ASSESSMENT OF PHARMACOVIGILANCE SYSTEM IN INDONESIA ACCORDING TO WHO PHARMACOVIGILANCE INDICATORS: CHALLENGES AND POSSIBLE SOLUTIONS

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ABSTRACT

Due to the potential of Indonesia as a market and a huge number of emerging new products, a comprehensive pharmacovigilance evaluation is critical in overcoming challenges and assure product safety. This article evaluates the current pharmacovigilance establishment in Indonesia in accordance with indicators stated in the manual published by WHO to identify actual challenges and solution. Evidence of compliance with each indicator was based on data published by the Indonesian national agency of drug and food control that can be accessed on the official website. Furthermore, the collected data were categorized and summarized in tables. From the table, evidence of compliance for indicators CST6, CP6-7, and CO3-8 cannot be found on any official website. These indicators are related to a system for reporting therapeutic ineffectiveness and suspected medication errors, the cost and the number of medicine-related hospital admissions and medicine-related deaths, and low human resources and report numbers. Major cause of the issues, which is reflected in the low number of annualy taken actions, is the low number of reports of Adverse Drug Reactions (ADR) which are highly dependent on the Healthcare Professionals' (HCPs) and industries' pharmacovigilance competency and system. Improving HCP's competency and procurement of resources necessary to arrange the required system are considered as effective solutions for attaining a comprehensive pharmacovigilance system.

Keywords: Assessment, national agency of drug and food control, pharmacovigilance, WHO Indicators

INTRODUCTION

Indispensable use of medication requires a surveillance system since medicine utilization may cause undesirable and/or unexpected side effects. Every medicine has been through multiple stages of safety and efficacy testing. However, the population involved in the clinical is relatively small compared to the real population which is more heterogenous in various aspects including genetics, concurrent disease, diet, and environment. Therefore, continues surveillance of drug efficacy and safety is critical. Other than the drug response, crucial aspect needs to be supervised including the consistency of the produced drug quality, drugs misuse or abuse, and medical error (WHO, 2022).

A practical manual for the pharmacovigilance system assessment has been published by WHO. The manual consists of several indicators which are based on the expected function of pharmacovigilance establishment described by WHO. The method provided in the manual assists the worker to conduct the reflection of the pharmacovigilance system which can be evaluated based on the facility, comprehensive process, and outcome. Therefore, the manual is suitable to be used as a reference to evaluate the current state of pharmacovigilance establishment in Indonesia (WHO, 2015).

With a population of 256 million people, Indonesia has become a large size potential market for drugs, traditional medicine, and cosmetics. In 2021, The National Agency for Food and Drug Control of Indonesia (NA-FDA) accepted marketing authorization document for 16,729 prescription and non-prescription drug, 9,263 traditional medicines, 3,626 health supplement, and 96.611 cosmetics, which are increasing annually, especially during the COVID-19 pandemic (Direktorat Pengawasan Obat Tradisional dan Suplemen Kesehatan, 2019; Direktorat Registrasi Obat BPOM RI, 2020). A comprehensive pharmacovigilance evaluation is critical in identifying and overcoming challenges, in order to assure product safety and especially due to the potential of Indonesia as a market and a huge number of emerging new products. Hence, this article will evaluate the current pharmacovigilance establishment in Indonesia in accordance with indicators stated in the manual published by WHO. Furthermore, we will identify the possible solutions to fill the recognized gap in the establishment and overcome the challenges.

METHOD

The indicators described in the assessment manual are grouped into Core Structural (CS), Core Process (CP), and Core Outcome (CO). Evidence for each indicator was investigated individually and determined based on findings in either the Indonesian pharmacovigilance related regulations and documents found in a public website that frequently disseminate information regarding pharmacovigilance activities. Main reference websites were the NA-FDA main website (https://www.pom.go.id/new/) and the website for drug' side effect monitoring or E-MESO (https://e-meso.pom.go.id/subsite/). Documents from both websites which are bulletins for Drugs' side effect Monitoring, and Pharmacovigilance Modules from E-MESO website, and also The Annual Report of the Directorate of Supervision of Traditional Medicines and Health Supplement, and Directorate of Drugs' Security, Quality and Export-Import Supervision from 2017 until 2021. Taken action regarding pharmacovigilance decisions which are published in safety communication page on the E-MESO website and NA-FDA's clarification page on the main NA-FDA website (https://www.pom.go.id/new/browse/more/klarifikasi) was summarized into a table. Furthermore, each taken action was analyzed to determine whether or not it was taken based on national pharmacovigilance activities and as a part of post-marketing surveillance (PMS) activity. This information was used to provide evidence for CO2 and CP9 indicators. Recent regulations regarding pharmacovigilance are including Regulation of the Food and Drug Supervisory Agency Number 26 and 80 of 2017' issued by the President of the Republic of Indonesia (2017a and 2017b). Other documents utilized are curriculum related to demonstrating the incorporation of pharmacovigilance into the national curriculum of the various healthcare professions including medical doctor, dentist, nurse, midwife, and pharmacist (CST8). Evidence for indicators other than those previously mentioned were obtained by directly citing the documents.

The summary of the evidence was Illustrated as a table with a format and sequence similar to the representation shown in the WHO assessment manual. Furthermore, indicators with low or no compliance evidence were considered challenges and several solutions addressing these challenges were investigated and elaborated.

RESULTS AND DISCUSSION

Pharmacovigilance system in Indonesia

Based on the Guideline for good pharmacovigilance practices (GVP) published by European Medicines Agency (EMA), competent authorities shall establish a system of process and quality assurance to implement pharmacovigilance to achieve objectives, including evaluation of acquired data, data processing and management, independence in conducting pharmacovigilance, effective communication, establishing effective communication with parties involved (patients, healthcare professionals (HCPs), marketing authorisation holders

and the general public), and conducting inspections (pre-authorisation inspections and post-marketing inspections) (European Medicines Agency, 2012).

The drug and food control system, including pharmacovigilance in Indonesia, is mainly carried out by the NA-FDA, as the legal authority, which doubles as the executor and supervisor of the implementation of pharmacovigilance by health professionals and pharmaceutical industries. Several efforts that NA-FDA has made as the implementation of pharmacovigilance, including the provision of ADR and SE reporting systems. Most incidence found by involved parties were reported to NA-FDA by filling a form in the e-MESO website which also provide information related to the number of monthly reported cases, additional risk minimization measure of recently released drugs, recent findings related to drugs safety , and annual profile of side effects and adverse drug reactions (ADRs) (RI, 2022b, 2022a).

The actions taken based on the local and foreign signals are illustrated in the case of policresulen and ranitidine withdrawal respectively. Policresulen ADR had been investigated two years before the withdrawal. Thirty-eight cases related towards side effects of policresulen had been reported, including canker sore, which developed into noma like lession. After conducted further drug safety research in collaboration with clinical and pharmacology experts, NA-FDA decided that policresulen could not be used for antiseptic and haemostatic to treat ENT-related diseases, stomatitis aftosa, and odontological disease. Market authorization of policresulen was revoked, and the manufacturer should withdraw all products marketed within a month after the instruction was officially made. All professionals were instructed to stop the administration of policresulen and report customer' complaint related to the utilization of policresulen.

Another case of pharmacovigilance action taken was related to ranitidine. On 13 September 2019, US-FDA published a warning about the discovery of carcinogenic impurities, N-nitroso dimethylamine (NDMA), in products containing ranitidine. Preliminary information regarding the finding was published by NA-FDA in 17 September 2019. In 4 October 2019, NA-FDA released an instruction to all pharmaceutical industries and distribution regarding the termination of production and withdrawal of ranitidine-containing product that has NDMA impurities above the acceptable concentration. NA-FDA and the pharmaceutical industries conducted NDMA testing for the further decision regarding ranitidine-containing product market authorization. In November 2019, several ranitidine-containing products were allowed to be in the market after proving that the NDMA content is under the allowed maximum concentration (Rufaidah, 2020; RI, 2022d, no date).

