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In this edition

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Editorial

Dear reader

We are pleased to report that the autumn 2025 edition of Vigilance News was a great success. The new format appears to be proving itself, with both the English-language original articles and the associated summaries in four languages being keenly read.

This latest edition, number 36, covers another diverse range of medical and regulatory topics.

An article from Ente Ospedaliero Cantonale in Lugano discusses the use of natural language processing to improve the detection of adverse drug reactions in hospital discharge summaries. Such tools could help reduce underreporting. A further article from Swissmedic's Safety of Medicines Division and Legal Division Medicines deals with the Swiss pharmacovigilance reporting system and reminds reporters of their legal reporting obligations. Against this background, however, it should not be forgotten that suspicion reports are also important for medical, scientific and ethical reasons. In addition, the Swissmedic article on the implementation phase of ICH Guideline E2D(R1) will certainly be of particular interest to all those readers who have direct professional involvement in pharmacovigilance.

A more medical and scientific perspective is provided by an article from Lausanne University Hospital (CHUV), which presents three case reports on immune checkpoint inhibitor-associated myositis with myasthenia gravis-like presentation and myocarditis. A further article from Swissmedic reminds readers that fixed drug eruption (FDE) may occur during therapy with tetracyclines. In addition to a concise overview of the clinical presentation and pathophysiology of FDE, readers will also find a summary of the measures undertaken by Swissmedic to increase awareness among healthcare professionals and patients.

Last but not least, an article from the Safety of Medicines Division provides an overview of risk management activities in 2025. The highlights include the "Safety Update – product information updates" service and the introduction of "Red Safety Information" and "Blue Safety Information" symbols to specifically direct attention to DHPCs or officially ordered safety information. The pharmacovigilance figures for last year provided in the seventh and final article are also impressive. They document the fact that Swissmedic receives a large number of valuable suspicion reports that aid signal detection. It is also heartening to note that many healthcare professionals are fully aware of the importance of the pharmacovigilance system.

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

Christoph Küng
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Safety of medicines and case reports

Improving the detection of adverse drug reactions in hospital discharge summaries using natural language processing

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Summary

Adverse drug reactions (ADRs) remain a major public health concern, yet underreporting persists in hospitals due to time constraints and the complexity of documentation. Discharge summaries contain valuable safety information, but their free-text format hinders systematic review. As part of the QUADRATIC study, we developed and validated natural language processing (NLP) models to identify potential ADRs in Italian-language hospital discharge summaries from the Ente Ospedaliero Cantonale hospital network in southern Switzerland. The logistic regression model with bag-of-words representation demonstrated a high level of precision and interpretability, making it possible to rank documents by ADR likelihood. In the operational setting, the highest-ranked summaries will be presented daily to pharmacovigilance experts via a dedicated interface integrated into the electronic health record system, which will support review by highlighting predictive text segments. The model can be recalibrated using structured feedback, which will ensure alignment with clinical practice. The long-term objective is to support differentiation between potentially reportable and non-reportable ADRs on the basis of national legislation. By embedding interpretable artificial intelligence directly into the electronic health record workflow, this approach enhances case detection, supports expert decision-making and improves underreporting, demonstrating a practical, scalable model for hospital-based pharmacovigilance.

Introduction

Adverse drug reactions (ADRs) continue to represent a significant public health concern and remain a central focus of post-marketing safety surveillance (1, 2). In Switzerland, spontaneous reporting of ADRs coordinated by Swissmedic constitutes the backbone of pharmacovigilance activities. Despite a robust regulatory framework, underreporting by healthcare professionals persists, particularly in hospital settings, where time constraints, competing clinical priorities and complex documentation processes may limit systematic ADR identification and notification (3–5). In this context, strengthening hospital-based detection mechanisms is a strategic priority in improving the volume, completeness and timeliness of ADR reporting.

Hospitals generate large volumes of clinical documentation that contain valuable safety-related information. Among these documents, discharge summaries provide a comprehensive narrative of the patient's hospital management, including diagnoses, therapeutic interventions, clinical evolution and complications. Suspected ADRs are frequently described in these summaries, either as a cause of admission or as an event occurring during hospitalisation. However, because this information is embedded in free-text narratives, systematic large-scale screening by manual review is not feasible. Natural language processing (NLP) offers an opportunity to transform unstructured clinical text into actionable information (6–9).

As part of the QUADRATIC (QUality Adverse Drug Reaction AcTIve Control) study – a one-year research initiative funded by the Swiss National Science Foundation and conducted jointly by the Institute of Pharmacological Sciences of Southern Switzerland and the Dalle Molle Institute for Artificial Intelligence Research (IDSIA USI-SUPSI) – NLP models were developed and validated to identify potential ADRs in Italian-language discharge summaries from the Ente Ospedaliero Cantonale (EOC) hospital network in southern Switzerland. The scientific results of the study have been accepted for publication in *Clinical Pharmacology & Therapeutics* (10).

While QUADRATIC focused on methodological validation of NLP models for detecting potential ADRs, the present article highlights the ongoing operational implementation of the system within GECO, the EOC electronic health record platform, and the current development of a dedicated interface tailored to the daily workflow of pharmacovigilance professionals at the Regional Pharmacovigilance Centre in Lugano.

From research to practice: operational deployment of QUADRATIC

In the implemented configuration, discharge summaries are automatically processed once finalised within GECO. The textual content is analysed within the secure IT infrastructure of the hospital using a logistic regression model with bag-of-words representation, previously identified in the QUADRATIC study as the most suitable approach in terms of precision, ranking capability, computational efficiency and interpretability (9). The model assigns each document a probability score that reflects the likelihood of the summary containing a potential ADR. Documents predicted as positive are ranked accordingly.

The system is calibrated to present the highest-ranked discharge summaries per day for expert review. This prioritisation mechanism ensures that the tool supports, rather than overloads, routine pharmacovigilance activities. The QUADRATIC study showed that, during validation under simulated real-life conditions, this ranking-based approach enabled identification of substantially more discharge summaries containing confirmed ADRs within a fixed review capacity than the previously used rule-based screening system, which relies on patterns of regular expressions referring to drugs and clinical events (signs and symptoms), managed and continuously refined by the pharmacovigilance team.

A dedicated pharmacovigilance interface is currently under development within GECO. Through this interface, pharmacovigilance experts can access a dashboard displaying the highest-ranked list of discharge summaries flagged as potentially containing ADRs, together with relevant contextual information. Each case can be opened directly within the electronic health record environment, allowing review to take place seamlessly within the existing workflow. The outcome of the assessment, namely confirmation or rejection of the suspected ADR, is recorded within the same system, thus ensuring traceability and documentation.

To enhance transparency and usability, an additional function is being implemented to highlight within the discharge summary the words or text segments that most strongly contributed to the model's positive classification. Because logistic regression assigns interpretable weights to individual terms, it is possible to identify the lexical features that influenced a specific prediction. By visually emphasising these elements, the system supports rapid orientation within lengthy clinical narratives and increases trust in the algorithm's reasoning, while leaving the final judgment entirely to the human expert.

A structured feedback mechanism is incorporated into the workflow to ensure continuous improvement. The expert's final assessment of each reviewed case is stored and linked to the model's prediction. These accumulated data enable periodic performance evaluation, recalibration of decision thresholds and, when appropriate, retraining of the model to address potential changes in documentation practices or emerging patterns of ADR reporting.

Looking ahead, it is planned to evolve the system beyond a purely binary distinction between "ADR present" and "ADR not present" towards a classification that is more closely aligned with regulatory practice. The longer-term objective is to support differentiation between potentially reportable and non-reportable ADRs according to national legislation (mandatory reporting of serious and/or previously unknown ADRs). In this perspective, the system would not autonomously determine whether a case is reportable or not, but would assist pharmacovigilance experts by prioritising cases more likely to fulfil reporting criteria. This shift reflects the practical reality of pharmacovigilance, where the central question is not only whether an ADR occurred, but whether it meets the threshold for regulatory notification.

Conclusion

The integration of NLP-based screening into hospital pharmacovigilance demonstrates how digital tools can strengthen post-marketing safety surveillance in a pragmatic and responsible manner. By embedding an interpretable system within the electronic health record environment and aligning it with real-life workflow constraints, the initiative enhances case detection while preserving expert oversight and regulatory compliance. Importantly, by systematically screening routine clinical documentation, the system also contributes to mitigating the widely recognised problem of underreporting in spontaneous reporting systems. As the system evolves towards prioritising potentially reportable ADRs, it offers a scalable model of artificial intelligence that supports expert decision-making and contributes to enhanced case detection and improved reporting.

References

1
European Commission. Strengthening Pharmacovigilance to Reduce Adverse Effects of Medicines; Brussels, 2008.

2
World Health Organization. Safety of Medicines - A Guide to Detecting and Reporting Adverse Drug Reactions. Geneva: WHO; 2002.

3
Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385–396. doi: 10.2165/00002018-200629050-00003.

4
García-Abeijon P, et al., Factors Associated with Underreporting of Adverse Drug Reactions by Health Care Professionals: A Systematic Review Update Drug Saf. 2023;46:625–636 doi: org/10.1007/s40264-023-01302-7.

5
Beeler P, et al. Hospitalisations Related to Adverse Drug Reactions in Switzerland in 2012–2019: Characteristics, In-Hospital Mortality, and Spontaneous Reporting Rate. Drug Saf. 2023 Aug;46(8):753–763. doi: 10.1007/s40264-023-01319-y.

6
Sheikh, A. Realising the potential of health information technology to enhance medication safety. BMJ Quality & Safety 2020;29(1):7–9. doi: 10.1136/bmjqs-2019-010018.

7
Golder S, Xu D, O'Connor K, Wang Y, Batra M, Hernandez GG. Leveraging Natural Language Processing and Machine Learning Methods for Adverse Drug Event Detection in Electronic Health/Medical Records: A Scoping Review. Drug Saf. 2025;48(4):321–337. doi: 10.1007/s40264-024-01505-6.

8
Murphy RM, et al. Adverse drug event detection using natural language processing: A scoping review of supervised learning methods. PLoS One. 2023;18(1):e0279842. doi: 10.1371/journal.pone.0279842.

9
Syrowatka A, et al. Key use cases for artificial intelligence to reduce the frequency of adverse drug events: a scoping review. Lancet Digit Health. 2022;4(2):e137–e148. doi: 10.1016/S2589-7500(21)00229-6.

10
Franchini A, Noseda R, et al. NLP in Support of Pharmacovigilance: QUality Adverse Drug Reaction AcTIve Control (QUADRATIC). Clin Pharmacol Ther. 2026 Feb 27. doi: 10.1002/cpt.70250.

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Immune checkpoint inhibitor-associated myositis with myasthenia gravis-like presentation and myocarditis

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Summary

Immune checkpoint inhibitors (ICIs) are associated with potentially severe immune-related adverse events (irAEs). We present three patients who developed ICI-associated myositis with myasthenia gravis-like manifestations, including one with myocarditis. Electroneuromyography showed inflammatory myopathy.

1. A 75-year-old man with melanoma developed myalgia, muscle weakness, ptosis, diplopia, and hypophonia after one cycle of ipilimumab-nivolumab followed by two cycles of nivolumab. His condition gradually improved, with spontaneous resolution at five months.

2. A 95-year-old woman with sarcoma developed myalgia, muscle weakness, ptosis, diaphragmatic paresis, and myocarditis with third-degree atrioventricular block and heart failure after two cycles of pembrolizumab. Despite intravenous immunoglobulin (IVIG) and corticosteroids (CS), her condition deteriorated, resulting in a fatal outcome.

3. A 66-year-old woman with hepatocellular carcinoma developed myalgia and muscle weakness, with diaphragmatic paralysis after tremelimumab and two cycles of durvalumab. She required non-invasive ventilatory support and was treated with CS and IVIG. Her condition gradually improved.

ICI-associated myositis overlap syndrome typically presents early with heterogeneous features. Prompt recognition of this irAE, ICI discontinuation and multidisciplinary management are key to achieving the best possible outcome.

Introduction

In recent years, checkpoint inhibitor immunotherapy has significantly improved survival in several malignancies, and the number of approved agents and indications continues to expand. However, these treatments are associated with a wide spectrum of immune-related adverse events (irAEs). Among these, immune-mediated myositis is an uncommon (0.3–0.6%) but potentially severe complication, particularly when associated with bulbar or respiratory involvement, or myocarditis (1). We present three patients who developed this condition during treatment with immune checkpoint inhibitors (ICIs) and describe their clinical presentation, diagnostic evaluation and therapeutic management. These observations were reported to Swissmedic in anonymised form.

