Editorial Team

Guest Author

Ibrahim Twaha Sebyala

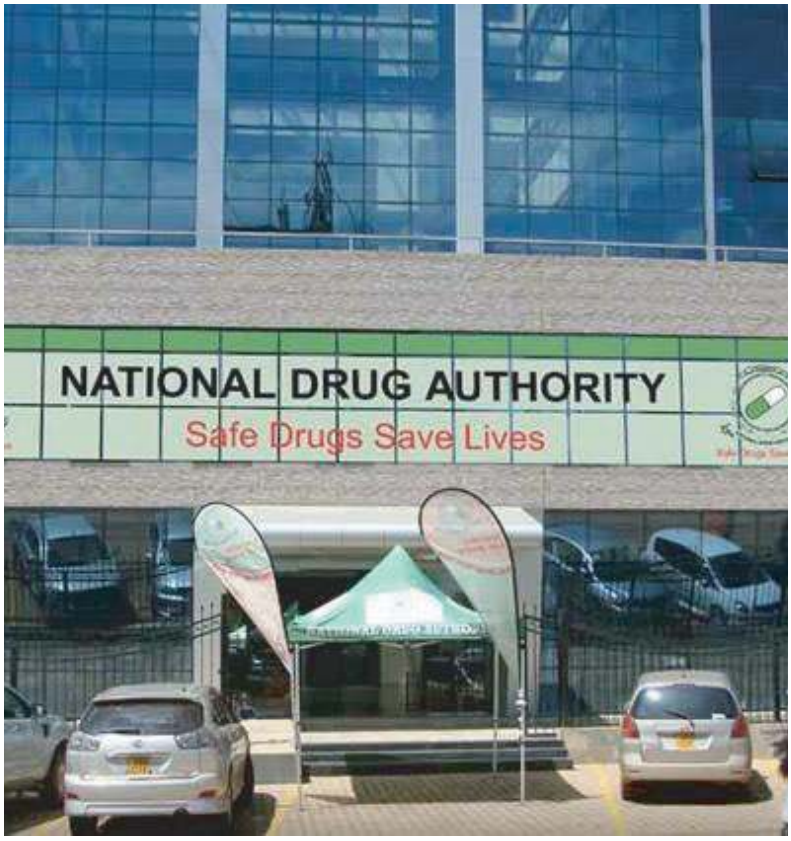


TABLE OF CONTENTS

Comment from the Secretary to the Authority

National Drug Authority is committed to ensuring the availability at all times of essential efficacious and cost-effective drugs for all Ugandans as a means of promoting human and animal health. The National Drug Authority recognizes the importance of patient involvement in healthcare interventions which ensures that medical care meets patient needs. To this end, National Drug Authority continues to place more emphasis on public and patient awareness to enhance monitoring of adverse experiences during therapy. This is evidenced by the fact that patients were the leading reporters of adverse events in this quarter and we are encouraged by their increased communication with the National Drug Authority.

Continuous engagements and communication with the various stakeholders in the pharmacovigilance space is critical in completing the feedback loop. During this quarter, we held our annual Pharmacovigilance stakeholders meeting. The meeting was organized to offer a feedback platform to our stakeholders in order to drive discussions on how to build on successes and devise strategies to the challenges identified in the index year. This was a good meeting because we had face-to-face interactions that generated valuable feedback.

As we conclude the year 2022, I want to extend my sincere gratitude for your efforts in reporting adverse events as well as to extend our commitment to support you in all aspects of Pharmacovigilance.

David Nahamya
Secretary to the Authority

A note from the Director Product Safety

The year 2022 has been another productive year for the pharmacovigilance unit at the NDA. The unit continued to engage health care workers and support vaccination efforts through Adverse Drug Reaction (ADR) reports collection and causality assessment.

We are open to discussions and any innovations you may have to improve our engagements with you. We encourage you to continue to report ADRs using our various platforms as listed on the back cover page of the Bulletin.

Dr. Helen Byomire Ndagije
Director Product Safety

CASE SERIES: NEW ONSET HYPERTENSION FOLLOWING INITIATION OF DOLUTEGRAVIR

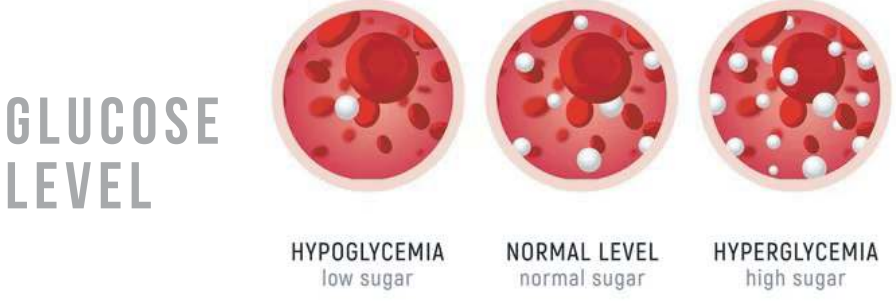
Hypertension is a common comorbidity among people living with HIV and the use antiretroviral therapy has been noted as one of the factors associated with the development of hypertension (1). Indeed, integrase strand transfer inhibitors (INSTIs) and protease inhibitors (PIs) have been associated with metabolic imbalances which are a predictor of hypertension (2,3). Although there is a rapid transitioning of PLWH to Dolutegravir based regimens as first line therapy, there is a paucity of data on the association between dolutegravir and hypertension. Nevertheless, dolutegravir has been associated with development of hyperglycemia and obesity which are renowned risk factors for development of hypertension.

