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ADVERSE DRUG REACTION NEWS

HSA Health Sciences Authority

Health Product Safety Information Summary

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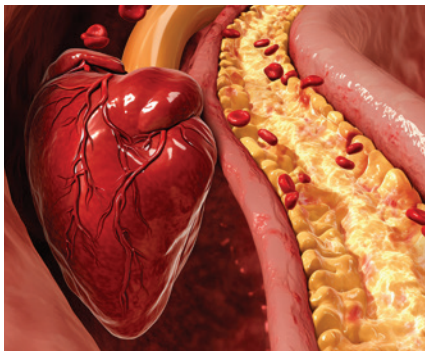
A 66-year-old female with end-stage renal disease on maintenance haemodialysis presented to the Emergency Department with acute confusion post-dialysis. She had a history of hypertension, diabetes mellitus and peripheral vascular disease. On arrival, she was disoriented with high blood pressure and subsequently developed fever, tachycardia, and restlessness with involuntary limb movements. Her blood pressure remained persistently elevated despite nitroglycerin and nicardipine, and she required intubation. A trial dose of intravenous labetalol led to rapid improvement. Serial bloods were persistently haemolysed; creatine kinase, myoglobin and lactate dehydrogenase were elevated, with undetectable haptoglobin, indicating rhabdomyolysis. Electroencephalogram showed generalised encephalopathy. Magnetic resonance imaging and magnetic resonance angiography brain showed only tiny foci of diffusion restriction. Cerebrospinal fluid was negative for infection or autoimmune markers. She had recently received symptomatic treatment - Sedilix®-DM Linctus, Vasican, Fedac, azithromycin and throat lozenges - for an upper respiratory tract infection.

What could have caused the hypertensive encephalopathy and rhabdomyolysis in this patient?



This is a case of a 52-year-old male with a history of coronary artery disease and prior anterior ST-elevated myocardial infarction (STEMI) when he was 30 years old. He had undergone angioplasty with a bare metal stent and was prescribed medication (aspirin, enalapril and lovastatin). Seventeen years later, he suffered severe calcific neointimal hyperplasia in the bare metal stent and was treated with repeat balloon angioplasty and adjunctive intravascular lithotripsy. His condition was subsequently managed with aspirin, ezetimibe and atorvastatin. Four years later, he suffered a second STEMI (inferior) and underwent coronary thrombectomy and balloon angioplasty, followed by 24-hour intravenous infusion of eptifibatide. He was prescribed ticagrelor and continued treatment with ezetimibe and

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atorvastatin. Four months later, routine blood tests detected elevated serum creatine kinase and liver function tests. Apart from generalised muscle weakness, his physical examination was unremarkable and level of high sensitivity troponin I was normal. He had no overt evidence of pigmenturia.

What could have caused the elevation of serum CK in this patient?

WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop 2025

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The World Health Organisation (WHO), Uppsala Monitoring Centre (UMC), and Health Sciences Authority (HSA) successfully conducted the 2025 WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop on 28 to 29 August 2025. This virtual workshop marked HSA's sixth collaborative training initiative with WHO and UMC. Under the theme 'Supporting Smart Pharmacovigilance Systems', the programme focused on strengthening pharmacovigilance capabilities among regulators from national regulatory agencies and pharmacovigilance centres worldwide.

HSA participated in WHO-UMC 10th annual #MedSafetyWeek social media campaign

The Health Sciences Authority (HSA) was one of over 100 regulatory agencies and organisations that participated in the annual #MedSafetyWeek campaign[1] organised by Uppsala Monitoring Centre (UMC), the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring this year. The 2025 global campaign marked the 10th anniversary of #MedSafetyWeek. The theme this year was "We can all help make medicines safer" and focused on how patients, caregivers, and healthcare professionals can have the power to help make medicines safer for everyone through reporting of adverse effects.