Patient 1

A 75-year-old man was diagnosed with a nodular melanoma of the calf which was treated surgically in 2023. The patient was otherwise in good health, and his only regular medication was pantoprazole 40 mg once daily. With local recurrence and distant metastases, first-line ipilimumab-nivolumab combination was started in December 2024 (Day 0) and discontinued after one administration because of cytokine release syndrome. Nivolumab monotherapy was resumed in February 2025, with 240 mg iv on Day 56 and again on Day 70. From Day 71, the patient developed progressive fatigue, myalgia, proximal and axial muscle weakness, hand edema, bilateral ptosis and diplopia, hypophonia, and dyspnea at rest, prompting presentation to the emergency department on Day 84.

On admission, the patient was slightly tachypneic at 23/min with an oxygen saturation of 96% on room air. Neurological examination revealed mild pelvic girdle weakness (Medical Research Council (MRC) grade 4+/5), bilateral ptosis, diplopia on sustained lateral gaze, and hypophonia. Laboratory tests showed mildly elevated creatine kinase (CK) (304 U/L) with normal aspartate aminotransferase (AST) and alanine aminotransferase (ALT). Both anti-acetylcholine receptor (anti-AChR) and anti-muscle-specific kinase (anti-MuSK) antibodies were negative. Troponin I was only mildly and transiently elevated, with a peak observed value of 36 ng/L. ECG, echocardiography and cardiac magnetic resonance imaging (MRI) did not reveal any significant abnormalities. Whole-body and orbital MRI showed muscle edema and mild fatty atrophy, with electroneuromyography (ENMG) findings also consistent with inflammatory myopathy (Table 1).

The final diagnosis was ICI-induced myositis with a myasthenia gravis-like presentation. The patient received neither corticosteroids nor any immunomodulatory therapy and was discharged after 9 days. Neuromuscular symptoms and hand edema gradually improved, with complete resolution at five months. The patient is considered in complete oncologic remission.

Patient 2

A 95-year-old woman was diagnosed in 2024 with a high-grade spindle cell sarcoma of the leg and a solitary pulmonary metastasis. The patient's usual medications were valsartan/hydrochlorothiazide 80/12.5 mg once daily and metformin 500 mg twice daily. She underwent surgical resection at the time of sarcoma diagnosis. Her clinical course was complicated by multiple local recurrences requiring surgery and rapidly progressing pulmonary metastases treated with radiotherapy in 2025. In July 2025, palliative immunotherapy with pembrolizumab 200 mg iv was initiated (Day 0), and repeated on Day 20. From Day 25, the patient developed new-onset symptoms that progressed sequentially, beginning with profound fatigue and gait impairment necessitating a cane, followed by diffuse myalgias, and culminating in dyspnea immediately before hospitalisation on Day 38.

On admission, the patient had an oxygen saturation of 97% on room air and exhibited proximal muscle weakness (MRC grade 4/5) and left-sided ptosis. Laboratory evaluation showed elevation of CK (1814 U/L, CK-MB 136 U/L), AST (192 U/L), and ALT (149 U/L). Myositis-associated antibodies, including anti-synthetase antibodies, were negative. Troponin I was initially 1001 ng/L and subsequently peaked at 4224 ng/L. The initial ECG was normal, whereas echocardiography revealed left ventricular hypokinesia and right diaphragmatic paresis. ENMG was consistent with inflammatory myopathy (Table 1).

The final diagnosis was ICI-induced myositis with myasthenia-like presentation and concomitant myocarditis. She was treated with low-dose intravenous immunoglobulin (IVIG) (0.4 g/kg daily for 5 days), starting on Day 43. Corticosteroids were not used as first-line therapy due to the presence of a chronic lower leg wound. Despite IVIG therapy, the patient's condition worsened, with progressive respiratory compromise and significant dysphagia leading to recurrent aspiration. On Day 51, she developed a third-degree atrioventricular block with bradycardia (50 bpm). Oral prednisone (1 mg/kg/day) was initiated on Day 65. Her condition

continued to deteriorate, and she subsequently suffered a stroke. She was then transitioned to palliative care and died on Day 67.

Patient 3

A 66-year-old woman was diagnosed with hepatocellular carcinoma in 2024. Despite multiple liver-directed therapies and resection of pulmonary metastases, her disease progressed. Immunotherapy was initiated in January 2026 with tremelimumab 300 mg and durvalumab 1500 mg iv (Day 0), followed by a second durvalumab 1500 mg dose on Day 28. She was not receiving any other medications. From Day 29 onward, she developed progressive fatigue, muscle weakness and myalgias, dyspnea, pharyngeal discomfort and difficulty managing oral secretions. She was sent to the emergency department on Day 35.

On admission, the patient was tachypneic with an oxygen saturation of 91% on room air. Arterial blood gas analysis revealed a paO2 of 64 mmHg without hypercapnia; peak expiratory flow was 200 L/min, and forced vital capacity was 1.34 L. Neurological examination revealed moderate scapular girdle weakness (MRC grade 4/5) and severe neck flexion weakness (MRC grade 3/5), with right diaphragmatic paralysis confirmed by neuromuscular ultrasound. Laboratory tests demonstrated increased CK (7,286 U/L, CKmb <6%), AST (630 U/L) and ALT (687 U/L). Troponin I was only mildly and transiently elevated, reaching a peak value of 42 ng/L. ECG, echocardiography and coronary CT did not reveal any significant abnormalities. ENMG was consistent with inflammatory myopathy (Table 1).

The final diagnosis was ICI-induced myositis with a myasthenia gravis-like presentation. She was admitted to the intensive care unit for non-invasive ventilation (NIV). Treatment with methylprednisolone (1 mg/kg) and low-dose IVIG (0.4 g/kg daily for 5 days) was initiated on Day 36. Her condition gradually improved, and she was transferred to the medical ward on Day 45 while still requiring NIV. She was discharged home on Day 61 with nocturnal NIV.

Table 1: Three cases of immune checkpoint inhibitor–induced myositis overlap syndrome: clinical presentation, management, and outcomes

Data	Patient 1	Patient 2	Patient 3
Patient characteristics			
Age (years)	75	95	66
Sex (F, M)	M	F	F
Cancer	melanoma	sarcoma	hepatocellular carcinoma
ICIs	ipilimumab, nivolumab	pembrolizumab	tremelimumab, durvalumab
irAEs clinical presentation			
Days after 1st ICIs dose	71	25	29
Fatigue	X	X	X
Myalgia	X	X	X
Limb weakness	X	X	X
Neck weakness	X	X	X
Diaphragmatic paresis/paralysis	–	X	X
Ptosis	X	X	–
Diplopia	X	–	–
Dysphonia	X	–	–

Data	Patient 1	Patient 2	Patient 3
Dysphagia	–	X	–
Abnormal vitals	–	X	X
Arrhythmia	–	X	–
Dyspnea	X	X	X
Respiratory support (NIV)	–	–	X
Investigations			
CK (25–140 U/L)	304	1,814	7,286
CKmb (%; <6% of total CK)	–	7	5
AST (M: 14–50 U/L, F: 9–32 U/L)	30	192	630
ALT (M: 11–60 U/L, F: 9–36 U/L)	25	149	687
Troponin I hs (<26 ng/L)	36	4,224	42
Troponin T hs (<14 ng/L)	842	2,492	1,279
NT-proBNP (varies by age/sex)	normal range	1.7x uln	normal range
Anti-AChR, anti-MuSK Abs	negative	–	–
Polymyositis + antisynthetase Abs	–	negative	–
ENMG	inflammatory myopathy	inflammatory myopathy	inflammatory myopathy
ECG	normal	3° AV block, 50 bpm	normal
Echocardiography	normal	hypokinesia	normal
Coronary angiography or CT	–	–	normal
Myositis	X	X	X
Myasthenia gravis-like signs	X	X	X
Myocarditis	–	X	–
Other irAEs	–	low TSH	low TSH
Treatment			
Corticosteroids	–	X	X
IVIG	–	X	X
Outcome at discharge	alive	dead	transferred to ward

ICIs: immune checkpoint inhibitors; irAEs: immune-related adverse events; NIV: non-invasive ventilation; CK: creatine kinase; CKmb: creatine kinase myocardial band; troponin I hs: high-sensitivity troponin I; troponin T hs: high-sensitivity troponin T; NT-proBNP: N-terminal pro-B-type natriuretic peptide; uln: the upper limit normal; anti-AChR Abs: anti-acetylcholine receptor antibodies; anti-MuSK Abs: anti-muscle-specific kinase antibodies; ENMG: electroneuromyography; ECG: electrocardiogram; 3° AV block: third-degree atrioventricular block; bpm: beats per minute; TSH: thyroid stimulating hormone; IVIG: intravenous immunoglobulin. Normal ranges with corresponding units are indicated in parentheses.

Discussion

Although uncommon, ICI-induced myositis is the most frequent neurological irAE (2). The coexistence of myositis, myasthenia gravis-like manifestations and myocarditis is sometimes referred to as triple-M overlap syndrome (3).

The clinical presentation is heterogeneous, ranging from simple myalgia to widespread muscle involvement. Respiratory, bulbar and cardiac involvement can be life-threatening. This heterogeneity is illustrated by our cases: Patient 1 experienced a relatively mild, self-limited course of myositis; Patient 2 developed severe myositis with myocarditis, resulting in a fatal outcome; and Patient 3 presented with myositis involving the respiratory muscles leading to respiratory failure.

ICI-induced myositis typically presents early in the course of ICI therapy, usually after the first or second treatment cycle, providing a key temporal diagnostic clue (4, 5). In our series, symptom onset was similarly rapid: Patient 1 developed symptoms soon after the second cycle of nivolumab, following a two-month pause after a single cycle of dual ICI therapy, and Patients 2 and 3 both manifested symptoms shortly after their second cycle.

ICI-induced myositis and autoimmune myasthenia gravis have overlapping clinical presentations, which can result in misdiagnosis (6). Both ICI-induced myositis and myasthenia gravis may present with bulbar symptoms (dysarthria, dysphonia, dysphagia, difficulty managing oral secretions), respiratory symptoms (dyspnea, respiratory failure) and ocular symptoms (ptosis, diplopia). Despite these similarities, the two conditions differ in several aspects. In ICI-induced myositis, muscle weakness typically lacks the characteristic daily fluctuation and fatigability observed in myasthenia gravis and instead follows a rapidly progressive course over days to weeks. Myalgias are more commonly observed in ICI-induced myositis than in myasthenia gravis. Antibodies classically associated with myasthenia gravis, such as anti-AChR and anti-MuSK, are typically negative in ICI-induced myositis.

Of note, ICIs can also exacerbate or unmask myasthenia gravis (7, 8). Distinguishing ICI-induced myositis from myasthenia gravis is essential because treatment differs. ENMG is the examination of choice to distinguish inflammatory myopathy from myasthenia gravis. In our series of three patients, ENMG findings were consistent with inflammatory myopathy, and anti-AChR and anti-MuSK antibodies were negative in the single patient tested. MRI can support the diagnosis of myositis. Of note, involvement of the extraocular muscles, as demonstrated on MRI in Patient 1, is characteristic of ICI-induced myositis, whereas it is atypical in other forms of myositis (6).

Myocarditis is associated with worse outcomes than cases without cardiac involvement. It may initially be subtle and limited to troponin elevation, but can rapidly progress to life-threatening arrhythmia, or heart failure (9). In our series, Patient 2 presented with markedly elevated troponin I that rose rapidly, whereas Patients 1 and 3 had only mild, transient troponin I elevations (<2× the upper limit of normal). These mild elevations are consistent with subclinical myocarditis. This condition warrants close clinical and biochemical cardiac monitoring given the risk of progression to clinically overt myocarditis. Troponin I is more specific for myocardial injury, while troponin T, expressed in skeletal muscle, rises alongside CK in myositis, even in the absence of cardiac injury.

Patients with suspected ICI-induced myositis should undergo prompt and systematic evaluation for respiratory and bulbar muscle involvement, as well as myocarditis. The initial assessment should comprise a neuromuscular specialist-led clinical evaluation and ENMG, along with paraclinical investigations including ECG and laboratory blood tests, such as C-reactive protein, CK, CK-MB, aldolase, AST, ALT, lactate dehydrogenase, and troponin I, with further tests guided by clinical and biochemical findings (10). In case of respiratory symptoms, assessment should include measurement of negative inspiratory force and forced vital capacity, with repeated testing over time to monitor changes. Echocardiography, and cardiac imaging when appropriate, together with

serial ECG and troponin I measurements, should be performed when myocarditis is suspected. Finally, non-drug-related differential diagnoses should be excluded through appropriate investigations when indicated (e.g., coronary artery disease or acute viral infection in the setting of cardiac involvement) (11).