We explored 21 cases of dolutegravir induced hypertension from a retrospective review of reports submitted to the national pharmacovigilance center. 60% of the cases were female and 75% of the patients had not recovered at the time of submitting the reports. Only 1 patient had the drug withdrawn and they went on to recover (positive dechallenge). Two patients were known hypertensives who were previously stable on their antihypertensive medication but stopped responding to treatment after transitioning to dolutegravir. Additionally, majority of these patients were on a fixed dose combination of Tenofovir, Lamivudine and dolutegravir. Tenofovir is a known renal toxic drug and its effect on these patients cannot be ruled out.

This rapid review suggests a possible association between dolutegravir based regimens and development of hypertension. Despite the limited data, a study conducted by (1) found that the use of the dolutegravir based regimens was a significant predictor of hypertension. Additionally, studies have also indicated that the use ART including dolutegravir among PLWH has been associated with weight gain, altered lipid metabolism and accelerated atherosclerosis which increases blood pressure.

As stated earlier, majority of patients were also taking tenofovir, a drug that has been shown in several studies to have the potential to cause nephrotoxicity. Renal failure interferes with salt excretion, leading to volume overload and consequent hypertension (4). Besides renal disease and long duration of Antiretrovial therapy, other possible causes of elevated hypertension in PLWH have been documented to include chronic inflammation, increased microbial translocation, and higher levels of behavioral risk factors among **Persons Living with HIV (PLWH)** (5).

Hypertension has always been a known comorbidity among PLWH. Long term use of Antiretrival Therapy (ART) has also been documented as a predictor for hypertension among PLWH. Although there is limited to link the association between dolutegravir and development of hypertension, there is reason to assume the correlation. Moreover, there is evidence to suggest dolutegravir induced metabolic disorders among PLWH which is a known risk factor for development of hypertension. We recommend that health care providers profile this event through active monitoring of blood pressure measurements at baseline and routinely.



References

1. Musekwa R, Hamooya BM, Koethe JR, Nzala S, Masenga SK. Prevalence and correlates of hypertension in HIV-positive adults from the Livingstone Central Hospital, Zambia. Pan Afr Med J. 2021;39:237.
2. Bailin SS, Gabriel CL, Wanjalla CN, Koethe JR. Obesity and Weight Gain in Persons with HIV. Curr HIV/AIDS Rep. 2020 Apr;17(2):138–50.
3. Eckard AR, McComsey GA. Weight gain and integrase inhibitors. Curr Opin Infect Dis. 2020 Feb;33(1):10–9.
4. Salem MM. Pathophysiology of hypertension in renal failure. Semin Nephrol. 2002 Jan;22(1):17–26.
5. Davis K, Perez-Guzman P, Hoyer A, Brinks R, Gregg E, Althoff KN, et al. Association between HIV infection and hypertension: a global systematic review and meta-analysis of cross-sectional studies. BMC Med [Internet]. 2021;19(1):105. Available from: https://doi.org/10.1186/s12916-021-01978-7

QUARTERLY ADR SUMMARY

A total of 1892 adverse drug reaction reports were submitted to the National Drug Authority between 1st October to 31st December 2022. 1423 of these were Adverse Events Following Immunisation (AEFIs) following COVID-19 vaccination while 469 were adverse drug reactions to other drugs and vaccines. 85% of the reactions were reported for individuals in 18-44 years age group. 92%of the reactions reported were not serious and only 8% of the reported reactions were serious.

VARIABLE	COUNT (Parameter)	%
Gender		
Female	677	36
Male	1210	64
Unknown	5	0
Age		
28 days to 23 months	14	0.8
2 - 11 years	14	0.8
12 - 17 years	59	3.5
18 - 44 years	1426	85.6
45 - 64 years	91	5.5
65 - 74 years	13	0.8
≥ 75 years	2	0.1
Unknown	47	2.8
Seriousness		
Not serious	1746	92
Serious	146	8
Reported Preferred Terms		
PT: Malaise	421	25.3
PT: Injection site pain	356	21.5
PT: Headache	320	19.2
PT: Pyrexia	267	16
PT: Pain in extremity	115	6.9
PT: Dizziness	55	3.3
PT: Asthenia	53	3.2
PT: Arthralgia	52	3.1
PT: Pain	42	2.5
PT: Rash	29	1.7

