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In this edition

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Editorial

Dear reader

You will have noticed straight away that this issue of Vigilance News has a new format. We are now publishing original articles in English only. In addition, we are providing a summary of these articles in four languages as a quick source of information. These changes are a response to the page load figures for the different language versions of Vigilance News.

At the same time, we once again cover a very interesting selection of current topics, as well as offering two annual reports that you may have been eagerly awaiting.

A publication from CHUV (Lausanne University Hospital) addresses a rare but potentially serious adverse drug reaction to semaglutide. Moreover, a further article also looks into this GLP-1 agonist as well as tirzepatide, providing an overview of the benefits and risks of both active substances.

A case report from Ente Ospedaliero Cantonale in Lugano deals with the potential risks of fluoroquinolones. This article should be viewed in connection with two warning letters about fluoroquinolones previously published by Swissmedic.

Another contribution highlights the importance of pharmacovigilance in paediatric medicine, where off-label use is frequent and there is a range of specific challenges.

The information on a new information service on Swissmedic's website is relevant from a medical and regulatory perspective. Since November 2025, there has been a monthly table summarising the key safety-related changes to Information for healthcare professionals. As a result, medical professionals can see at a glance which changes they need to be aware of.

We regard this as a helpful service for prescribers and dispensing outlets and as a measure to implement the sole recommendation issued by the Swiss Federal Audit Office after it audited Swissmedic in 2023.

The annual report on veterinary medicinal product and vaccine vigilance for 2024 has been published. A significant percentage of the reported cases involve a suspected lack of efficacy.

Finally, this issue contains the yearly vaccinovigilance report, which, in addition to suspicion reports for COVID-19 vaccines, contains a wealth of information on other vaccines.

Swissmedic encourages you to continue submitting reports of suspected adverse reactions to medicinal products and vaccines. You can find full information on submitting reports at www.swissmedic.ch.

I hope you find this latest edition interesting and enjoyable reading.

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Safety of medicines and case reports

Fluoroquinolone-associated disability

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Summary

Fluoroquinolones are effective broad-spectrum antibiotics, but their use is limited by the risk of severe and potentially irreversible adverse drug reactions (ADRs). We describe the case of a young woman treated with a *Helicobacter pylori* eradication regimen that included levofloxacin, who developed acute neuropsychiatric symptoms – confusion and suicidal intent – followed by a chronic, disabling, multisystem syndrome consistent with a so-called fluoroquinolone-associated disability (FQAD). The clinical manifestations affected her cardiorespiratory, musculoskeletal, neurological, psychiatric, dermatological, vascular, ocular, oral, gastrointestinal and gynaecological systems, leading to profound impairment of quality of life, work incapacity and social withdrawal. The polysymptomatic presentation has not yet resolved and persists more than nine months after onset. FQAD is a labelled rare but serious condition characterised by persistent multisystemic ADRs, where oxidative stress and mitochondrial toxicity are considered central mechanisms. Antioxidant therapies and, in certain cases, hyperbaric oxygen therapy have been attempted and yielded some benefit, but controlled trials are lacking. This case highlights the need for cautious use of fluoroquinolones, strict adherence to prescribing guidelines and greater awareness of FQAD as a real clinical entity. Pharmacovigilance reporting remains essential to improve recognition and management.

Introduction

Fluoroquinolones are highly effective antibiotics with many advantageous pharmacokinetic properties, including high oral bioavailability, a large volume of distribution and broad-spectrum antimicrobial activity. However, they are also associated with an adverse effect profile that can be severe and potentially irreversible. Precisely because of the risk of developing such adverse drug reactions (ADRs), in 2018 the regulatory authority Swissmedic, in agreement with the marketing authorisation holders, announced that the indications for fluoroquinolone use had been restricted (1). In particular, they should be employed in uncomplicated infections only if other antibiotics normally recommended for the initial treatment of the corresponding infections have been deemed inappropriate or have failed. Here we present a case of serious and persistent ADRs associated with the use of a fluoroquinolone.

Case report

We present the case of a young woman with a known history of coeliac disease (on a strict gluten-free diet), von Willebrand disease and borderline personality disorder.

She underwent a follow-up oesophagogastroduodenoscopy for her known coeliac disease, which revealed a *Helicobacter pylori* infection. In response, she was prescribed an eradication therapy consisting of pantoprazole 40 mg 1-0-1 and amoxicillin 500 mg 2-0-2 for five days. A few days later, for an additional five days, she received pantoprazole 40 mg 1-0-1, metronidazole 500 mg 1-1-1 and levofloxacin 500 mg 0-1-0.

One day after starting levofloxacin, she reported the acute onset of mental confusion, tinnitus, difficulty driving, pallor, dark urine, metallic taste, muscle cramps,

anxiety, sadness, nightmares, nervousness, severe nausea, extreme fatigue, impaired thermoregulation, epigastric pain, sensation of suffocation, intense headache and psychotic symptoms including paranoia, dissociation, obsessive rituals, aggressiveness, delusions and racing thoughts, which culminated in suicidal behaviours the next day.

Another day later, during a car trip, the patient experienced sudden cramps in the hands and feet (described by the patient as "hands and feet twisted, with fingers that would not close"), numbness of the tongue and a sensation of intense heat in the head, which prevented her from driving further and forced her to call emergency services. However, hospital admission was not considered necessary.

Over time, the patient developed a wide range of persistent and progressively more debilitating symptoms affecting multiple organ systems.

- From a cardiorespiratory perspective, she experienced dyspnoea, intermittent and worsening chest pain and arterial hypotension with near-fainting episodes.

- The musculoskeletal system was affected by lower-limb oedema and heaviness with walking difficulties, progressive loss of muscle mass and strength (especially in the trunk and arms), disabling musculoskeletal pain, neck stiffness, tremors, spasms and fasciculations, increased sensitivity to pain and impaired fine motor skills that caused the patient to drop objects.

- Neurological and psychiatric symptoms included brain fog, poor concentration, word-finding difficulties, migraine with aura, visual snow, blurred vision, intermittent loss of taste and smell, insomnia, depression and a confirmed psychiatric diagnosis of post-traumatic stress disorder. The patient also reported anxiety, psychomotor agitation, chronic fatigue and impaired thermoregulation with an intolerance to cold.

- Dermatological and vascular manifestations comprised pain and redness of the palms in response to cold, cold extremities with sensory loss and paraesthesia, primary Raynaud's phenomenon of the hands and feet, petechiae after showering or movement, scattered red dots on the body, cutaneous rash with capillary rupture, hair and eyelash loss, increased susceptibility to sunburn, skin abrasions with fissuring (groin, axillae, Achilles tendon), urticaria triggered by food, showering, fragrances or movement and generalised pruritus.

- Ocular and oral involvement included conjunctival hyperaemia, keratoconjunctivitis, ocular dryness, burning mouth syndrome, hoarseness with fluctuating voice loss and excessive thirst.

- From a gastrointestinal standpoint, the patient developed pale bulky stools with blood, abdominal pain (predominantly in the lower right quadrant) and reduced appetite.

- She manifested low-grade fever and rhinorrhoea.

- At the gynaecological level, she experienced amenorrhea for two months.

Taken together, these symptoms resulted in a marked impairment of quality of life, progressive functional decline and dependence on parental support for daily activities.

This was followed by a series of medical examinations.

Pulmonology evaluation: Pulmonary function tests were completely normal, as was exhaled NO measurement. The clinical picture was not typical for asthma. Anamnesis suggested possible vocal cord dysfunction. No evidence of respiratory disease was found.

Cardiology evaluation: The patient presented with a series of symptoms unrelated to the heart. The heart was structurally normal, with only a small functional ejection murmur. However, as previously documented,

she showed signs of autonomic dysfunction, manifesting as inappropriate sinus tachycardia (recently well controlled), arterial hypotension and Raynaud's phenomenon.

ENT evaluation: Findings were consistent with possible laryngopharyngeal reflux. Treatment with proton pump inhibitors and antacids was prescribed, along with behavioural recommendations.

Neurology evaluation: Neurophysiological testing was normal, with no evidence of sensory-motor polyneuropathy of large fibres in either upper or lower limbs, and no signs of myopathy. To exclude small-fibre neuropathy, a skin biopsy was performed, which was normal.

Brain MRI (native): No pathological findings.

Rheumatology evaluation: Schirmer's test was negative. Autoimmune panel was negative. Capillaroscopy was normal. Conclusions: There was no evidence of connective tissue disease, particularly Sjögren's syndrome. No clinical or laboratory findings suggested systemic sclerosis. The most likely diagnosis was primary Raynaud's phenomenon. In the presence of diffuse soft tissue tenderness, there was no evidence of inflammatory arthropathy. From a rheumatological standpoint, the cause of musculoskeletal symptoms remained unclear; a chronic pain syndrome of soft tissues should be considered.

The patient also attended the emergency department several times for worsening dyspnoea, headache with aura and nonspecific abdominal pain. Dermatological, gynaecological and ophthalmological evaluations did not reveal any significant findings.

Overall, physicians concluded that the patient was suffering from a polysymptomatic disorder with predominant neurological/neuromuscular involvement, associated with pathological fatigue, progressive exertional dyspnoea sometimes accompanied by chest pain and a marked thermoregulatory disturbance (intolerance to both heat and cold). The patient also exhibited Raynaud's phenomenon. Ocular sicca syndrome, for which eye drops had been prescribed, had been present for years, as had arterial hypotension, though without presyncopal or syncopal episodes.

Despite multiple diagnostic investigations, no major pathological findings were identified. The polysymptomatic presentation, which significantly compromises the patient's daily life, has not yet resolved and persists more than nine months after onset. A diagnosis of possible fluoroquinolone-associated disability was therefore made.

Discussion

This patient was prescribed an eradication regimen for *Helicobacter pylori* consisting of amoxicillin, followed by levofloxacin in combination with metronidazole and pantoprazole. The use of levofloxacin in this context represents an off-label indication. The rationale for this choice is not known; it is possible that the decision was guided by an antibiogram.

The patient experienced two acute events in close temporal association with the initiation of eradication therapy: the first characterised by severe confusion, the second by suicidal intent. Subsequently, she developed a chronic, disabling polysymptomatic syndrome with numerous manifestations, including pathological fatigue, progressive exertional dyspnoea sometimes accompanied by chest pain, marked thermoregulatory disturbances (intolerance to both heat and cold), cold sensitivity with Raynaud's phenomenon and other manifestations that required multiple specialist evaluations. These symptoms have persisted for months, resulting in incapacity for work and study, with significant social consequences. The clinical picture has been classified as a so-called fluoroquinolone-associated disability (FQAD).

This syndrome is reported in the Swiss product information for levofloxacin and other fluoroquinolones (a class effect) as a very rare adverse event that is serious, persistent (lasting months or years), potentially disabling and in some cases irreversible (2). Multiple sensory

systems and, at times, several organs simultaneously may be affected. Reported adverse effects include tendinitis, tendon rupture, arthralgia, pain in the extremities, gait disturbances, peripheral neuropathy with paraesthesia, central nervous system effects (hallucinations, anxiety, depression, insomnia, headache and confusion, fatigue, cognitive impairment, memory loss) and disturbances of sensory function (hearing, vision, taste and smell). The UpToDate database also highlights the possibility of fluoroquinolone-associated disability, encompassing a range of multisystemic adverse effects (3).

In 2015, the FDA reviewed its database for all serious adverse events reported in previously healthy individuals who had received a fluoroquinolone for acute bronchitis, urinary tract infection, or acute rhinosinusitis between 1997 and 2015 (11). Of the 1,122 reports, 178 met the criteria for events involving two or more body systems and lasting ≥30 days after discontinuation of the fluoroquinolone. Three-quarters of the reported cases occurred in women aged 30 to 59 years. Almost all presented with musculoskeletal symptoms; two-thirds had neuropsychiatric or peripheral nervous system manifestations. The patterns of symptoms and degree of association were similar across the three most commonly reported (and prescribed) fluoroquinolones, namely levofloxacin, ciprofloxacin and moxifloxacin. Given the large number of fluoroquinolone prescriptions during the study period, the authors concluded that the overall risk of developing fluoroquinolone-associated disability is probably extremely low. No individual fluoroquinolone appeared to have a stronger association with FQAD than the others.

Several PubMed-indexed articles describe cases of FQAD (4–9). The literature indicates that symptoms may appear during treatment and persist or even worsen after discontinuation of the drug (4). A case of delayed onset has also been reported, in which the first symptoms developed five days after completion of a 24-day course of levofloxacin (6).

The frequency of these ADRs cannot be precisely estimated from the available data, but the reported incidence ranges between at least 1/1,000 and 1/10,000, which places it in the category of a rare adverse event (10).

Some risk factors have been identified for specific fluoroquinolone-related ADRs, such as the concomitant use of corticosteroids, which increases the risk of tendinopathies and, in particular, tendon rupture. Such factors may influence both the onset and severity of ADRs, including FQAD. The potential role of NSAIDs has also been discussed in the literature, as their concomitant or subsequent use following fluoroquinolone therapy may contribute to the development, worsening or reactivation of prolonged ADRs. However, the available evidence does not currently support changes to the product information. At present, no patient group can be considered completely exempt from the risk of serious and persistent fluoroquinolone-related ADRs, and no specific risk factors for FQAD have yet been identified.

The mechanisms hypothesised to underlie FQAD are complex and multifactorial. Most studies have highlighted the central role of oxidative stress and mitochondrial toxicity, with DNA damage, inhibition of the respiratory chain, energy deficits and consequent excessive production of free radicals. This oxidative imbalance results in turn in damage to both muscle and nerve tissue. Additional proposed mechanisms include inhibition of cell proliferation and migration, reduction of the extracellular matrix, increased expression of matrix metalloproteinases (MMPs), induction of apoptosis, ischemic phenomena and the chelating properties intrinsic to fluoroquinolones.

Most of the data on the risk of FQAD involve systemic products. Evidence regarding topical fluoroquinolones is much more limited, although there have been reports of long-lasting tendinopathies associated with topical formulations (10).

The therapeutic approaches most frequently reported in the literature for the management of FQAD involve the use of antioxidant strategies and, in some cases, hyperbaric oxygen therapy (4–9). Antioxidant therapies are based on the administration of substances such as

reduced glutathione, ascorbic acid, α-lipoic acid, coenzyme Q10 and magnesium, with the aim of counteracting oxidative stress and supporting mitochondrial function, both considered key mechanisms of persistent fluoroquinolone-induced damage. However, the available evidence comes only from isolated case reports or small case series in which partial improvements have been observed and there have been no controlled studies to confirm the efficacy of such interventions. Hyperbaric oxygen therapy has also been described in individual cases as a possible supportive option, with reports of limited benefits to tendon, neurological or general well-being. Here too, the rationale is based on the potential to increase tissue oxygenation and promote cellular repair, indirectly reducing oxidative stress. Nevertheless, the evidence remains preliminary and does not allow this treatment to be regarded as an established therapeutic strategy.