From the cases presented above it can be concluded that the overall pharmacovigilance process is complete, consisting of receiving signal reports, causality assessment, evidence-based decision-making, information dissemination, compliance assessment, and regulatory update. The process in ADR/SE report organization, acknowledgement, causality analysis, and response are also described in the E-MESO user manual and the annual report of the Directorate of safety, quality, and export-import supervision of drugs and narcotics reports. Every pharmaceutical industry is responsible for conducting pharmacovigilance through a dedicated system that should be reported to the NA-FDA frequently, proven by the increasing number of reporting industries annually. In conclusion, most of the process related to pharmacovigilance has been established, demonstrating the compliance of CST 7.

Evidence regarding WHO pharmacovigilance assessment indicators

The summary of indicator compliance evidence can be seen in table 1. In the Core Structural category, compliance evidence for two indicators, namely the existence of a standard reporting form for reporting therapeutic ineffectiveness and suspected medication errors, could not be found on any official website. CST 1-5, 7, and 9-10 compliance evidence can be found on the NA-FDA's website, national regulations, and annual report of NA-FDA. For CST6, the evidence was obtained by searching websites to report each mentioned subset of indicators. Meanwhile, the compliance evidence for CST8 was obtained from the educational curriculum for each HCPs. In the Core Process category, most of the evidence could be found in the recent bulletins, annual reports, and E-MESO website manual book. For

CP2 and CP9, the evidence was summarized from the most recent five annual reports (2017-2021), which can be seen in graph 1 and table 2, respectively. Evidence regarding the percentage of total reports attributed to therapeutic ineffectiveness and medication errors received in the previous calendar year (CP6-7) could not be found on any official and accessible website.

Most of the evidence for the core outcome category was found in the list of regulatory actions from the last five NA-FDA annual report, which is summarized in table 3. The explanation of each action taken are described in the safety communication and the NA-FDA website. Evidence regarding the number of medicine-related hospital admissions per 1000 admissions and the number of medicine-related deaths per 1000 persons served by the hospital per year (CO3-8) could not be found on any publicly accessible website. The number in the evidence column for CO1 was derived from the total number of signal identification in each actions taken by the NA-FDA. According to the manual, a signal is defined as: ”reported information on a possible causal relationship between an adverse event and a drug, the relationship being previously unknown or incompletely documented. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. In this document, signal refers to a previously unreported ADR, problems of use and poor-quality medicines". Based on the definition, the evidence of a previously unknown drug response in the taken action elaboration is considered a signal. The causality approval was based on the action taken, which indicates the acknowledgement of a causal relationship between the drug and the response. The evidence for CO2 indicator was derived from the categorization of taken action into a label, safety warning for HCPs or direct healthcare professional communication (DHPC), public safety warning, product withdrawal, and other restrictions **Graph 2**. The number of taken action in each category was cumulated based on the year of occurrence.

Identified challenge and possible solutions regarding pharmacovigilance establishment in Indonesia

The result of WHO pharmacovigilance indicators analysis reveals that the number of actions taken is very low and most of them are the manifestation of foreign signals, which is 39 compared to 5 **Table III**. This might be due to the low number of the total annual report (<10.000), especially from the country with approximately 250 million population. The number of reports regarding herbals is more critical since the number of reports in 2021 is only 65 (RI, 2018; Tradisional and Kesehatandan Suplemen, 2018; Direktorat Pengawasan Obat Tradisional dan Suplemen Kesehatan, 2019, 2020). Compared to the ratio of the number of marketed traditional drugs and conventional drugs, the reports number of the herbals theoretically should be at least half of the conventional drugs. The low report number does not indicate the low occurrence of ADR/SE since the case of herbals containing active pharmaceutical ingredients is high, which theoretically should cause more side effects since it was consumed more frequently or irregularly (Nurbaiti, 2017; Ulya, 2020). These reports number are closely related to the pharmacovigilance activity of HCPs and pharmaceutical industries.

To obtain marketing authorization every pharmaceutical industry should report regarding their pharmacovigilance system activities and findings. In 2021 the number of pharmaceutical industries that conduct pharmacovigilance activities increased annually which could be related to the increasing number of ADR/SE report from the industry, from 1798 reports in 2020 to 3849 in 2021. Compared to conventional medicine industries, implementation of the pharmacovigilance system and surveillance from NA-FDA in the herbals industry is still low which should be at least similar to those of conventional drugs, including for micro and small herbal industries.

The low report number is also related to the analysis of CST8 indicator results, which reveal that although most of the education curricula of HCPs had included pharmacovigilance, most of the HCP still have a low depth of pharmacovigilance comprehension, low level of

ADR-reporting skills, and lack of practical knowledge, combined with the probability of unsupportive attitude such as ignorance, frightened by legal liability, and lack of importance awareness (Kudri and Barliana, 2018; Lovia, 2019). Foreseeing, recognizing, managing, and reporting ADRs are critical parts of rational and safe prescribing since drugs are indispensable in every HCP work activity (Reumerman et al., 2018). Based on a qualitative study regarding Nurse' Knowledge of ADR, and the curriculum of medical doctor, midwife, pharmacist, dentist, and nurse, it can be concluded that most HCPs receives lectures about drug response assessment and therapeutic monitoring, but still lack of experience in identifying response as side effect or ADRs. Current dissemination of pharmacovigilance in class mostly through non-interactive power-point lectures which inadequately equipped the students with necessary analytical thinking and legal procedure knowledge to be implemented during daily practice as HCPs. A research about the study method for pharmacovigilance discovered that previous training or experience in reporting ADRs increases the student's knowledge significantly. In addition, clinical experience is considered more educational compared to lectures and solving fictional cases (Yardley, 2012; Dekker et al., 2015; Brinkman et al., 2017; Schutte et al., 2017). These methods can improve students' awareness of the importance of reporting ADRs since the perception of the ADRs is more realistic, which will improve their consideration in choosing and prescribing drugs. The students' knowledge awareness and knowledge might significantly improve after the training. The training should be maintained by frequent dissemination throughout academic training as early as possible in the undergraduate phase. Hence, the knowledge gap and unsupportive attitude related to pharmacovigilance can be reduced significantly and persistently.

In the case of traditional medicine, the involvement of the general public in ADRs or side effects should be encouraged since most of the traditional medicine utilization is for self-medication, which is not directly supervised by HCPs. In addition, most traditional medicine can be obtained in a public market which does not provide a healthcare professional to consult with. Therefore, the general public is required to be more active in reporting ADR/SE. To enhance their awareness and knowledge in reporting ADR/SE. A consumer guideline in the form of a written manual and audio video, which can be published on social media, is a feasible method. The presentation of the educational material can be in a short clip or with an illustration which should be easily understood. This can be challenging since Indonesia is categorized as a country with a low literacy rate, requiring innovations in disseminating information. The general public should comprehend the ADRs definition, how to report ADRs, and the importance of reporting them, and make them realize that their report is a meaningful contribution that will protect others and future generations. A creative and frequent advertisement shown on a television channel is one of the effective ways to disseminate information since most Indonesian spend their leisure time watching television. A simple and responsive report system might improve the willingness of the citizens to report since most of Indonesians have low technology literacy and appreciate if they are sincerely heard.

The utilization of illegal medicine and herbals are highly possible because of the wide availability of the products, which is supported by the marketplace and manufacturers (Wardhani, no date; Online, 2017; Aria, 2018; dinkes purbalingga, 2019; Farmasetika, 2019; RI, 2019b), especially in the era of 4.0 which enabling people to buy things online. This cause the supervision of products for sale in both online and offline store to be critical. One of the possible solutions is to give an online store an NA-FDA recommendation which can differentiate store that has been proven to sell only original and high-quality products, especially for herbals and cosmetics. The criteria for obtaining the recommendations is including the legality and quality of the product for sale, reliable advertisement, and good management. The collaboration between NA-FDA and e-commerces brings through the possibility to insert the recommendation logo on the authorized store webpage. Overall the process is similar to opening a drug store that sells products including OTC, herbals, and skincare. The extension of the recommendation period validity can be obtained by reporting the history of selling products which should show only legal products. These approaches are

a feasible methods that can urge the seller to be more aware of the product they sell, and it is expected that the recommendation logo can guide the customer to choose a responsible store which can implicate the selling improvement of the recommended store.