ICI therapy should be discontinued in all cases of myositis from grade 2 and above. The decision to initiate corticosteroids in cases of myositis is primarily guided by the severity of muscle involvement. Patient 1, who had mild myositis including ocular manifestations, did not receive corticosteroids and experienced a favourable, albeit slow, recovery, consistent with the typically gradual repair of immune-mediated muscle injury. For cases of myositis with respiratory or bulbar involvement, or myocarditis, first-line treatment consists of high-dose corticosteroids, either intravenous methylprednisolone or oral/intravenous prednisone. Therapy with plasma exchange or IVIG should be considered shortly after corticosteroids if there is no clear improvement. Other immunomodulatory therapies such as interleukin-6 antagonists (12), rituximab (9, 13), or TNF-alfa antagonists may be considered after failure of first- and second-line treatments (11). However, evidence supporting these monoclonal antibodies is limited and mainly comes from case reports or small case series. In antibody-positive cases, which are suggestive of true myasthenia gravis, pyridostigmine, an acetylcholinesterase inhibitor, should be initiated.

Published data indicate that concurrent ICI-induced myositis and myocarditis are associated with substantial in-hospital mortality of approximately 40% (4, 5, 14). In contrast, in a cohort of 10 patients with myositis overlap syndrome treated very early with combined corticosteroids and IVIG, a single death was reported (15). This highlights the critical importance of early recognition and prompt, appropriate management to enhance patient outcomes. Myositis overlap syndrome is a rare irAE that often presents with nonspecific early symptoms, making diagnosis challenging. However, it can rapidly progress to severe organ failure. Given these challenges, early involvement of a highly specialised multidisciplinary team, engaged in both assessment and treatment, is essential to optimise patient outcomes.

Risk factors for the development of myositis overlap syndromes remain incompletely characterised. Among treatment-related factors, dual ICI therapy is a recognised risk factor (16). The ICIs most frequently involved in published cases of myositis overlap syndrome, ipilimumab, nivolumab, and pembrolizumab, are also among the most widely prescribed agents (4), making it difficult to determine whether these agents truly carry a higher risk than less-used ICIs. Notably, myositis overlap syndrome has been described with mogamulizumab, a C-C chemokine receptor type 4-targeted monoclonal antibody, suggesting that similar myositis overlap syndrome could potentially occur with other non-ICI immunotherapies (17). In our series of three patients, ICIs administered included programmed cell death protein 1 (PD-1) inhibitors, cytotoxic T lymphocyte antigen 4 (CTLA-4) inhibitors and programmed death ligand 1 (PD-L1) inhibitors, with one patient receiving monotherapy and the other two receiving dual therapy. From a patient-related perspective, older age, known or latent autoimmune disease and specific HLA haplotypes have been suggested as risk factors (1, 18). However, no validated test or risk stratification tool currently exists to predict the development of ICI-induced myositis overlap syndrome.

Re-exposure to ICIs after serious irAEs, such as myositis overlap syndrome, is generally avoided due to the risk of recurrence. Available case reports and small series indicate that while some patients may tolerate re-challenge without relapse, others experience recurrent symptoms or serious complications, with no reliable way to predict who will relapse (9, 14, 19). Therefore, rechallenge may only be considered when cancer progresses and no other effective therapeutic options are available, after careful assessment of the individual risk-benefit balance and thorough discussion with the patient, ideally using ICI monotherapy. Secondary prophylactic strategies are largely empirical, with still limited evidence to guide their use (20). The optimal immunomodulatory approach, including timing and

duration, as well as its impact on the recurrence of irAEs and antitumour efficacy, remains to be better defined.

Conclusion

Myositis overlap syndrome is an uncommon but usually severe complication of ICI therapy. It is characterised by rapid onset and potentially life-threatening cardiopulmonary involvement.

Clinicians should maintain a high index of suspicion, particularly during the early cycles of ICI treatment. Prompt recognition and timely management are associated with improved outcomes. Management of these complex irAEs requires a well-coordinated, highly trained multidisciplinary team.

Ongoing efforts should focus on better defining risk factors, optimising therapeutic strategies, and exploring approaches for safe ICI rechallenge.

Reporting serious adverse drug reactions to Swissmedic provides real-world data that help identify safety signals, improve understanding of these reactions, and support the dissemination of safety information at the national level.

Editorial comment

IrAEs – such as myocarditis, myositis, and neuromuscular events – are included in the approved labeling of many ICIs, together with warnings and management guidance. Swissmedic continues to actively evaluate regulatory approaches related to ICIs and irAEs, including particular clinical presentations such as ICI-induced myositis with myasthenia gravis-like features and myocarditis (triple-M overlap syndrome).

References

1
Salem JE, Ajrouche A, Rozes A, Pinto S, De Rycke Y, Tubach F. Incidence and risk factors of immune checkpoint inhibitor myocardial and muscle toxicity: a French nationwide study. Eur Heart J. 2026 Mar 5;47(9):1014–30. doi:10.1093/eurheartj/ehaf682 PubMed PMID: 40884033.

2
Marini A, Bernardini A, Gigli GL, Valente M, Muñiz-Castrillo S, Honnorat J, et al. Neurologic Adverse Events of Immune Checkpoint Inhibitors: A Systematic Review. Neurology. 2021 Apr 20;96(16):754–66. doi:10.1212/WNL.0000000000011795

3
Gómez L, Lozano T, Jovani V, Martínez-Banaclocha N. Triple M overlap syndrome following pembrolizumab treatment: importance of multidisciplinary approach. BMJ Case Rep. 2025 Jan;18(1):e260349. doi:10.1136/bcr-2024-260349

4
Lipe DN, Qdaisat A, Krishnamani PP, Nguyen TD, Chaftari P, El Messiri N, et al. Myocarditis, Myositis, and Myasthenia Gravis Overlap Syndrome Associated with Immune Checkpoint Inhibitors: A Systematic Review. Diagnostics (Basel). 2024 Aug 16;14(16):1794. doi:10.3390/diagnostics14161794 PubMed PMID: 39202282; PubMed Central PMCID: PMC11353298.

5
Longinow J, Zmaili M, Skoza W, Kondoleon N, Marquardt R, Calabrese C, et al. Immune checkpoint inhibitor induced myocarditis, myasthenia gravis, and myositis: A SINGLE-CENTER case series. Cancer Medicine. 2023 Feb;12(3):2281–9. doi:10.1002/cam4.5050

6
Vicino A, Hottinger AF, Latifyan S, Boughdad S, Becce F, Prior JO, et al. Immune checkpoint inhibitor-related myositis and myocarditis: diagnostic pitfalls and imaging contribution in a real-world, institutional case series. J Neurol. 2024 Apr;271(4):1947–58. doi:10.1007/s00415-023-12134-x PubMed PMID: 38141128; PubMed Central PMCID: PMC10973051.

7
Emile J, Cauquil C, Carpentier D, Routier E, Robert C. Fatal myasthenia gravis (MG) associated with myositis and myocarditis in a patient with pre-existing MG treated by adjuvant nivolumab for a stage III melanoma. European Journal of Cancer. 2024 Jul;205:114098. doi:10.1016/j.ejca.2024.114098

8
Nelke C, Pawlitzki M, Kerkhoff R, Schroeter CB, Aktas O, Neuen-Jacob E, et al. Immune Checkpoint Inhibition–Related Myasthenia-Myositis-Myocarditis Responsive to Complement Blockade. Neurol Neuroimmunol Neuroinflamm. 2024 Jan;11(1):e200177. doi:10.1212/NXI.0000000000200177

9
Inan B, Duzgun U, Ergul-Ulger Z, Bekircan-Kurt CE, Ceylan BN, Karadas O, et al. Nivolumab- and ipilimumab-induced myositis, myasthenia gravis, and myocarditis in a patient with metastatic melanoma. Anti-Cancer Drugs. 2025 Aug;36(7):600–5. doi:10.1097/CAD.0000000000001727

10
Saygin D, Ghosh N, Reid P. Immune Checkpoint Inhibitor–Associated Myositis: A Distinct Form of Inflammatory Myopathy. J Clin Rheumatol. 2022 Oct;28(7):367–73. doi:10.1097/RHU.0000000000001874

11
Schneider BJ, Naidoo J, Santomasso BD, Lacchetti C, Adkins S, Anadkat M, et al. Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: ASCO Guideline Update. JCO. 2021 Dec 20;39(36):4073–126. doi:10.1200/JCO.21.01440

12
Gonçalves H, Augusto D, Pereira P, Ferreira-Campinho C, Correia AM, Ferreira C, et al. Tocilizumab in immune checkpoint inhibitor-induced myositis, myocarditis, and myasthenic syndrome: a rare case report and review of the literature. ARP Rheumatol. 2025;4(4):300–4. doi:10.63032/RFPY6607 PubMed PMID: 41480886.

13
Aziz IN, Gajjar R, Nandyal S, Oredipe O, Qaddorah S, Amdetsion GY, et al. Use of rituximab for fulminant and refractory cases of immune checkpoint inhibitor induced myocyte injury clinically presenting with features of myasthenia gravis: a case series. Eur Heart J Case Rep. 2025 Dec;9(12):ytaf593. doi:10.1093/ehjcr/ytaf593 PubMed PMID: 41368047; PubMed Central PMCID: PMC12684965.

14
Furlepa M, Watts I, Carr AS. Management of Triple M Syndrome: A Narrative Review of Immune Checkpoint Inhibitor-Induced Myasthenia Gravis, Myositis and Myocarditis. Cancers (Basel). 2025 Jun 20;17(13):2063. doi:10.3390/cancers17132063 PubMed PMID: 40647363; PubMed Central PMCID: PMC12249040.

15
Weaver JM, Dodd K, Knight T, Chaudhri M, Khera R, Lilleker JB, et al. Improved outcomes with early immunosuppression in patients with immune-checkpoint inhibitor induced myasthenia gravis, myocarditis and myositis: a case series. Support Care Cancer. 2023 Sep;31(9):518. doi:10.1007/s00520-023-07987-x

16
Aldrich J, Pundole X, Tummala S, Palaskas N, Andersen CR, Shoukier M, et al. Inflammatory Myositis in Cancer Patients Receiving Immune Checkpoint Inhibitors. Arthritis & Rheumatology. 2021 May;73(5):866–74. doi:10.1002/art.41604

17
Virgen CA, Sparks JA, Nohria A, O'Hare MJ, Goyal A, Said JT, et al. Mogamulizumab-Associated Myositis With and Without Myasthenia Gravis and/or Myocarditis in Patients With T-Cell Lymphoma. The Oncologist. 2023 Aug 3;28(8):e694–8. doi:10.1093/oncolo/oyad155

18
Müller-Jensen L, Flatz L, Hasan Ali O, Mohr R, Lachmann N, Mödl L, et al. HLA-A*01:01-B*08:01-C*07:01 is linked to early-onset immune checkpoint inhibitor-induced myositis and myocarditis. J Immunother Cancer. 2025 Sep 22;13(9):e011590. doi:10.1136/jitc-2025-011590 PubMed PMID: 40987493; PubMed Central PMCID: PMC12458757.

19
Lin X, Guan W, Li B, Deng H, Chen Y, Yang Y, et al. A case report and literature review on respiratory failure with immune checkpoint inhibitors: a life-threatening adverse event. Immunopharmacology and Immunotoxicology. 2023 Nov 2;45(6):780–7. doi:10.1080/08923973.2023.2228480

20
Petit PF, Daoudlarian D, Latifyan S, Bouchaab H, Mederos N, Doms J, et al. Tocilizumab provides dual benefits in treating immune checkpoint inhibitor-associated arthritis and preventing relapse during ICI rechallenge: the TAPIR study. Ann Oncol. 2025 Jan;36(1):43–53. doi:10.1016/j.annonc.2024.08.2340 PubMed PMID: 39241964.

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Fixed drug eruption in association with tetracyclines

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Summary

Fixed drug eruption (FDE) is a well-recognised cutaneous adverse drug reaction characterised by the recurrence of well-demarcated lesions at identical sites following re-exposure to the causative medication. Although typically localised and self-limiting, FDE may occasionally manifest in generalised or bullous forms, known as generalised bullous fixed drug eruption (GBFDE), which have the potential for significant morbidity. Early diagnosis is essential to ensure immediate discontinuation of the offending drug and to prevent possible complications. Numerous drugs have been implicated, e.g. antibiotics or NSAIDs.

This article provides a concise overview of the clinical presentation and pathophysiology of FDE, highlights its association with tetracyclines, and summarises the measures undertaken by Swissmedic to increase awareness among healthcare professionals and patients to ensure timely diagnosis and management.