From 3 to 9 November 2025, HSA screened an animation video across our social media platforms LinkedIn[2], Instagram[3], Twitter[4] and YouTube[5], highlighting that everyone has a role to play in ensuring medicine safety by reporting adverse effects to healthcare professionals. HSA monitors the adverse event reports submitted by healthcare professionals to identify key safety concerns and to ensure continued safe use of medicines in Singapore. HSA also collaborated with the Ministry of Health, Pharmaceutical Society of Singapore and the Health Promotion Board to post the animation video on their social media platforms to increase outreach during this week-long campaign.

Healthcare professionals are encouraged to report suspected adverse effects, especially serious ones, following their patients' use of medicine at https://www.hsa.gov.sg/adverse-events. Read more about how such reports can enhance the safety of medicines at https://www.hsa.gov.sg/consumer-safety/articles/details/AEreporting-medicinesafety.

Follow us on LinkedIn, Instagram, X and YouTube to view the animations for #MedSafetyWeek and for the latest happenings.

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1. https://who-umc.org/medsafetyweek/
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4. HSA X https://twitter.com/HSAsg
5. HSA YouTube https://youtube.com/shorts/6coTI-QUu-w

Dear Healthcare Professional Letters on safety concerns

Useful Information

Doctors, dentists and pharmacists can claim continuing education points for reading each issue of the HSA ADR News Bulletin. Doctors can apply for one non-core Continuing Medical Education (CME) point under category 3A, dentists can apply for one Continuing Professional Education (CPE) point under category 3A and pharmacists can apply for one patient-care Continuing Professional Education (CPE) point under category 3A per issue of the bulletin.

How to report suspected AEs to HSA?

For any suspected AEs, please report to us via the following:

HSA_productsafety@hsa.gov.sg

https://www.hsa.gov.sg/adverse-events

For any enquiries or assistance on AE reporting, please call us at 6866 1111

All website references were last accessed on 1 December 2025.

Summary of illegal health products reported to HSA in 2024 and 2025

Key Points

- HSA detected 22 illegal health products for the period January 2024 to December 2025, with those marketed for pain or inflammatory conditions and slimming as the most frequently adulterated categories.
- Those for pain or inflammatory conditions were predominantly adulterated with steroids, while sibutramine was the primary adulterant detected in slimming products.
- HSA identified counterfeit 'LACTOGG' capsules which lacked the probiotic strain *Lactobacillus rhamnosus* GG specified on the product packaging.
- Healthcare professionals are essential partners in HSA's efforts to detect potentially adulterated and counterfeit products through vigilant history-taking and reporting.

Between January 2024 and December 2025, HSA issued 12 press releases (https://go.gov.sg/hsa-press-releases) covering 22 illegal health products: 20 adulterated products, one product with lead exceeding permissible limits and one counterfeit product. Laboratory testing confirmed that the illegal health products contained potent ingredients while the counterfeit product did not contain the probiotic strain that was listed on its packaging. The illegal health products were marketed for indications such as pain and inflammatory conditions (45%), slimming (32%), aesthetic purposes (9%), weight gain (5%) and glucose support (5%).

Majority (68%) of the illegal health products were sold through online e-commerce platforms such as Shopee and Lazada and social media channels such as Instagram and TikTok. Other sources included neighbouring countries, local physical retail shops, local peddlers and an Ayurvedic yoga wellness centre. HSA had taken appropriate actions against the sellers, such as working with platform administrators to remove their listings, seizing stocks from physical retail shops, and initiating product recalls.

Common potent ingredients detected

Steroids were the most common potent ingredient found in the illegal health products across all categories. The potent ingredients and the issues detected in the illegal health products are summarised in Table 1. Majority of the illegal health products marketed for pain and inflammatory conditions were tested to contain steroids such as dexamethasone, prednisolone, clobetasol and betamethasone. One product, 'ayukalp Mahayograj Guggulu' from an Ayurvedic yoga wellness centre, caused lead poisoning in a consumer in her 30s as it contained lead exceeding the permissible limit of 10 ppm by 6,000 times.