ADRs and side effects might cause hospitalization or even death. In the USA, ADRs were one of the leading mortality causes following ischemic cardiopathy, cancer, and stroke. The indicators related to this are CP6-7 and CO3-8, suggesting the review of drug's effectiveness review and harmful effect, and effective mechanisms to ensure the safe use of the medicine. The benefit and risk of drug should be assessed continuedly, especially during PMS. Therefore, a system to collect data related to medicine administration and its effect is necessary for risk management since the benefit can be obtained through a correct administration and the harmful effect can be prevented by careful and thoughtful medicine utilization and prescription. Currently, therapeutic drug monitoring (TDM) has become a standard clinical practice which should be conducted for the long term, including for outpatient and chronic disease treatment. The therapy response should be assessed and put into the personal medical record which are integrated with a single-centred database operated by the government. The single-centered database collects data from every healthcare facility which provide complete personal medical record although the patient changes healthcare facility. Hence, the accumulated data can be used as the basis of a particular medicine's effectiveness and medication error assessment. Building the assessment or reporting system for the identification of medication error and drugs ineffectiveness requires more resources, including facilities, infrastructures, and human resources. Meanwhile, current number of resources of both Directorates of traditional medicine surveillance and Directorate of safety, quality, and export-import supervision of drugs and narcotics are still short on staff. This is based on the analysis of workload, which is still almost 50% shortage. In addition, in the 2021 annual report, budget realization is already above 90%. which indicatse more resources are required to establish comprehensive pharmacovigilance (RI, 2021b).

One of the urgencies of pharmacovigilance system improvement is due to the financial instability of Social Security Agency of Health or BPJS. Since the establishment of BPJS in 2014 until 2020, the condition of national Health Social Security Agency (BPJS), which is aimed to ensure health accessibility for the low-to-middle economic class, is still unsustainable due to the fiscal imbalance. This is caused by high expense which is not covered by the citizens' mandatory monthly insurance premium (Pratama, 2020; Bineraksi, 2021). Effective prevention and management of both communicable and non-communicable diseases are one of the solutions to decrease BPJS' budget, which is closely related to the performance of pharmacovigilance system. Therefore, all of the mentioned efforts in improving pharmacovigilance are necessary and should be considered as an investment because the occurrence of ADRs is always possible in every drug administration, and it may contribute to unnecessary hospitalization, which increases patient and healthcare system burden.

Table I. The Summary of Indicator Compliance Evidence.

No		Indicators	Found Data	References
Core structural indicators				
1	CST1	Existence of a pharmacovigilance center, department or unit with a standard accommodation	National center for Pharmacovigilance: The National Agency of Drug and Food Control (NA-DFC), specifically, directorate of safety, quality, and export-import supervision of drugs, narcotics reports. Pharmacovigilance in the region was held by pharmacovigilance center in 22	(BPOM, 2020; RI, 2022c)

			regions including Jakarta, Bandung, Medan, Palembang, Semarang, Serang, Surabaya, Yogyakarta, Ambon, Aceh, Mataram, Padang, Makassar, Denpasar, Manado, Pekanbaru, Kendari, Jayapura, Kupang, Samarinda, Banjarmasin, dan Bandar Lampung.	
2	CST2	Existence of a statutory provision (national policy, legislation) for pharmacovigilance	Statutory and the responsibilities of Indonesian Na-FDC is clearly stated in the regulation.	(Presiden Republik Indonesia, 2017b, 2017a)
3	CST3	Existence of a medicine's regulatory authority or agency	It is clearly stated in the regulation of the president of the republic of Indonesia number 80-year 2017 that NA-FDC of Indonesia is responsible and has rights to conduct drug surveillance during pre- and post-marketing.	(Presiden Republik Indonesia, 2017b, 2017a)
4	CST4	Existence of any regular financial provision (e.g. statutory budget) for the pharmacovigilance center	in the NA-FDC annual report year 2021, directorate of safety, quality, and export-import supervision of drugs, narcotics reports. received Rp 7,480,765,000 and the budget realization was Rp. 7,476,944,507.	(RI, 2021b)
5	CST5	The pharmacovigilance center has human resources to carry out its functions properly	in the NA-FDC annual report year 2021, The human resource is 59, which is still short of staff according to workload analysis which resulted in the requirement of 114 staff.	(RI, 2021b)
6	CST6	CST6. Existence of a standard ADR reporting form in the setting		
	Subset indicators: The standard reporting form provides for reporting:			
	CST6a	CST6a: suspected medication errors;	Currently, the system for reporting suspected medication errors and therapeutic ineffectiveness is not clear. The current report system mainly focuses on the occurrence of adverse drug reactions and side effects.	N/A

	CST6b	CST6b: suspected counterfeit/substandard medicines;	Contact for counterfeit drug report submission: https://www.pom.go.id/new/browse/more/issue/12/6	-
	CST6c	CST6c: therapeutic ineffectiveness;	Currently the system for reporting suspected medication errors and therapeutic ineffectiveness is not clear. Current report system mainly focusses on the occurrence of adverse drug reaction and side effect	N/A
	CST6d	CST6d: suspected misuse, abuse of and/or dependence on medicines;	Website for suspected misuse, abuse of and dependence on medicines report submission: https://bnn.go.id/satuan-kerja/ittama/pengaduan/	-
	CST6e	CST6e: ADRs by members of the general public	Current report system mainly focusses on the occurrence of adverse drug reaction and side effect, which can be accessed only by a healthcare professional both in the healthcare facility or pharmaceutical industry. The public can report ADR/SE by contacting the related drug manufacturer or the healthcare professional who is able to fill out the form in the national ADR/SE monitoring website.(for ex: https://www.otsuka.co.id/sideeffect)	-
7	CST7	CST7. A process is in place for collection, recording and analysis of ADR reports	The process was described in the annual report and the manual book of the national ADR/SE monitoring website. The national pharmacovigilance center will receive and evaluate each submitted report based on the form completion and ADR/SE validity. all reports will be acknowledged, and each report will be replied to according to the completion of the form. each reporter will be asked to complete the form to continue the causality analysis process, and the confirmed result will be sent to WHO.	(BPOM, 2020; RI, 2021b, 2022a)
8	CST8	CST8. Incorporation of pharmacovigilance into the national curriculum of the various health-care professions (includes subset indicators:		
	CST8a	CST8a: for medical doctors;	Pharmacovigilance as part of the pharmacology to identify ADR/SE	(Riset et al., 2020)

			but not including reporting to NA-FDC	
	CST8b	CST8b: for dentists;	Pharmacovigilance as part of the pharmacology to identify ADR/SE but not including reporting to NA-FDC	(Riset, Dan and Tinggi, 2020b)
	CST8c	CST8c: for pharmacists;	Pharmacovigilance as one of the main components of pharmaceutical service practice which including ADR/SE report to NA-FDC	(JURUSAN FARMASI – Fakultas Kedokteran Universitas BrawijaYA, 2018; Kudri and Barliana, 2018)
	CST8d	CST8d: for nurses or midwives;	Pharmacovigilance as part of the pharmacology to identify ADR/SE but not including reporting to NA-FDC	(Lovia, 2019; Riset, Dan and Tinggi, 2020a)
	CST8e	CST8e: for others - to be specified)	Pharmacovigilance as part of the pharmacology to identify ADR/SE but not including reporting to NA-FDC	
9	CST9	CST9. Existence of a newsletter, information bulletin or website for dissemination of pharmacovigilance information	Bulletin and safety communication which can be accessed on the website: https://e-meso.pom.go.id/subsite/ . The bulletin is published twice annually	(RI, 2021a)
10	CST10	CST10. Existence of a national ADR or pharmacovigilance advisory committee or an expert committee in the setting capable of providing advice on medicine safety	Causality analysis involving the committee of side effect review which consist of pharmacology expertise and a representative from a professional organization which include medical doctor association and medical specialist association. The list of Side effect monitoring experts: dr. Wawaimuli Arozal, M. Biomed, PhD; dr. Nafrialdi, SpPD, SpFK, PhD; dr. Instiaty, PhD, Sp.FK; dr. Vivian Soetikno, Ph.D., Sp.FK; Dr. dr. Evy Yunihastuti, Sp.PD, K-Al, FINASIM; Prof. Dr. dr. Suhardjono, Sp.PD-KGH, KGer; dr. Anshari Saifuddin, SpPD; Dr. dr. Prasetyadi Mawardi, Sp. KK(K),	(RI, 2021a)