System Organ Classifications

VARIABLE	COUNT	%
General disorders and administration site conditions	1067	66.1
Nervous system disorders	387	24
Musculoskeletal and connective tissue disorders	194	12
Skin and subcutaneous tissue disorders	58	3.6
Gastrointestinal disorders	51	3.2
Metabolism and nutrition disorders	32	2
Others	105	6.7
Reported suspected active ingredients		
Covid-19 Vaccine	1423	75
TDF/3TC/DTG	152	11
Dolutegravir	47	2
Linezolid	33	2
Isoniazid	24	1
RHZE	23	1
ABC/3TC/DTG	21	1
Tenofovir	18	1
Levofloxacin	17	1
Unknown	16	1
Medroxyprogesterone	11	1
Seriousness criteria		
Involved Disability	60	45
Life Threatening	42	32
Other Medically Important condition	12	9
Patient Died	1	1
Prolonged Impatient Hospitalisation	17	13
Top reporting facilities		
Mildmay Hospital	120	25
Kiruddu National referral Hospital	76	16
Jinja Regional referral Hospital	68	14
Soroti Regional referral Hospital	24	5
MJAP Mulago	23	5
Lira Regional referral Hospital	21	4

VARIABLE	COUNT (Parameter)	%
Luweero Hospital	20	4
Taso Masaka	19	4
Kalangala HCIV	14	3
Reporter qualification		
Clinical medical officer	202	11
Medical Officer	25	1
Nurse	24	24
Other	54	3
Patient	1415	75
Pharmacist	158	8
Pharmacy Technician	13	1

SAFETY LABEL VARIATIONS OCTOBER TO DECEMBER 2022

Product Name	Licence Holder	Summary of Approved Changes	Date of NDA Approval
Goserelin acetate (Zoladexla®)	Astra Zeneca UK Ltd	Addition of a new indication i.e. management of oestrogen-receptor (ER) positive early and advanced breast cancer in pre-and perimenopausal women.	13th December 2022
Dolutegravir + Abacavir + Lamivudine (Triumeq®)	GlaxoSmithKlie Pharmaceutical Kenya Ltd.	Update of SmPC to include human transfer of dolutegravir via placenta and breast milk.	13th December 2022
Tamoxifen (Novadex®)	Astra Zeneca UK Ltd	A warning on toxic epidermal necrolysis and a risk of exacerbation of hereditary angioedema with tamoxifen. The adverse reaction of 'Depression' and 'toxic epidermal necrolysis' with a frequency of rare and exacerbation of hereditary angioedema with a frequency of not known under section 4.8.	13th December 2022

Insulin Lispro (Humalog®)	Eli Lilly Export S.A	Additional text regarding patients not sharing needles, information on reporting of adverse drug reactions; replacing information regarding use of Humalog with a pump infusion set..	25th November 2022
Zolendronic acid (Zometa®)	Norvatis Pharma Services Inc	The infertility section was updated to clarify that fertility is decreased in rats dosed subcutaneously with 0.01 mg/kg/day of zolendronic acid. There are no data available in humans.	17th November 2022
Dolutegravir Sodium+Rilpirive Hydrochloride (Juluca®)	GlaxoSmithkline Pharmaceutical Kenya Ltd.	Update 1: TSC 3-Sections: Pregnancy and Lactation - Update to include human data on transfer of DTG via placenta and breast milk based on the population pharmacokinetic analysis of the DolPHIN-1 study. Dolutegravir readily crosses the placenta in humans. In HIV infected pregnant women, the median (range) of foetal umbilical cord concentrations of dolutegravir were 1.28 (1.21 to 1.28) fold greater compared with maternal peripheral plasma concentrations. There is insufficient information on the effects of dolutegravir on neonates.	17th November 2022
Zinc chloride + denatured alcohol menthol 95% + thymol (Tartar Control Listerine® Antiseptic)	Johnson & Johnson Pty Ltd	Section 4.6: Fertility, pregnancy and lactation: There are no adequate and well-controlled studies in pregnant women. However, because with recommended use only small volumes of Tartar Control Listerine® Antiseptic would be expected to be swallowed, it is considered unlikely that the recommended use of Tartar Control Listerine® Antiseptic will present a risk to the pregnant woman or foetus. It is not known whether Tartar Control Listerine® Antiseptic is excreted in human breast milk. However because with recommended use only small volumes would be expected to be swallowed, it is considered unlikely that the recommended use will present a risk to the infant.	14th November 2022

