: http://www.dav.gov.vn/default.aspx?action=detail&newsid=1312&type=3. Accessed 06 Jun 2017.
10. Ministry of Health. Vietnamese National Drug Formulary. Medical Publishing House; 2015.
11. Minitry of Health. Pharmacopoeia Vietnamica, editio IV. National government publication; 2009.
12. Ministry of Health. National Guideline of Pharmacovigilance. According to Decision 2111/QD-BYT from the Ministry of Health; 2015. http://canhgiacduoc.org.vn/SiteData/3/UserFiles/HDQGCGD%20Final%2029_05_2015.pdf. Accessed 15 Dec 2016.
13. Ministry of Health. Decision No. 1088/QĐ-BYT: Promulgation of guidelines on Monitoring adverse drug reaction in health establishments. 2013. http://canhgiacduoc.org.vn/SiteData/3/

UserFiles/VanBanPhapQuy/Guidline%20ADR_2013.04.04.pdf. Accessed 15 Dec 2016.
14. Ministry of Health. Decision No. 107/QĐ-AIDS: Promulgation of guidelines on Monitoring adverse reactions related to antiretroviral drugs in an HIV/AIDS prevention and treatment program. 2014. http://canhgiacduoc.org.vn/SiteData/3/UserFiles/VanBanPhapQuy/QD%20107%20AIDS/107.pdf. Accessed 15 Dec 2016.
15. Tran NH. Annual summary of ADR reporting 2016. Bulletin of Pharmacovigilance - National DI&ADR Monitoring Center. 2017;1:9–13. http://magazine.canhgiacduoc.org.vn/Uploads/Volume/Files/38_BanTinCGD.so1_2017.pdf. Accessed 15 June 2017.
16. National Assembly. Law on pharmacy 105/2016/QH13. Issued 06 Apr 2016. http://moj.gov.vn/vbpq/en/lists/vn%20bn%20php%20lut/view_detail.aspx?itemid=6838. Accessed 5 Dec 2016.
17. Post-approval safety data management: definitions and standards for expedited reporting: ICH E2D. http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/post-approval-safety-data-management-definitions-and-standards-for-expedited-reporting.html. Accessed 15 Sept 2016.
18. Bergvall T, Norén GN, Lindquist M. vigiGrade: a tool to identify well-documented individual case reports and highlight systematic data quality issues. Drug Saf. 2014;37:65–77.
19. Nguyen PT, Tran NH, Dao XT, Nguyen HA, Vu DH, Le TH. Adverse drug reactions of antiretroviral therapy: results from an active surveillance in Vietnam. In: Proceeding of the 8th Indo-China Conference on Pharmaceutical Sciences, PO-CP-7, pp 568–575, Ho Chi Minh city, Vietnam, 4-5 Dec 2013.
20. World Health Organization. Inter-regional workshop on pharmacovigilance for new drugs and novel regimens for the treatment of drug-resistant tuberculosis. Meeting Report. 12–14 November 2014. Hanoi, Vietnam (WHO/HTM/TB/2015.07). www.who.int/entity/tb/challenges/meeting_report_pv_workshop_hanoi_2014.pdf. Accessed 15 Dec 2016.
21. Ministry of Health—Drug Administration of Vietnam. Official dispatch No. 10787/QLD-CL: Circulation suspension and withdrawal of Relab 20% (albumin).Off. Dispatch Sept 7, 2013. http://canhgiacduoc.org.vn/SiteData/3/UserFiles/VanBanPhapQuy/CV%2010787%20QLD%20%20Relab.pdf. Accessed 15 Jan 2017.
22. Ministry of Health—Agency of Medical Services Administration. Official dispatch No. 789/KCB-NV: Severe drug adverse reaction related to allopurinol. Off. Dispatch Nov 9, 2013. http://canhgiacduoc.org.vn/GioiThieuChung/Vanbanphapquy/vbpqview.aspx?documentid=263. Accessed 15 Jan 2017.
23. Ministry of Health—Agency of Medical Services Administration. Official dispatch No. 13/KCB-NV: rug adverse reactions related to iodinated contrast media. Off. Dispatch Aug 11, 2014. http://canhgiacduoc.org.vn/SiteData/3/UserFiles/VanBanPhapQuy/13%20KCB-%20NV%20thuoc%20can%20quang.pdf. Accessed 15 Jan 2017.
24. Ministry of Health—Drug Administration of Vietnam. Official dispatch No. 20958/QLD-CL: Circulation suspension Levelmy (l-ornithin-l-aspartat) Lot number 022014 due to case series of adverse drug reactions. Off. Dispatch Mar 12, 2014. http://canhgiacduoc.org.vn/SiteData/3/UserFiles/QLD%2020958%203122014.pdf. Accessed 15 Jan 2017.
25. World Health Organization. Minimum requirements for a functional national pharmacovigilance system. Geneva: WHO. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_2010_2.pdf. Accessed 15 Dec 2016.
26. Suwankesawong W, Dhippayom T, Tan-Koi W-C, Kongkaew C. Pharmacovigilance activities in ASEAN countries. Pharmacoepidemiol Drug Saf. 2016;25(9):1061–9.
27. Nguyen TTH, Nguyen PC, Nguyen HA, Le TT, Nguyen TPN, Tran TLA. Spontaneous reporting of adverse drug reactions in ten province general hospitals: healthcare professionals' knowledge, attitude and practice. Vietnam Pharm J. 2016;7(483):2–5 + 56 (**ISSN: 0866-7861**).
28. Nguyen TTH, Nguyen HA, Tran TLA, Le TT. Essential pharmacovigilant solutions for effective ADR reporting in 10 Vietnam provincial hospitals. Vietnam Pharm J. 2016;10(486):45–59 **(ISSN: 0866-7861)**.
29. Nation Pharmacovigilance Centre. Bulletin of Pharmacovigilance (Vietnam). http://magazine.canhgiacduoc.org.vn/home. Accessed 15 Dec 2016.
30. Larsson M, Binh NT, Tomson G, Chuc NT, Falkenberg T. Private pharmacy staff in Hanoi dispensing steroids - theory and practice. Pharm Pract. 2006;4(2):60–7.
31. Nga DTT, Chuc NTK, Hoa NP, et al. Antibiotic sales in rural and urban pharmacies in northern Vietnam: an observational study. BMC Pharmacol Toxicol. 2014;15:6–10. doi:10.1186/2050-6511-15-6.