Conclusion

The use of fluoroquinolones carries the risk of serious, potentially irreversible and disabling adverse events that may simultaneously affect multiple sensory systems and organs, a condition known as fluoroquinolone-associated disability (FQAD). It is therefore essential to maintain vigilance with regard to this class of antibiotics, as inappropriate use is not only associated with significant adverse effects, but also contributes substantially to the development of antimicrobial resistance. Fluoroquinolones are classified in the "Watch" group under the World Health Organization's AWaRe classification and should be regarded as second-line agents compared to other molecules that have a lower impact on resistance.

FQAD must be acknowledged as a real clinical entity and not minimised or erroneously attributed to psychological causes. Greater awareness within the medical community, aimed at acknowledging the organic nature of this condition, is crucial both for ensuring timely diagnosis and for fostering the development of targeted therapeutic strategies, which remain under investigation.

The reporting of suspected ADRs is one of the key pillars of drug safety, playing a vital role in the detection of potential drug risks at an early stage and the continuous monitoring of the benefit/risk profile of all available medicines. Healthcare professionals are encouraged to report serious and/or previously unknown side effects to Swissmedic via the electronic portal ElViS or to a regional pharmacovigilance centre.

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References

1
HPC – Systemisch angewendete Fluorochinolone

2
Arzneimittelinformation-Publikationssystem (AIPS). Swissmedic, Bern, Switzerland. Available from: http://www.swissmedicinfo.ch/

3
UpToDate®. Fluoroquinolones – Adverse effects – Other adverse effects – Persistent multisystem adverse effects. UpToDate Inc., Waltham, MA, USA. Available from: http://www.uptodate.com

4
Golomb BA, Koslik HJ, Redd AJ. Fluoroquinolone-induced serious, persistent, multisymptom adverse effects. BMJ Case Rep. 2015;2015:bcr2015209821. doi:10.1136/bcr-2015-209821

5
Cohen JS. Peripheral neuropathy associated with fluoroquinolones. Ann Pharmacother. 2001;35(12):1540–7. doi:10.1345/aph.1A009

6
Pietruszyński R, Pietruszyńska-Reszetarska A, Sokal J, Domżalski M. Antioxidant therapy in the management of fluoroquinolone-associated disability. Arch Med Sci. 2020;16(6):1483–6. doi:10.5114/aoms.2020.99008

7
Landers ZD, Mazhar A. Fluoroquinolone-Induced Multisystem Toxicity: A Case Report. Cureus. 2024;16(5):e61174. doi:10.7759/cureus.61174

8
Freeman MZ, Cannizzaro DN, Naughton LF, Bove C. Fluoroquinolones-Associated Disability: It Is Not All in Your Head. NeuroSci. 2021;2(3):235–53. doi:10.3390/neurosci2030017

9
Wilcox MA, Villasis-Keever A, Sena AG, Knoll C, Fife D. Evaluation of disability in patients exposed to fluoroquinolones. BMC Pharmacol Toxicol. 2020;21(1):40. doi:10.1186/s40360-020-00428-9

10
Medicines and Healthcare products Regulatory Agency (MHRA). Review of risk minimisation for disabling and potentially long-lasting/irreversible side effects associated with fluoroquinolone antibiotics. 2019. Available from: https://www.gov.uk/government/publications/review-of-risk-minimisation-for-disabling-and-potentially-long-lastingirreversible-side-effects-associated-with-fluoroquinolone-antibiotics

11
US Food and Drug Administration (FDA). Fluoroquinolone safety labeling changes. 2017 Apr 4. Available from: https://www.fda.gov/media/104060/download

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Semaglutide and tirzepatide for weight management – updates on efficacy and harms

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Summary

Semaglutide and tirzepatide, initially developed for the treatment of type 2 diabetes mellitus, have gained broad use in the management of body weight. Their benefits further include the reduction of cardiovascular risk, nephroprotective effects, improvements in obstructive sleep apnoea and, potentially, in metabolic dysfunction-associated steatotic liver disease. For approved indications in Switzerland, please refer to the specific products' information at www.swissmedicinfo.ch. The therapeutic benefits of these agents must be weighed against their adverse reactions. The safety profile of both substances is dominated by gastrointestinal harms. Recently, non-arteritic ischemic optic neuropathy was identified as a very rare adverse drug reaction of semaglutide, while an increased risk of suicidal ideation was ultimately not confirmed by the current evidence. However, given that the risk cannot be fully excluded, an assessment is ongoing. Continuous pharmacovigilance is essential for monitoring potential harms, especially given the need for long-term treatment when using semaglutide and tirzepatide for weight management. Finally, healthcare professionals should guide the treatment to optimise outcomes and minimise adverse events.

Introduction

Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP) are incretin hormones produced in the gastrointestinal tract upon meal ingestion to regulate postprandial glucose and lipid metabolism (1). Due to their glucoregulatory and anorectic properties, several GLP-1 and dual GIP/GLP-1 receptor agonists have been developed and initially approved for the treatment of type 2 diabetes mellitus (T2DM). The results of randomised controlled trials demonstrated their effectiveness in reducing weight and cardiovascular (CV) risk as well, leading to approvals for weight management in adults without diabetes (2) (see "Efficacy"). These products have recently become very popular for weight management as an adjunct to lifestyle modification (3, 4).

Overweight and obesity are defined as abnormal or excessive fat accumulation that poses a risk to health. Since 1990, adolescent obesity has quadrupled globally (5), while overweight and obesity rates in adults have more than doubled, with an estimated 1.00 billion adult males and 1.11 billion adult females living with obesity and overweight in 2021. These rates are forecast to increase further, leading to an even greater burden of obesity-related diseases such as diabetes, cardiovascular disease and cancer (6). In 2022, about 30% of the Swiss population were overweight, and 12.1% were obese (7). Obesity is one of the largest contributors to the global burden of disease (8).

GLP-1 and GLP-1/GIP receptor agonists facilitate weight loss through reduced caloric intake by acting on the gastroenteric (delayed gastric emptying) and central nervous (appetite suppression and increased satiety) systems (see "Efficacy"). Furthermore, they regulate postprandial glucose and lipid metabolism by improving glycaemic control, stimulating lipogenesis (GIP) or pro-

moting lipolysis (GLP-1). GLP-1 and GIP exert an insulinotropic effect by binding to pancreatic β-cells (1). Moreover, they regulate glucagon secretion from pancreatic α-cells by exerting a glucagonostatic effect during hyperglycaemia (GIP + GLP-1) or a glucagonotropic effect during hypoglycaemia (GIP). GIP and GLP-1 receptors are both expressed in multiple tissues, including the brain region involved in appetite regulation, the cardiovascular and immune systems (leukocytes), the gastrointestinal tract, adipose tissue and kidneys (9).

In this article, we present an update on the efficacy and harms of the GLP-1 and dual GLP-1/GIP receptor agonists authorised in Switzerland for weight management – namely semaglutide (Wegovy) and tirzepatide (Mounjaro) – based on recent scientific evidence (Table 1).

Table 1: GLP-1 and dual GLP-1/GIP receptor agonists authorised in Switzerland for weight management

Active substance	Mechanism of action	Trade name	Date of first MA
Semaglutide	GLP-1 receptor agonist	Wegovy	15.02.2022
Tirzepatide	GLP-1/GIP receptor agonist	Mounjaro	02.11.2022

The trade name and date of first marketing authorisation refer to Switzerland. Trade names may differ outside Switzerland (e.g., Mounjaro is Zepbound in the USA and Canada). MA: marketing authorisation; GLP-1: Glucagon-like peptide-1; GIP: Glucose-dependent insulinotropic peptide.

Efficacy

GLP-1, a polypeptide released by cells in the distal gut in response to glucose intake, lowers plasma glucose by i) inhibiting glucagon secretion; ii) stimulating insulin secretion; iii) slowing gastric emptying; and iv) increasing satiety (10). Similarly, glucose-dependent insulinotropic peptide (GIP), which is secreted by K-cells in the proximal small intestine, stimulates insulin secretion and modulates glucagon release in a glucose-dependent manner. Endogenous GLP-1 and GIP are rapidly inactivated by dipeptidyl peptidase-4 (DPP-4).

Semaglutide is a DPP-4-resistant recombinant GLP-1 analogue with "mono-agonist" properties. Its benefits include glucose-lowering effects (e.g.,11), weight loss (12, 13) and cardiovascular and renal protection (14–16). The fact that patients often require elevated doses of semaglutide to achieve significant weight loss triggered the development of "multi-agonists". Multi-agonists merge structural features from different members of the glucagon superfamily into a single molecule with improved efficacy (17, 18). Tirzepatide was the first twincretin (i.e., a dual-agonist of GLP-1/GIP) to receive marketing approval. Its benefits include antihyperglycaemic action (e.g., 19) and weight loss (20–23). It is also efficacious in the treatment of obstructive sleep apnoea (OAS) in obese people (24). Metabolic dysfunction-associated steatotic liver disease (MASLD) has recently emerged as another condition that could potentially be treated with semaglutide or tirzepatide (25, 26). Table 2 summarises the currently approved indications for semaglutide and tirzepatide in Switzerland, in the United States of America or in the European Union.

Table 2: Currently approved indications of semaglutide and tirzepatide in Switzerland, in the United States of America or in the European Union

Active Substance	Indication	Target population	Trade name
Semaglutide (GLP-1 receptor mono-agonist)	T2DM	Adults with T2DM	Ozempic®
	Weight management	Obese (BMI ≥ 30 kg/m²) **or** overweight (BMI ≥ 27 kg/m²) adults with at least one weight-related comorbidity (e.g., hypertension, dyslipidaemia, OSA, CV disease, prediabetes, T2DM)	Wegovy®
	CV risk reduction	Adults with overweight **and** preexisting CV disease	Wegovy®
		Adults with T2DM at high CV risk	Ozempic®
	Nephroprotection*	Adults with T2DM **and** CKD	Ozempic®
	Obesity-related HFpEF*	Adults with HFpEF **and** obesity ±T2DM	Wegovy®**
	MASH*	Adults with moderate to advanced liver fibrosis (consistent with stages F2 to F3)	Wegovy®**
Tirzepatide (GLP-1/GIP dual receptor agonist	T2DM	Adults with T2DM	Mounjaro®
	Weight management	Obese (BMI ≥ 30 kg/m²) **or** overweight (BMI ≥ 27 kg/m²) adults with at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, OSA, CV disease, prediabetes, T2DM)	Mounjaro®
	OSA*	Adults with OSA **and** obesity ±T2DM	Mounjaro®**

T2DM: Type 2 diabetes mellitus; BMI: Body mass index; OSA: Obstructive sleep apnoea; CV: Cardiovascular; CKD: Chronic kidney disease; HFpEF: Heart failure with preserved ejection fraction; MASH: Metabolic dysfunction-associated steatohepatitis.

* As yet (2 October 2025), this indication is not approved in Switzerland.
** For approved indications in Switzerland please refer to the specific products' information at www.swissmedicinfo.ch.

Table 3 illustrates the clinical data supporting the treatment benefits of semaglutide and tirzepatide for the cardiovascular system, kidney function and obstructive sleep apnoea. Metabolic dysfunction-associated steatotic liver disease (MASLD) has recently emerged as another condition that could potentially be treated with semaglutide or tirzepatide (25, 26).

Table 3: Clinical data supporting indications of semaglutide and tirzepatide

Indication	Substance	Clinical Endpoint	ETD HR [95% CI]	Reference
CV risk reduction	Semaglutide	MACE	0.80 [0.72, 0.9] 0.74 [0.58, 0.95]	(14) (15)
Obesity-related HFpEF		KCCQ-CSS	7.8 [4.8, 10.9] 7.3 [4.1, 10.4]	(27) (28)
Nephroprotection		Major kidney disease events	0.76 [0.66, 0.88]	(16)
OSA	Tirzepatide	AHI	-23.8 events/h [-29.6, -17.9]	(24, 29)

ETD: Estimated treatment difference versus placebo; HR: Hazard ratio; CV: Cardiovascular; MACE: Major CV events defined as the composite of CV death, non-fatal myocardial infarction and non-fatal stroke; HFpEF: Heart failure with preserved ejection fraction; KCCQ-CSS: Kansas City Cardiomyopathy Questionnaire Clinical Summary Score; Major kidney disease events: Composite of i) onset of kidney failure (initiation of long-term dialysis, kidney transplantation or a sustained reduction in eGFR to <15 ml/min/1.73 m²; ii) ≥50% reduction in eGFR; and iii) death from any kidney-related/CV cause; AHI: apnoea-hypopnea index, which is the hourly number of events of apnoea (drop in airflow ≥90% from baseline for ≥10 s) **and** hypopnea (abnormal respiratory event lasting ≥10 s with ≥30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with ≥ 4% O_2 desaturation).

Harms

In this section, we discuss selected harms that were recently assessed or resulted in the updating of the Information for healthcare professionals (HCPs) for GLP-1 and dual GLP-1/GIP receptor agonists authorised in Switzerland for weight management – namely semaglutide (Wegovy) and tirzepatide (Mounjaro) (Table 4).

Information on all harms associated with these medicinal products based on the current scientific evidence is provided in the products' information at www.swissmedicinfo.ch.