Introduction

Fixed drug eruption (FDE) is a dermatological condition associated with a wide range of drugs. Although FDE is generally considered benign and self-limiting, it may occasionally present in more extensive or severe forms, leading to significant complications. This article briefly reviews the clinical features and pathophysiology of FDE, highlights its association with tetracyclines and outlines the measures implemented by Swissmedic to enhance patient safety.

Fixed drug eruption

FDE is a cutaneous adverse drug reaction (ADR) characterised by the recurrence of well- demarcated round to oval, erythematous to violaceous patches at the same anatomical site each time a specific medication is used. Lesions typically develop within hours of drug intake and may present as blisters, vesicles or bullae. Commonly affected sites include the lips, genitalia, hands and feet. Mucosal involvement is uncommon. Following resolution of the acute episode, hyperpigmentation can persist for weeks to months (1). Systemic symptoms such as fever, chills and fatigue are uncommon (2).

Although FDE is usually not considered a serious condition, it can cause significant discomfort and long-term, persistent hyperpigmentation after resolution of the acute lesion, and it recurs with re-exposure if the offending agent is not identified and avoided. Subsequent drug use can increase the spread of the lesions, which may include additional sites (1).

Although rare, generalised bullous fixed drug eruption (GBFDE) represents a severe and potentially life-threatening variant of FDE. No generally accepted definition of GBFDE exists (3). Cho et al (2014) defined GBFDE as extensive FDE involvement affecting at least 10% of the body surface area and involving at least three out of the following six anatomical sites: Head/neck, anterior trunk, back, upper extremities, lower extremities and genitalia (4). Owing to overlapping clinical features, GBFDE may be misdiagnosed as Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), which are also often medication-induced (5, 6). Systemic symptoms, visceral involvement and atypical blisters or spots without a prior history of FDE-like episodes may indicate SJS/TEN. In contrast, rapid onset (often within 24 to 48 hours) and recurrence at the identical sites upon re-exposure to

the causative drug favour a diagnosis of GBFDE. (6, 7). Although GBFDE was previously thought to be associated with a better prognosis than SJS/TEN (1), recent data indicate that GBFDE can be similarly life-threatening, with a mortality rate of up to 15% (3).

FDE and its severe variant GBFDE are classified as a type IV (delayed) hypersensitivity reaction. The etiopathology involves drug-specific CD8+ T cells in the localised skin areas. Following initial drug exposure, these cells persist in the affected skin and are rapidly reactivated upon re-exposure. Upon re-exposure, these T lymphocytes are activated, releasing multiple immunological mediators and leading to localised inflammation, keratinocyte apoptosis and the characteristic sharply demarcated lesion. Residual post-inflammatory hyperpigmentation reflects melanophage accumulation, and neutrophilic infiltrates may be observed, particularly in bullous forms (8, 9).

Prompt identification, relying on a thorough history of drug exposure and clinical-pathological correlation, as well as immediate withdrawal of the offending drug constitute the cornerstone of management. Typical localised FDE is usually benign and self-limiting within seven to 10 days of discontinuation of the culprit medication. Topical corticosteroids or oral antihistamines may be used. Systemic corticosteroids or cyclosporine may be required in certain cases (7). In contrast, GBFDE may require hospitalisation and intensive care treatment for aggressive wound care (1).

A wide range of drugs has been implicated in the induction of FDE, including nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen and ibuprofen, as well as several antibiotics, notably trimethoprim/sulfamethoxazole and levofloxacin (1). Over time, a potential association between tetracycline use and FDE has been recognised.

Tetracyclines

The first tetracycline antibiotic, chlortetracycline, was discovered in the 1940s and was followed by tetracycline, doxycycline, and minocycline. As a drug class, tetracyclines inhibit bacterial protein synthesis and are effective against a broad spectrum of gram-positive, gram-negative, and atypical pathogens. They are considered bacteriostatic (10, 11).

Tetracycline antibiotics are classified as first-generation (e.g. tetracycline, demeclocycline), second-generation (e.g. doxycycline, lymecycline, minocycline) and third-generation (e.g. tigecycline) tetracyclines. The third-generation tetracyclines were developed to address high resistance rates (11). Structurally, tetracyclines share a common four-ring (tetracyclic) core with variations in the side chain (10, 11). The tetracycline antibiotics authorised in Switzerland can be found in Table 1.

Table 1: Tetracycline antibiotics authorised in Switzerland*:

Active substance	Product
Doxycycline	Doxycyclin-Mepha Doxysol Supracyclin Tabs Doxyclin Doxylag 100 Oracea
Lymecycline	Tetralysal
Minocycline	Minocin Akne
Tigecycline	Tigecyclin Leman Tygacil
Tetracycline (+metronidazole, + bismuth)	Pylera
Demeclocycline (+triamcinolone)	Ledermix

* For details, see respective product information (www.swissmedicinfo-pro.ch). The updates to product information for generics are delayed as these are adapted at a later date to those of the original product.

Tetracycline and FDE

Although a few case reports began documenting FDE associated with tetracyclines in the late 1960s and 1970s, involving either the active substance tetracycline itself (12, 13) or related substances such as minocycline (14) and doxycycline (15, 16), the available evidence has gradually accumulated over a period of several decades. Some of the reports described a possible temporal relationship (13, 17) or positive dechallenge or rechallenge (including positive results from topical or oral provocation tests) (12, 14, 16, 18, 19), suggesting a causal association. Serious cases, some of which required in-patient treatment, were described (17, 19). Cross-reactivity among different tetracycline antibiotics has also been noted (13, 15).

In recent years, however, more comprehensive pharmacovigilance analyses have strengthened the evidence base and prompted renewed attention to this safety signal. In an observational study from Bangladesh published in 2023, doxycycline emerged as the second most commonly suspected drug after NSAIDs (20). Later, a large-scale analysis of 19,604,736 reports in the FDA Adverse Event Reporting System (FAERS), published in 2025, identified the drugs most frequently associated with FDE. While ibuprofen, paracetamol, fluconazole, trimethoprim/sulfamethoxazole and ciprofloxacin were the five most commonly reported agents, doxycycline remained notable, ranking tenth overall (21).

A search done by Swissmedic in 2025 of VigiBase, the WHO global database of ADR reports from member countries, retrieved a total of over 100,000 ICSRs (Individual Case Safety Reports) concerning tetracycline antibiotics (active substances) authorised in Switzerland. Tetracycline was suspected in over 1,000 fixed eruption (MedDRA preferred term [PT]) cases, whereas doxycycline was reported in 790 cases and minocycline in 26 cases. In addition, 17 ICSRs of generalised bullous fixed drug eruption (PT) were reported in association with doxycycline (22).

When interpreting the cases, it is important to note that the reported reactions are based on spontaneous reports. Due to limitations in the data, it is difficult to derive a causal relationship between the above-mentioned products and FDE/GBFDE from VigiBase data. Any results and conclusions drawn in this article do not represent the opinions of Uppsala Monitoring Centre, the WHO Collaborating Centre for International Drug Monitoring, or of the World Health Organization. Taken together, the combination of clinical evidence and newly available large-scale pharmacovigilance data provides a more robust understanding of the association between tetracyclines and FDE.

Discussion

Based on the most recent data from various sources, including scientific literature and pharmacovigilance reports, Swissmedic issues regular updates of the product information (Information for healthcare professionals and Patient information) for medicinal products authorised in Switzerland. This process ensures that healthcare professionals and patients have access to up-to-date and accurate information that supports safe and effective medication use.

The management of FDE, which may in some cases become severe, requires prompt identification and immediate discontinuation of the causative drug. Awareness among healthcare professionals is essential to ensure timely recognition. In this context, appropriate labelling in the product information is crucial. Swissmedic recently assessed the available data and the adequacy of labelling for tetracyclines authorised in Switzerland. Accordingly, Swissmedic has requested an update of the product information for tetracyclines authorised in Switzerland to explicitly include FDE in the ADR section.

This update is effective with the latest versions of the product information (Information for healthcare professionals and Patient information) for the tetracycline preparations listed above. These are available on swissmedicinfo-pro.ch and swissmedicinfo.ch. Only Ledermix, which contains demeclocycline and is used solely in dentistry, was excluded from this update because Swissmedic considers contact with oral mucosa and systemic exposure to be negligible.

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Reporting adverse drug reactions

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

References

1
Anderson HJ, Lee JB. A Review of Fixed Drug Eruption with a Special Focus on Generalized Bullous Fixed Drug Eruption. Medicina (Kaunas). 2021;57(9). doi: 10.3390/medicina57090925.

2
Shaker G, Mehendale T, De La Rosa C. Fixed Drug Eruption: An Underrecognized Cutaneous Manifestation of a Drug Reaction in the Primary Care Setting. Cureus. 2022;14(8):e28299. doi: 10.7759/cureus.28299.

3
Loo LY, Ngiam N, Sultana R, Lee HY. Generalized Bullous Fixed Drug Eruption: A Systematic Review. J Allergy Clin Immunol Pract. 2026.doi: 10.1016/j.jaip.2026.01.003.

4
Cho YT, Lin JW, Chen YC, Chang CY, Hsiao CH, Chung WH, et al. Generalized bullous fixed drug eruption is distinct from Stevens-Joh nson syndrome/toxic epidermal necrolysis by immunohistopathological features. J Am Acad Dermatol. 2014;70(3):539–48. doi: 10.1016/j.jaad.2013.11.015.

5
Samman L, Fernandez C, Dukharan V, Dominguez P. Clinical cues for distinguishing bullous fixed drug eruption from Stevens-Johnson syndrome: A case report. SAGE Open Med Case Rep. 2024;12:2050313X241307117. doi: 10.1177/2050313X241307117.

6
Paulmann M, Reinkemeier F, Lehnhardt M, Mockenhaupt M. Case report: Generalized bullous fixed drug eruption mimicking epidermal necrolysis. Front Med (Lausanne). 2023;10:1125754. doi: 10.3389/fmed.2023.1125754.

7
Mima Y, Yamamoto M, Obikane H, Norimatsu Y, Iozumi K. Ibuprofen-Induced Multiple Fixed Drug Eruption Confirmed by Re-Challenge: A Case Report and Literature Review. Diagnostics (Basel). 2024;15(1). doi: 10.3390/diagnostics15010048.

8
Shiohara T, Mizukawa Y. Fixed drug eruption: a disease mediated by self-inflicted responses of intraepidermal T cells. Eur J Dermatol. 2007;17(3):201–8. doi: 10.1684/ejd.2007.0149.

9
Teraki Y, Moriya N, Shiohara T. Drug-induced expression of intercellular adhesion molecule-1 on lesional keratinocytes in fixed drug eruption. Am J Pathol. 1994;145(3):550–60.

10
LaPlante KL, Dhand A, Wright K, Lauterio M. Re-establishing the utility of tetracycline-class antibiotics for current challenges with antibiotic resistance. Ann Med. 2022;54(1):1686–700. doi: 10.1080/07853890.2022.2085881.

11
Kounatidis D, Dalamaga M, Grivakou E, Karampela I, Koufopoulos P, Dalopoulos V, et al. Third-Generation Tetracyclines: Current Knowledge and Therapeutic Potential. Biomolecules. 2024;14(7). doi: 10.3390/biom14070783.

12
Minkin W, Cohen HJ, Frank SB. Fixed-drug eruption due to tetracycline. Report of a case. Arch Dermatol. 1969;100(6):749.

13
Brodin MB. Fixed-drug eruption to tetracycline. Arch Dermatol. 1970;101(5):621.

14
LePaw MI. Fixed drug eruption due to minocycline-report of one case. J Am Acad Dermatol. 1983;8(2):263–4. doi: 10.1016/s0190-9622(83)80199-6.

15
Correia O, Delgado L, Polonia J. Genital fixed drug eruption: cross-reactivity between doxycycline and minocycline. Clin Exp Dermatol. 1999;24(2):137. doi: 10.1046/j.1365-2230.1999.00436.x.

16
Gul U, Gonul M, Soylu S, Kaya I. Doxycycline-induced fixed drug eruption. J Dermatolog Treat. 2008;19(2):126–7. doi: 10.1080/09546630701759561.

17
Podder I, Chandra S, Das A, Gharami RC. Doxycycline Induced Generalized Bullous Fixed Drug Eruption. Indian J Dermatol. 2016;61(1):128. doi: 10.4103/0019-5154.174197.

18
Brehon A, Lourenco J, Badaoui A, Amsler E, Lopez Zaragoza JL, Soria A, et al. Doxycycline-induced fixed drug eruption: The new epidemic? J Eur Acad Dermatol Venereol. 2025;39(4):e303–e5. doi: 10.1111/jdv.20280.