			FINSDV, FAADV; dr. Roro Inge Ade Krisanti, Sp. KK(K), FINSDV, FAADV; dr. Daniel P. L. Tobing, Sp.JP(K), FIHA; Prof. Dr. Hindra Irawan Satari, dr., Sp.A(K)., M.Trop.Paed; Dr. dr. Julitasari Sundoro, MSc-PH; Dr. apt. Yusransyah, M.Sc; Dr. apt Rina Mutiara, M. Pharm.	
Core process indicators				
11	CP1	Total number of ADR reports received in the previous calendar year (also expressed as number of ADRs per 100 000 persons in the population)	8.691 reports from the total population of approximately 269,603,400 (https://www.bps.go.id/indicator/12/1886/1/jumlah-penduduk-hasil-proyeksi-menurut-provinsi-dan-jenis-kelamin.html)	(RI, 2021b)
12	CP2	Current total number of reports in the national, regional or local database	National: 33,233 (1 January 2017 - 5 October 2022)	(RI, 2017, 2018, 2019a, 2020, 2021b)
13	CP3	Percentage of total annual reports acknowledged and/or issued feedback	100%	(RI, 2021b, 2022a)
14	CP4	Percentage of total reports subjected to causality assessment in the previous calendar year	91.72%	(RI, 2021b)
15	CP5	Percentage of total annual reports satisfactorily completed and submitted to the national pharmacovigilance center in the previous calendar year		
	CP5a	Subset indicator CP5a: of the reports satisfactorily completed and submitted to the national pharmacovigilance center, percentage of reports committed to the WHO database	24% reports and committed to the WHO (2021)	(RI, 2021a)

16	CP6	Percentage of total reports attributed to therapeutic ineffectiveness received in the previous calendar year	Not Available	N/A
17	CP7	Percentage of reports on medication errors reported in the previous year	Not Available	N/A
18	CP8	Percentage of registered pharmaceutical companies having a functional pharmacovigilance system	60% (130 from the total of 206 in 2019), additional 33 and 24 industries have reported the Pharmacovigilance activity in 2020 and 2021 respectively.	(RI, 2019a)
19	CP9	Number of active surveillance activities initiated, ongoing or completed during the past five calendar years	12 PMS and 1 CEM (2017 - 2021)	(RI, 2017, 2018, 2019a, 2020, 2021b)
Core outcome or impact indicators				
20	CO1	Number of signals detected in the past 5 years by the pharmacovigilance center	Year 2021: signal from local = 0, foreign = 10 Active substance	(RI, 2017, 2018, 2019a, 2020, 2021b)
21	CO2	Number of regulatory actions taken in the preceding year as a consequence of national pharmacovigilance activities includes		
	CO2a	number of product label changes (variation)	3	(RI, 2017, 2018, 2019a, 2020, 2021b)
	CO2b	number of safety warnings on medicines to: (i) health professionals, (ii) general public	12	(RI, 2017, 2018, 2019a, 2020, 2021b)

	CO2c	number of withdrawals of medicines	0	(RI, 2017, 2018, 2019a, 2020, 2021b)
	CO2d	number of other restrictions on use of medicines	2	(RI, 2017, 2018, 2019a, 2020, 2021b)
22	CO3	Number of medicine-related hospital admissions per 1000 admissions	Not Available	N/A
21	CO4	Number of medicine-related deaths per 1000 persons served by the hospital per year	Not Available	N/A
22	CO5	Number of medicine-related deaths per 100 000 persons in the population	Not Available	N/A
23	CO6	Average cost (US$) of treatment of medicine-related illness	Not Available	N/A
24	CO7	Average duration (days) of medicine-related extension of hospital stay	Not Available	N/A
25	CO8	Average cost (US$) of medicine-related hospitalization	Not Available	N/A

Table II. Summary of pharmacovigilance deduced from taken action

No	Year	Drug Substance	Discovery or Description	Reference
1	2022	Paxlovid	every manufacturer that are granted Emergency use Authorization should conduct Post Authorization Safety Study /PASS	https://www.pom.go.id/new/view/more/pers/655/Badan-POM-Terbitkan-Emergency-Use Authorization-

				Paxlovid--Sebagai-Obat-COVID-19.html
2	2022	Molnupiravir	every manufacturer that are granted Emergency use Authorization should conduct Post Authorization Safety Study /PASS	https://www.pom.go.id/new/view/more/pers/636/SIARAN-PERS-Badan-POM-Terbitkan-Emergency-Use-Authorization-untuk-Obat-Molnupiravir.html
3	2022	Covovax	every manufacturer that are granted Emergency use Authorization should conduct Post Authorization Safety Study /PASS	https://menpan.go.id/site/berita-terkini/bpom-terbitkan-izin-penggunaan-darurat-untuk-vaksin-covovax
4	2021	Favipiravir	Result of Post-Marketing Surveillance: Safety evaluation and drug effectiveness of favipiravir in patients COVID-19 after EUA granted from NA-FDA	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
5	2021	Remdesivir	Result of Post-Marketing Surveillance: Safety evaluation and drug effectiveness of Remdesivir in patients COVID-19 after EUA granted from NA-FDA	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
6	2020	Dexamethasone	Administration of Dexamethasone lower mortality only in severe case COVID-19	https://www.pom.go.id/new/view/more/klarifikasi/117/PENJELASAN-BADAN-POM-RI-TENTANG--INFORMASI-PENGGUNAAN-DEKSAMETASON--PADA-PENYAKIT-NEW-CORONA-VIRUS-2019--COVID-19-.html
7	2019	Carbimazole / Thiamazole	Result of Post-Marketing Surveillance: Risk for acute pancreatitis and risk updates during pregnancy.	https://e-meso.pom.go.id/web/useruploads/images/5e0aa9456b1e2_Buletin%20Berita%20MESO%20Vol.%2037%20No.

				%202%20Edisi%20November%202019.pdf
8	2019	Tocilizumab	Result of Post-Marketing Surveillance: Risk of hepatotoxicity	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJSZ
9	2019	Atezolizumab	Result of Post-Marketing Surveillance: Risk of immune-associated myositis	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJSa
10	2018	Nintedanib	Result of Post-Marketing Surveillance: Safety information regarding severe liver injury and the mandatory regular liver function monitoring related to use Ofev (Nintedanib) in patients Idiopathic Pulmonary Fibrosis (IPF).	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5yc
11	2017	Transtuzumab	risk of Dupuytren's contracture and plantar fascial fibromatosis	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5qV
12	2017	Bendamustine Hydrochloride	DPHC from PT Roche related to Increasing Mortality risk	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5ub

Table III. Summary of taken action for the last 5 years

No	Year	Drug Substance	Discovery or Description	Regulatory actions	Category / Signal Source	Reference
1	2022	Paxlovid	Every manufacturer that is granted Emergency use Authorization should conduct Post Authorization Safety Study /PASS.	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1210629060442--Buletin%20Vol.%2039%20Edisi%20Juni%202021.pdf
2	2022	Molnupiravir	Every manufacturer that is granted Emergency use Authorization should conduct Post Authorization Safety Study /PASS.	assisting Post Authorization Safety Study /PASS including drafting study and statistic analysis training protocol. 2. Dissemination of information through MESO News Bulletin.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
3	2022	Covovax	Every manufacturer that are granted Emergency use Authorization should conduct Post	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	N/A

			Authorization Safety Study /PASS.			
4	2021	Favipiravir	Result of Post-Marketing Surveillance: Safety evaluation and drug effectiveness of favipiravir in patients COVID-19 after EUA granted from NA-FDA.	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJaX
5	2021	Remdesivir	Result of Post-Marketing Surveillance: Safety evaluation and drug effectiveness of Remdesivir in patients COVID-19 after EUA granted from NA-FDA.	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/120/PENJELASAN-BADAN-POM-RI-TENTANG--KEAMANAN-PRODUK-METFORMIN.html
6	2020	Dexamethasone	Administration of Dexamethasone lower mortality only in severe case COVID-19.	-DHPC from the manufacturer and Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJiY

7	2019	Carbimazole / Thiamazole	Result of Post-Marketing Surveillance: Risk for acute pancreatitis and risk updates during pregnancy.	-DHPC from the manufacturer and Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJac
8	2019	Tocilizumab	Result of Post-Marketing Surveillance: Risk of hepatotoxicity.	- Dissemination of security information through News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
9	2019	Atezolizumab	Result of Post-Marketing Surveillance: Risk of immune-associated myositis.	- Dissemination of security information through News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
10	2018	Nintedanib	Result of Post-Marketing Surveillance: Safety information regarding severe liver injury and the mandatory regular liver function monitoring related to use Ofev (Nintedanib) in	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/117/PENJELASAN-BADAN-POM-RI-TENTANG--INFORMASI-PENGGUNAAN-DEKSAMETASON--PADA-PENYAKIT-NEW-CORONA-VIRUS-2019--COVID-19-.html

			patients Idiopathic Pulmonary Fibrosis (IPF).			
11	2017	Transtuzumab	risk of Dupuytren's contracture and plantar fascial fibromatosis.	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/111/PENJELASAN-BADAN-POM-RI--Tentang--Informasi-Keamanan-Penggunaan-Ibuprofen--Pada-Penyakit-New-Corona-Virus-2019--Covid-19-.html
12	2017	Bendamustine Hydrochloride	DPHC from PT Roche related to Increasing Mortality risk.	Risk Minimization Activities (RMinA)	DHCP / Foreign	
13	2020	Ibrutinib (imbruvica)	HBV reactivation and hepatic failure	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/5fc4801899eef_Buletin Berita MESO Vol 38 No.2 Edisi November 2020.pdf
14	2017	Ruxolitinib	-	Risk of peripheral neuropathy (signal from WHO-UMC Bulletin)	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5qb
15	2021	Eritromisin	Infantile Hypertrophic Pyloric Stenosis risk	- Dissemination of security information through News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf

16	2017	Gadolinium	-	Risk of drug retention in brain after repeated usage (foreign signal).	DHCP / Foreign	
17	2019	Infliximab	Mycosis fungoides risk	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	No link
18	2017	Ciprofloxacin and Enalapril Interaction	-	Increasing risk of kidney failure (signal from WHO-UMC Bulletin)	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5uT
19	2021	Non-Steroidal Anti Inflammatory Drugs (NSAIDs)	NSAID safety for pregnancy (20 weeks	- Dissemination of security information through News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
20	2021	Atorolimumab	Severe drug eruption risk	-DHPC from the manufacturer and Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJaa
21	2021	Docetaxel	Tumor Lysis Syndrome and Myositis risk	- Dissemination of security information through News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--

						Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
22	2020	Montelukast	Serious neuropsychiatric risk	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/5fc4801899eef_Buletin%20Berita%20MESO%20Vol%2038%20No.2%20Edisi%20November%202020.pdf
23	2020	Emicizumab (Hemlibra)	Microangiopathies thrombotic, thromboembolism and intervention in coagulation laboratory tests.	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJWa
24	2020	Cyproterone acetate	Meningioma risk	- Dissemination of security information through the News Bulletins MESO.	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/files/reference/cyproterone%201.pdf
25	2020	Angiotensin Converting Enzyme Inhibitor (ACE-i) And Angiotensin II Receptor Blocker (ARB)	Safety Information	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO.	DHCP / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/112/PENJELASAN-BADAN-POM-RI--Tentang--Informasi-Keamanan-Penggunaan-Obat--Golongan-Angiotensin-Converting-Enzyme-Inhibitor--ACE-i---dan-Angiotensin-II-Receptor-Blocker--ARB---Pada-Kondisi-Pandemi-Penyakit-New-Corona-Virus-2019--COVID-19-.html

26	2021	Selective Serotonin Reuptake Inhibitor (SSRI), Serotonin - Norepinephrine Reuptake Inhibitors (SNRI)	Risk of postpartum hemorrhage	1. Further Safety Investigation 2. Dissemination of security information via the MESO News Bulletin, and website (https://www.pom.go.id, and https://e-meso.pom.go.id)	DHCP / Foreign	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
27	2019	Carbimazole / Thiamazole	Risk for acute pancreatitis and risk updates during pregnancy	- Update labels (update product information) related to the risk. - Publication of safety information for health workers in Direct Healthcare form Professional Communications (DHPC) by product manufacturer. - Dissemination of safety information through the e-meso.pom.go.id subsite, and the MESO News Bulletin.	Label/ Foreign	https://e-meso.pom.go.id/web/useruploads/images/5e0aa9456b1e2_Buletin%20Berita%20MESO%20Vol.%2037%20No.%202%20Edisi%20November%202019.pdf
28	2018	Gadolinium	-	Early safety warning publication related to Risk of drug retention in brain after repeated usage.	Label/ Foreign	https://e-meso.pom.go.id/web/useruploads/uploaded_pdf/en/5b57e0b326386_Gadolinium%20dan%20risiko%20retensi%20pada%20jaringan%20otak.pdf

29	2019	Tocilizumab	Risk of hepatotoxicity	- Update labels (update product information) related to the risk- Publication of safety information for health workers in Direct Healthcare form Professional Communications (DHPC) by product manufacturer- Dissemination of safety information through the e-meso.pom.go.id subsite, and the MESO News Bulletin.	Label/ Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJSZ
30	2017	Bendamustine Hydrochloride	Ribomustine	DPHC from PT Roche related to Increasing Mortality risk.	Label/ Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5ub
31	2019	Atezolizumab	Immune-related myositis risk	-Update labels (updating product information) related to the risk - Distribution of security information for health workers in the form of Direct Healthcare Professional Communications (DHPC) by product owner - Dissemination of security information through the e-meso.pom.go.id subsite, and the MESO News Bulletin	Label/ Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJSa

32	2017	Dengue vaccine	Dengvaxia	Temporary termination due to increasing risk of hospitalization	Other Restriction / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/45/KLARIFIKASI-BADAN-POM-TERKAIT-BEREDARNYA-ISU--PRODUK-OBAT-PARASETAMOL-YANG-MENGANDUNG-VIRUS-BERBAHAYA.html
33	2017	Vemurafenib	Zelboraf	risk of Dupuytren's contracture and plantar fascial fibromatosis	Other Restriction / Foreign	https://e-meso.pom.go.id/web/useruploads/uploaded_pdf/ind/594733aa1281a_Safety%20Communication%20DHPC%20Zelboraf%20(Vemurafenib).PDF
34	2021	COVID-19 m-RNA vaccine	Risk of myocarditis and pericarditis	1. Update information on the Moderna COVID-19 Vaccine Factsheet which linked to risk of blood clotting2. Dissemination of security information via the MESO News Bulletin, website https://www.pom.go.id, and https://e-meso.pom.go.id	Other Restriction / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/128/PENJELASAN-BADAN-POM-RI-TENTANG--INFORMASI-LEBIH-LANJUT-KEAMANAN-VAKSIN-COVID-19-ASTRAZENECA.html
35	2021	Covid-19 vaccine Astrazeneca	Blood Clot risk	1. Update information on the Astrazeneca COVID-19 Vaccine Factsheet which linked to risk of blood clotting 2. Dissemination of security information via the MESO News Bulletin, website https://www.pom.go.id, and https://e-meso.pom.go.id	Other Restriction / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/127/PENJELASAN-BADAN-POM-RI-TENTANG-INFORMASI-KEAMANAN-VAKSIN-COVID-19-ASTRAZENECA.html

36	2021	Covid-19 vaccine Astrazeneca	Fatal or severe immune reaction after the administration of COVID-19 vaccine from Astrazeneca batch CTMAV547	1. Sampling and quality testing of AstrazenecaCOVID-19 Vaccine batch CTMAV547 was carried out 2. Coordination with Ministry of Health, Provincial -FDA related to temporary suspension on distribution and use of Astrazeneca vaccines COVID-19 batch CTMAV547 3. Dissemination of security information via the MESO News Bulletin, website https://www.pom.go.id, and https://e-meso.pom.go.id	Other Restriction / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJab
37	2020	Chloroquine and Hydroxychloroquine	Risk of heart malfunction	- Implementation of the evaluation safety study of chloroquine and Hydroxychloroquine administration in COVID-19 patients. - Revocation of Emergency Use Authorization - Dissemination of POM Agency explanations through the website www.pom.go.id and MESO News Bulletin	Other Restriction / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/121/PENJELASAN-BADAN-POM-RI-TENTANG-Pencabutan-Emergency-Use-Authorization-Hidroksiklorokuin-dan-Klorokuin-untuk-Pengobatan-COVID-19.html
38	2018	Explanation of NA-FDA on the active role of the community in drug and food control		Report analysis	Public / Foreign	https://www.pom.go.id/new/view/more/klarifikasi/75/PENJELASAN-BADAN-POM-RI--TENTANG-PERAN-AKTIF-MASYARAKAT-DALAM-PENGAWASAN-OBAT-DAN-MAKANAN.html