Table 4: Selected harms concerning tirzepatide and semaglutide discussed in this section

Selected harm	Assessment output
Gastroenteric harms	
Delayed gastric emptying, gastroparesis, aspiration / pneumonia aspiration (in association with anaesthesia and preparation for endoscopy)	Confirmed risks of delayed gastric emptying and gastroparesis as a class effect of GLP-1 receptor agonists due to their pharmacodynamic effects. Given that residual gastric content is a known risk factor for intraoperative aspiration, guidelines for perioperative and periendoscopic management of patients receiving GLP-1 and GLP-1/GIP receptor agonists have been issued.
Dysgeusia	Confirmed adverse drug reaction based on reported cases (PV, clinical trials). Pathomechanisms not fully elucidated.
Gallbladder-related disorders	Confirmed risk as a class effect of GLP-1 receptor agonists due to the suppression of postprandial secretion of cholecystokinin, attenuating gallbladder motility and contractility. The frequency is higher for semaglutide (common), than for tirzepatide (uncommon).
Thyroid cancer	Increased risk not confirmed for humans. Increased risk for both tirzepatide and semaglutide in preclinical carcinogenicity studies in rodents. Significance of these findings for medullary thyroid cancer (MTC) risk in humans is unknown: GLP-1 receptor expression in thyroid cells is higher in rodents, and C-cell tumours in rodents are caused by a non-genotoxic mechanism specifically mediated by the GLP-1 receptor, to which rodents are particularly susceptible. Furthermore, obesity and T2DM are risk factors for thyroid cancer in humans.
Non-arteritic ischemic optic neuropathy (NAION)	The European Medicines Agency (EMA) confirmed the risk of NAION for semaglutide as a very rare adverse reaction based on a review of the available evidence, including clinical trial data, epidemiological studies and post-marketing surveillance. The EMA recommended a label update to reflect this risk for semaglutide. There is currently no evidence of a link between tirzepatide and NAION. This safety issue is under evaluation by Swissmedic at present (2 October 2025).
Suicidal ideation	Currently available evidence does not support a causal association. Further close monitoring of the potential risk is warranted to confirm and strengthen the available evidence.

Gastroenteric harms

Delayed gastric emptying, gastroparesis, aspiration and pneumonia aspiration

Gastroparesis is characterised by delayed gastric emptying. Its pathophysiology is complex and often involves vagus nerve dysfunction. This condition is a frequent and serious complication of diabetic autonomic neuropathy (30, 31). Delayed gastric emptying may increase the risk of oesophageal regurgitation, pulmonary aspiration and pneumonia. Intraoperative pulmonary aspiration is a potentially life-threatening complication associated with general anaesthesia or deep sedation (32).

Inhibition of gastric motility and delay of gastric emptying have been identified as a class effect of GLP-1 receptor agonists. The frequency of residual gastric content after routine pre-operative fasting – a known risk factor for intraoperative aspiration – was increased in patients on GLP-1 receptor agonists (33). Individuals receiving GLP-1 receptor agonists, especially those with pre-existing gastric motility disorders such as diabetic autonomic neuropathy, may therefore have a higher risk of aspiration in the perioperative setting. Recognising these risks, the American Society for Metabolic and Bariatric Surgery and the American Society for Gastro-

intestinal Endoscopy have released guidelines for perioperative and periendoscopic management of patients on GLP-1 and GLP-1/GIP receptor agonists, including recommendations for upper endoscopies, to minimise the risk of aspiration (34, 35).

Dysgeusia

Dysgeusia refers to an altered taste sensation, sometimes described as metallic. It is quite common, with prevalence rates from 0.6–20% and increasing with age, and of variable duration depending on the aetiology (36). The pathomechanisms of dysgeusia are linked to neurological damage to the gustatory pathways at the peripheral or central level. Infections (especially viral, e.g. COVID-19 infection) and inflammatory responses, trauma and psychological factors can also result in altered taste sensation. Systemic diseases such as diabetes and cancer may also cause dysgeusia as a result of metabolic changes (37). Conditions of altered taste and smell can overlap, and multiple medications are associated with dysgeusia, including chemotherapy, anti-inflammatory, diuretics and antihypertensive agents.

Dysgeusia is a recognised rare side effect of tirzepatide and semaglutide. The underlying pathomechanisms have not been fully elucidated and are likely a complex interaction between gustatory processing at both peripheral and central nervous system level, and gastrointestinal effects. GLP-1 is produced in taste bud cells, and its receptors are present on nearby gustatory nerves. Activation of these receptors modulates sensitivity to taste, especially sweetness (38). Central signalling pathways – such as those in the brainstem – may also be altered by these medications, further affecting taste perception (39). Additionally, GLP-1 receptor agonist-induced changes in gastric motility and delayed gastric emptying can indirectly impact taste by influencing gut-brain interactions linked to taste processing. This multifactorial disruption produces dysgeusia in some patients who are taking semaglutide and tirzepatide. This rare side effect was confirmed by data from the clinical trial and post-marketing settings.

Gallbladder-related disorders

Cholelithiasis is a common condition affecting approximately 10–15% of the general population worldwide (40). Gallstones can be composed of cholesterol or pigment, and their formation is influenced by, for example, impaired gallbladder motility, imbalance in bile composition, genetic factors and metabolic factors that result in excessive liver cholesterol secretion. The risk factors for cholelithiasis are female sex, older age, obesity, pregnancy and rapid weight loss (41, 42). GLP-1 receptor agonists suppress the postprandial secretion of cholecystokinin, consequently impairing gallbladder motility and contractility (43). GIP is also involved in gallbladder motility (44). These mechanisms reduce bile flow, facilitate the development of gallstones and contribute to alterations in lipid metabolism that promote biliary cholesterol crystallisation.

Data summarised in the Information for HCPs show that in clinical trials, acute gallbladder disease, including cholelithiasis, occurred in 0.6% of tirzepatide-treated patients, whereas no cases were reported in the controls. Cholelithiasis and cholecystitis were reported in 1.6% and 0.6% of patients taking semaglutide, compared to 1.1% and 0.3% of patients taking placebo, respectively. Given the mechanism of action, the increased risk of cholelithiasis and cholecystitis is considered a class effect.

Although asymptomatic in the majority of cases, cholelithiasis can cause nausea, diarrhoea and anorexia. It may require cholecystectomy and lead to life-threatening conditions such as acute cholecystitis (41). Considering that obesity and drastic weight loss are risk factors for these conditions, it is important for patients taking semaglutide or tirzepatide and for HCPs to be aware of this risk.

Thyroid cancer

Medullary thyroid cancer (MTC, also called C-cell carcinoma) is a rare neuroendocrine tumour representing 1% to 5% of all thyroid cancers, but accounting for approximately 13% of thyroid cancer-related mortality. Although the mechanism is not known, epidemiological

studies have shown an association between obesity and T2DM and an increased risk of several cancers, including thyroid cancer (45). GLP-1 receptors are present in thyroid tissues, and preclinical studies with GLP-1 and GLP-1/GIP receptor agonists in rodents demonstrated an increased risk of MTC. Data summarised in the Information for HCP show that in a two-year carcinogenicity study in rats, tirzepatide caused an increase in MTC at all doses, and semaglutide caused MTC at clinically relevant exposures.

The significance of these findings for humans is unknown. Expression of GLP-1 receptors in thyroid tissues is higher in rodents compared with humans (46). Moreover, the MTC in rodents is caused by a non-genotoxic mechanism specifically mediated by the GLP-1 receptor, to which rodents are particularly susceptible. Clinical trials and post-marketing surveillance have not demonstrated a clear causal link between GLP-1 receptor agonists and thyroid cancer in humans. However, the risks cannot be completely excluded, especially since patients with MTC or with a history of multiple endocrine neoplasia type 2 (MEN2) were not treated with either semaglutide or tirzepatide in clinical studies. The Information for HCPs contains information on the carcinogenicity studies, the uncertainty of their relevance to the risk for humans and a warning for cautious use in patients with MTC or MEN2.

Suicidal ideation

Several classes of medications have been associated with suicide-related events, including antidepressants (47), anticonvulsants (48) and hormonal contraceptives (49). Concerns have been raised regarding a potential association between GLP-1 receptor agonists and psychiatric effects, including suicidal ideation. Given the presence of GLP-1 receptors in the central nervous system, neuropsychiatric effects due to incretin-based therapies are biologically plausible. However, there is also evidence to support the positive effects of GLP-1 RA on patients' wellbeing (50), and many patients treated with GLP-1 receptor agonists suffer with obesity, T2DM, weight control failure or other comorbidities, which themselves are associated with increased risk of depression or suicidal ideation (51–53).

Case reports of suicidal thoughts and thoughts of self-injury from people using liraglutide and semaglutide triggered an EMA review of this risk. A cohort study in the United Kingdom conducted with 27,000 patients with T2DM over a 10-year period did not support a causal association with GLP-1 receptor agonists (54). A recent retrospective cohort study did not find an association between semaglutide and suicidal ideation in patients with overweight and T2DM compared to non-GLP1 receptor agonists or anti-obesity or anti-diabetes medications (55). The evidence regarding tirzepatide and suicide-related events is limited and contrasting. An analysis of reports submitted to the EudraVigilance database identified psychiatric adverse events associated with tirzepatide, with a total of 0.7% of events classified as suicidal ideation (56). However, an analysis of adverse events related to tirzepatide from the U.S. Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) did not specifically highlight suicide-related events (57). In conclusion, the currently available evidence does not support a causal association between the use of GLP-1 or GLP-1/GIP receptor agonists and suicidality (58). Given that the risk cannot be fully excluded, an assessment is ongoing. While it is important to recognise and validate community concerns, care should also be taken to avoid creating undue concern where the available evidence does not substantiate a safety signal.

Non-arteritic ischemic optic neuropathy (NAION)

Non-arteritic anterior ischemic optic neuropathy (NAION) is an idiopathic, ischemic insult of the optic nerve head, presenting as an acute, painless, monocular vision loss, often with optic disc oedema and visual field defects (59). Vision loss is generally irreversible, and no effective treatment is currently available (60). Despite being the second most common optic neuropathy in adults after glaucoma, its aetiology remains unknown. However, NAION is believed to be a multifactorial aetiology primarily linked to vascular insufficiencies, in which reduced blood flow leads to ischemic damage of the optic nerve head. Anatomical predisposition, such as a crowded optic nerve head, appears to play a central role in susceptibility. Additional systemic and cardiovas-

cular risk factors – including diabetes mellitus, hypertension, hyperlipidemia, obstructive sleep apnoea and smoking – may exacerbate vascular compromise and contribute to ischemic injury (60). A recent large Danish epidemiological study of 424,152 persons suggested that exposure to semaglutide in adults with T2DM is associated with an approximately two-fold increase in the risk of NAION compared to non-users (61). A retrospective matched US cohort study also suggests an association between semaglutide and NAION (62). Data from clinical trials also point to a slightly higher risk in people taking semaglutide compared to placebo. By contrast, there is currently no direct evidence linking tirzepatide to NAION.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) reviewed the available evidence on NAION with semaglutide and recommended adding it to the semaglutide product information as a "very rare" adverse event (63). This potential harm is currently being assessed by Swissmedic.

Conclusions

While both semaglutide and tirzepatide demonstrate significant efficacy in weight reduction, balancing their efficacy and safety for weight management necessitates individual assessments by HCPs and personalised treatment plans. The benefits depend on individual goals, such as the appropriateness of these treatments for specific obesity cases that may require surgical intervention instead, as well as the patient's tolerance for potential adverse events to reach those goals. Overall, continuous safety monitoring of marketed medicines is crucial for their safe use, particularly for those potentially intended for long-term or even life-long therapy, such as semaglutide and tirzepatide. Given the frequent updates based on the assessment of new scientific evidence and PV data, it is therefore crucial to refer to the most current product information which can be found at www.swissmedicinfo.ch.

Reporting adverse drug reactions

By reporting adverse drug reactions, HCPs contribute significantly to patient safety. HCPs in Switzerland are required to report serious and/or previously unknown side effects to Swissmedic. This reporting is crucial for early detection of potential drug risks and continuous monitoring of the benefit-risk profile of all available medicines. Reports can be submitted via the Electronic Vigilance System (ElViS) portal (see: Reporting adverse drug reactions for healthcare professionals).

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References

1
Drucker DJ, Holst JJ. The expanding incretin universe: from basic biology to clinical translation. Diabetologia. 2023;66(10):1765–79.

2
Moll H, Frey E, Gerber P, Geidl B, Kaufmann M, Braun J, et al. GLP-1 receptor agonists for weight reduction in people living with obesity but without diabetes: a living benefit–harm modelling study. EClinicalMedicine. 2024;73.

3
Chakhtoura M, Haber R, Ghezzawi M, Rhayem C, Tcheroyan R, Mantzoros CS. Pharmacotherapy of obesity: an update on the available medications and drugs under investigation. EClinicalMedicine. 2023;58.

4
Xie Y, Choi T, Al-Aly Z. Mapping the effectiveness and risks of GLP-1 receptor agonists. Nature Medicine. 2025;31(3):951–62.

5
(WHO) WHO. Obesity and overweight 2025 [Available from: https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight.

6
Ng M, Gakidou E, Lo J, Abate YH, Abbafati C, Abbas N, et al. Global, regional, and national prevalence of adult overweight and obesity, 1990–2021, with forecasts to 2050: a forecasting study for the Global Burden of Disease Study 2021. The Lancet. 2025;405(10481):813–38.

7
(MonAM) SMSoAaND. Overweight and obesity (age: 15+) 2025 [Available from: https://ind.obsan.admin.ch/en/indicator/monam/overweight-and-obesity-age-15.

8
Brauer M, Roth GA, Aravkin AY, Zheng P, Abate KH, Abate YH, et al. Global burden and strength of evidence for 88 risk factors in 204 countries and 811 subnational locations, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. The Lancet. 2024;403(10440):2162–203.

9
Liu QK. Mechanisms of action and therapeutic applications of GLP-1 and dual GIP/GLP-1 receptor agonists. Frontiers in endocrinology. 2024;15:1431292.

10
Andersen A, Lund A, Knop FK, Vilsboll T. Glucagon-like peptide 1 in health and disease. Nature reviews Endocrinology. 2018;14(7):390–403.

11
Sorli C, Harashima SI, Tsoukas GM, Unger J, Karsbol JD, Hansen T, et al. Efficacy and safety of once-weekly semaglutide monotherapy versus placebo in patients with type 2 diabetes (SUSTAIN 1): a double-blind, randomised, placebo-controlled, parallel-group, multinational, multicentre phase 3a trial. Lancet Diabetes Endocrinol. 2017;5(4):251–60.

12
Davies M, Faerch L, Jeppesen OK, Pakseresht A, Pedersen SD, Perreault L, et al. Semaglutide 2.4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): a randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial. Lancet. 2021;397(10278):971–84.

13
Wilding JPH, Batterham RL, Calanna S, Davies M, Van Gaal LF, Lingvay I, et al. Once-Weekly Semaglutide in Adults with Overweight or Obesity. The New England Journal of Medicine. 2021;384(11):989–1002.

14
Lincoff AM, Brown-Frandsen K, Colhoun HM, Deanfield J, Emerson SS, Esbjerg S, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. The New England Journal of Medicine. 2023;389(24):2221–32.

15
Marso SP, Bain SC, Consoli A, Eliaschewitz FG, Jódar E, Leiter LA, et al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes (SUSTAIN-6). New England Journal of Medicine. 2016;375 (19):1834–44.