Sibutramine was the predominant adulterant detected in slimming products. Other adulterants detected in these products included frusemide, phenolphthalein or sennosides. A product marketed for weight gain, 'EZ Empire Be Perfect', was detected with steroids and cyproheptadine whilst products marketed for aesthetic purposes were found to contain steroids, mercury, salicylic acid and triclosan (a preservative not allowed in cosmetic creams).

Recall of 'Curalin advanced glucose support'

A company recall of 'Curalin advanced glucose support', a traditional medicine, was conducted after HSA testing revealed the presence of two prescription-only antidiabetic medicines, glibenclamide and metformin. The illegal health product, imported from the United States of America for local distribution, was marketed to "help support healthy blood glucose levels", "promote energy levels" and "help support carbohydrate and fat metabolism" and was labelled to contain traditional herbs.

Recall of 'Pi De Kang Dermatitis Cream'

HSA alerted the public to stop using 'Pi De Kang Dermatitis Cream' after it was tested to contain clobetasol and miconazole. The product had been imported by Da Zhong Tang Pte Ltd and supplied by Chinese Medical Centre Pte Ltd as a "Skin itching cream". HSA directed Da Zhong Tang Pte Ltd and Chinese Medical Centre Pte Ltd to conduct a consumer recall of all batches of the product that they had supplied to their customers.

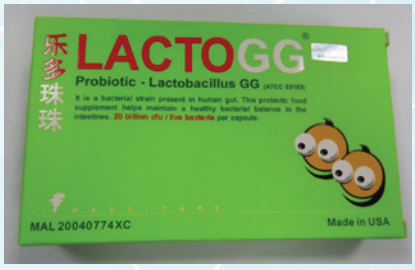
Curalin advanced glucose support

Pi De Kang Dermatitis Cream

Counterfeit 'LACTOGG' capsules

HSA investigated counterfeit 'LACTOGG' capsules following adverse effects experienced by an entire family after consuming the product. A consumer in his 40s and his wife experienced abdominal discomfort, vomiting, and diarrhoea, whilst their toddler developed high fever and abnormal-coloured faeces. The consumer had purchased the capsules from Shopee at prices significantly below those of genuine products. He became suspicious when his children complained the capsules tasted different and he noticed printing irregularities on the product packaging and discoloured powder contents.

In contrast to the genuine product, HSA's analysis revealed that the counterfeit capsules lacked the probiotic strain *Lactobacillus rhamnosus* GG that was listed on the packaging. The fake products also displayed poor quality printing and mismatched batch numbers between the outer packaging and blister packs.



Counterfeit LACTOGG capsules with poor quality printing (irregular spacing of words) on packaging.

Conclusion

Healthcare professionals serve as frontline guardians in detecting use of adulterated or counterfeit health products in their patients. Their clinical expertise and direct patient contact enable them to recognise patterns of adverse effects associated with health products. Reporting of such cases to HSA enables HSA to take the relevant regulatory actions to safeguard public health.

Table 1. Summary of potent ingredients and issues detected in the illegal products (n=22)

Date of press release	Product name	Potent ingredients and issues detected					
		Steroids	Antihistamines	NSAIDs	Sibutramine	Mercury and salicylic acid	Others
Products marketed for pain and inflammatory conditions (n=10)							
1 February 2024	'Gu Jie Ling'	✓	✓				
3 May 2024	'Natural Herbs'	✓					
	'La Mu Cao Capsules'	✓		✓			Amoxicillin, Paracetamol
	'Special Skin Treatment'	✓					
26 August 2024	'Touch Skin by Dermacare Skin Relief Treatment Cream'	✓					
23 December 2024	'ayukalp Mahayograj Guggulu'						Lead (exceeding the permissible limit)
25 March 2025	'Tong Mai 9 Gu Jiao Rou'	✓		✓			
2 April 2025	'Setia Herba'	✓		✓			
23 July 2025	'Pi De Kang Dermatitis Cream'	✓					Miconazole
19 November 2025	'HW Beauty Serbuk Campuran Kurma, Madu & Limau Kasturi'	✓		✓			
Products marketed for slimming (n=7)							
12 January 2024	'Nature Slim'				✓		
	'Slimming Seven Days by Figure Up'				✓		
	'Energy Booster Figure-Up New Look Strong Version'				✓		
28 June 2024	'Sausando Cellulite Pills'				✓		Phenolphthalein, frusemide
	'Pelangsing Double Strong'			✓	✓		N-desmethyl -sibutramine
25 March 2025	'Re5hape hi Morning'				✓		
	'Re5hape bye Night'						Sennosides
Products marketed for weight gain (n=1)							
25 March 2025	'EZ Empire Be Perfect'	✓	✓				
Products marketed for aesthetic purposes (n=2)							
28 June 2024	'88 Total White Underarm Cream'	✓				✓	
25 October 2024	'Q-Nic Care Whitening Underarm Cream'	✓				✓	Triclosan
Products marketed for glucose support (n=1)							
5 May 2025	'CuraLin advanced glucose support'						Glibenclamide, metformin
		Counterfeit product					
23 December 2024	'LACTOGG' capsules						Absence of probiotic strain as listed