19
Nitya S, Deepa K, Mangaiarkkarasi A, Karthikeyan K. Doxycycline induced generalized bullous fixed drug eruption - A case report. J Young Pharm. 2013;5(4):195–6. doi: 10.1016/j.jyp.2013.12.001.

20
Jannat T, Uddin J, Zakariah R, Talukder RI, Mortuza MG, Islam B, et al. An Observational Study of Fixed Drug Eruption in A Tertiary Care Hospital in Bangladesh. Mymensingh Med J. 2023;32(1):49–53.

21
Shrestha P, Stone CA, Jr., Phillips EJ. Fixed drug eruption and generalized bullous fixed drug eruption: Insights from an analysis of the FDA Adverse Event Reporting System. J Allergy Clin Immunol Pract. 2025;13(1):236–7 e1. doi: 10.1016/j.jaip.2024.09.024.

22
VigiBase. Available from: https://vigilyze.who-umc.org/ [accessed on 06.02.2026].

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Regulatory

Adverse drug reactions (ADRs) – the reporting obligation in Switzerland

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Summary

In Switzerland, the reporting of adverse drug reactions (ADRs) is a legal obligation for healthcare professionals. Under Article 59 of the Therapeutic Products Act (TPA) and Article 63 of the Therapeutic Products Ordinance (TPO), doctors, pharmacists and other professionals entitled to administer or dispense medicinal products are required to report serious or unexpected ADRs to Swissmedic. For submitting a report, the mere suspicion of a causal relationship is sufficient. ADR reports from healthcare professionals are the foundation of a functioning spontaneous reporting system. The Swissmedic reporting tool ElViS should be used for reporting. By reporting, healthcare professionals make an indispensable contribution to the continuous post-marketing monitoring of the safety of medicinal products.

Introduction

Since 2002, a nationally harmonised legal obligation to report ADRs has been in place in Switzerland. This obligation is legally enshrined in the Therapeutic Products Act (TPA) and further detailed in the Therapeutic Products Ordinance (TPO).

This article aims to provide an overview of the legal framework and practical implementation of the ADR reporting obligation for healthcare professionals in Switzerland.

What is the definition of an ADR?

An ADR is a harmful, unintended reaction to a medicinal product.

ADRs may occur when the medicinal product is used in accordance with the medicinal product information, but also when used outside the terms of the marketing authorisation. Use that is not in accordance with the product information includes off-label use, overdose, misuse, abuse and medication errors. It also includes reactions following occupational exposure to the medicinal product (GVP Module VI, EMA, Rev. 2).

Who is required to report ADRs?

In addition to the manufacturer or marketing authorisation holder of the medicinal product, Art. 59 para. 3 TPA requires "*any person who professionally dispenses therapeutic products or administers them … or who is entitled to do so*" to report suspected ADRs and quality defects. Thus, the Act establishes a reporting obligation for all persons who are entitled to dispense or administer medicinal products in the course of their professional activities.

Consequently, the group of persons legally obliged to report ADRs includes not only doctors, dentists, veterinarians, and pharmacists, but also other healthcare professionals who are entitled to dispense and/or

administer medicinal products – such as midwives, nurses and medical or pharmaceutical assistants.

The reporting obligation also extends to medical professionals who are authorised, by virtue of their professional qualifications, to administer or dispense medicinal products but who do not generally make use of this authorisation in their daily professional practice, such as forensic pathologists.

What has to be reported?

The Act and Ordinance require reporting of the following:

- "Suspected **serious** adverse drug reactions".
  A serious ADR is fatal or life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect or is otherwise considered medically significant.

- "Suspected, **unexpected** adverse drug reactions".
  "Unexpected" ADRs are adverse reactions whose nature, extent or outcome differ from the product information for the medicinal product. This means that non-serious ADRs must also be reported if they are not listed as an adverse reaction in the medicinal product information or, for example, if their impact is not adequately described.

Reporting adverse reactions that are serious or occur in vulnerable patient populations (e.g. deaths, reactions in children) is particularly important. Unexpected and serious reactions are of special interest from a pharmacovigilance perspective as they may indicate new safety aspects of a medicinal product.

In addition to ADRs, the following must also be reported:

- Observations of serious or previously unknown facts that may compromise drug safety.

- Suspected **quality defects**

- Suspected **illegal trading in medicinal products**, in particular suspected falsified medicinal products.

Suspected quality defects and illegal trading in medicinal products must be reported to Swissmedic's Market Monitoring of Medicines Division (see Quality defect report or Report regarding suspected illegal trading in medicinal products).

Is suspicion enough?

Yes. The reporting obligation applies to **suspected** ADRs. Reporters are not required to provide proof of a causal relationship between the use of a medicinal product and the occurrence of an ADR. The reporting obligation applies as soon as a medicinal product is suspected of having a harmful and unintended effect on a patient.

Concerns/uncertainties such as:

- "I'm not sure",

- "Other drugs may have contributed",

- "The patient was in poor health already".

are not a reason not to report the case.

Well-documented reports of suspected adverse drug reactions may provide early signals of previously unknown risks.

What information must the report contain? Do the patient's personal data have to be disclosed?

According to the Therapeutic Products Ordinance, the report should contain all available relevant information.

Swissmedic can process reports if they contain:

- basic information on the patient (such as date of birth, age, sex),
- a description of the suspected ADR,
- the name of the suspected medicinal product or active ingredient, and
- the reporter's contact details for confirmation of receipt and for follow-up questions, if necessary.

Information on the patient's medical history, ongoing diseases and concomitant medications is relevant for the scientific assessment of the ADR report. In general, the validity of the case assessment increases with the amount and quality of the available information.

Data that allow the unique identification of a patient, such as full name, (e-mail) address or telephone number, should not be submitted to Swissmedic.

Is there a legally prescribed reporting timeline?

The Therapeutic Products Ordinance stipulates the following reporting timelines for suspected quality defects, ADRs or facts that compromise drug safety:

		Reporting timeline
Serious adverse drug reactions / **facts that compromise drug safety**		≤ 15 days
Unexpected adverse drug reactions / **facts that compromise drug safety**		≤ 60 days
Quality defects		
Class of defect	**Definition**	
Class I	Potentially life-threatening or may seriously endanger health	24 hours
Class II	May cause illness or lead to incorrect treatment, but does not constitute a Class I defect	3 calendar days
Class III	No serious threat to health expected	15 calendar days

Swissmedic's pharmacovigilance team will still accept and process your report if it is submitted after the reporting deadline. Every report is a contribution to patient safety.

How do I report?

ADR reporting via Swissmedic's electronic vigilance system ElViS is the preferred route for healthcare professionals. ElViS can also be used to submit case-related documents, such as laboratory reports or hospital discharge reports. After successful submission, users can locally save their report and confirmation of receipt for their own records. Data protection and security meet the highest standards.

Further information is available on the Swissmedic website under Reporting adverse drug reactions for healthcare professionals (swissmedic.ch).

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What happens to my report?

Your report will be processed and assessed in close collaboration with regional pharmacovigilance centres. Each report is carefully assessed for new safety-relevant information that could lead to the identification of a safety-signal.

Reports are then forwarded, with reporter and patient details anonymised, to the international WHO UMC database in Uppsala, Sweden, and to the concerned marketing authorisation holders.

What are the consequences of not reporting?

Failure to comply with the reporting obligation may result in administrative and criminal proceedings (e.g. a fine) and can be indirectly relevant from a liability perspective. In a legal dispute, failure to report an ADR could, for example, be interpreted as an indication of insufficient professional diligence or inadequate risk awareness.

Of far greater importance to the public, however, is the potential negative impact on patient safety in Switzerland if new safety risks are not identified or are identified only with a delay because healthcare professionals have failed to report.

The spontaneous reporting system remains the most important method for monitoring the safety of medicinal products after authorisation. However, this system only functions if healthcare professionals actually report suspected cases of adverse drug reactions, thereby fulfilling their reporting obligations. Rare and very rare ADRs cannot be reliably detected in clinical trials due to the restricted number of study participants and trial duration. Moreover, vulnerable patient populations are generally underrepresented in clinical trials.

Post-marketing reports play a crucial role in the continuous monitoring of the benefit-risk profile of all marketed medicinal products and in the early identification of potential drug risks, thereby allowing for the timely implementation of appropriate risk-minimisation measures.

The success of the system largely depends on the attentiveness of healthcare professionals and on the quality and quantity of the information they provide.

Core statements

- ADR reporting is not voluntary – it is a legal obligation for healthcare professionals.
- Suspicion is sufficient (causality does *not* have to be proven).
- Serious ADRs must always be reported.
- Swissmedic's reporting tool ElViS is the preferred reporting route (Reporting adverse drug reactions for healthcare professionals)
- The quality of the report increases its usefulness.
- Reporting is encouraged also in cases of uncertainty as to whether the event really represents an adverse drug reaction.

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ICH E2D(R1) Guideline on Safety Data Management entered the implementation phase of the ICH Process

Valeriu Toma

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Summary

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline E2D(R1) on "Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports" reached Step 4 – the adoption of the harmonised Guideline following finalisation of the expert working group's document – of the ICH Process in September 2025. The Guideline then entered Step 5, the implementation phase of the ICH Process (1).

The revised Guideline provides guidance on definitions and standards for post-approval individual case safety reporting, as well as good case management practices. Where applicable, the Guideline notes where regional or local regulatory requirements may vary and, in such cases, marketing authorisation holders (MAHs) should consider specific regional/local requirements (2).

Overview

Since the original publication of Guideline ICH E2D in 2003, new sources of post-approval safety information have emerged or are more frequently used – e.g. digital platforms, social media, mobile health technologies, market research programmes, patient support programmes, non-interventional studies, literature – which vary in their characteristics and their contributions to the quality of the safety data received. Revised Guideline ICH E2D(R1) thus provides updates on the definitions, standards and regulatory guidance for the management and reporting of post-approval drug safety information. It aims to support appropriate safety surveillance of medicinal products based on current practices and needs. New guidance is also included, focusing on the management of safety data from non-interventional studies with primary data collection (data collected specifically to address the study objectives) and safety data from non-interventional studies with secondary use of data (use of existing data for a different purpose than the one for which they were originally collected).

The revision redefines core concepts and introduces a unified framework for managing post-marketing safety information across regions. It harmonises definitions, minimum ICSR criteria and good case management practices that connect traditional pharmacovigilance with emerging real-world evidence (RWE).

Key changes

- Expanded definitions: New terms and definitions for digital platforms, organised data collection systems (ODCS), patient support programmes (PSPs) and market research programmes (MRPs) reflect the expanding sources of post-approval safety data (2).

- Clarified ICSR criteria: Establishes minimum reporting elements for expedited and routine reports, harmonising expectations across regulators (2).

- Integration of digital platforms: Provides specific guidance on when MAHs must monitor platforms under their responsibility and how to manage adverse event data identified on external sites.

- Non-interventional studies (NIS): Distinguishes between primary and secondary data collection, outlining MAH responsibilities for identifying and reporting AEs/ADRs arising from real-world data sources.

- Revised section on "Other observations": Expands the scope to include lack of efficacy, medication error, misuse, overdose, occupational exposure and exposures during pregnancy or breastfeeding.

- Good case management practices: Updates standards for patient and reporter identifiability, narratives, causality assessment, duplicate management and contractual oversight of third parties.

ICH E2D(R1) transforms E2D from a narrow reporting guide into a comprehensive global framework that integrates various data sources into pharmacovigilance practice.

Implementation by ICH regulatory members is expected from late 2025 onwards, with regional guidance to follow.

Swissmedic is currently examining local pharmacovigilance requirements in the light of the new specifications in E2D(R1), including the following potentially impacted areas:

- Solicited reports from PSPs, MRPs or from other digital platforms

- Technical implementation of new values in the ICH E2B(R3) data element "Study Type Where Reaction(s)/ Event(s) Were Observed"

- Reporting of "Other observations" such as lack of efficacy, medication errors, misuse, abuse and occupational exposure

- Safety reporting from literature sources

- Reports of exposure to medicinal products during pregnancy or breastfeeding and parent-child reports

- Reporting of adverse events following immunization (AEFI)

The ongoing national process is intended to achieve optimal harmonisation with regional EU/EMA implementation.

Challenges of implementing ICH E2D(R1)

Key challenges during the implementation of the revised Guideline may include:

- Divergent regional/local regulations and rules: While E2D(R1) aims to achieve global harmonisation, countries often modify global guidelines, creating complex, varied local requirements that companies are required to manage.