16
Perkovic V, Tuttle KR, Rossing P, Mahaffey KW, Mann JFE, Bakris G, et al. Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes. The New England Journal of Medicine. 2024;391(2):109–21.

17
Tschop MH, Finan B, Clemmensen C, Gelfanov V, Perez-Tilve D, Muller TD, et al. Unimolecular Polypharmacy for Treatment of Diabetes and Obesity. Cell Metabolism. 2016;24(1):51–62.

18
Novikoff A, O'Brien SL, Bernecker M, Grandl G, Kleinert M, Knerr PJ, et al. Spatiotemporal GLP-1 and GIP receptor signaling and trafficking/recycling dynamics induced by selected receptor mono- and dual-agonists. Mol Metab. 2021;49:101181.

19
Rosenstock J, Wysham C, Frías JP, Kaneko S, Lee CJ, Fernández Landó L, et al. Efficacy and safety of a novel dual GIP and GLP-1 receptor agonist tirzepatide in patients with type 2 diabetes (SURPASS-1): a double-blind, randomised, phase 3 trial. The Lancet. 2021;398(10295):143–55.

20
Aronne LJ, Sattar N, Horn DB, Bays HE, Wharton S, Lin WY, et al. Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: The SURMOUNT-4 Randomized Clinical Trial. Jama. 2024;331(1):38–48.

21
Garvey WT, Frias JP, Jastreboff AM, le Roux CW, Sattar N, Aizenberg D, et al. Tirzepatide once weekly for the treatment of obesity in people with type 2 diabetes (SURMOUNT-2): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. Lancet. 2023;402(10402):613–26.

22
Jastreboff AM, Aronne LJ, Ahmad NN, Wharton S, Connery L, Alves B, et al. Tirzepatide Once Weekly for the Treatment of Obesity. The New England Journal of Medicine. 2022;387(3):205–16.

23
Wadden TA, Chao AM, Machineni S, Kushner R, Ard J, Srivastava G, et al. Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial. Nat Med. 2023;29(11):2909–18.

24
Malhotra A, Grunstein RR, Fietze I, Weaver TE, Redline S, Azarbarzin A, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity. The New England Journal of Medicine. 2024;391(13):1193–205.

25
Loomba R, Hartman ML, Lawitz EJ, Vuppalanchi R, Boursier J, Bugianesi E, et al. Tirzepatide for Metabolic Dysfunction-Associated Steatohepatitis with Liver Fibrosis. The New England Journal of Medicine. 2024;391(4):299–310.

26
Sanyal AJ, Newsome PN, Kliers I, Ostergaard LH, Long MT, Kjaer MS, et al. Phase 3 Trial of Semaglutide in Metabolic Dysfunction-Associated Steatohepatitis. The New England Journal of Medicine. 2025;392(21):2089–99.

27
Kosiborod MN, Abildstrom SZ, Borlaug BA, Butler J, Rasmussen S, Davies M, et al. Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. The New England Journal of Medicine. 2023;389(12):1069–84.

28
Kosiborod MN, Petrie MC, Borlaug BA, Butler J, Davies MJ, Hovingh GK, et al. Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes. The New England Journal of Medicine. 2024;390(15):1394–407.

29
Packer M, Zile MR, Kramer CM, Baum SJ, Litwin SE, Menon V, et al. Tirzepatide for Heart Failure with Preserved Ejection Fraction and Obesity. The New England Journal of Medicine. 2025;392(5):427–37.

30
Deirmenjian JM, Dagher C. 6486 Gastroparesis Exacerbation by a GLP-1 Agonist. Journal of the Endocrine Society. 2024;8(Supplement_1).

31
Van den Houte K, Scarpellini E, Verbeure W, Mori H, Schol J, Masuy I, et al. The Role of GI Peptides in Functional Dyspepsia and Gastroparesis: A Systematic Review. Frontiers in Psychiatry. 2020;11:172.

32
Nason KS. Acute Intraoperative Pulmonary Aspiration. Thoracic surgery clinics. 2015;25(3):301–7.

33
Baig MU, Piazza A, Lahooti A, Johnson KE, Rangwani S, Gouda Z, et al. Glucagon-like peptide-1 receptor agonist use and the risk of residual gastric contents and aspiration in patients undergoing GI endoscopy: a systematic review and a meta-analysis. Gastrointest Endosc. 2025;101(4):762–71.e13.

34
Kindel TL, Wang AY, Wadhwa A, Schulman AR, Sharaiha RZ, Kroh M, et al. Multisociety clinical practice guidance for the safe use of glucagon-like peptide-1 receptor agonists in the perioperative period. Surgery for Obesity and Related Diseases. 2024;20(12):1183–6.

35
Sharaiha RZ, Shukla AP, Sen S, Chan WW, Broome DT, Anca D, et al. American Society for Gastrointestinal Endoscopy position statement on perioperative endoscopic management of patients on glucagon-like peptide-1 receptor agonists and sodium-glucose cotransporter-2 inhibitors. Gastrointestinal Endoscopy. 2025;101(2):285–94.

36
Thomas DC, Chablani D, Parekh S, Pichammal RC, Shanmugasundaram K, Pitchumani PK. Dysgeusia: A review in the context of COVID-19. The Journal of the American Dental Association. 2022;153(3):251–64.

37
Jafari A, Alaee A, Ghods K. The etiologies and considerations of dysgeusia: A review of literature. Journal of Oral Biosciences. 2021;63(4):319–26.

38
Jensterle M, DeVries JH, Battelino T, Battelino S, Yildiz B, Janez A. Glucagon-like peptide-1, a matter of taste? Reviews in Endocrine and Metabolic Disorders. 2021;22(4):763–75.

39
Khan FI, Vazquez SG-S, Mehdi Z, Somawardana I, Dongre R, Razmi S, et al. Otolaryngologic Side Effects of GLP-1 Receptor Agonists. 2025;135(7):2291–8.

40
Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. Gut and Liver. 2012;6(2):172–87.

41
Sun H, Warren J, Yip J, Ji Y, Hao S, Han W, et al. Factors Influencing Gallstone Formation: A Review of the Literature. 2022;12(4):550.

42
He L, Wang J, Ping F, Yang N, Huang J, Li Y, et al. Association of Glucagon-Like Peptide-1 Receptor Agonist Use With Risk of Gallbladder and Biliary Diseases: A Systematic Review and Meta-analysis of Randomized Clinical Trials. JAMA Internal Medicine. 2022;182(5):513–9.

43
Rehfeld JF, Knop FK, Asmar A, Madsbad S, Holst JJ, Asmar M. Cholecystokinin secretion is suppressed by glucagon-like peptide-1: clue to the mechanism of the adverse gallbladder events of GLP-1-derived drugs. Scandinavian Journal of Gastroenterology. 2018;53(12):1429–32.

44
Zeng Q, Xu J, Mu X, Shi Y, Fan H, Li S. Safety issues of tirzepatide (pancreatitis and gallbladder or biliary disease) in type 2 diabetes and obesity: a systematic review and meta-analysis. 2023; Volume 14 - 2023.

45
Hu W, Song R, Cheng R, Liu C, Guo R, Tang W, et al. Use of GLP-1 Receptor Agonists and Occurrence of Thyroid Disorders: a Meta-Analysis of Randomized Controlled Trials. 2022; Volume 13 - 2022.

46
Morales DR, Bu F, Viernes B, DuVall SL, Matheny ME, Simon KR, et al. Risk of Thyroid Tumors With GLP-1 Receptor Agonists: A Retrospective Cohort Study. Diabetes Care. 2025.

47
Stübner S, Grohmann R, Greil W, Zhang X, Müller-Oerlinghausen B, Bleich S, et al. Suicidal Ideation and Suicidal Behavior as Rare Adverse Events of Antidepressant Medication: Current Report from the AMSP Multicenter Drug Safety Surveillance Project. International Journal of Neuropsychopharmacology. 2018;21(9):814–21.

48
Klein P, Devinsky O, French J, Harden C, Krauss GL, McCarter R, et al. Suicidality Risk of Newer Antiseizure Medications: A Meta-analysis. JAMA Neurology. 2021;78(9):1118–27.

49
Skovlund CW, Mørch LS, Kessing LV, Lange T, Lidegaard Ø. Association of Hormonal Contraception With Suicide Attempts and Suicides. The American Journal of Psychiatry. 2018;175(4): 336–42.

50
Gamble J-M, Chibrikov E, Midodzi WK, Twells LK, Majumdar SR. Examining the risk of depression or self-harm associated with incretin-based therapies used to manage hyperglycaemia in patients with type 2 diabetes: a cohort study using the UK Clinical Practice Research Datalink. 2018;8(10):e023830.

51
Khaledi M, Haghighatdoost F, Feizi A, Aminorroaya A. The prevalence of comorbid depression in patients with type 2 diabetes: an updated systematic review and meta-analysis on huge number of observational studies. Acta Diabetologica. 2019;56(6):631–50.

52
Luppino FS, de Wit LM, Bouvy PF, Stijnen T, Cuijpers P, Penninx BWJH, et al. Overweight, Obesity, and Depression: A Systematic Review and Meta-analysis of Longitudinal Studies. Archives of General Psychiatry. 2010;67(3):220–9.

53
Ju YJ, Han K-T, Lee T-H, Kim W, Park JH, Park E-C. Association between weight control failure and suicidal ideation in overweight and obese adults: a cross-sectional study. BMC Public Health. 2016;16(1):259.

54
(EMA) EMA. Association between exposure to GLP-1 receptor agonists and risk of suicide-related and self-harm-related events 2024 [Available from: https://catalogues.ema.europa.eu/node/3953/administrative-details.

55
Wang W, Volkow ND, Berger NA, Davis PB, Kaelber DC, Xu R. Association of semaglutide with risk of suicidal ideation in a real-world cohort. Nat Med. 2024;30(1):168–76.

56
Tobaiqy M, Elkout H. Psychiatric adverse events associated with semaglutide, liraglutide and tirzepatide: a pharmacovigilance analysis of individual case safety reports submitted to the EudraVigilance database. International Journal of Clinical Pharmacy. 2024;46(2):488–95.

57
Li J, Xie J, Han Y, Zhang W, Wang Y, Jiang Z. A real-world disproportionality analysis of tirzepatide-related adverse events based on the FDA Adverse Event Reporting System (FAERS) database. Endocrine Journal. 2025;72(3):273–83.

58
Di Stefano R, Rindi LV, Baldini V, Rossi R, Pacitti F, Jannini EA, et al. Glucagon-Like Peptide-1 receptor agonists, dual GIP/GLP-1 receptor agonist tirzepatide and suicidal ideation and behavior: A systematic review of clinical studies and pharmacovigilance reports. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2025;19(4):103238.

59
Hayreh SS. Management of non-arteritic anterior ischemic optic neuropathy. Graefe's Archive for Clinical and Experimental Ophthalmology. 2009;247(12):1595–600.

60
Simonsen E, Lund LC, Ernst MT, Hjellvik V, Hegedüs L, Hamann S, et al. Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish–Norwegian cohort study. 2025;27(6):3094–103.

61
Grauslund J, Taha AA, Molander LD, Kawasaki R, Möller S, Højlund K, et al. Once-weekly semaglutide doubles the five-year risk of nonarteritic anterior ischemic optic neuropathy in a Danish cohort of 424,152 persons with type 2 diabetes. International Journal of Retina and Vitreous. 2024;10(1):97.

62
Hathaway JT, Shah MP, Hathaway DB, Zekavat SM, Krasniqi D, Gittinger JW, Jr, et al. Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide. JAMA Ophthalmology. 2024;142(8):732–9.

63
(EMA) EMA. PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy 2025 [Available from: https://www.ema.europa.eu/en/news/prac-concludes-eye-condition-naion-very-rare-side-effect-semaglutide-medicines-ozempic-rybelsus-wegovy.

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Non-arteritic anterior ischemic optic neuropathy (NAION) in a patient treated with semaglutide

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Summary

Non-arteritic anterior ischemic optic neuropathy (NAION) is a condition that can result in acute monocular vision loss. Recently, several sources have reported cases of NAION in patients treated with semaglutide. A 68-year-old female patient who has had well controlled type 2 diabetes (T2D) for 12 years and which has been treated with semaglutide for approximately 2 years, presented with sudden loss of vision in her right eye. Ophthalmological investigations ruled out arteritic or inflammatory causes and supported a diagnosis of NAION in the right eye. Recent studies have investigated a possible link between the occurrence of NAION and semaglutide. In June 2025, a review by the European Medicines Agency concluded that NAION is a very rare side effect of semaglutide that could affect up to 1 in 10,000 patients taking semaglutide. Epidemiological studies suggest that semaglutide exposure is thus associated with an approximate doubling of this risk in patients with T2D compared with people not receiving the drug. The mechanism involved is still poorly understood. This is therefore a newly recognised adverse effect with a low estimated absolute risk, but one that prescribers and patients should be aware of because the drug is widely prescribed. This risk still needs to be better characterised.

Introduction

Although non-arteritic ischemic optic neuropathy (NAION) is a rare condition (up to 10 cases per 100,000 people per year), it is still considered to be the most common cause of acute blindness in older people. Its aetiology has not been clearly identified (1–2). It consists in an ischemic (non-arteritic) lesion of the optic nerve that can result in acute loss of vision in the affected eye. Several risk factors have been associated with NAION, including diabetes, arterial hypertension, sleep apnoea, etc. The underlying mechanism remains poorly understood, but the most commonly proposed hypothesis is that of hypoperfusion of the optic nerve leading to localised oedema and ischemia.

Several alerts have recently drawn attention to the risk of NAION in patients treated with semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, which is widely prescribed as part of first-line recommendations for the treatment of overweight type 2 diabetes (T2D) patients, in particular those at high cardiovascular risk (2).

We report here the case of a patient who developed NAION while receiving semaglutide treatment and briefly outline current knowledge and available literature concerning this potential adverse effect of semaglutide.

Observation

We report here the case of a 68-year-old female patient with a 12-year history of non-insulin requiring T2D for which semaglutide treatment was initiated about two years earlier. She had no history of macrovascular or microvascular complications (no retinopathy or nephropathy). She was also known to have hypercholesterolaemia, for which she was taking long-term treatment with atorvastatin, and was also receiving low dose aspirin as part of cardiovascular prophylaxis.

While her diabetes appeared to be under control (HbA1c 6.4%), the patient consulted her ophthalmologist urgently, reporting that for the past week she had experienced a loss of peripheral vision in her right eye with a sudden decrease in visual acuity that had remained unchanged since the onset of symptoms, without any associated pain, phosphenes or photophobia.