Serious Skin Reactions due to use of Modafinil and Armodafinil

Press release issued on 10 March 2025

HSA alerted the public about nine cases of serious skin rash following consumption of modafinil or armodafinil in the period February 2024 to February 2025. This followed a previous warning issued in November 2023[1] when three consumers were hospitalised for serious adverse reactions after inappropriate use of these medicines.

All nine consumers (seven males, two females, aged 18 to 57 years) had obtained modafinil and armodafinil from street peddlers in Geylang or from friends to improve alertness and "boost energy and health". Six developed Stevens-Johnson syndrome (SJS) and the other three developed Toxic Epidermal necrolysis (TEN).

Since the press release in March 2025, HSA has received another five reports of serious skin reactions with modafinil or armodafinil use. Based on the information received by HSA, some of the users had taken the product for energy or alertness and had obtained them from friends or through Telegram.

Both modafinil and armodafinil are not registered in Singapore but are available under the Special Access Route (SAR), which allows doctors to apply to HSA for unregistered medicines to treat their patients' medical conditions.

Healthcare professionals are encouraged to report severe cutaneous adverse reactions (SCAR) and other serious adverse events suspected to be due to modafinil or armodafinil to HSA (https://www.hsa.gov.sg/adverse-events). It would also be helpful to clarify with patients on the source of their medication to facilitate HSA's enforcement actions.

Reference

1. https://www.hsa.gov.sg/announcements/press-release/hsa-alert-modafinil_armodafinil

AE Case in Focus 1: Test Yourself

A 66-year-old female with end-stage renal disease (ESRD) on maintenance haemodialysis presented to the Emergency Department with acute confusion post-dialysis. She had a history of hypertension, diabetes mellitus and peripheral vascular disease. On arrival, she was disoriented with a blood pressure of 253/97 mmHg. Within 12 hours, she developed fever, tachycardia, and restlessness with involuntary limb movements. Despite initiation of intravenous nitroglycerin and maximal dose nicardipine, her blood pressure remained persistently elevated. Her mentation failed to improve, requiring intubation for airway protection. A trial dose of intravenous labetalol led to rapid improvement, suggesting a sympathomimetic effect. Serial bloods were persistently haemolysed; creatine kinase (CK) and myoglobin were elevated, lactate dehydrogenase (LDH) exceeded 2,800 U/L, and haptoglobin was undetectable, indicating rhabdomyolysis. Electroencephalogram (EEG) showed generalised encephalopathy. Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) brain showed only tiny foci of diffusion restriction. Cerebrospinal fluid (CSF) was negative for infection or autoimmune markers. During medication reconciliation, it was noted that she received symptomatic treatment for an upper respiratory tract infection two months prior. She was prescribed Sedilix®-DM Linctus (dextromethorphan, promethazine, pseudoephedrine), Vasican (bromhexine), Fedac (triprolidine, pseudoephedrine), azithromycin and throat lozenges.