39	2020	Ulipristal acetate (Esmya)	Risk of serious liver injury in which in some cases need a liver transplant.	- Cancellation of marketing authorization - Voluntary withdrawal and extermination product - Distribution of security information for health workers in Direct Healthcare form Professional Communications (DHPC) by the product manufacturer. - Dissemination of security information through the e-meso.pom.go.id subsite, and the MESO News Bulletin.	Withdrawal / Foreign	https://e-meso.pom.go.id/web/useruploads/uploaded_pdf/ind/5e97fb9fb6421_DHCPL_Esmya_Ulipristal%20Acetate%205%20mg.pdf
40	2019	Angiotensin Receptor Blocker (ARB)	Withdrawal of antihypertensive drugs which uses materials raw Valsartan, Irbesartan, and Losartan production Zhejiang Hua Hai Pharmaceuticals, China, due to the presence of impurities Nitroso dimethylamine (NDMA)/ Nitrosodiethylamine (NDEA)	- stop Production and distribution of the drug as well as the withdrawal of the drug (Valsartan, Irbesartan, and Losartan) which use raw material from Zhejiang hua hai Pharmaceuticals, China - Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletin MESO	Withdrawal / Foreign	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJOW

41	2019	Hydrochlorothiazide	The risk of non-melanoma skin cancer	- Dissemination of safety information through the e-meso.pom.go.id subsite, and the MESO News Bulletin	DHCP / Local	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJST
42	2017	Rosuvastatin and Ticagrelor	Drug-drug Interaction	Rhabdomyolysis risk (signal from WHO-UMC Bulletin)	DHCP / Local	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5uU
43	2017	Ambroxol	-	Severe cutaneous adversereaction/SCARS and indication review for bronchial asthma	Label/ Local	https://e-meso.pom.go.id/web/useruploads/uploaded_pdf/ind/5923bff8ebd7c_Surat%20IDI%20Perbaikan%20Indikasi%20Ambroksol%20Hidroklorida.pdf
44	2018	Policresulen 36% concentrate	-	Product withdrawal and License suspension due to chemical burn risk on oral mucosa	Withdrawal / Local	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5uc
45	2019	Ranitidine	Nitroso dimethylamine (NDMA) impurities	- Temporary termination of production, product distribution - Withdrawals (voluntary and mandatory) Ranitidine containing drug products which have NDMA contamination exceeds the allowed	Withdrawal / Local	https://www.pom.go.id/new/view/more/klarifikasi/103/PENJELASAN-BADAN-POM-RI--TENTANG-PERKEMBANGAN-LEBIH-LANJUT-PENARIKAN-PRODUK-RANITIDIN--YANG-TERKONTAMINASI-N-

				threshold - Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO		NITROSODIMETHYLAMINE--NDMA-.html
46	2017	Artesunate	-	Reponses after the Occurrence of ADR	DHCP / -	file:///C:/Users/maodi/Downloads/592e989040b77_Follow%20Up%20Comunication%20Artesunate-2.pdf
47	2017	Loratadine dan Desloratadine	-	Weight Gain risk in children (signal from WHO-UMC Bulletin)	DHCP / -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5qc
48	2021	Remdesivir	Safety evaluation and drug effectiveness Remdesivir in patients COVID-19 after given Emergency Use Authorization (EUA)	assisting Post Authorization Safety Study /PASS including drafting study and statistic analysis training protocol 2. Dissemination of information through MESO News Bulletin	DHCP / -	https://e-meso.pom.go.id/web/useruploads/images/1211130121418--Buletin%20Berita%20MESO%20Edisi%20Nov%20(ok).pdf
49	2018	Methylprednisolone	-	information dissemination of hepatotoxicity after administration of Intravenous High-Dose Methylprednisolone	DHCP / -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaem

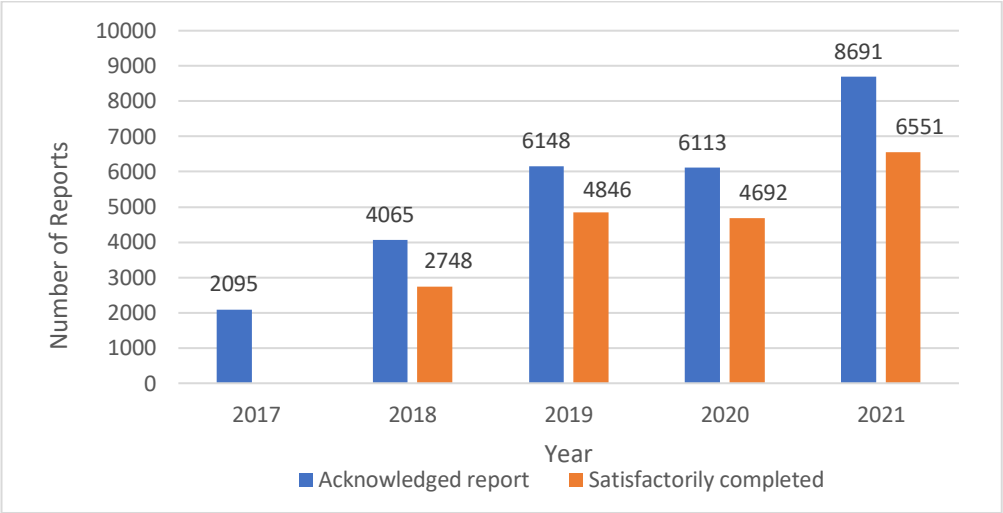
						ZekmaDRV3eY2MObol2V06WrzpdxZJOV
50	2021	Na-FDA Explanation on the Use of Ivermectin	COVID-19 Patient	Further clinical studies and the limit of expiration is 6 months	DHCP / -	https://www.pom.go.id/new/view/more/klarifikasi/136/PENJELASAN-BADAN-POM-RI-Tentang-Informasi-Penggunaan-Ivermectin.html
51	2018	irbesartan, losartan, Valsartan	Angiotensin receptor blocker(ARB) Withdrawal in Europe	Information dissemination	DHCP / -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJOW
52	2021	Metformin	Nitroso dimethylamine (NDMA) Impurities content above allowed concentration	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO	DHCP / -	No link
53	2017	Noscapine	-	Response of noscapine re-evaluation	DHCP / -	Not found
54	2018	Pirfenidone	risk minimization activity trough Safety Checklist	information dissemination of hepatotoxicity after administration of Intravenous High-Dose Methylprednisolone	DHCP / -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5yW

55	2018	Capecitabine	Recommended contraindications for patients who have a deficiency dihydropyrimidin e dehydrogenase (DPD) and addition of Warning and Attention regarding recommendations testing for DPD . deficiency based on local test availability and current guidelines"	PT Roche Indonesia convey Dear Healthcare Professional Communication(DHPC) for health workers professionals related to contraindication recommendations for patients who have dihydropyrimidine deficiency dehydrogenase (DPD) and Added Warning and Caution regarding recommendations testing for DPD . deficiency based on test availability local and current guidelines.	Label/ -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJOV
56	2020	Etonogestrel (Implanon NXT)	Update for application and removal of Implanon NXT to minimize deeper installation risk possible consequences, including rare occurrences in intravascular insertion and	- Dissemination of security information through the website www.pom.go.id, e meso.pom.go.id, and News Bulletins MESO	Label/ -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJWV

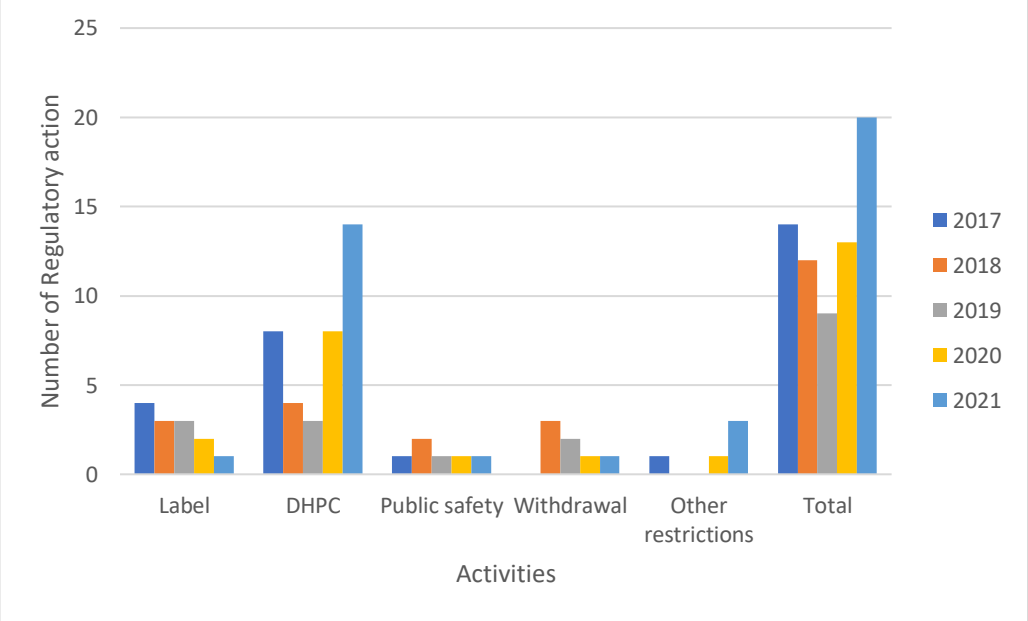
			neurovascular injury.			
57	2020	Pirfenidone (Esbriet)	on the use of chloroquine and	- Product information update - Distribution of security information for health workers in Direct Healthcare form Professional Communications (DHPC) by the product manufacturer - Dissemination of security information through the e-meso.pom.go.id subsite, and the MESO News Bulletin.	Label/ -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJWW
58	2021	Rituximab	Risk of off label use and error in subcutaneous formulation	1. Dissemination of Comparison Card for Subcutaneous Formulation dan Step by Step Guide for Subcutaneous Formulation From the drug manufacturer 2. Dissemination of security information through News Bulletins MESO	Label/ -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxZJaZ
59	2017	Transtuzumab	Herceptin	The importance of heart function monitoring	Label/ -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5qV
60	2018	Nintedanib		Safety Communication from PT Boehringer Ingelheim related to	Label/ -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJ

				Severe liver injury risk in Idiopathic Pulmonary Fibrosis (IPF)Patients		nEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5yc
61	2018	NA-FDA explanation concerning circulation of prescription drug sold online		Report analysis	Public / -	https://www.pom.go.id/new/view/more/klarifikasi/97/PENJELASAN-BPOM-RI-TENTANG-PEREDARAN-OBAT-KERAS-YANG-DIJUAL-ONLINE-DARING.html
62	2019	Vaccine	NA-FDA EXPLANATIONS About the correlation between Autism and Thiomersal Content in Vaccines	Safety communication WHO	Public / -	https://www.pom.go.id/new/view/more/klarifikasi/106/PENJELASAN-BADAN-POM-Tentang-Tidak-Ada-Kaitan-Autisme-Dengan-Kandungan-Thiomersal-Dalam-Vaksin.html
63	2017	Paracetamol	Fake News	NA-FDC Clarification	Public / -	https://www.pom.go.id/new/view/more/klarifikasi/45/KLARIFIKASI-BADAN-POM-TERKAIT-BEREDARNYA-ISU--PRODUK-OBAT-PARASETAMOL-YANG-MENGANDUNG-VIRUS-BERBAHAYA.html
64	2020	Explanation of Na-FDC About Herbal Products and Health Supplements		Explanation to use the product according to indications	Public / -	https://www.pom.go.id/new/view/more/klarifikasi/110/PENJELASAN-BADAN-POM-RI--Tentang-Produk-Herbal-dan-Suplemen-Kesehatan-Yang-Digunakan-

		Used to Help Maintain Body Endurance				Untuk-Membantu-Memelihara-Daya-Tahan-Tubuh.html
65	2020	Na-FDA Explanation Regarding the Issue of Herbal Products That Can Cure COVID-19 Patients		The NA-FDA Agency urges the public to be more careful and use herbal products safely and appropriately	Public / -	https://www.pom.go.id/new/view/more/klarifikasi/119/PENJELASAN-BADAN-POM-RI-Tentang-Isu-Produk-Herbal-yang-Dapat-Menyembuhkan-Pasien-COVID-19-.html
66	2018	Valsartan	Withdrawal of hypertension medication containing valsartan in Europe	Withdrawal of valsartan containing product and information dissemination in E-MESO website	Withdrawal / -	https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnEppWYxtLQoJOVlqeZnqJcnZWf2KCXcJqIn5ulp9KkdLiUmpfX3IN2o56eqKaemZekmaDRV3eY2MObol2V06WrzpdxY5yY
67	2018	Pancreatin		Contain pig's DNA	Withdrawal / -	https://www.pom.go.id/new/view/direct/daftar-recall



Graph 1. Annual Number of ADR/SE Reports (RI, 2017, 2018, 2019a, 2020, 2021b)



Graph 2. Annual Number of Regulatory Actions (RI, 2017, 2018, 2019a, 2020, 2021b)

CONCLUSION

From the result of the WHO pharmacovigilance indicator assessment, it can be concluded that the root of the current pharmacovigilance issues, reflected in the low number of annually taken actions, is the low number of reports which are highly dependent with the HCPs and industries pharmacovigilance competency. Improving their pharmacovigilance knowledge and comprehension, parallel with procurement of resources necessary to arrange the required system, including human resource are considered effective midterm goals as a part of the main purpose, which is attaining comprehensive pharmacovigilance system. Parallel development of online store recommendations and single-centred medical record can support NA-FDA in conducting a comprehensive pharmacovigilance system.

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REFERENCES

Aria, P. (2018) 'BPOM Perkirakan Kerugian Akibat Obat Palsu Rp 46 Miliar'. Available at: ttps://katadata.co.id/pingitaria/digital/5e9a55f7ee360/bpom-perkirakan-kerugian-akibat-obat-palsu-rp-46-miliar.

Bineraksi, R. (2021) 'BPJS Kesehatan Cetak Laba Rp 497 M di 2021'. Available at: https://www.cnbcindonesia.com/market/20220630130226-17-351773/bpjs-kesehatan-cetak-laba-rp-497-m-di-2021.

BPOM (2020) 'Modul Farmakovigilans: Dasar Project For Ensuring Drug And Food Safety'.

Brinkman, D. J. et al. (2017) 'Essential competencies in prescribing: A first european cross-sectional study among 895 final-year medical students', Clinical Pharmacology and Therapeutics, 101(2), pp. 281–289. doi: 10.1002/cpt.521.

Dekker, R. S. et al. (2015) 'A novel approach to teaching pharmacotherapeutics - Feasibility of the learner-centered student-run clinic', European Journal of Clinical Pharmacology, 71(11), pp. 1381–1387. doi: 10.1007/s00228-015-1916-x.

Dinkes Purbalingga (2019) 'BPOM Wilayah Banyumas Temukan Obat Palsu dan Tanpa Izin Edar'. Available at: https://dinkes.purbalinggakab.go.id/bpom-wilayah-banyumas-temukan-obat-palsu-dan-tanpa-izin-edar/.

Direktorat Pengawasan Obat Tradisional dan Suplemen Kesehatan (2019) 'Laporan Tahunan 2019 Direktorat Pengawasan Obat Tradisional dan Suplemen Kesehatan Badan Pengawas Obat dan Makanan', p. 1699.

Direktorat Pengawasan Obat Tradisional dan Suplemen Kesehatan (2020) '2020 Annual Report of the Directorate of Supervision of Traditional Medicines and Health Supplements'.

Direktorat Registrasi Obat BPOM RI (2020) 'Laporan Tahunan 2020 Direktorat Registrasi Obat Badan Pengawas Obat dan Makanan'.

European Medicines Agency (2012) 'Module I – Pharmacovigilance systems and their quality systems', Reg.S09, (February), pp. 1–47. Available at: http://www.jfda.jo/Download/JPC/TheGoodPharmacovigilancePracticev2.pdf.