Desloratadine (Aerius®)	MSD (Pty) Ltd	Update of section 4.8 of the SmPC to reflect increased incidence of new onset seizure in patients 0 to 19 years	3rd November 2022
Tramadol hydrochloride + Paracetamol (Tramapa Fort®)	Ferrer International	4.4. Special warnings and precautions for use: Sleep related breathing disorders - Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage	3rd November 2022
Clopidogrel (Clopidogrel Norvatis Access®)	Sandoz NVS Kenya	SmPC and PIL update for section 4.4; "Special warnings and precautions for use" following update of the same to the innovator product.	20th October 2022
Levonogestrel (Mirena®)	Bayer East Africa Ltd	Update of the paragraph on expulsion in section 4.4 (special warning and precaution for use) of Mirena SmPC with respect to factors associated with an increased risk of expulsion.	20th October 2022
Capecitabine (Sandoz® Capecitabine)	Sandoz GMBH Kenya	Update of core data sheet to include angioedema among the adverse drug reactions under section 4.8.	19th October 2022
Loperamide HCL (Imodium®)	Janssen-Cilag Pharmaceutical (Pty) Ltd	Overdose: Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing or intentionally overdosing with excessively large doses of Loperamide.	14th October 2022
Dolutegravir sodium (Tivicay®)	GlaxoSmithKline Pharmaceutical Kenya Ltd.	Update of safety information to include human data on transfer of DTG via placenta and breast milk based on the population pharmacokinetic analysis of the DolPHIN-1 study in sections; before you (take/use), product, pregnancy and lactation and ATC code update.	5th October 2022
Darunavir (Prezista®)	Janssen-Cilag Pharmaceutical (Pty) Ltd	SmPC Section 4.5 update: Added text to address co-administration of cutaneously administered corticosteroids sensitive to CYP3A inhibition.	3rd October 2022

Discussion of updates to the safety labels of selected products:

Mirena®

In clinical trials with Mirena in the contraception indication, the incidence of expulsion was low (<4% of insertions) and in the same range as that reported for other IUDs and IUSs. Mirena **can be expelled from the uterine cavity without the patient noticing it, leading to loss of contraceptive protection.** Possible symptoms of partial or complete expulsion of Mirena may include bleeding and pain. As Mirena normally decreases menstrual flow, an increase in menstrual flow may be indicative of an expulsion.

The risk of expulsion is increased in:

01. **Women with history of heavy menstrual bleeding** (including women who use Mirena for the treatment of heavy menstrual bleeding)
02. **Women with higher than normal BMI** at the time of insertion; this risk increases gradually with increasing BMI.

Interpretation and recommendation:

Women should be counselled on possible symptoms of expulsion and how to check the threads of Mirena and advised to contact a healthcare professional if the threads cannot be felt. A barrier contraceptive (such as a condom) should be used until Mirena has been confirmed to be in the correct position. Partial expulsion may decrease the effectiveness of Mirena. A partially expelled Mirena should be removed. A new system can be inserted at the time of removal, provided pregnancy has been excluded.

> **"Women with history of heavy menstrual bleeding (including women who use Mirena for the treatment of heavy menstrual bleeding)"**

Prezita® (Darunavir)

Findings:

In a clinical study where ritonavir 100 mg capsules twice daily were co-administered with 50 µg intranasal fluticasone propionate (4 times daily) for 7 days in healthy subjects, fluticasone propionate plasma concentrations increased significantly, whereas the intrinsic cortisol levels decreased by approximately 86% (90% CI 82-89%).

Greater effects may be expected when fluticasone is inhaled. Systemic corticosteroid effects including Cushing's syndrome and adrenal suppression have been reported in patients receiving ritonavir and inhaled or intranasally administered fluticasone. The effects of high fluticasone systemic exposure on ritonavir plasma levels are unknown.

Other corticosteroids: interaction not studied. Plasma concentrations of these medicinal products may be increased when co-administered with Darunvir with low dose ritonavir, resulting in reduced serum cortisol concentrations.

CORTICOSTEROIDS

Any of a group of hormones produced in the adrenal cortex or made synthetically.

Interpretation and recommendation:

Concomitant use of PREZISTA with low dose ritonavir and corticosteroids (all routes of administration) that are metabolised by CYP3A may increase the risk of development of systemic corticosteroid effects, including Cushing's syndrome and adrenal suppression. Co-administration with CYP3A-metabolised corticosteroids is not recommended unless the potential benefit to the patient outweighs the risk, in which case patients should be monitored for systemic corticosteroid effects. Alternative corticosteroids which are less dependent on CYP3A metabolism e.g. beclomethasone should be considered, particularly for long term use.

FOREIGN SAFETY UPDATES

Hormonal contraceptives – Risk of depressed mood and depression Ireland

The Health Products Regulatory Authority (HPRA) has announced that the warning of depressed mood and depression in the product information for hormonal contraceptives (both combined and progesterone-only products) have been expanded to highlight that depression can be a risk factor for suicidal behaviour and suicide.

The update has been made following a review of available data by the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA).

Women prescribed with hormonal contraceptives should be advised to contact their physician in case of mood changes and depressive symptoms, even if occurrence is shortly after initiating treatment with a hormonal contraceptive.

References

1. Drug Safety Newsletter, HPRA, August 2022 (link to the source within www.hpra.ie

Hydroxychloroquine - Risks of hepatic impairment Japan.

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the product information for hydroxychloroquine (Plaquenil®) should be revised to include the risk of hepatic impairment. Hydroxychloroquine is indicated for the treatment of cutaneous lupus erythematosus and systemic lupus erythematosus.

Japanese (two) and International (21) cases of hepatic impairment were evaluated. Of these cases, four of the international cases were assessed to have a reasonably possible causal relationship between the drug and hepatic impairment. It was concluded that hepatic impairment is a clinically significant adverse reaction for hydroxychloroquine.