What could have caused the hypertensive encephalopathy and rhabdomyolysis in this patient?

HSA would like to thank Dr Yap Eng Soo, Consultant, Department of Haematology; Dr Jasmine Tan, Medical officer, Dr Jared Louis Andre D'Souza, Consultant, and Dr Seth Ting, Consultant, Department of Intensive Care Medicine; at Ng Teng Fong General Hospital for contributing this article.

Answers can be found on page 6.

AE Case in Focus 2: Test Yourself

A 52-year-old male had a history of coronary artery disease with prior anterior ST-elevated myocardial infarction (STEMI) when he was 30 years old. He had undergone angioplasty with a bare metal stent and was prescribed aspirin, enalapril and lovastatin to manage his condition. Seventeen years later, he suffered severe calcific neointimal hyperplasia in the bare metal stent and was treated with repeat balloon angioplasty and adjunctive intravascular lithotripsy. Subsequently, his condition was managed with aspirin 100 mg, ezetimibe 10 mg every morning and atorvastatin 10 mg every evening. Four years later at 51 years old, he suffered a second STEMI (inferior) and underwent coronary thrombectomy and balloon angioplasty, followed by 24-hour intravenous infusion of eptifibatide. As this was his second STEMI, he was prescribed ticagrelor 90 mg twice daily as antiplatelet therapy, and continued treatment with ezetimibe 10 mg and atorvastatin 10 mg.

Four months after ticagrelor was added to his treatment regimen, he presented to the emergency department when routine blood tests detected elevated serum creatine kinase (CK) levels of 2,222 U/L and subsequently 3,225 U/L four days later. His liver function test levels of alanine transaminase (ALT), aspartate transaminase (AST) and alkaline phosphatase (ALP) were all elevated. Apart from generalised muscle weakness, his physical examination was unremarkable and level of high sensitivity troponin I (hs-TNI) was normal. He had no overt evidence of pigmenturia.

What could have caused the elevation of serum CK in this patient?

HSA would like to thank Professor Eric Chan from the Department of Pharmacy and Pharmaceutical Sciences, National University of Singapore for contributing this article.

Answers can be found on page 7.

Answer to AE Case in Focus 1: Test Yourself

Pseudoephedrine toxicity is the suspected cause of this renally impaired patient's hypertensive encephalopathy and rhabdomyolysis. She was found to have elevated pseudoephedrine levels in the blood. During medication reconciliation, it was noted that she was prescribed two pseudoephedrine-containing products (i.e., Sedilix®-DM linctus and Fedac tablets) although it was unclear if she had taken both products at the same time. Her overall clinical features were suggestive of posterior reversible encephalopathy syndrome (PRES) with rhabdomyolysis. Although MRI/MRA performed on Day two revealed only two tiny foci of diffusion restriction with no vasogenic oedema or vessel beading (Figure 1), there is emerging evidence that imaging findings may lag behind or even remain absent in cases of sympathomimetic-induced PRES/reversible cerebral vasoconstriction (RCVS).[1] She recovered fully after supportive care, resuming dialysis with no neurological deficits.

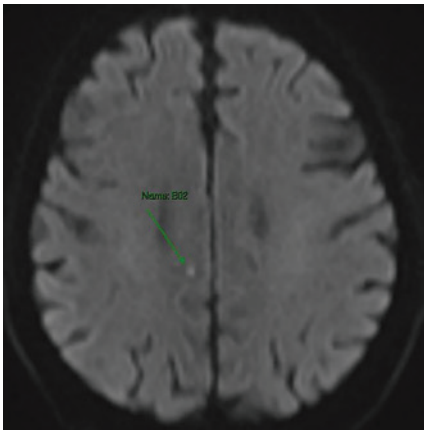


Figure 1: MRI (DWI) image showing a tiny focus of restricted diffusion on the right parasagittal parietal lobe/ right body of the corpus collosum, suspicious of an acute infarct.