The ophthalmological examination revealed a significant decrease in visual acuity in the right eye to 0.08, but normal acuity in the left eye. Intraocular pressure was normal in both eyes. A slit lamp examination revealed a normal eyelid, calm conjunctiva, fluo-negative cornea and a calm and deep anterior chamber. The examination also noted the presence of a corticonuclear cataract on both sides, calm vitreous and a flat retina at 360°. In the right eye, there was papillary oedema with peripapillary haemorrhages above and below the optic nerve. In the left eye, the retina and papilla were normal. The visual field examination showed almost complete loss of the visual field in the right eye and an almost circumferential loss of the peripheral visual field in the left, which could be consistent with a cortical cataract. Fluorescein angiography revealed no signs of vasculitis that could be consistent with an arteritic cause. Laboratory tests showed no signs of inflammation. These observations led to a diagnosis of NAION in the right eye.

Semaglutide was subsequently discontinued on the basis of the first publications on cases of NAION in patients treated with semaglutide suggesting a possible involvement of this treatment. Follow-up several months after the event showed that the ocular symptoms remained unchanged.

Discussion

The Swiss monograph for semaglutide mentions the possible development of diabetic retinopathy complications as a reported adverse reaction to this treatment. However, NAION is not reported as a specific entity.

One of the first publications on this issue reported an approximately 4- and 7-fold increase, respectively, in the risk (hazard ratio, HR) of NAION in T2D patients and overweight/obese patients treated with semaglutide compared to patients treated with antidiabetic/anti-obesity drugs other than GLP-1 receptor agonists (2). This was a retrospective propensity score-matched study of a cohort of 16,800 patients referred to a tertiary neuro-ophthalmology centre in the USA for suspected NAION over a period of 6 years (12/2017–11/2023). Among the T2D patients (n=710, including 194 exposed to semaglutide), there were 17 cases of NAION in the semaglutide group vs. six in the non-GLP-1 group, representing a cumulative incidence over 36 months of 8.9% (95% CI, 4.5–13.1%) vs. 1.8% (95% CI, 0–3.5%) and an HR of 4.28 (95% CI, 1.62–11.29, p<0.001). In overweight/obese patients (n=979, including 361 exposed to semaglutide), there were 20 cases in the semaglutide group vs. 3 in the non-GLP-1 receptor agonist group, representing a cumulative incidence over 36 months of 6.7% (95% CI, 3.6–9.7%) in the semaglutide group vs. 0.8% (95% CI, 0–1.8%) in the non-GLP-1 receptor agonist group and a HR of 7.64 (95% CI, 2.21-26.36, p<0.001). This increased risk was confirmed after adjusting for possible confounding factors, including glycaemic control quality. The highest risk was observed during the first year after semaglutide was prescribed. In addition to the classical limitations of this type of retrospective analysis based on health databases, the authors mentioned a possible selection bias (specialised tertiary centre) that might cause overestimation of the apparent increase in the risk of NAION associated with semaglutide prescription. They also highlighted the lack of information on medication adherence

(actual use of semaglutide) at the time of ophthalmological diagnosis and that their study was therefore not designed to investigate potential causality.In addition, a dechallenge and rechallenge experiment cannot be considered in the context of NAION for obvious clinical reasons, given that NAION is usually considered irreversible (3).

Furthermore, more extensive data from 14 databases (37.1 million subjects with T2D, including 810,390 new users of semaglutide) published very recently concluded that there was a modest increase in the risk of NAION in T2D patients newly treated with semaglutide alone compared to patients taking empagliflozin (SGLT2 inhibitor) with a HR of 2.27 (95% CI, 1.16-4.46, p=0.02), while there was no significant difference between the semaglutide group and the "other GLP-1 receptor agonist" group (dulaglutide and exenatide or other non-GLP-1 receptor agonist drugs (empagliflozin, sitagliptin, glipizide)) (4). It should be noted that NAION was not diagnosed in all cases by specialised neuro-ophthalmologists and that patients over the age of 65 (the age group at risk of NAION) were not included in several databases. Furthermore, a Danish study showed a doubling of the risk of NAION after 5 years of exposure in more than 424,000 patients with T2D (increased incidence: 0.22 vs. 0.09 cases/1,000 patients/year), even after adjustment for glycaemic control (5). These data were corroborated by an analysis of two Danish and Norwegian health registries that compared the risk of NAION in T2D patients who initiated treatment with semaglutide vs. treatment with an SGLT2 inhibitor, with a pooled HR of 2.81 (95% CI, 1.67-4.75) and an incidence difference of +1.41 (95% CI, +0.53 to +2.29)/10,000 patients/year. However, analysis of the risk of NAION associated with semaglutide treatment for obesity was inconclusive (6).

In contrast, another analysis of data from seven observational studies found no statistically significant increase in the relative risk of NAION with semaglutide or other GLP-1 receptor agonists (HR: 2) (7). In another retrospective cohort study involving follow-up over a period of six years (21 countries, 37,314 participants with T2D, 129,690 participants with obesity and 130,216 participants with T2D and obesity), semaglutide did not appear to be associated with an increased risk of NAION (8).

We did not identify in the literature a convincing, well-established, mechanistic link between GLP-1 receptor agonists and the occurrence of NAION (1). GLP-1 receptors are expressed in the ganglion cells of the retina that form the optic nerve. GLP-1 receptor agonists increase sympathetic nervous system activity, which could modulate optic nerve perfusion and potentially increase the risk of NAION (9).

In this context, the European Medicines Agency (EMA) launched a review of treatments containing semaglutide in relation to the risk of NAION in January 2025 through its Pharmacovigilance Risk Assessment Committee (PRAC). In June 2025, following this assessment and review, the PRAC concluded that NAION is a very rare adverse effect of semaglutide that could affect up to 1 in 10,000 patients taking this medication (10). According to the same source, the results of epidemiological studies suggest that exposure to semaglutide in patients with T2D could thus result in a two-fold increase in the risk of NAION compared to subjects not receiving this treatment. In the light of this assessment, a change to the European product monograph was recommended.

Conclusion

In practice, the apparent increase in the relative risk of developing NAION associated with semaglutide treatment, albeit with a small increase in absolute risk, must be weighed against the multiple proven benefits of GLP-1 receptor agonists in patients with T2D and in the treatment of obesity. However, given the widespread prescription of these treatments, even a small risk could possibly translate into a few clinically significant situations. As a precautionary measure, patients should be informed of this apparent risk of NAION with semaglutide and told that the increase in absolute risk is small and that some studies have not shown a consistent risk. Prescribers now need to be particularly vigilant when managing patients on semaglutide who experience vision alterations, regardless of the suspected cause.

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References

1
Rizzo JF 3rd. Unraveling the Enigma of Nonarteritic Anterior Ischemic Optic Neuropathy. J Neuroophthalmol. 2019 Dec;39(4):529–544.

2
Hathaway JT, Shah MP, Hathaway DB, Zekavat SM, Krasniqi D, Gittinger JW Jr, Cestari D, Mallery R, Abbasi B, Bouffard M, Chwalisz BK, Estrela T, Rizzo JF 3rd. Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide. JAMA Ophthalmol. 2024 Aug 1;142(8):732–739.

3
Rizzo JF 3rd, Hathaway JT. Semaglutide and Risk of NAION-Additional Insights. JAMA Ophthalmol. 2025 Apr 1;143(4):315–316.

4
Cai CX, Hribar M, Baxter S, Goetz K, Swaminathan SS, Flowers A, Brown EN, Toy B, Xu B, Chen J, Chen A, Wang S, Lee C, Leng T, Ehrlich JR, Barkmeier A, Armbrust KR, Boland MV, Dorr D, Boyce D, Alshammari T, Swerdel J, Suchard MA, Schuemie M, Bu F, Sena AG, Hripcsak G, Nishimura A, Nagy P, Falconer T, DuVall SL, Matheny M, Viernes B, O'Brien W, Zhang L, Martin B, Westlund E, Mathioudakis N, Fan R, Wilcox A, Lai A, Stocking JC, Takkouche S, Lee LH, Xie Y, Humes I, McCoy DB, Adibuzzaman M, Areaux RG Jr, Rojas-Carabali W, Brash J, Lee DA, Weiskopf NG, Mawn L, Agrawal R, Morgan-Cooper H, Desai P, Ryan PB. Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy. JAMA Ophthalmol. 2025 Apr 1;143(4):304–314.

5
Grauslund J, Taha AA, Molander LD, Kawasaki R, Möller S, Højlund K, Stokholm L. Once weekly semaglutide doubles the five-year risk of nonarteritic anterior ischemic optic neuropathy in a Danish cohort of 424,152 persons with type 2 diabetes. Int J Retina Vitreous. 2024 Dec 18;10(1):97.

6
Simonsen E, Lund LC, Ernst MT, Hjellvik V, Hegedüs L, Hamann S, Jørstad ØK, Gulseth HL, Karlstad Ø, Pottegård A. Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish-Norwegian cohort study. Diabetes Obes Metab. 2025 Jun;27(6):3094–3103.

7
Klonoff DC, Hui G, Gombar S. Real-World Evidence Assessment of the Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide. J Diabetes Sci Technol. 2024 Nov;18(6):1517–1518.

8
Chou CC, Pan SY, Sheen YJ, Lin JF, Lin CH, Lin HJ, Wang IJ, Weng CH. Association between Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy: A Multinational Population-Based Study. Ophthalmology. 2025 Apr;132(4):381–388.

9
Hebsgaard JB, Pyke C, Yildirim E, Knudsen LB, Heegaard S, Kvist PH. Glucagon-like peptide-1 receptor expression in the human eye. Diabetes Obes Metab. 2018 Sep;20(9):2304–2308.

10
PRAC (06.06.2025) : PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy. https://www.ema.europa.eu/en/news/prac-concludes-eye-condition-naion-very-rare-side-effect-semaglutide-medicines-ozempic-rybelsus-wegovy.

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Enhancing drug safety: the role of pharmacovigilance in paediatrics

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Summary

Despite extensive preclinical testing and clinical trials conducted prior to marketing authorisation, the safety profile of a medicinal product remains incomplete at the time of commercialisation. In children, developmental physiology – which alters pharmacokinetics (PK) and pharmacodynamics (PD) – frequent off-label use, the lack of age-appropriate pharmaceutical formulations and continuous dose adjustments related to growth all increase the risk of adverse drug reactions (ADRs). These factors highlight the need for robust post-marketing pharmacovigilance to ensure the identification and management of drug-related risks in paediatric populations.

Pharmacovigilance databases, such as VigiBase®, contain relatively few paediatric reports, reflecting underreporting driven by lower drug use compared to adults, difficulties in recognising ADRs, potential legal concerns related to reporting ADRs associated with off-label use and insufficient training of healthcare professionals (HCPs) in detecting and reporting ADRs.

Effective paediatric PV, which enables early detection of ADRs and the safe use of medicines, requires increased awareness and training of healthcare professionals, as well as close collaboration with regulatory authorities to optimise data collection, reporting and data quality.

Developmental differences in pharmacokinetics (PK) and pharmacodynamics (PD)

Children and adults differ markedly in weight, height, body composition and the growth and maturation of organs. These physiological processes are complex, non-linear and particularly pronounced in neonates and young children, contributing to the considerable heterogeneity within the paediatric population. This also significantly influences drug PK (absorption, distribution, metabolism and elimination of drugs) and PD, leading to potential differences in drug responses compared to adults, as well as among different paediatric age groups (e.g., neonates versus adolescents). Consequently, extrapolating adult clinical-trial safety data to paediatrics is challenging and underscores the need for enhanced post-marketing pharmacovigilance in this age group. Neonates exhibit delayed gastric emptying, reduced hydrochloric acid secretion and an immature intestinal microbiota, which can alter the solubility and bioavailability of orally administered drugs. In contrast, transdermal absorption is enhanced due to thinner, more permeable skin and a higher body surface area-to-weight ratio, which increases the risk of systemic toxicity from topical agents. Drug distribution is also age-dependent. In neonates, total body water content can reach up to 80%,

resulting in a larger volume of distribution for hydrophilic drugs and requiring higher weight-adjusted doses to achieve therapeutic plasma concentrations. Additionally, lower plasma protein levels may result in a higher proportion of unbound (active) drug, potentially leading to increased toxicity. Immature renal function and underdeveloped hepatic enzymatic systems – including cytochrome P450 isoenzymes (CYP) and uridine 5'-diphospho-glucuronosyltransferases (UGTs) – contribute to reduced drug clearance in neonates. Conversely, certain metabolic pathways may become transiently overactive in older infants and children (e.g. "supermetabolism"), requiring higher doses, in relative terms, of some drugs. Furthermore, the developmental immaturity of target organs and receptor systems can influence both drug efficacy and safety (1, 2)

Limited availability of paediatric-specific PK and PD data

Despite the well-established differences between adults and children as regards PK and PD, paediatric populations are still underrepresented in or excluded from clinical trials. This persistent gap is driven by a complex interplay of ethical, practical and economic factors. From an ethical perspective, enrolling children in clinical research poses unique challenges. Children are considered a vulnerable population, and ethical guidelines require additional safeguards to prevent exploitation or unnecessary risk. Obtaining informed consent is inherently more complex, as it requires not only parental or guardian permission but also, in many cases, assent from the child – depending on their age and maturity.

In practice, conducting paediatric trials presents unique methodological challenges. Paediatric diseases may have a low prevalence, making recruitment difficult and often prolonging trial timelines. Age-related physiological variability – from neonates to adolescents – also necessitates stratification into narrower age groups, which further complicates study design. The volume and frequency of blood sampling, a core component of PK studies, are limited by safety concerns, which makes it difficult to obtain robust PK data.

From a commercial standpoint, pharmaceutical companies may lack strong financial incentives to invest in paediatric research. The paediatric market is typically smaller than the adult market, particularly for rare diseases or off-patent drugs. As a result, many medications used in paediatric practice are prescribed off-label, with insufficient evidence of their safety or efficacy in children (3, 4).

High prevalence of off-label drug use in children

The limited number of drugs formally approved for paediatric use has led to a widespread reliance on off-label prescribing, under which medications are used outside their authorised age group, dosage, formulation or indication. It is estimated that between 50 and 60% of all paediatric prescriptions are off-label, and this figure can be as high as 80% in specialised settings such as neonatal and paediatric intensive care units (5–10).

Variability in dosing due to insufficient paediatric data and increased susceptibility to medication errors

Off-label use is often unavoidable in paediatrics when no authorised alternatives exist, but it carries distinct risks. The absence of age-specific PK and PD data frequently forces clinicians to extrapolate from adult regimens, an approach that may not accurately capture children's therapeutic needs or safety profiles. Children may experience subtherapeutic or supratherapeutic drug effects, increasing the likelihood of adverse drug reactions (ADRs) or toxicity.