References

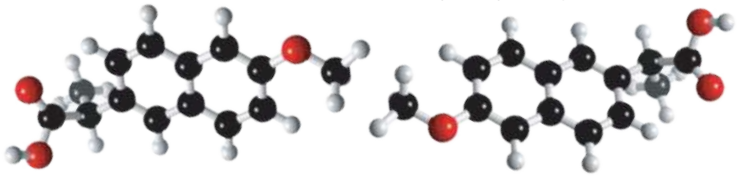
1. Revision of Precautions, MHLW/PMDA, 30 August 2022 (link to the source within www.pmda.go.jp/english/)

Non-steroidal anti-inflammatory drugs (NSAIDs) - Risks of maternal, fetal and neonatal adverse effects in pregnancy New Zealand.

The Medsafe has announced that the product information for non-steroidal anti-inflammatory drugs (NSAIDs) are to be updated and aligned regarding the risks of maternal, fetal and neonatal adverse effects for the use in pregnancy.

The Medicines Adverse Reactions Committee (MARC) reviewed the safety of NSAID use in pregnancy. NSAIDs used in early pregnancy is associated with an increased risk of miscarriage and congenital malformation; NSAIDs used in the second or third trimester may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment; and NSAIDs used in the third trimester may cause premature closure of the fetal ductus arteriosus, fetal renal impairment, inhibition of platelet aggregation, and may delay labour and birth.

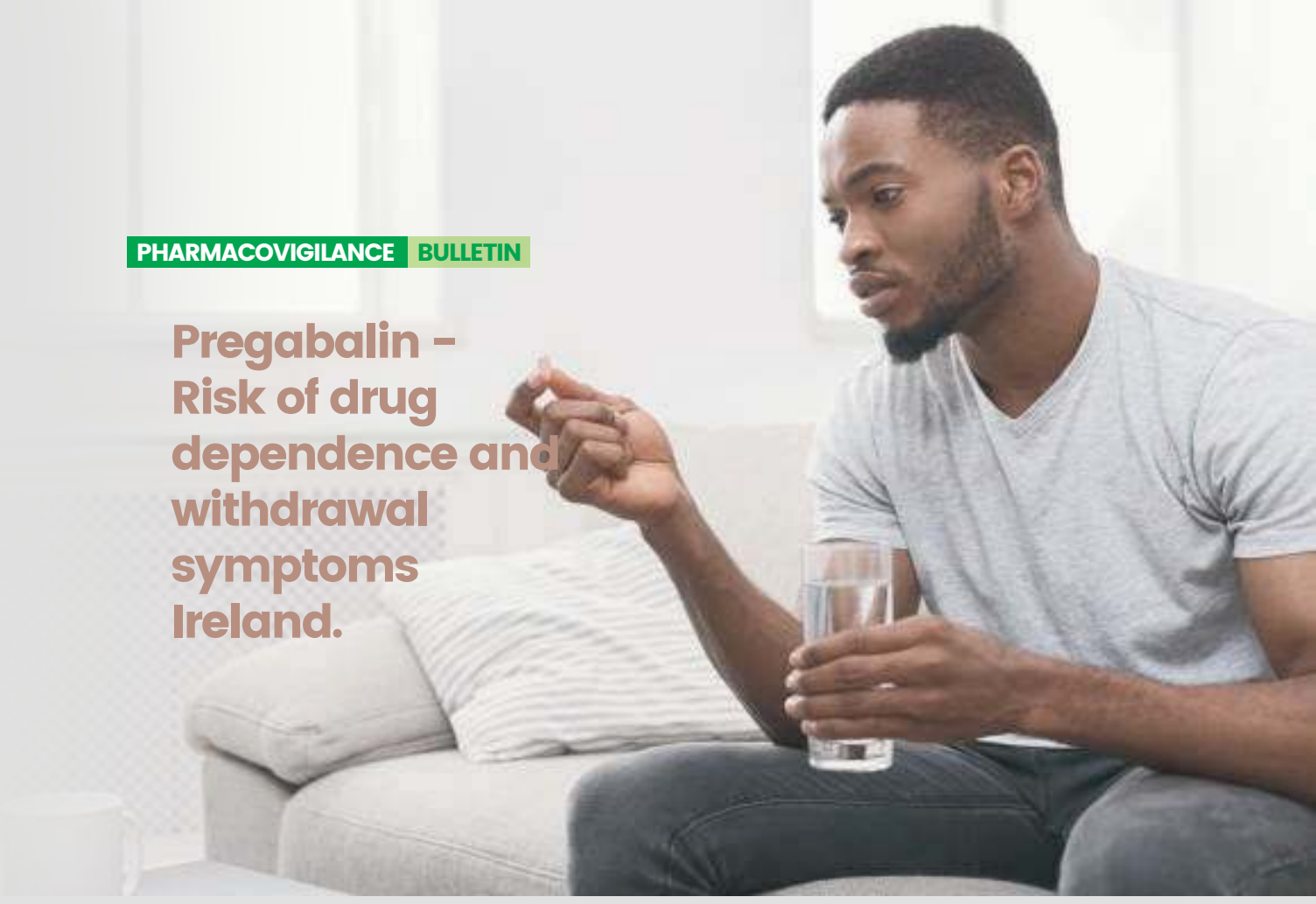
Health-care professionals are advised that NSAIDs are contraindicated in the third trimester of pregnancy; NSAIDs should not be used during the first two trimesters of pregnancy unless the expected benefits to the mother outweigh the risks to the fetus. If there is a compelling need for NSAID treatment during the first or second trimester, use should be limited to the lowest effective dose and shortest duration possible. Health-care professionals should enquire about NSAID use in women who are pregnant or planning pregnancy and advise them not to self-medicate with these medicines during pregnancy.