About pseudoephedrine

Pseudoephedrine is widely used for the relief of nasal congestion by vasoconstricting the blood vessels in the nasal passages. It is a direct and indirect sympathomimetic amine that primarily acts on α- and β-adrenergic receptors. It is almost exclusively renally excreted in unchanged form. In patients with ESRD, its clearance is markedly impaired, allowing even therapeutic doses to accumulate and induce adrenergic toxicity.[2] Dose reduction should be considered in renally impaired patients with close monitoring for adverse effects.[3]

Pseudoephedrine toxicity in a renal-impaired patient

The typical features of pseudoephedrine toxicity include hypertension, tachycardia, agitation, psychosis, and, less commonly, seizures or cerebrovascular complications. In the above case where pseudoephedrine was consumed by an ESRD patient on dialysis, accumulation of the drug leading to elevated levels could have contributed to toxicity manifesting as both neurological complications (i.e., PRES) and rhabdomyolysis.

PRES is a rare neurological condition involving cerebral ischaemia, and typically presents with headaches, visual deficits, mental changes, seizures and brain oedema. Rare cases of PRES linked to pseudoephedrine use have been reported overseas. HSA has previously highlighted this safety signal regarding the association between PRES and pseudoephedrine in the ADR News Bulletin[4] and has worked with the product registrants of pseudoephedrine-containing products to strengthen the warnings on PRES and their related symptoms in the product labels of pseudoephedrine-containing products registered locally.[5] Apart from the above case, HSA has not received any other reports of PRES associated with pseudoephedrine use. Of note, the patient's ESRD is a risk factor for both pseudoephedrine toxicity and PRES. The prognosis for patients with PRES is generally favourable as the symptoms tend to be reversible and most patients make a full recovery, as in this case.[6]

Pseudoephedrine toxicity is known to cause rhabdomyolysis. This is due to the adrenergic effects caused by pseudoephedrine which can lead to increased muscle metabolic demand leading to muscle breakdown.[7] Although initial creatine kinase was normal in this patient, her myoglobin was markedly elevated, with transient CK rise, LDH >2,800 U/L, and undetectable haptoglobin. This constellation of features — in the absence of clinical haemolysis, thrombotic microangiopathy (TMA) features, or autoimmune haemolytic anaemia — was likely due to pseudoephedrine-induced rhabdomyolysis, an effect previously reported in high-dose sympathomimetic toxicity.[6,8]

One of the most striking features in this case was the mimicking of haemolysis of serum samples which was due to the presence of myoglobin in this patient's sample. Although the biochemical profile of elevated LDH and undetectable haptoglobin initially suggested intravascular haemolysis, the markedly raised myoglobin levels confirmed rhabdomyolysis as the underlying process, representing a biochemical mimic of haemolysis rather than true red cell destruction (Figure 2).

Myoglobinaemia is known to interfere with certain laboratory assays, producing a haemolysed appearance and artefactually low measurements (e.g., falsely low haptoglobin).[9] The overlap with true haemolysis can lead to diagnostic confusion, particularly when samples are visibly red and non-coagulable.

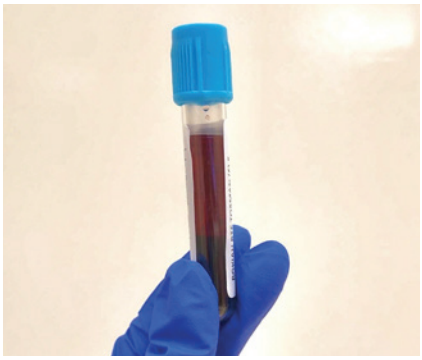


Figure 2: Persistent haemolysis of serum sample

HSA's advisory

Pseudoephedrine is primarily eliminated through the kidneys, and accumulation in renally impaired patients could potentially lead to increased risk of adverse events. Healthcare professionals are advised to review the patient's renal status prior to prescribing or dispensing pseudoephedrine-containing products, as well as to ask patients about their medication history, including recent prescriptions and over-the-counter products that they may still be consuming. This is to prevent inadvertent concurrent use of multiple pseudoephedrine-containing products which could lead to subsequent toxicity.