Moreover, the absence of standardised, evidence-based dosing guidance contributes to significant variability in prescribing practices across clinicians and institutions. The absence of age-appropriate formulations increases the risk of dosing errors, complicates drug administration and often necessitates the use of compounded or imprecisely divided preparations, which also can lead to subtherapeutic or supratherapeutic drug effects (9).

Difficulties in recognising and attributing ADRs in the paediatric population

Identifying and attributing ADRs in children is inherently more complex than in adults, owing to a combination of developmental, clinical and communication-related factors. Young children, particularly infants and toddlers, are often unable to articulate or reliably describe subjective symptoms. While an adult may report symptoms such as dizziness, nausea or visual disturbances, a young child may only exhibit non-specific signs such as crying, irritability, poor feeding or altered sleep patterns. These behaviours can easily be misattributed to common paediatric illnesses, growth-related changes or normal developmental phases, delaying recognition of a potential drug reaction. Furthermore, the lack of age-appropriate diagnostic tools and validated assessment scales for paediatric populations complicates ADR detection and monitoring (9, 10).

Post-marketing surveillance and paediatric-specific adverse drug reactions

Pharmacovigilance follows and monitors the safety of drugs once they are on the market. One of the most commonly used methods for detecting ADRs is spontaneous reporting. Spontaneous reporting systems provide a way for healthcare providers, parents, caregivers and patients to report suspected ADRs; and despite the above-mentioned limitations, post-marketing surveillance has made it possible to identify ADRs specific to the paediatric population, which has resulted in the refinement of drugs labelling, safety warnings or approved indications. Sulfonamides have been linked to kernicterus in premature infants, while chloramphenicol has been associated with "grey baby syndrome" due to the limited metabolic capacity of neonates (11). Both are contraindicated in young children. Cisapride was withdrawn from the market due to rare but potentially serious cardiac effects in children (12). Codeine was long used in paediatrics as an analgesic and antitussive. Multiple paediatric cases of respiratory depression in CYP2D6 ultra-rapid metabolisers led regulators to contraindicate codeine in children under 12 years and – in some countries (e.g., the United States) – to restrict its use in all patients under 18 years (13).

Paediatric cases in pharmacovigilance databases

Several studies have analysed ADRs in children as reported in national pharmacovigilance databases (14, 15, 16). The ADRs most frequently reported are commonly associated with vaccines and antibiotics. In terms of clinical manifestations, general disorders, skin reactions and nervous system disorders are the most prevalent.

As at 15 August 2025, VigiBase – the WHO global database of spontaneous ADR reports from member countries – contained 41,616,340 de-duplicated reports, of which 3,074,041 (7.4%) were paediatric reports (0–17 years). In Switzerland, paediatric individual case safety reports (ICSRs) accounted for 8,445 out of a total of 182,231 total reports (4.6%), which suggests possible differences in reporting practices relative to the global dataset.

Among the Swiss paediatric reports, healthcare professionals (HCPs) were the most common primary reporters (7,413; 87.8%), followed by patients/parents/relatives (607; 7.2%); reporter qualification unknown was noted in 425 (5.0%) cases. Serious cases accounted for 4,267 (50.5%) of paediatric reports; of these 353 (4.2%) had a fatal outcome and 88 (1.0%) involved a congenital anomaly. By sex, 3,999 (47.4%) involved females, 3,941 (46.7%) males and sex was unknown in 505 (6.0%) cases. The age distribution is presented in Figure 1; about one quarter of cases (N=2,179; 25.8%) involve infants aged 0–1 year. The most frequently suspected or interacting medicines belong to ATC J07 (vaccines; N = 2,757) (Table 1). Of these reports, 46% concern children aged 0–5 years. The most commonly reported ADRs are pyrexia, injection-site erythema and injection-site swelling. The predominance of reports concerning vaccines is consistent with their systematic administration from birth, Switzerland's high vaccination coverage and the particularly stringent pharmacovigilance to which vaccines are subjected. Given that vaccines are designed to elicit an immune response, mild and expected events – such as fever or transient local inflammatory reactions – are commonly observed. As

vaccination is administered to generally healthy populations, these reactions, although anticipated, are more frequently reported. The most common reactions are shown in Figure 2.

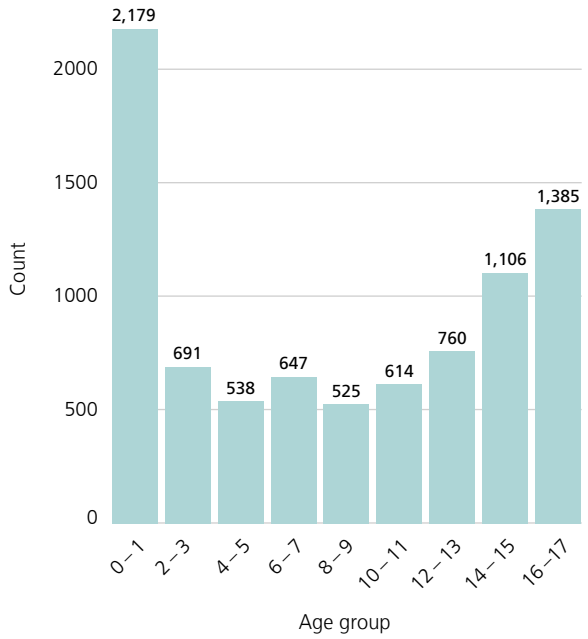

Figure 1: Age distribution of paediatric reports in the Swiss PV database

Table 1: The 10 pharmacological groups most commonly involved in paediatric ICSRs

ATC Code	Pharmacological group	Frequency
J07	Vaccines	2,757
N06	Psychoanaleptics	811
N05	Psycholeptics	748
J01	Anti-bacterials for systemic use	718
L04	Immunosuppressants	584
L01	Antineoplastic agents	555
N02	Analgesics	534
N03	Antiepileptics	448
M01	Anti-inflammatory and anti-rheumatic products	228
B03	Anti-anaemic preparations	196

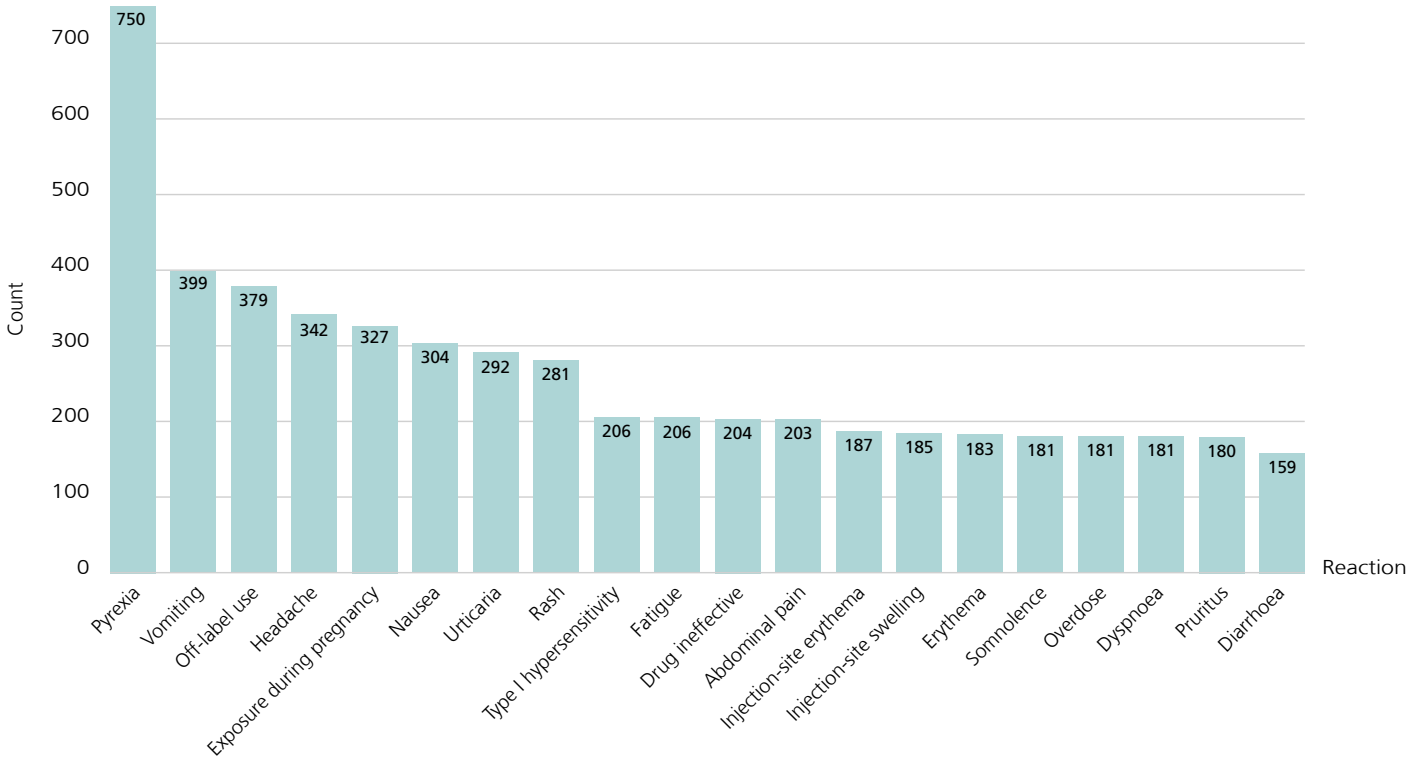

Figure 2: 20 most common reactions reported in the paediatric population

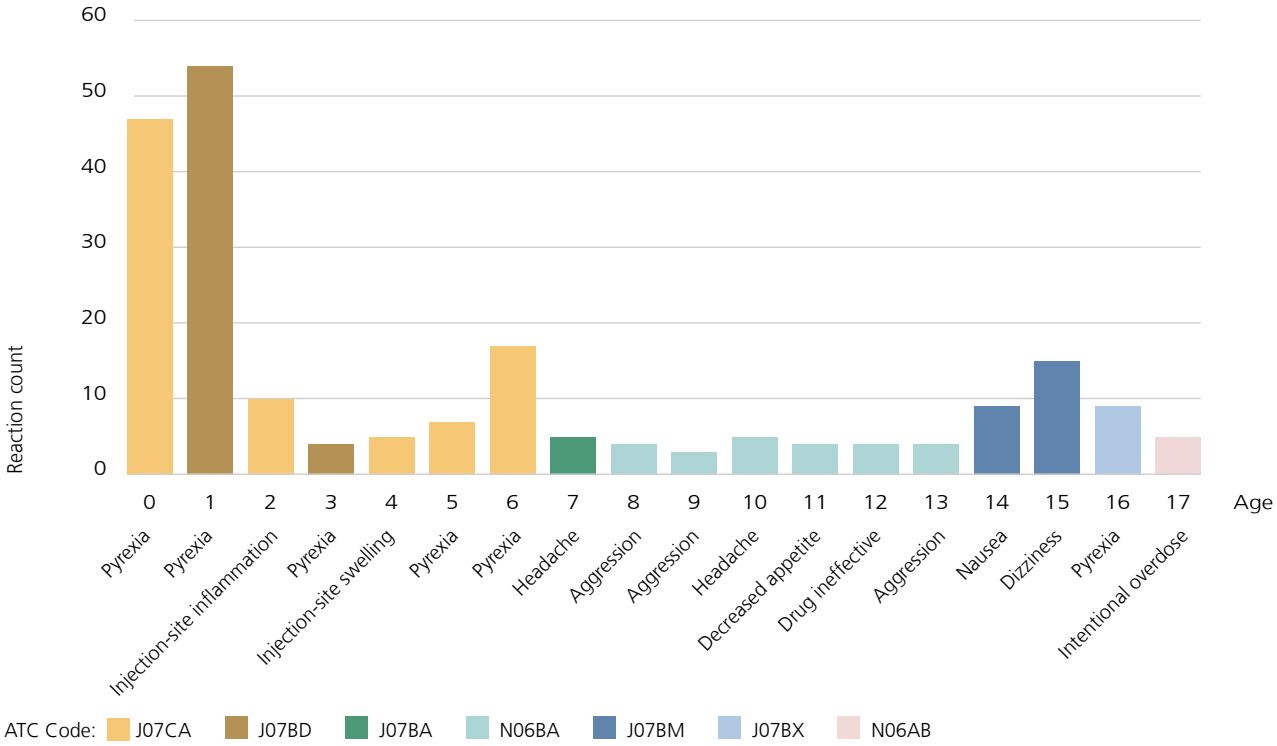

Figure 3: Most common ATC Codes and reactions across ages (J07BA: Encephalitis vaccines; J07BD: Measles vaccines; J07BM: Papillomavirus vaccines; J07BX: Other viral vaccines; J07CA: Bacterial and viral vaccines, combined; N06AB: Selective serotonin reuptake inhibitors (SSRIs); N06BA: Centrally acting sympathomimetics)

The visualization in Figure 3 highlights the most common ATC codes and reported reactions across ages. For younger age groups (0–8 years), vaccines (ATC codes J07) dominate, with reactions such as Pyrexia and Injection site-related issues being prevalent. These reactions are expected and align with established vaccine safety profiles. As age increases, medications used for mental health conditions (ATC code N06) become more common, with reactions such as aggression, and dizziness frequently reported. These are also expected however, an impact of the underlying condition cannot be ruled out. This trend reflects the shift in medical needs and treatments as children grow older.

Conclusion

The safety profiles of medicines for paediatric use are often less well characterised at the time of market approval owing to smaller or limited clinical trials. This uncertainty is compounded by frequent off-label prescribing, inappropriate dosage forms and the need for continuous dose adjustments, all of which elevate the risk of medication errors and ADRs.

Pharmacovigilance databases such as VigiBase® contain relatively few paediatric cases, primarily as a result of underreporting. Possible causes include lower overall medication use in children and the aforementioned difficulty in recognising and attributing adverse effects to medication. Other causes include HCP reluctance to report ADRs because of frequent off-label prescribing and the fear of legal liability, as well as a lack of pharmacovigilance training and awareness among HCPs.

Effective paediatric pharmacovigilance requires careful clinical observation, close collaboration between caregivers, HCPs and regulatory authorities to enable timely detection and management of ADRs. To strengthen these systems globally, greater emphasis on education, awareness and research is needed to ensure prompt identification of ADRs and support for the safe, effective use of medicines in children.