References

1. Prescriber Update, Medsafe, 1 September 2022 (link to the source within www.medsafe.govt.nz/)

Pregabalin – Risk of drug dependence and withdrawal symptoms Ireland.



The Health Products Regulatory Auhority (HPRA) has announced that the product information for pregabalin has been updated to expand the warning regarding drug dependence and withdrawal symptoms. The updated warnings state that pregabalin can cause drug dependence at therapeutic doses, and that patients with a history of substance abuse may be at higher risk for pregabalin misuse, abuse and dependence.

Pregabalin is indicated for the treatment of neuropathic pain in adults, as adjunctive therapy in adults for specific forms of epilepsy, and for generalized anxiety disorder in adults.

The update has been made following a review of available data by the PRAC of the EMA.

Health-care professionals should carefully evaluate an individual patient's risk of misuse, abuse and dependence before prescribing pregabalin and monitor patients treated with pregabalin for symptoms of misuse, abuse or dependence, such as development of tolerance, dose escalation and drug-seeking behaviour. The occurrence of withdrawal symptoms following discontinuation of pregabalin may indicate drug dependence. It is recommended discontinuation of pregabalin should be done gradually over a minimum of one week independent of the indication.

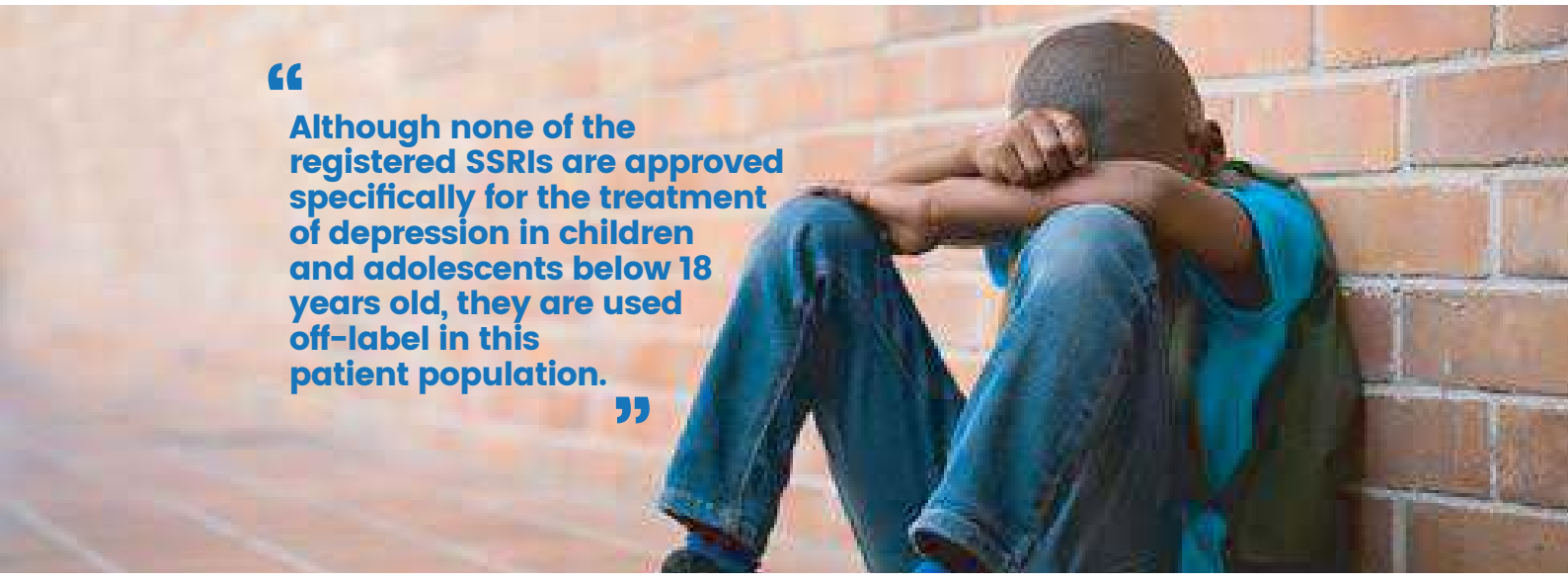
References

1. Drug Safety Newsletter, HPRA, August 2022 (link to the source within www.hpra.ie)
(See also WHO Pharmaceuticals Newsletter No.2, 2021: Gabapentin, pregabalin and Risk of dizziness, somnolence, abuse and dependence in New Zealand)

Selective Serotonin Reuptake Inhibitors (SSRIs) - Risk of suicidality Singapore.