Farmasetika (2019) 'BPOM Temukan 419 Item Obat Palsu di Tangerang'. Available at: https://farmasetika.com/2019/12/04/bpom-temukan-419-item-obat-palsu-di-tangerang/.

Jurusan Farmasi – Fakultas Kedokteran Universitas Brawijaya (2018) 'Dokumen Kurikulum Program Studi Profesi Apoteker Jurusan Farmasi – Fakultas Kedokteran Universitas Brawijaya 2017 – 2018 1.'

Kudri, A. M. and Barliana, M. I. (2018) 'Pengetahuan dan Kesadaran Apoteker dan Pasien dalam Melaporkan Adverse Drug Reaction (ADR) terhadap Keamanan Obat', Farmaka, 16(2), pp. 525–530. Available at: http://jurnal.unpad.ac.id/farmaka/article/view/17602.

Lovia, Santilla., Yelly Oktavia Sari, Dedy Almasdy, dan Fitri Amelin, (2019) 'Studi Kualitatif Pengetahuan Perawat tentang Adverse Drug Reaction (ADR) di Bangsal Rawat Inap Anak RSUP DR. M. Djamil Padang', Jurnal Sains Farmasi & Klinis, pp. 95–103.

Nurbaiti (2017) 'Ini Daftar 59 Obat Tradisional Temuan BPOM yang Mengandung BKO', Http://Www.Swaranews.Co.Id. Available at: http://www.swaranews.co.id/blog/2017/05/03/pelayanan-perizinan-di-surabaya-transparan-dan-tanpa-pungutan/.

Online, T. (2017) 'BPOM Temukan Obat Palsu di Pasar Sentiong Balaraja'. Available at: https://tangerangonline.id/2017/06/06/bpom-temukan-obat-palsu-di-pasar-sentiong-balaraja/.

Pratama, W. P. (2020) 'Meski Defisit, Pendapatan Iuran BPJS Kesehatan Lebih Tinggi dari Beban Klaim'. Available at: https://finansial.bisnis.com/read/20200728/215/1272134/meski-defisit-pendapatan-iuran-bpjs-kesehatan-lebih-tinggi-dari-beban-klaim.

Presiden Republik Indonesia (2017a) 'Peraturan Badan Pengawas Obat dan Makanan Nomor 26 Tahun 2017'.

Presiden Republik Indonesia (2017b) 'Peraturan Presiden Republik Indonesia Nomor 80 Tahun 2017 Tentang Badan Pengawas Obat Dan Makana'. Available at: https://jdih.kemenkeu.go.id/fulltext/2009/9tahun2009perpres.htm.

Reumerman, M. et al. (2018) 'Urgent need to modernize pharmacovigilance education in healthcare curricula: review of the literature', European Journal of Clinical Pharmacology, 74(10), pp. 1235–1248. doi: 10.1007/s00228-018-2500-y.

RI, B. P. O. dan M. (2017) 'Laporan Tahunan BPOM 2017'.

RI, B. P. O. dan M. (2018) 'Laporan Tahunan 2018 Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor ONPPZA'. Available at: https://www.swcorp.gov.my/laporan-tahunan-2018/.

RI, B. P. O. dan M. (2019a) 'Laporan Tahunan 2019 Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor ONPPZA'.

RI, B. P. O. dan M. (2019b) 'Penjelasan Badan Pom Terkait Temuan Obat Palsu Di Semarang'. Available at: https://www.pom.go.id/new/view/more/klarifikasi/99/Penjelasan-Badan-POM--Terkait-Temuan-Obat-Palsu-Di-Semarang.html.

RI, B. P. O. dan M. (2020) 'Laporan Tahunan Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor BPOM 2020', Bpom.

RI, B. P. O. dan M. (2021a) 'Buletin Berita Meso'.

RI, B. P. O. dan M. (2021b) 'Laporan Tahunan 2021 Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor ONPPZA'.

RI, B. P. O. dan M. (2022a) 'E-MESO User Manual Book'.

RI, B. P. O. dan M. (2022b) E-Meso Website. Available at: https://e-meso.pom.go.id/subsite/?zpukom%2FXrJnElJah2NeJoJmfppyccm5cnZWf2KWgcLjHoKqYoMtXgsagnQ%3D%3D (Accessed: 10 October 2022).

RI, B. P. O. dan M. (2022c) Location of Regional Pharmacovigilance center. Available at: https://www.pom.go.id/new/view/direct/balai%0A.

RI, B. P. O. dan M. (2022d) ranitidin. Available at: https://www.pom.go.id/new/view/more/klarifikasi/102/Penjelasan-BPOM-RI-Tentang-Penarikan-Produk-Ranitidin--Yang-Terkontaminasi-N-Nitrosodimethylamine--Ndma-.html.

RI, B. P. O. dan M. (no date) Isu Keamanan Obat Mengandung Policresulen Cairan Obat Luar Konsentrat. Available at: https://www.pom.go.id/new/view/more/klarifikasi/80/Penjelasan-BPOM-RI--Terkait-Isu-Keamanan-Obat-Mengandung-Policresulen-Cairan-Obat-Luar-KonsentraT.html.

Riset, K. et al. (2020) DOKUMEN Kurikulum Tahun 2020 Program Studi Pendidikan Dokter Fakultas Kedokteran Universitas Sam Ratulangi DOKUMEN Penyusunan Kurikulum Pendidikan Tinggi Program Studi Pendidikan Dokter.

Riset, K., Dan, T. and Tinggi, P. (2020a) DOKUMEN Kurikulum Pendidikan Tinggi Program Studi Ilmu Keperawatan Fakultas Kedokteran Universitas Sam Ratulangi DOKUMEN Penyusunan Kurikulum Pendidikan Tinggi Program Studi Ilmu Keperawatan Fakultas Kedokteran , Universitas Sam Ratulangi.

Riset, K., Dan, T. and Tinggi, P. (2020b) DOKUMEN Kurikulum Pendidikan Tinggi Program Studi Pendidikan Dokter Gigi Fakultas Kedokteran Universitas Sam Ratulangi DOKUMEN Penyusunan Kurikulum Pendidikan Tinggi Program Studi Pendidikan Dokter Gigi.

Rufaidah, A. (2020) 'Tanggung Gugat Badan Pengawas Obat dan Makanan Terhadap Peredaran Ranitidine', Jurist-Diction, 3(6), p. 2039. doi: 10.20473/jd.v3i6.22956.

Schutte, T. et al. (2017) 'Feasibility and Educational Value of a Student-Run Pharmacovigilance Programme: A Prospective Cohort Study', Drug Safety, 40(5), pp. 409–418. doi: 10.1007/s40264-016-0502-1.

Tradisional, D. P. O. and Kesehatandan Suplemen (2018) 'Laporan Tahunan 2018 Direktorat Pengawasan Obat Tradisional Dan Suplemen Kesehatan', (110), pp. 120–187.

Ulya, F. N. (2020) 'BPOM Temukan 1.658.205 Obat Tradisional dan Kosmetik Mengandung Bahan Kimia Obat Artikel ini telah tayang di Kompas.com dengan judul "BPOM Temukan 1.658.205 Obat Tradisional dan Kosmetik Mengandung Bahan Kimia Obat", Klik untuk baca: https://nasional.komp', Kompas.com. Available at: https://nasional.kompas.com/read/2022/10/06/14120491/bpom-temukan-1658205-obat-tradisional-dan-kosmetik-mengandung-bahan-kimia.

Wardhani, A. K. (no date) 'Obat Palsu Beredar di 197 Apotek, BPOM Berikan Trik Agar Konsumen Tak Jadi Korban, Cukup CEKLIK'. Available at: https://www.tribunnews.com/kesehatan/2019/07/26/obat-palsu-beredar-di-197 apotek-bpom-berikan-trik-agar-konsumen-tak-jadi-korban-cukup-ceklik.

WHO (2015) 'WHO pharmacovigilance indicators: A practical manual for the assessment of pharmacovigilance systems'.

WHO (2022) 'What is Pharmacovigilance?' Available at: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance.

Yardley, S., Teunissen, P. W. and Dornan, T. (2012) 'Experiential learning: AMEE Guide No. 63', Medical Teacher, 34(2). doi: 10.3109/0142159X.2012.650741.