References

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Answer to AE Case in Focus 2: Test Yourself

The patient's presentation of elevated serum creatine kinase (CK) levels almost tenfold higher than the upper reference range was initially attributed to either an adverse cardiovascular event, immune-mediated myositis, or statin-induced muscle injury. Electrocardiography (ECG) was performed and high sensitivity troponin I (hs-TNI) levels were assessed. Both investigations yielded unremarkable results, thus mitigating concerns for recurrent STEMI. Subsequent tests confirmed that the muscle injury was not associated with immune-mediated myositis. When assessed collectively, the elevations of serum CK, ALT, AST, and ALP pointed to skeletal muscle rather than heart tissue injury.

Notwithstanding that the atorvastatin dose was relatively low, the clinical evidence pointed toward statin-associated myopathy. A previous study demonstrated that there was drug-drug interaction (DDI) between ticagrelor and atorvastatin, leading to increased systemic exposure of atorvastatin by approximately 1.3-fold.[1] However, this increase in systemic exposure was deemed to be marginal and the co-prescription of ticagrelor and atorvastatin was not contraindicated.

Ticagrelor: A P2Y12 receptor antagonist

Ticagrelor is an oral, reversible P2Y12 receptor antagonist that provides potent platelet inhibition for the prevention of thrombotic cardiovascular events, including cardiovascular death, myocardial infarction and stroke. It is often co-administered with aspirin and typically prescribed at a dose of 90 mg twice daily for the first year following acute coronary syndrome, then 60 mg twice daily as long-term therapy in patients who are at a high risk of developing thrombotic events.

Drug interaction mechanisms between ticagrelor and HMG-CoA reductase inhibitors

The drug interaction between ticagrelor and HMG-CoA reductase inhibitors, commonly known as statins, may arise from several pharmacokinetic pathways that increase the plasma concentrations of the latter. One mechanism involves the inhibition of ATP-binding cassette transporter G2 (ABCG2), also known as breast cancer resistance protein (BCRP), which mediates the efflux of various drugs in the small intestine (Figure 1). Both atorvastatin and rosuvastatin are recognised substrates of BCRP, and it has been reported that ticagrelor's inhibition of ABCG2 contributes to elevated plasma levels of these drugs due to reduced intestinal efflux transport activity.[2,3] The clinical significance of this interaction may be more pronounced in the Asian population, where various genetic polymorphisms of the ABCG2 gene are frequent, which may lead to reduced intestinal efflux transport activity of HMG-CoA reductase inhibitors that are affected by this pathway.[3]

Another possible mechanism contributing to this drug interaction involves the inhibition of CYP3A4 enzyme. Ticagrelor has been shown to inhibit the CYP3A4 enzyme, which is responsible for the metabolism of atorvastatin and simvastatin. This potentially results in an increase in the plasma concentrations of HMG-CoA reductase inhibitors and enhances the risk of drug-related adverse effects. However, as ticagrelor is not considered a strong CYP3A4 inhibitor, this interaction may be insufficient to fully account for the adverse events observed in clinical practice.[4] Notably, other HMG-CoA reductase inhibitors such as pravastatin and pitavastatin are not significantly metabolised by CYP3A4 and may have a lower potential for clinically significant interactions with ticagrelor.

Local situation

To date, HSA has not received other reports of muscle-related adverse events due to the concomitant administration of ticagrelor and HMG-CoA reductase inhibitors. Information regarding the DDI between ticagrelor and rosuvastatin, atorvastatin, and simvastatin are included in the local package insert for Brilinta® (ticagrelor).

HSA's advisory

The clinical significance of the interaction between ticagrelor and HMG-CoA reductase inhibitors is yet to be fully understood, although case reports regarding this interaction have been published.[5,6] Healthcare professionals are advised to take into consideration the risk of DDI between ticagrelor and HMG-CoA reductase inhibitors in their patients, including those who have previously tolerated treatment with HMG-CoA reductase inhibitors without muscle-related adverse effects.