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Abbreviations

ADR	Adverse drug reaction
CYP	Cytochrome P450 isoenzymes
HCP	Healthcare professional
ICSR	Individual Case Safety Report
PK	Pharmacokinetics
PD	Pharmacodynamics
WHO	World Health Organization

References

1
Kearns GL, Abdel-Rahman SM, Alander SW, Blowey DL, Leeder JS, Kauffman RE. Developmental pharmacology--drug disposition, action, and therapy in infants and children. N Engl J Med. 2003 Sep 18;349(12):1157–67. doi: 10.1056/NEJMra035092.

2
van den Anker JN, Schwab M, Kearns GL. Developmental pharmacokinetics. Handb Exp Pharmacol. 2011;205:51–75. doi: 10.1007/978-3-642-20195-0_2.

3
Sammons HM, Choonara I. Learning Lessons from Adverse Drug Reactions in Children. Children (Basel). 2016 Jan 8;3(1):1. doi: 10.3390/children3010001.

4
Joret-Descout P, Prot-Labarthe S, Brion F, Bataille J, Hartmann JF, Bourdon O. Off-label and unlicensed utilisation of medicines in a French paediatric hospital. Int J Clin Pharm. 2015 Dec;37(6):1222-7. doi: 10.1007/s11096-015-0191-3. Epub 2015 Sep 22.

5
Gore R, Chugh PK, Tripathi CD, Lhamo Y, Gautam S. Pediatric Off-Label and Unlicensed Drug Use and Its Implications. Curr Clin Pharmacol. 2017;12(1):18–25. doi: 10.2174/1574884712666170317161935.

6
Andrade PHS, Santos ADS, Souza CAS, Lobo IMF, da Silva WB. Risk factors for adverse drug reactions in pediatric inpatients: a systematic review. Ther Adv Drug Saf. 2017 Jun;8(6):199-210. doi: 10.1177/2042098617702615. Epub 2017 Apr 25.

7
Choonara I. Unlicensed and off-label drug use in children: implications for safety. Expert Opin Drug Saf. 2004 Mar;3(2):81-3. doi: 10.1517/eods.3.2.81.27342.

8
Gill AM, Leach HJ, Hughes J, Barker C, Nunn AJ, Choonara I. Adverse drug reactions in a paediatric intensive care unit. Acta Paediatr. 1995 Apr;84(4):438-41. doi: 10.1111/j.1651–2227.1995.tb13667.x.

9
Impicciatore P, Choonara I, Clarkson A, Provasi D, Pandolfini C, Bonati M. Incidence of adverse drug reactions in paediatric in/out-patients: a systematic review and meta-analysis of prospective studies. Br J Clin Pharmacol. 2001 Jul;52(1):77–83. doi: 10.1046/j.0306-5251.2001.01407.x.

10
Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2009;32(1):19–31. doi: 10.2165/00002018-200932010-00002.

11
Neubert A. Pharmacovigilance in pediatrics: current challenges. Paediatr Drugs. 2012 Feb 1;14(1):1–5. doi: 10.2165/11596590-000000000-00000.

12
Enger C, Cali C, Walker AM. Serious ventricular arrhythmias among users of cisapride and other QT-prolonging agents in the United States. Pharmacoepidemiol Drug Saf. 2002 Sep;11(6):477–86. doi: 10.1002/pds.725.

13
Swissmedic, HPC – Cough and cold preparations containing codeine or dihydrocodeine, 13.07.2027.

14
Aldea A, García Sánchez-Colomer M, Fernández Quintana E, García Sáiz M. Paediatric adverse drug reactions reported to the Spanish Pharmacovigilance System from 2004 to 2009. Eur J Clin Pharmacol. 2012 Sep;68(9):1329-38. doi: 10.1007/s00228-012-1255-0. Epub 2012 Mar 14.

15
Marques J, Ribeiro-Vaz I, Pereira AC, Polónia J. A survey of spontaneous reporting of adverse drug reactions in 10 years of activity in a pharmacovigilance centre in Portugal. Int J Pharm Pract. 2014 Aug;22(4):275–82.

16
Aagaard L, Weber CB, Hansen EH. Adverse drug reactions in the paediatric population in Denmark: a retrospective analysis of reports made to the Danish Medicines Agency from 1998 to 2007. Drug Saf. 2010 Apr 1;33(4):327–39. doi: 10.2165/11319100-000000000-00000.

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Regulatory

Swissmedic informs: Publication of safety-related updates to the Information for healthcare professionals with effect from November 2025

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Summary

Starting in November 2025, Swissmedic is launching a new initiative to improve communication of safety-related updates to the Information for healthcare professionals.

The key feature of this initiative will be a monthly overview of safety-related updates to the Information for healthcare professionals in the "Safety of Medicines" newsletter, highlighting active substances whose Information for healthcare professionals has been recently updated with new safety information. Furthermore, a cumulative list of safety-related updates will be accessible as an Excel file on the Swissmedic website.

When new safety information about a medicinal product emerges, the product information, i.e. the Information for healthcare professionals and Patient information, is updated accordingly. Although the updated product information is published on swissmedicinfo.ch, the updates that have been made may go unnoticed by healthcare professionals.

To address this issue, Swissmedic is set to enhance the communication of safety-related updates through a new initiative aimed at healthcare professionals.

Starting in November 2025, Swissmedic will provide a monthly overview of safety-related updates to the Information for healthcare professionals ("Safety Update – Updates to Information for healthcare professionals", see Figure 1) in its "Safety of Medicines" newsletter (see box "How to subscribe to the 'Safety of Medicines' newsletter"). This table will provide healthcare professionals with a clear overview of active substances whose Information for healthcare professionals has been recently updated with new safety information.

Additionally, a cumulative list of all safety-related updates to the Information for healthcare professionals will be accessible on the Swissmedic website at swissmedic.ch/safetyupdates as an Excel file, and a link to this safety update page will be included in all future editions of Vigilance News.

How to subscribe to the "Safety of Medicines" newsletter

The "Safety of Medicines" newsletter provides the latest news on pharmacovigilance topics, i.e. (D)HPC, Safety Update – Updates to information for healthcare professionals, Pharmacovigilance in the spotlight and Vigilance News. Anyone wishing to subscribe to the newsletter can do so by visiting the newsletter subscription page on the Swissmedic website (https://www.swissmedic.ch/swissmedic/en/home/news/news.html).

Online version

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Newsletter

Safety of medicines/market monitoring of medicines

Human medicines

Safety Update – Information for healthcare professionals updates

November 2025

This overview contains selected active substances or active substance groups whose Information for healthcare professionals has been, or will be, updated with new safety-related information. These updates are currently available in German, French, or Italian.

Wirkstoff(e)	Neue Sicherheitsinformation	Angepasste Rubrik(en)	(D)HPC
Paracetamol	Schwerwiegende Hautreaktionen (Akutes generalisiertes pustulöses Exanthem (AGEP), Stevens-Johnson-Syndrom (SJS) und toxisch-epidermale Nekrolyse (TEN)	Warnhinweise und Vorsichtsmassnahmen, Unerwünschte Wirkungen	–
Paracetamol	Harmonisierung der Rubrik «Schwangerschaft, Stillzeit» nach aktuellem Erkenntnisstand	Schwangerschaft, Stillzeit	–
Cemiplimab	Pankreatitis	Warnhinweise und Vorsichtsmassnahmen, Unerwünschte Wirkungen	–
Sertraline	Multiple Acyl-Coenzym-A-Dehydrogenase-Mangel (MADD)-ähnliche Störung	Unerwünschte Wirkungen	–
Tislelizumab	Hämophagozytische Lymphohistiozytose (HLH)	Warnhinweise und Vorsichtsmassnahmen, Unerwünschte Wirkungen	–
Enzalutamid	Interferenz mit Chemilumineszenz-Mikropartikel-Immunoassay (CMIA) (falsch erhöhte Digoxin-Plasmaspiegel): Überwachung des Digoxinspiegels mit Tests, die nicht die CMIA-Methode verwenden, wird empfohlen	Interaktionen	–
…	…	…	

All updates to the product information (Safety Updates) since 1 November 2025 are available at www.swissmedic.ch/safetyupdates.

Important information

The updates to product information for generics are delayed as these are adapted at a later date to those of the original product. Please note that this is not a complete overview since not all changes to individual Information for healthcare professionals are presented in detail, and the safety information listed for individual medicinal products containing an active substance or substance class may already be included in the Information for healthcare professionals.

The information is subject to possible legal remedies. In all cases, the current versions of the Information for healthcare professionals available at www.swissmedicinfo-pro.ch are binding.

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You have registered using the e-mail address verteu@hetnet.nl to receive this Newsletter. Please add the sender address from this message to the "Safe sender list" in your e-mail programme to make sure you receive the Swissmedic Newsletters.

Swissmedic | Swiss Agency for Therapeutic Products | Hallerstrasse 7 | 3012 Berne | Switzerland | www.swissmedic.ch

Figure 1: Safety Updates – Information for healthcare profesionnals upates

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Statistical review 2024

Summary of adverse events following immunization reported in Switzerland during 2024

Valeriu Toma

Safety of Medicines Division, Swissmedic, Bern, Switzerland

Summary

During 2024, Swissmedic received a total of 504 case reports of suspected "adverse events following immunization (AEFIs)" from Switzerland. Although lower in number than in 2023, almost half of these reports were submitted in relation to COVID-19 vaccines. Overall, these figures are a consequence of a continuing, but decreasing, number of COVID-19 vaccinations, and most of these reports describe known reactions. In addition, 260 AEFI reports were submitted for **non**-COVID vaccines during 2024, which is a similar number compared with 2023 (264 reports) and higher than in 2022 (217 reports). The focus of this report is on **non**-COVID vaccines. Nevertheless, a brief summary of COVID-19 AEFI reports received during 2024 is presented in the final section, see also (1).

AEFI reports were recorded, assessed and analysed in the Swiss pharmacovigilance database. Swissmedic is encouraging reporting of AEFIs in high quality, which enables early detection of new safety signals. Important safety issues are evaluated in international collaboration with other regulatory agencies and/or with the participation of the Human Medicines Expert Committee (HMEC) of Swissmedic, if necessary. An increased AEFI reporting rate, followed by an assessment of relevant cases, can lead to risk minimisation measures in order to ensure vaccine safety.

Figure 1 compares the number of reports by age group and sex. The largest number of AEFI reports involved adults (95 reports), followed by the elderly (41 reports), infants (41 reports), adolescents (17 reports) and children (12 reports). Overall in 2024, the number of reports concerning females (150 reports; 57.7%) exceeded those concerning males (85 reports; 32.7%). In 25 AEFI reports (9.6%), the sex of the persons remained unknown. In 54 case reports (20.8%), the age group of the patients was not recorded.

Figure 2 shows the number of spontaneous AEFI reports by vaccine group (ATC code) and seriousness. Generally, a safety report is assessed as "serious" if it involves an adverse event leading to death, to hospitalisation or to prolongation of an existing hospitalisation, if it is life-threatening or results in a significant or persistent disability or a congenital anomaly. Furthermore, a report is assessed as "medically important" (and therefore, also as "serious") even if it does not fulfil the aforementioned criteria for "seriousness", but involves an event considered to be significant by medical judgement. All other reports are assessed as "non-serious" (e.g. self-limiting adverse events with good recovery). Of the 260 spontaneous reports received in 2024, 162 (62.3%) were "non-serious", 58 (22.3%) included only medically important events and 40 (15.4%) of the reports involved AEFIs with serious consequences.

Generally, considering all vaccines in 2024, the relative frequency (percentage) of "serious", including "medically important", cases taken together (98 reports; 37.7%) was quite similar to 2023 (36%) and 2022 (37.3%).

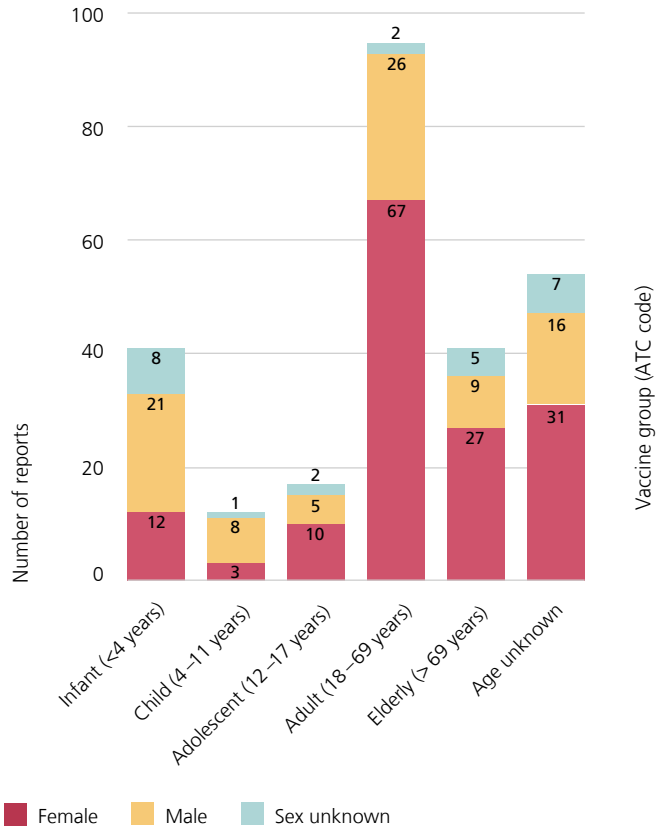

Figure 1: Number of AEFI reports by age group and sex, 2024

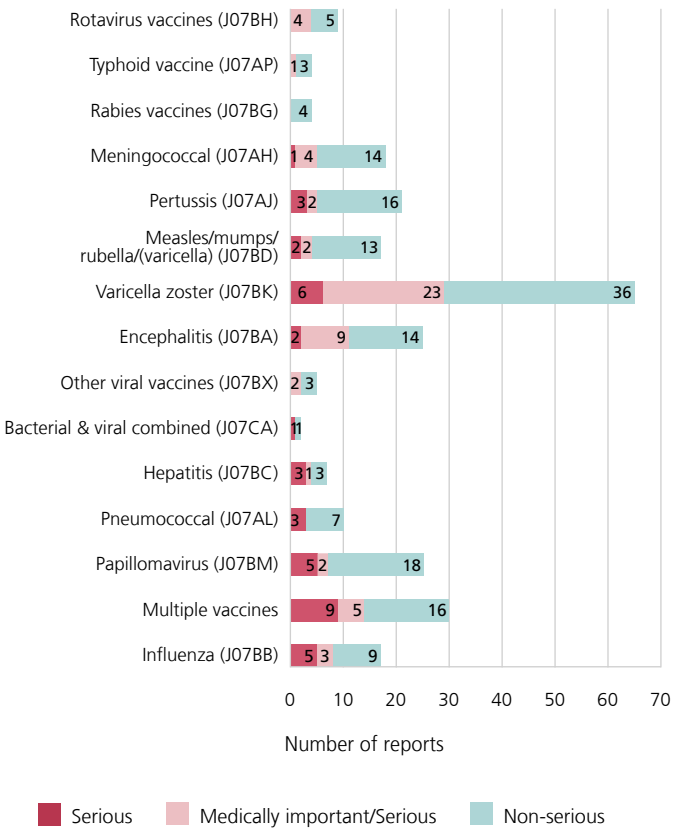

Figure 2: Number of reports by vaccine group (ATC code) and seriousness, 2024

Case reports where several (n >1) different vaccines were administered and were reported relating to suspected AEFIs are shown in Figure 2 as "Multiple vaccines". Many of these cases concerned multiple immunisations in children.