- The use of new values in ICH E2B(R3) data element "Study Type Where Reaction(s)/ Event(s) Were Observed" (E2B(R3) C.5.4), which will help identify ICSRs issued by PSPs, MRPs or ODCSs with source data from digital platforms. This will require some IT updates and an implementation strategy for all stakeholders (regulatory authorities and MAHs) (3).

- The new definition for PSPs and other types of programmes initiated by MAHs which do not meet the definition criteria for PSPs. ICSRs from these "non-PSPs programmes" will be classified as spontaneous rather than solicited, and MAHs will need to update their processes.

- The requirement to have some documentation in place for ODCSs that are not conducted according to a protocol. Previously, such documentation was not specifically required in different regions/countries for these ODCS activities and MAHs will also need to update their processes.

- Specific report categories: Incorporating "Other observations" like lack of efficacy, medication errors, misuse, abuse and occupational exposure may expand the types of safety information needing management, often depending on specific regional/local requirements.

- System updates: Companies will need to update IT systems to manage new data types, definitions and reporting requirements efficiently.

- Training and resources: Developing and delivering adequate training for personnel on this updated guideline is crucial.

Swissmedic is taking these challenges on board by planning for an appropriate transition period during implementation, for example.

ICH has published the additional training material created by the expert working group to complement the revised guideline E2D(R1) and to support implementation (4).

References

1
The ICH E2D(R1) Guideline reaches Step 4 of the ICH Process https://www.ich.org/news/ich-e2dr1-guideline-reaches-step-4-ich-process

2
ICH E2D(R1) Post-Approval Safety Data – Definitions and Standards for Management and Reporting of Individual Case Safety Reports (Final Guideline) (Adopted 15 September 2025): https://database.ich.org/sites/default/files/ICH_E2D%28R1%29_Step4_FinalGuideline_2025_0819.pdf

3
ICH Information Paper Regarding Alignment of ICH E2B(R3) with ICH E2D(R1) Guideline: E2B(R3)_InfoPaper_MCApproved_20251216.pdf

4
Publication on ICH Official web site: ICH_E2D(R1)_TrainingMaterial_2025_1211.pdf

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Statistical review 2025

Risk management activities in 2025

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Summary

The 2025 risk management activities of the Safety of Medicines Division demonstrate the importance of systematic monitoring and targeted regulatory interventions in maintaining a favourable benefit-risk balance for medicinal products in Switzerland. The following summary highlights the key outcomes across signal management, PSUR evaluations, RMP reviews and new communication initiatives.

Signal management

- **153** safety signals evaluated, most triggered by **international sources**.
- Most frequently affected therapeutic areas:
  - **ATC L** (antineoplastic and immunomodulating agents)
  - **ATC N** (nervous system)
- Around **three quarters** of all evaluated signals required **risk minimisation measures**, mainly product information updates
- **279** procedures were conducted with marketing authorisation holders to implement these measures.
- **7** DHPCs/HPCs were issued to inform healthcare professionals about newly identified or critical risks.

PSUR evaluations

- **345** PSURs reviewed.
- **24** resulted in product information updates

Risk Management Plans (RMPs)

- **361** RMPs reviewed.
- Adjustments requested when needed to Safety Specifications, Pharmacovigilance Plans or Risk Minimisation Measures.

Communication initiatives

- Launch of the monthly "**Safety Update – product information updates**".
- Introduction of:
  - **Red Safety Information symbol** (for DHPCs)
  - **Blue Safety Information symbol** (for ordered information materials)
- Aim: To improve the visibility, consistency and recognisability of safety related information for healthcare professionals.

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The safety of medicines is monitored not only during clinical development, but also continuously after approval. Because clinical trials are conducted with a limited number of participants, apply narrowly defined inclusion and exclusion criteria, and take place under highly controlled conditions, they cannot fully capture all potential risks associated with a medicinal product. As a result, rare adverse drug reactions and important interactions often become apparent only during widespread real-world use.

To address these post-authorisation safety challenges, the Safety of Medicines Division* conducts risk management activities that focus on signal management in order to ensure early identification and assessment of potential risks, as well as timely implementation of appropriate risk minimisation measures. These activities are primarily triggered by signal notifications and by aggregated data from Periodic Safety Update Reports (PSURs). Effective Risk Management Plans (RMPs) support patient safety by identifying key risks, outlining pharmacovigilance activities, and specifying risk minimisation measures throughout the product life cycle.

Building on these risk management efforts, Swissmedic introduced a harmonised labelling system ("Red Safety Information" and "Blue Safety Information" symbols) to ensure that important regulatory communications on medicinal product safety are clearly identifiable and receive the necessary attention. In addition, Swissmedic launched a new "Safety Update – product information updates" service. This is aimed at healthcare professionals and is intended to further enhance communication and awareness of safety-related changes to the product information.

This report provides an overview of the key risk management instruments and activities employed by the Safety of Medicines Division in 2025.

* The risk management for blood transfusions, advanced therapy medicinal products (ATMPs) and veterinary medicinal products is covered by individual specialist divisions and is not addressed in this report. Quality deficiencies are also outside the remit of the Safety of Medicines Division.

Signal management – Core instrument for reducing the risks of medicines

Signal management process at Swissmedic

Signal management begins with the collection of safety information from national and international sources. On the one hand, signals are detected in collaboration with the regional pharmacovigilance centres by the ongoing analysis of individual case safety reports of adverse drug reactions across Switzerland. On the other hand, international data sources, including data from international adverse drug reactions databases, safety related investigations by other regulatory authorities, scientific publications or new data from studies, play a particularly critical role in ensuring drug safety in Switzerland. Marketing authorisation holders are therefore required to report to Swissmedic safety signals for their medicinal products that have been identified or assessed by other regulatory authorities such as the EMA, FDA, and MHRA.

The number of signal reports from international data sources has risen over the years; in 2025, Swissmedic processed 786 reports (initial and follow up). Most of these originated from safety-related procedures of the EMA and FDA.

Signal validation – the process of confirming that a detected safety signal is credible, relevant and supported by sufficient evidence to justify further investigation – is followed by a systematic signal evaluation that reviews all available data, conducts a contextual analysis, identifies the medicinal products concerned and determines whether regulatory action is required. The frequency and severity of the event under evaluation and the overall benefit-risk profile of the medicinal product are taken into account. Depending on the indication, dispensing category or therapeutic alternatives, the same risk may be acceptable in one case and unacceptable in another. Signal evaluation focuses on whether new risk minimisation measures are needed to ensure that the medicinal product can be used safely.

Within signal procedures, the affected marketing authorisation holders are requested to implement risk minimisation measures (RMMs) where necessary. For example, amendments to the medicinal product information may be necessary, such as the addition of new warnings, updated dosage recommendations or newly identified interactions. If particularly significant changes are needed, e.g. if the therapeutic recommendations for use are modified as a result of the newly identified risk, healthcare professionals are informed by means of a direct healthcare professional communication (DHPC). If risk minimisation measures are insufficient to ensure safe use of the medicinal product, the option of revoking the marketing authorisation remains as a last resort.

This structured approach ensures that new or emerging safety risks are systematically identified, assessed and appropriately mitigated (see Figure 1).

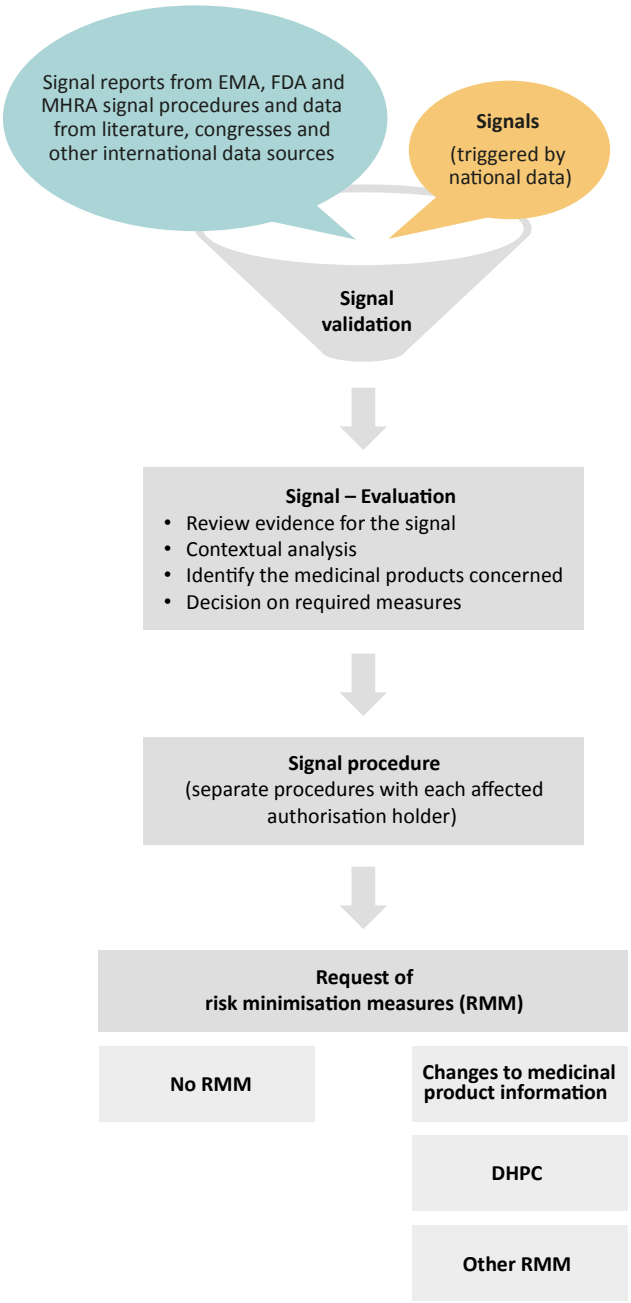

Figure 1: Schematic illustration of the signal management process at Swissmedic

Signal evaluation

In 2025, the Safety of Medicines Division completed a total of 153 signal evaluations addressing specific safety issues. More than 80% of these were primarily triggered by international data sources, highlighting their central importance in Swissmedic's signal management activities (see Figure 2).

A total of 27% of signal evaluations concerned antineoplastic and immunomodulating agents (ATC code L), mostly in the immunosuppressants (L04A), monoclonal antibodies and antibody-drug conjugates (L01F), protein kinase inhibitors (L01E) and antimetabolites (L01B) subgroups. In addition, medicinal products acting on the nervous system (ATC code N) accounted for around 20% of signal evaluations, mainly within the analgesics (N02), psycholeptics (N05) and psychoanaleptics (N06) subgroups (see Figure 3).