The Health Sciences Authority (HSA) has reminded health-care professionals of the risk of suicidality for selective serotonin reuptake inhibitors (SSRIs), where an increased risk is observed particularly in patients less than 25 years of age although a causal association remains to be conclusively established.

SSRIs are used for the treatment of depression, anxiety and other mood disorders. Although none of the registered SSRIs are approved specifically for the treatment of depression in children and adolescents below 18 years old, they are used off-label in this patient population.



Based on data from the electronic medical records, over the past five years, an increasing trend in the prescriptions of SSRIs was observed (around 4% increase from 2017 to 2020, followed by 9.1% increase from 2020 to 2021). Also, the proportion of patients less than 25 years of age are increasing among the patients prescribed SSRIs: the annual proportion of children or adolescents (<18 years) was stable at around 3.4% from 2017 to 2020 and increased to 4.1% in 2021, while those of young adults (18-24 years) steadily increased over the years from 11.2% in 2017 to 15.5% in 2021.

Health-care professionals are encouraged to refer to the available patient educational materials on SSRIs during medication counselling to their patients and/or caregivers. The materials include warnings on suicidality and mental state worsening and risks in young people aged below 25 years.

References

1. Safety Alerts, HSA, 30 August 2022 (link to the source within www.hsa.gov.sg)

WHO statement regarding COVID-19 Immunization errors in children

World Health Organization (WHO) is aware of an increasing number of reports regarding COVID-19 immunization errors in children.

The immunization errors have been reported through the passive vaccine safety surveillance systems and included in the media in a number of countries. On 19th May 2022, the US Advisory Committee on Immunization Practices (ACIP) presented data showing that half of all non-serious adverse events following Pfizer BNT162b2 immunization in children aged 5-11 years submitted to the Vaccine Adverse Event Reporting System (VAERS) surveillance system through 24 April 2022 included an event associated with immunization error (1). The Australian Therapeutic Goods Administration (TGA) also reported instances of immunization errors among 5–11-year-olds and made recommendations to reinforce the use of the paediatric version of the Comirnaty (Pfizer) vaccine which comes in a vial with an orange top (2).

According to the WHO global database of individual case safety reports (VigiBase data as of 10th July 2022), about 24% of all case safety reports in children after COVID-19 immunizations are related to immunization errors. The types of immunization errors include the use of adult dose in children, use in inappropriate age groups, underdose, overdose, use of unapproved COVID-19 vaccines, inappropriate scheduling between doses, preparation errors such as omitting a diluent before immunization, administering a COVID-19 vaccine instead of another vaccine, failure to adhere to requisite storage conditions and use of expired doses. Immunization errors have been reported with Pfizer-BioNTech, Moderna, AstraZeneca, Janssen, Sinovac, Novavax and other COVID-19 vaccines.

Although in very rare instances serious adverse events have been documented after immunization against COVID-19 disease, none of these were verified to be related to immunization errors of any kind. Children who received an incorrect dose of a COVID-19 vaccine or who received an inappropriately prepared vaccine have only reported expected adverse events like a sore arm, headache, and fever.

However, given the increasing number of reports of immunization errors in children, WHO would like to remind health-care providers to be alert when storing, preparing, and administering COVID-19 vaccines. National immunization programs and relevant stakeholders should implement risk minimization activities to reduce the occurrence of immunization errors, including procedures to check the date of birth and current age of the child. Vaccine providers should have access to clear instructions for vaccine administration, including visual aids, and vaccine vials should be clearly labelled (3). Training for healthcare providers involved in COVID-19 immunization of children should be reinforced.

If an immunization error does occur, healthcare providers should immediately inform individuals and/or their guardians as well as report the incident to the relevant local vaccine safety surveillance system or immunization programme. Children who have received an incorrect dose or an incorrectly prepared vaccine should be monitored for any adverse events. Some countries have also prepared guidance on what to do with subsequent doses if an error in administration occurs (4).

WHO will continue to consult the Global Advisory Committee on Vaccine Safety (GACVS) and other relevant experts as well as WHO advisory committees on the problem of immunization errors and will work closely with countries to manage potential risks, using science and data to drive response and recommendations.