As in 2023, during 2024 a higher number of cases was submitted relating to the herpes zoster vaccination, and these are shown in Figure 2 as ATC code "Varicella zoster (J07BK)". The majority of these case reports were assessed as "non-serious" (36 of 65 cases; 55.4%), which was a similar percentage to 2023 (54.8%).

Figure 3 shows the number of Swiss AEFI reports in 2024 grouped by primary reporter and seriousness. Healthcare professionals – providing medically confirmed data and good quality individual AEFI reports – were primary reporters in the vast majority of cases. Physicians submitted the largest number of AEFI reports (177 of 260), including a higher number of reports assessed as "serious" or "medically important" (68 of 177 reports). Consumers/patients submitted the second-highest number (31 AEFI reports), followed by pharmacists (30 reports).

Figure 4 shows the number of spontaneous AEFI reports by age group and seriousness. It is evident that the highest number of "serious" or "medically important" cases (37 of 95 AEFI reports in total) were recorded in the adult age group, followed by the elderly (22 of 41 reports), infants (16 of 41 reports), adolescents (5 of 17 reports) and children (4 of 12 reports).

AEFI reports received by Swissmedic in 2024 following COVID-19 vaccinations

In Switzerland, the COVID-19 vaccinations continued during 2024; Swissmedic received far fewer reports of suspected adverse reactions in this year (244 cases) compared to the previous years of the immunisation campaign (2023: 727 reports; 2022: > 5,000 reports).

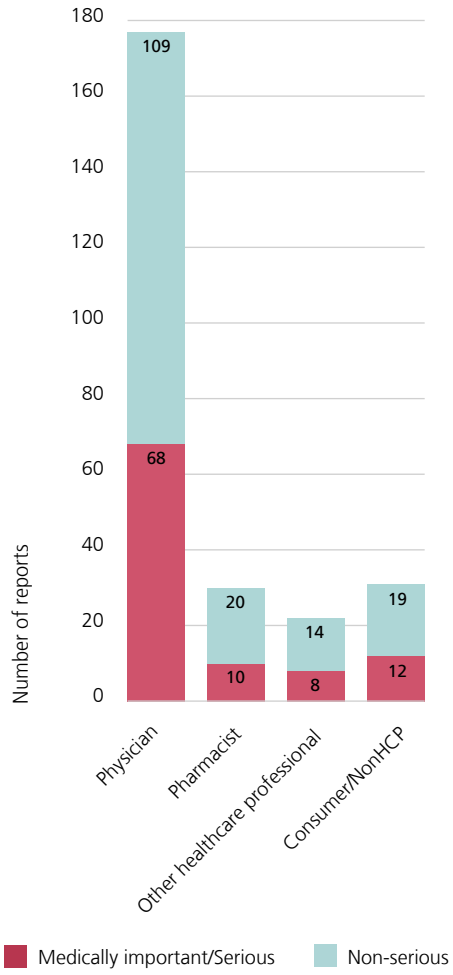

Figure 3: Number of AEFI reports by reporter qualification and seriousness, 2024

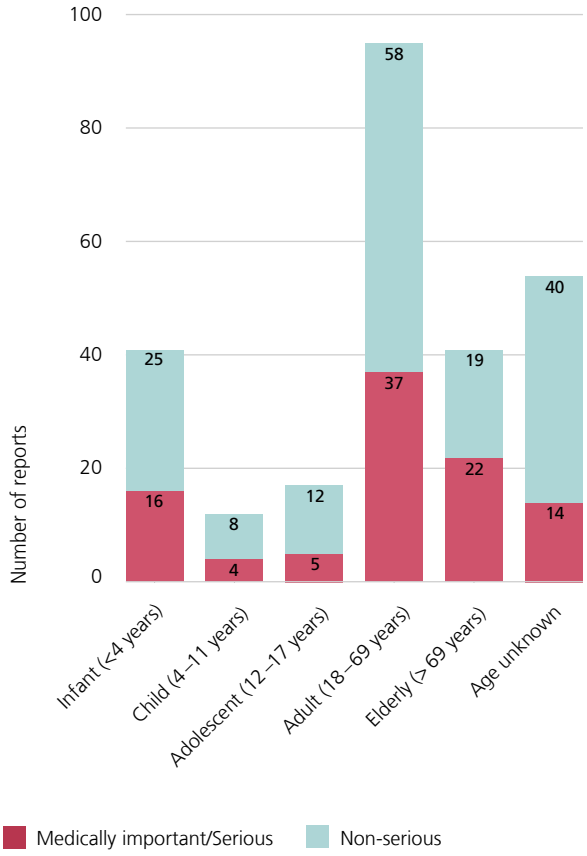

Figure 4: Number of AEFI reports by age group and seriousness, 2024

On 5 July 2024, Swissmedic published a "**Report of suspected adverse reactions to COVID-19 vaccines in Switzerland**" (1). This report presents, in a **cumulative** manner, a summary of the suspected adverse drug reactions following COVID-19 immunisation in the period from 1 January 2021 to the publication of the respective report by Swissmedic.

This report includes statistical data (cumulative figures), the ranking of the most frequently suspected reactions for all vaccines, the organ systems affected, as well as the ranking of reactions in non-serious and serious reports.

Among other topics, cases of longer-lasting symptoms with a temporal relationship to a vaccination against COVID-19 are addressed in this report. Swissmedic evaluates such reports thoroughly, continually reviews the latest drug safety findings, follows the scientific literature and works in close contact with international regulatory authorities.

Overall, the reports of suspected adverse reactions received and analysed did not alter the positive benefit-risk profile of the COVID-19 vaccines used in Switzerland, largely confirming their known safety profile. Known side effects of COVID-19 vaccines are listed in the continually updated, published Swiss product information texts (2).

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References

1
Reports of suspected adverse reactions to the COVID-19 vaccines in Switzerland; Swissmedic website, 05.07.2024

2
Arzneimittelinformation-Publikationssystem (AIPS). Swissmedic, Bern, Switzerland. Available from: http://www.swissmedicinfo.ch/

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Pharmacovigilance for veterinary medicinal products in 2024

Cedric R. Müntener, Michaela Weber
Veterinary Medicines Division, Swissmedic, Bern, Switzerland

Complete report:

Vigilance for veterinary medicinal products – Annual report 2024

Summary

In 2024, a total of 658 reports were submitted, marking a 42.4% increase compared with 2023. The most commonly affected species were dogs (365) and cats (197), followed by cattle (45) and horses (25). The most frequently involved medicinal product types were antiparasitics, vaccines, hormones, nervous system modulators and digestive tract treatments.

A significant number of the reports (188) involved suspected lack of efficacy, particularly for antiparasitics and hormonal implants used to induce temporary infertility in male dogs. In these last cases, efficacy was assessed by measuring testosterone levels, which were shown to be too high in 23 cases.

Reports on vaccines mainly involved local and systemic reactions to frequently used products in dogs and horses. Nervous system modulators were primarily represented by anti-NGF monoclonal antibodies in dogs and cats. Reports saw a sharp rise, likely due to increased awareness. Reports on digestive tract treatments were mainly represented by a new oral antidiabetic for cats (velagliflozin), which led to reports of hyperglycaemia, lethargy and even fatal ketosis in some cases.

Tox Info Suisse forwarded 206 cases, 73 animal exposures, mostly accidental ingestion of flavoured tablets, and 133 human exposures, often due to confusion with human medicines or accidental contact. One severe case of self-injection with a vaccine containing mineral oil led to necrosis and long-term disability.

16 safety signals were initiated, resulting in updates to product information to improve safety.

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Information on the Swissmedic website

Pharmacovigilance in the spotlight

Learning from adverse reaction reports – cases from pharmacovigilance

24.10.2025
Risk of intraoperative floppy iris syndrome in patients treated with tamsulosin

02.05.2025
Finasteride and persistent side effects

12.09.2025
Drug-induced aseptic meningitis

07.04.2025
Eosinophilic oesophagitis during oral immunotherapy for peanut allergy

07.08.2025
Drug-induced taste disorders

24.03.2025
Hyperkalaemia during treatment with a sartan and an NSAID

27.06.2025
Spironolactone and persistent hoarseness – a hormonally induced side effect

10.01.2025
Octenisept® and incorrect use to irrigate deep wounds

Reporting of ADRs by healthcare professionals

Explainer video

swissmedic

Healthcare Professional Communications

Some links are available in German only

18.11.2025
DHPC – Finasterid / Dutasterid
Neue Massnahmen zur Minimierung des Risikos für Suizidgedanken

10.11.2025
DHPC – Sevre-Long® (morphinum)
Perforation der Kapselhülle 24.10.2025

24.10.2025
DHPC – Lecigon (carbidopum / entacaponum / levodopum)
Reduzierte Haltbarkeit

07.10.2025
DHPC – Tegretol 2% (Propylenglykol)
Tegretol 2%, Suspension zum Einnehmen: Zusätzliche Vorsichtsmassnahmen bei Neugeborenen

02.09.2025
HPC – Erratum zur DHPC zu Tegretol 2% (Propyenglykol)
Zusätzliche Vorsichtsmassnahmen bei Neugeborenen

29.08.2025
DHPC – Urapidil Stragen i.v. (urapidilum)
Schwierigkeit beim Öffnen / Brechen bestimmter Ampullen

20.08.2025
HPC – Ocaliva® (Obeticholsäure)
Nicht bestätigter klinischer Nutzen; Verzicht auf die Zulassung von Ocaliva®

05.08.2025
DHPC – Mitem® (mitomycinum)
Einführung eines Einwegfiltersystems für die intravenöse Verabreichung

04.08.2025
DHPC – Entresto (sacubitrilum / valsartanum)
Fehlerhafte Angaben im Text der Packungsbeilage (Patienteninformation)

31.07.2025
DHPC – Rapamune (sirolimusum)
Unstimmigkeit Verfallsdatum

18.07.2025
DHPC – Co-Irbesartan Sandoz (hydrochlorothiazidum / irbesartanum)
Inkorrekte Angabe in der Patienteninformation

15.07.2025
DHPC – Aurora Pedanios 22/1 (medizinisches Cannabis)
Verkürzung Haltbarkeitsdatum

30.06.2025
Identification of Red safety information

30.06.2025
Einführung einer einheitlichen Kennzeichnung von Mitteilungen zur Arzneimittelsicherheit (DHPC) und behördlich angeordnetem Informationsmaterial
ab Juli 2025

23.05.2025
DHPC – Zoldorm (zolpidemi tartras)
Inkorrekte Angabe der Packungsgrösse auf der Seitenlasche

23.05.2025
HPC – Depo-Provera 150, Sayana, Farlutal (Medroxyprogesteronacetat)
Wichtige Sicherheitsinformation und neue Kontraindikation für injizierbare Formulierungen sowie neue Empfehlungen für hochdosierte orale Formulierungen

Announcements

03.11.2025
Simap: Swissmedic invites tenders for a Document and Records Management System (DRMS)
So that Swissmedic can efficiently process its business-relevant documents in the long term, it is launching an invitation for tenders to supply a records management system

01.11.2025
Changes to the guidance document Authorisation PSUR Signal Management TAM
References added to annual reports from the signal management process

01.11.2025
Modification of the information sheet Drug Safety Reporting Duties in Switzerland
Update of contact details and document links

01.11.2025
Safety Update – Information for healthcare professionals updates
Product information: new safety-related updates (November 2025)

31.10.2025
Summary report on authorisation – Omvoh®
Extension of therapeutic indication (01)

30.10.2025
Update of the position paper of Swissmedic and swissethics on decentralised clinical trials (DCTs) of medicinal products
Update of the position paper (new version 3.3)

30.10.2025
Summary report on authorisation – SWAN-PSMA-1007®
First authorisation

30.10.2025
Summary report on authorisation – Trecondi®
Extension of therapeutic indication (01)

28.10.2025
Summary report on authorisation – Filsuvez®
First authorisation

27.10.2025
Vigilance for veterinary medicinal products – Annual report 2024
Summary of adverse reactions reported in Switzerland in 2024

24.10.2025
Risk of intraoperative floppy iris syndrome in patients treated with tamsulosin
Learning from adverse reaction reports – cases from pharmacovigilance

24.10.2025
Summary report on authorisation – Wainzua®
First authorisation

24.10.2025
Summary report on authorisation – Ayvakyt®
First authorisation

24.10.2025
Summary report on authorisation – Palforzia®
Extension of therapeutic indication (01)

22.10.2025
Summary report on authorisation – Sogroya®
First authorisation

21.10.2025
Applicable EU legal acts
Section updated to reflect recent delegated regulations and reorganised to clarify the mechanisms

17.10.2025
Summary report on authorisation – Imcivree®
First authorisation

15.10.2025
Batch recall – Nobivac DHPPi ad us. vet. Lyophilisat zur Herstellung einer Injektionssuspension für Hunde
Rückruf der Charge A777B01 bis auf Stufe Detailhandel

13.10.2025
Focus on parenterals
The shorter version of our position paper explains the special features of parenteral products used in the cosmetic field in a targeted and practical manner

10.10.2025
Summary report on authorisation – Blenrep®
First authorisation

10.10.2025
Summary report on authorisation – Voxzogo®
First authorisation

10.10.2025
Summary report on authorisation – Spevigo®
Extension of therapeutic indication (01)

10.10.2025
Summary report on authorisation – Balversa®
First authorisation

08.10.2025
Fachwerbung bei Fortbildungsveranstaltungen mit Anwesenheit von Vertreterinnen und Vertretern von Patientenorganisationen und medizinischen Laien
Praxisänderung

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