Healthcare professionals are encouraged to report any suspected adverse events related to this drug interaction to the Vigilance and Compliance Branch of HSA.

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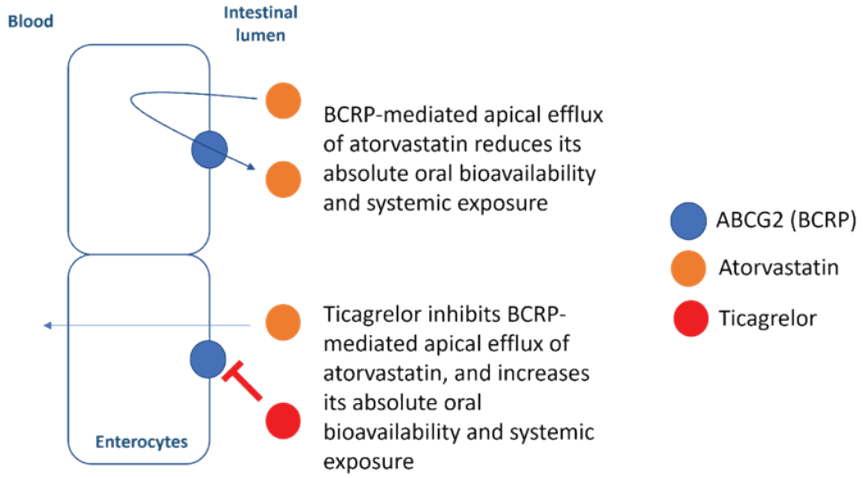

Figure 1. Mechanism of BCRP-mediated drug interaction between ticagrelor and atorvastatin

WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop 2025

The World Health Organisation (WHO), Uppsala Monitoring Centre (UMC), and Health Sciences Authority (HSA) successfully conducted the 2025 WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop on 28 to 29 August 2025. This virtual workshop marked HSA's sixth collaborative training initiative with WHO and UMC, building on successful workshops held in 2010, 2012, 2015, 2018, and 2021. The workshop achieved an extensive global reach, attracting 389 international participants spanning multiple continents. This diverse community of professionals represented key markets including ASEAN nations, Australia, Brazil, Canada, Egypt, India, Japan, Sweden, and the United States.

Under the theme 'Supporting Smart Pharmacovigilance Systems', the programme focused on strengthening pharmacovigilance capabilities among regulators from national regulatory agencies and pharmacovigilance centres worldwide. Keynote speakers on the first day of the event included local and international experts such as Dr Shanthi Pal (WHO), Dr Pinelopi Lundquist (UMC), and Ms Jalene Poh (HSA) who shared their experiences in pharmacovigilance strategies while learning from and building upon the past, fostering effective partnerships and embracing digitalisation. Other speakers — Dr Adrian Inoubli (WHO), Dr Phey Yen Han (HSA) and Dr Smaragda Lamprianou (WHO) — elaborated on the importance of regulatory cooperation, risk management plans, and pharmacovigilance activities during pregnancy and breastfeeding.

Talks on the second day focused on the causality assessment of adverse drug events, including adverse events following immunisation (AEFI) (presented by Dr Geraldine Hill and Dr Madhava Ram, WHO), good practices in signal detection by Dr Qun-Ying Yue (UMC), and the use of Vigitools from adverse event reporting to signal assessment (by Ryann Lirasan, UMC). Dr Sreemanee Raaj Dorajoo (HSA) also shared insights on the use of artificial intelligence and machine learning in pharmacovigilance, a topic that generated considerable interest amongst the audience.

Participants provided excellent feedback, describing the workshop as informative, comprehensive, and well-organised with valuable learning outcomes. HSA is honoured to be a co-host of this collaborative workshop with our distinguished training partners at WHO and UMC, and remains committed to advancing global drug safety through knowledge sharing and international collaboration in pharmacovigilance.

Figure 1. Speakers and organisers of the WHO-UMC-HSA Inter-Regional Pharmacovigilance Workshop 2025

Please send your enquiries, comments and suggestions to:

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