References

1. Shimabukuro T. COVID-19 vaccine safety updates: Primary series in children ages 5-11 years. Advisory Committee on Immunization Practices (ACIP). 19 May 2022 (https://www.cdc.gov/vaccines/acip/meetings/slides-2022-05-19.html)
2. Australian Therapeutic Goods Administration (TGA) COVID-19 vaccine weekly safety report - 10-02-2022. 10 February 2022 (https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-02-2022)
3. **Examples of practical guides on use of COVID-19 vaccines in children:**
   - **(i)** COVID Vaccine Dosing_Quick Reference by American Academy of Pediatrics (https://downloads.aap.org/AAP/PDF/COVID%20Vaccine%20Dosing_Quick%20Reference.pdf?_ga=2.233317982.1540468903.1657898439-1537646742.1653333380)
   - **(ii)** COVID-19 Vaccine Interim COVID-19 Immunization Schedule for 6 Months of Age and Older by US CDC (https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf)
4. **Examples of guidance on what to do with subsequent doses if an error in administration occurs:**
   - **(i)** US CDC: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html
   - **(ii)** Department of Health and Aged Care, Australia: https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-covid-19-vaccine-administration-errors

1This statement is published on the WHO website: https://www.who.int/news/item/30-08-2022-statement-covid-19-immunization-errors-children

2022 ANNUAL PHARMACOVIGILANCE STAKEHOLDER ENGAGEMENTS

The Directorate of Product Safety organized the 6th National Pharmacovigilance meeting to engage stakeholders' and give feedback on the different activities involved in medicine safety for the year 2021-2022 and to award the top performers via reporting ADEs. The meeting started with the Director Product Safety Dr. Helen Byomire Ndagije giving a presentation based on the theme and expounding on why we wanted to discuss a holistic approach to medication without harm. This was proceeded by a host of other presentations highlighting the local safety trends and the prospects of the new year in pharmacovigilance

One hundred thirty four (134) participants were received from all across the country and from the different disciplines. These included Doctors, Representatives of the Hospital Directors of Regional referral Hospitals, Pharmacists, Clinical Officers, MAHs, Nurses, representatives from national programs, implementing partners and leaders from the Ministry of Health.

Group photo of the participants at the 2022 Annual Pharmacovigilance Stakeholder's Meeting

The Secretary to the Authority, Mr. David Nahamya gave remarks about the achievements of the authority as well as the commitments in place with the stakeholders.

The Secretary to the Authority giving his remarks

Dr. Helen Ndagije presented about the meeting theme on patient safety

The guest of honor, Dr. Olaro Charles the Director Clinical services at the Min of Health Uganda. Dr. Olaro commended the NDA for the pharmacovigilance work

Dr. Olaro, the guest of honour, commended the NDA for the pharmacovigilance work of sensitization of health workers and continuous support supervision of Health Care Professionals (HCPs) at the health facility level. He reflected on the Covid-19 times and how the country is generally emerging out of the pandemic period and that health care work is proceeding well with improved funding. He reiterated frameworks and policies that protect patients such as empowering the patient through patient charters, patients right bill, public health amendments bill being tabled as the laws to protect the public.

He emphasized to the health care providers how important it is to do drug surveillance in order to maintain the safety of drugs and promote patient safety.

Dr. Olaro Charles, Director Clinical Services at Ministry of Health giving remarks

This was followed by presentations from the stakeholders represented by;

- Senior Consultant Physician Dr. Epuwatt spoke about the role of health workers in Patient safety.
- Regina Kamoga and she gave an update on community engagement activities carried out so far.
- MildMay Hospital which disseminated results of the Dolutegravir Study.
- Joseph Karara from NDA's Directorate of Product Assessment and Registration who gave a presentation highlighting safety of medical devices.

Awards were issued to the top reporters in the different categories as listed below;

Winner	Award
FALISY LULE	TOP REPORTING HEALTH WORKER FOR 2020-2021
JOHN LUKOMA	1ST RUNNER UP REPORTING HEALTH WORKER FOR 2020-2021
CHRISTINE TAKAN	2ND RUNNER UP REPORTING HEALTH WORKER FOR 2020-2021
KIRUDDU NATIONAL REF HOSPITAL	TOP NATIONAL REFERRAL HOSPITAL
MBARARA REGIONAL REF. HOSPITAL	TOP REPORTING REGIONAL REFERRAL HOSPITAL
KAYUNGA GENERAL HOSPITAL	TOP REPORTING GENERAL HOSPITAL
KITEBI HEALTH CENTER III	TOP REPORTING HEALTH CENTER
HABIB HUSSEIN	TOP LEGACY REPORTER

A photograph of the top reporters along with the guest of honor and representatives of the National Drug Authority

PV CONTINUING PROFESSIONAL DEVELOPMENT (CPDs) WITH DOCTORS

The National Drug Authority supported the Uganda Medical Association (UMA) grand doctors Conference on 11th-12th November 2022 as well as the Uganda Dental Association (UDA) annual general meeting on 25th November 2022.

Aspects on Pharmacovigilance were delivered during these conferences. A presentation on oral lesions related to drug reactions were given where Dental Surgeons were encouraged to report adverse drug reactions to the NDA.

The partnerships with the professional associations has been a helpful forum to improve on reporting of adverse drug reactions in Uganda. Doctors by virtue of the training are relied upon to provide.

VACCINE SAFETY WORKSHOP – DECEMBER 2022

Vaccine Safety workshop took place from December 5th to December 9th 2022 at Hotel Horizon Entebbe involving 39 participants from NDA, WHO, UNEPI, AFENET, National AEFI committee members and other major stakeholders vital to ensuring vaccine safety from all regions of the country.

Group photo of the Vaccine safety workshop attendees