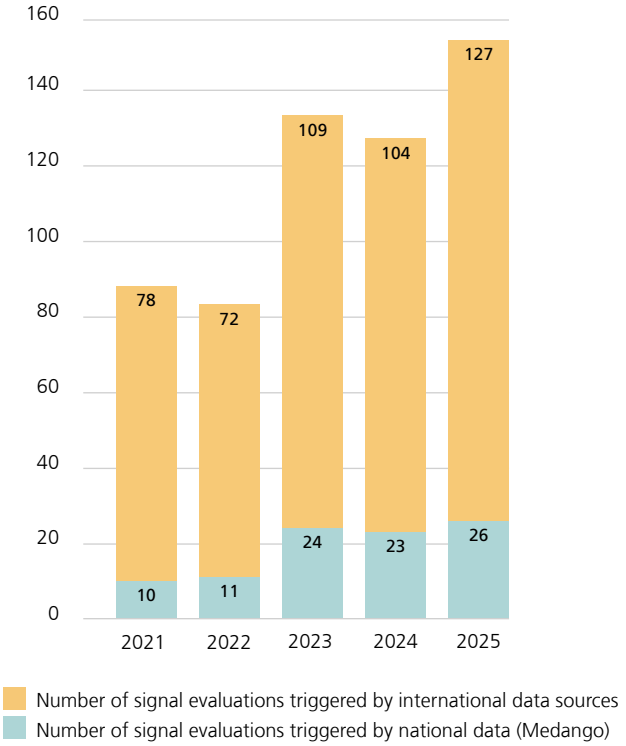

Figure 2: Number of signal evaluations by trigger source

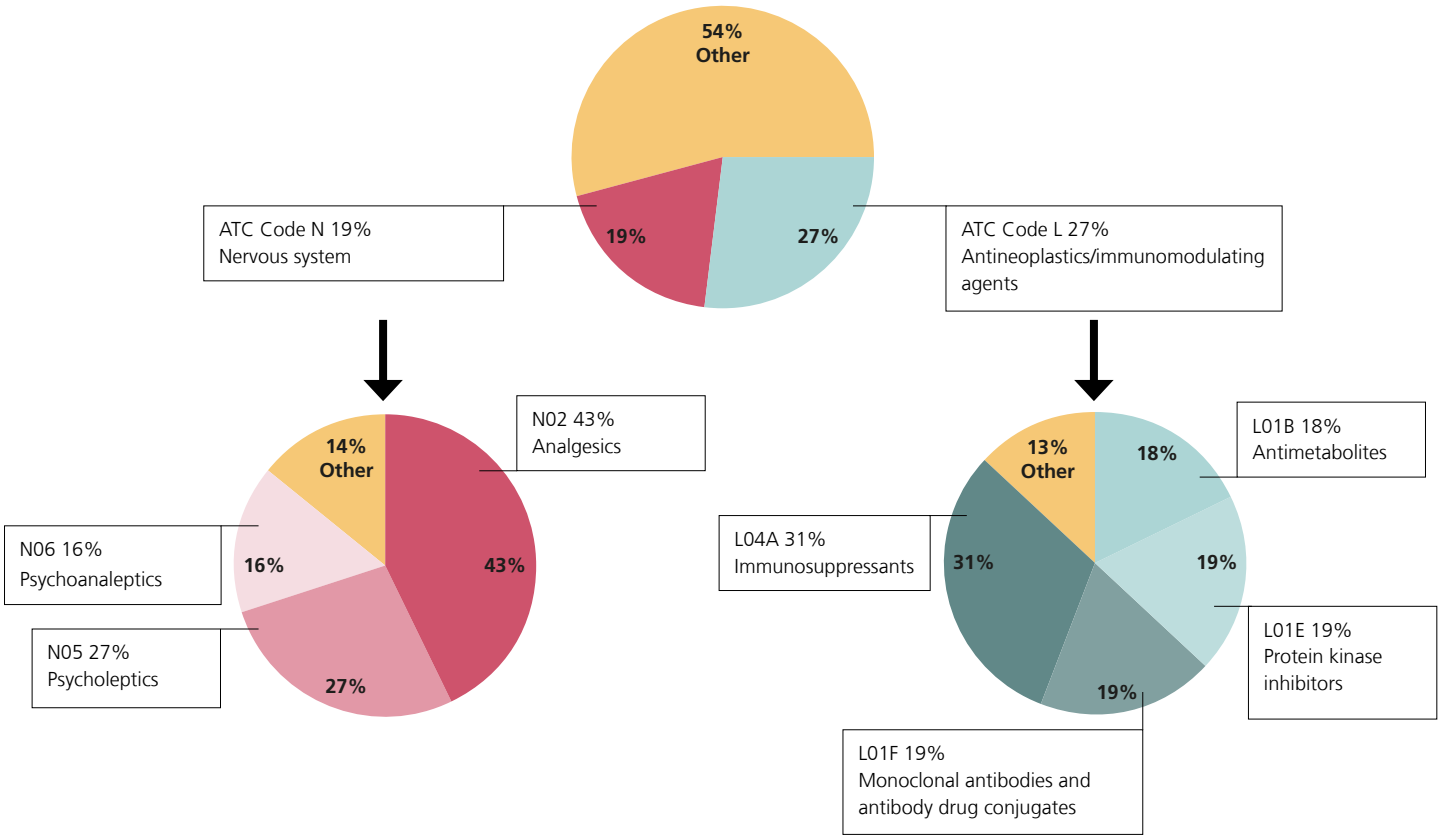

Figure 3: Medicinal products by ATC code for signal evaluations completed in 2025 (several medicinal products with different ATC codes may be involved in a specific signal evaluation)

Procedures for the implementation of risk minimisation measures

If risk minimisation measures are deemed necessary or if questions arise from the signal evaluation, Swissmedic conducts administrative procedures with the marketing authorisation holders concerned. Typically, several marketing authorisation holders are affected by a single signal evaluation. In 2025, a total of 279 procedures were conducted in order to review and implement risk minimisation measures (see Figure 4).

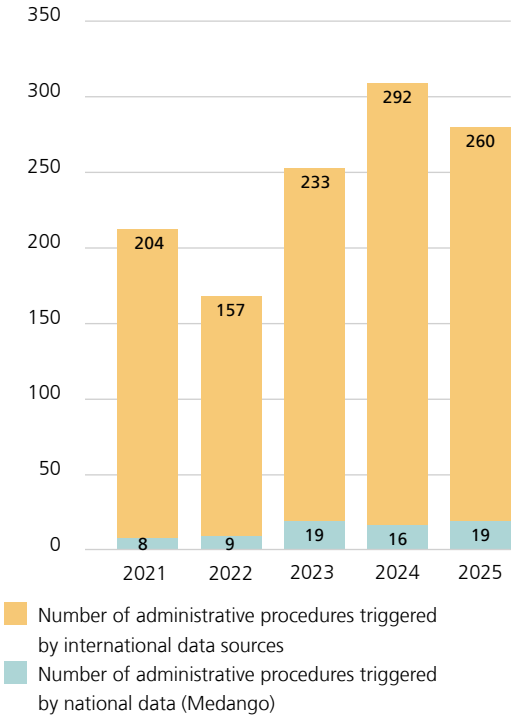

Figure 4: Number of administrative procedures with marketing authorisation holders

Outcome of signal evaluations and administrative procedures

Risk minimisation measures, usually involving changes to the medicinal product information (see Figure 5), were initiated in 73% (112 of 153) of the evaluated signals. The changes most frequently affected the "Warnings and precautions" and "Undesirable effects" sections (see Figure 6).

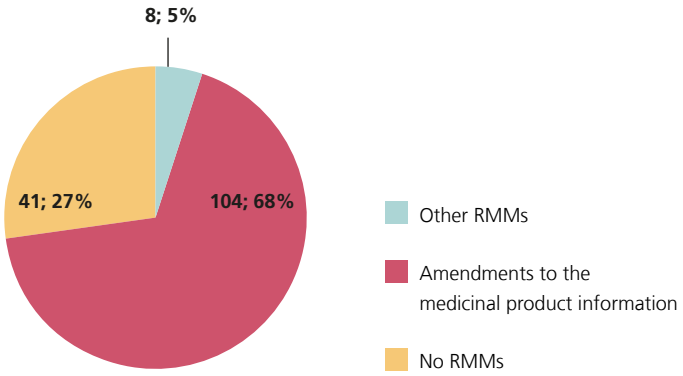

Figure 5: Results of the signal evaluation procedures completed in 2025

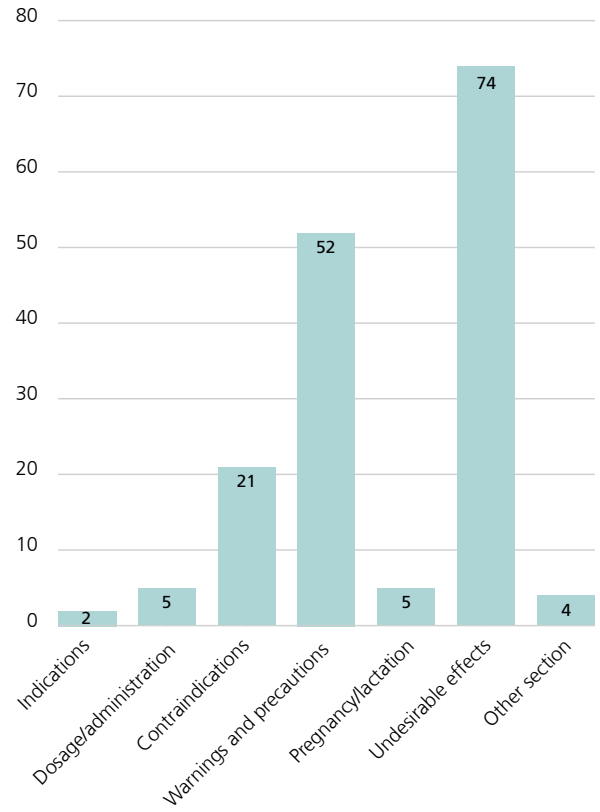

Figure 6: Changes to the medicinal product information by section (for the total of 104 changes to the PI, more than one section can be concerned)

Healthcare professionals were informed about seven specifically relevant newly identified risks by (D)HPC in 2025 (see Table 1).

Table 1: (D)HPCs published in 2025

Affected active substance or medicinal product	Issue	Month of publication
Fedratinib	Expiry of temporary Swissmedic authorisation	February
5-FU (i.v. administration)	Interpretation of the uracil level used for DPD phenotyping in the blood of patients with moderate or severe renal impairment	March
Metamizole	Risk minimisation measures for the early recognition of agranulocytosis, reduction of off-label use and avoidance of the simultaneous use of methotrexate	April
Medroxyprogesterone acetate (MPA)	Important safety information and new contraindication for injectable formulations and new recommendations for high-dose oral formulations	May
Obeticholic acid	Unconfirmed clinical benefit; discontinuation of authorisation for Ocaliva®	August
Tegretol 2%, oral suspension	Additional precautions for neonates	October
Finasteride, dutasteride	New measures to minimise the risk of suicidal ideation	November

Periodic Safety Update Reports – Continuous evaluation of drug safety

Another important risk management activity involves the comprehensive evaluation of the safety profiles of medicinal products using aggregated data submitted in Periodic Safety Update Reports (PSURs). These reports provide an integrated analysis of worldwide safety information, including cumulative adverse event data, exposure estimates, benefit-risk considerations and updates from ongoing or completed clinical studies. By systematically reviewing PSURs, regulatory authorities can identify emerging safety concerns, detect changes in the benefit-risk balance and determine whether additional risk minimisation measures, product information updates or regulatory actions are required.

In Switzerland, PSURs must be submitted, usually once a year, for four years after the authorisation of a medicinal product with a new active substance or a biosimilar. Swissmedic can extend the PSUR obligation or reimpose it at any time, for example if there are specific safety concerns.

A total of 345 PSURs were evaluated by the Safety of Medicines Division in 2025, roughly the same number as in previous years. The highest proportion of submitted PSURs – 51% or 175 PSURs – concerned antineoplastic and immunomodulating agents (ATC code L), followed by systemic antiinfectives (ATC code J), which accounted for 13% (44 PSURs). This distribution roughly reflects the number of new authorisations subject to the PSUR requirement over the last four years (see Figure 7).

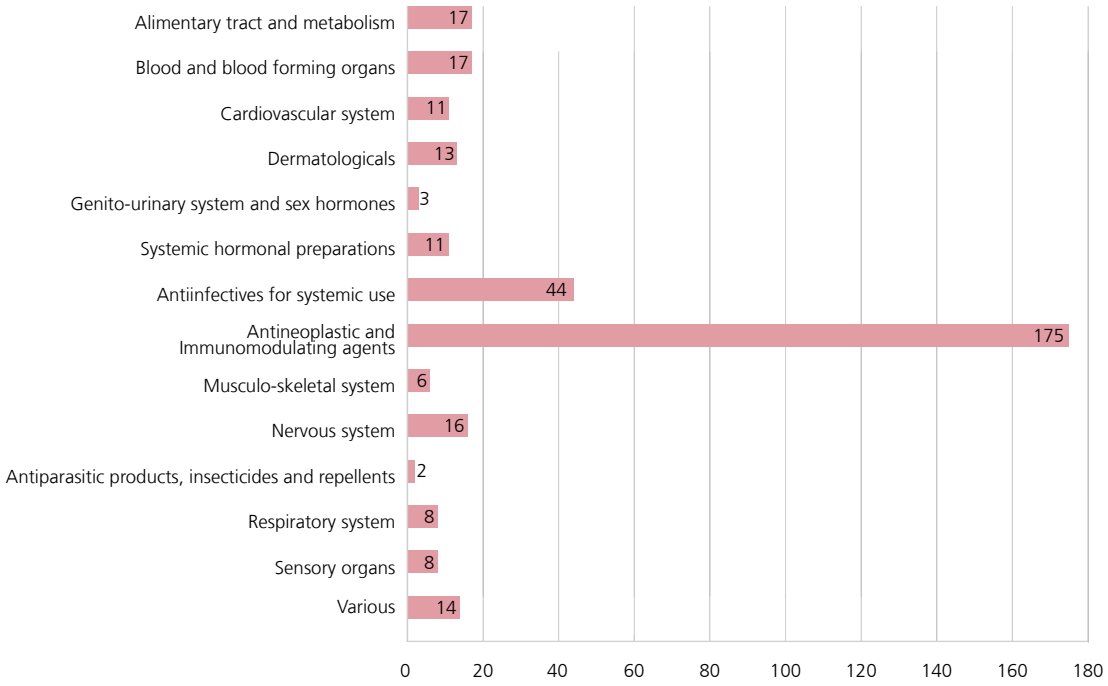

Figure 7: PSUR evaluations completed in 2025 by ATC code

Results of the PSUR evaluations

The PSUR review focuses on evaluating the current benefit-risk profile of the medicinal product, paying particular attention to ongoing and completed signal evaluations during the reporting period and the assessment of any need for risk minimisation measures.

In 2025, the PSUR evaluations resulted in changes to the product information in 24 cases. These changes primarily affected the "Warnings and precautions" and "Undesirable effects" sections (see Figure 8).

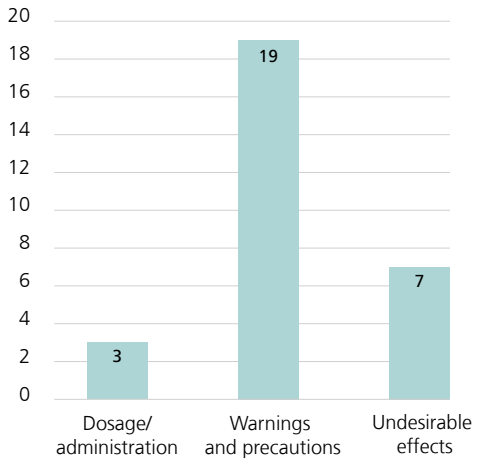

Figure 8: Changes to the medicinal product information (PI) by section in PSUR procedures completed in 2025 (24 changes to the PI, more than one section may be affected)

Risk Management Plans (RMPs) – Planning instrument

An RMP is an important planning instrument that covers particularly significant risks and knowledge gaps associated with a medicinal product, which usually have to be characterised more thoroughly (e.g. by post-authorisation safety studies (PASS)) or require additional risk minimisation measures, such as training materials for healthcare professionals or patients.

Structure

The content of RMPs is defined in internationally valid guidelines. Their key components are the Safety Specifications, the Pharmacovigilance Plan and the Risk Minimisation Measures:

- The Safety Specifications describe the safety profile of the medicinal product, primarily on the basis of study data. This section also identifies the particularly significant risks and knowledge gaps, collectively referred to as Safety Concerns.

- The Pharmacovigilance Plan outlines the activities required to further characterise the Safety Concerns and, in particular, describes activities that go beyond the mandatory routine activities (e.g. systems for the systematic recording of individual case reports). Post-Authorisation Safety Studies (PASS) are of relevance in this context.

- The Risk Minimisation Measures section describes the measures required to prevent or minimise the likelihood of, as far as possible, the occurrence of the risks summarised in the Safety Concerns section. The RMP specifies those actions that extend beyond routine measures – i.e. the medicinal product information – and may include information materials for patients or healthcare professionals.

In summary, the RMP documents the risk management system required to identify, characterise and minimise the most important risks associated with a particular medicinal product.

Since knowledge about risks and remaining uncertainties evolve over time, the RMP is a dynamic document that requires updating throughout the medicinal product's life cycle whenever new information becomes available.

Objective of Swissmedic's RMP review

The core focus of Swissmedic's RMP review is to verify that all significant risks and knowledge gaps are adequately addressed and that appropriate measures have been put in place to characterise and minimise them.

Specific emphasis is placed on ensuring the availability of appropriate information materials for Swiss patients and healthcare professionals where this is necessary. It is the marketing authorisation holder's responsibility to produce and distribute such officially ordered materials.

In 2025, Swissmedic reviewed 361 RMPs and, where necessary, requested amendments to the Safety Specifications, Pharmacovigilance Plan and/or Risk Minimisation Measures.

Public RMP summaries

RMP summaries are published on the Swissmedic website (RMP summaries) and provide an overview of the risks, pharmacovigilance activities and risk minimisation measures that have been defined for the medicinal product.

New initiatives to strengthen awareness of safety-related information

Risk communication is a fundamental component of drug safety, as it ensures that healthcare professionals and patients can clearly understand both the benefits and the potential risks associated with medicinal products. Effective communication helps translate complex safety information into practical guidance, facilitating informed treatment decisions and supporting the safe and appropriate use of medicines in everyday clinical practice. In addition, transparent and timely communication strengthens confidence in regulatory processes and fosters trust in regulatory authorities. By ensuring

that emerging risks and important updates are disseminated promptly and accurately, risk communication plays a critical role in maintaining the overall integrity and reliability of the healthcare system.

"Safety Update – product information updates"

To further improve communication on safety-related changes to the product information, Swissmedic has launched a new service for healthcare professionals called "Safety Update – product information updates". This service provides a monthly tabular overview of selected updates to the product information related to medicinal product risks. The monthly "Safety Update – product information updates" can be subscribed to via the "Safety of medicines" newsletter and is also available on the Swissmedic website (see Safety Update – product information updates).

Identifying DHPCs and information materials

The introduction of the "Red Safety Information" and "Blue Safety Information" symbols represents another important measure to improve awareness of safety-related information (see Figures 10 and 11). These symbols are designed to ensure that the target readership recognises officially ordered safety-related information as particularly important, thereby further improving drug and patient safety.

Since July 2025, DHPCs have carried the "Red Safety Information" symbol (see Figure 10).

Figure 10: "Red Safety Information" symbol

The "Blue Safety Information" symbol is used to clearly identify officially ordered information materials (see Figure 11).

Figure 11: "Blue Safety Information" symbol

The designations are intended to help recipients identify this important safety-related information in their inbox. Furthermore, the symbols enhance recognisability, thereby establishing a consistent visual marker. In this way, the intended recipients of DHPCs and information materials can be reached more reliably in the future.

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Pharmacovigilance: Human medicinal products Reports of suspected adverse drug reactions

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Summary

Swissmedic receives reports of suspected adverse drug reactions from various sources submitted in accordance with legal requirements. In 2025, a total of 15,022 reports were submitted to Swissmedic, comprising 10,208 initial reports corresponding to the reported suspected cases and 4,814 follow-up reports containing additional information. The analyses in this report were based on 8,981 initial reports after de-duplication and exclusion of reports not referring to 2025 (Figure 1). Most cases (n=7,951, 89%) were reported primarily by healthcare professionals. One third of these reports were submitted to Swissmedic directly or via the regional pharmacovigilance centres, while two thirds were sent by the marketing authorisation holders.

The age of the affected individuals ranged from 0 to 100 years (median: 59 years). Females accounted for 54% of cases, males for 39%, while sex was unknown in 7%.

Swissmedic assesses individual case safety reports in collaboration with the regional pharmacovigilance centres in Basel, Geneva, Lausanne, Lugano, and Zurich. In total, 2,208 reports underwent in-depth evaluation by the regional centres in 2025.

Introduction and guidance on the interpretation of the data

This report provides a statistical overview of adverse drug reactions reported to Swissmedic in 2025.

In accordance with legal requirements, Swissmedic receives reports of suspected adverse drug reactions from various sources. Reports may be submitted by healthcare professionals or directly by the affected individuals; a large proportion of reports are submitted via marketing authorisation holders (MAH). The reports may relate to cases that have occurred in clinical practice or hospital settings, cases originating from studies or other systematic observations, or cases published in scientific journals.

When interpreting data from the spontaneous reporting system, it is important to note that these reports represent suspected cases. This means that, at the individual case level, no definite causal relationship between the administered medicine or vaccine and the reported reaction can be established. Furthermore, and despite legal obligations, only a small percentage of adverse drug reactions are actually reported. Thus, data from the spontaneous reporting system are insufficient to make inferences regarding the true incidence or frequency of adverse drug reactions, as neither the total number of exposed individuals nor the actual total number of cases that have occurred is known.

Despite these limitations, spontaneous reports remain one of the most important pillars of pharmacovigilance and medicine safety. The majority of rare and previously unknown adverse reactions are first detected through this system and are subsequently confirmed using other sources of data. When interpreting the data presented here from the Swiss spontaneous reporting system, it

should also be noted that the number of reports may change over time. For example, additional information may become available after an initial report has been submitted, which may modify the data. As a result, figures reported in Swissmedic publications at different points in time may differ.

Total number of reports

In 2025, a total of 15,022 reports were processed. Of these, 10,208 were initial reports corresponding to the reported suspected cases and 4,814 were follow-up reports. The analyses presented below were based on 8,981 initial reports after deduplication and exclusion of reports not referring to 2025 (Figure 1).

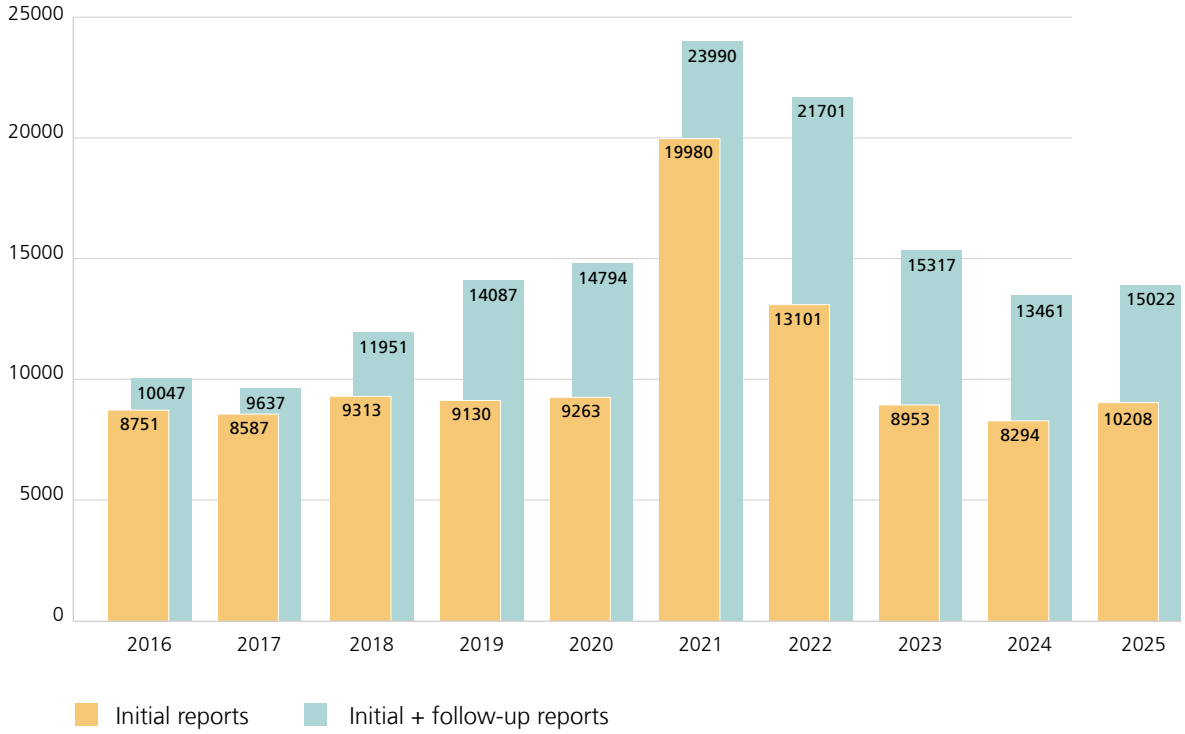

Figure 1: Number of reports received between 2016 and 2025. Blue bars: Initial reports + follow-up reports. Yellow bars: Initial reports.

Information on the reporter and sources

Reporters' qualification

Primary reporter: healthcare professionals

In 89% of cases (n=7,951), suspected cases were reported primarily by healthcare professionals, such as doctors and pharmacists.

Around two-thirds of these reports were submitted to Swissmedic by MAHs (n=5,301, 67%). In 33% of cases, Swissmedic received the healthcare professionals' reports via the regional pharmacovigilance centres or ElViS portal, by post, fax, letter or e-mail.

Primary reporter: non-healthcare professionals

In 11% (n=1,030), the primary reporters were patients/relatives or other non-healthcare professionals. Reports from non-healthcare professionals were received mostly via MAHs (75%, n=777), while one fifth was received via the online reporting tool for patients (21%, n=216).

Sender of the report

Of the 8,981 initial reports, 6,078 (68%) were submitted by MAHs and 2,903 (32%) were reported directly to Swissmedic.

Among the reports submitted by MAHs, 79% (n=4,773) were spontaneous reports, while 21% (n=1,305) originated from studies or other post-marketing observational programmes.

Swissmedic assesses individual case safety reports in close association with five regional pharmacovigilance centres in Basel, Geneva, Lausanne, Lugano, and Zurich. In total, 2,208 reports underwent in-depth evaluation by the regional centres in 2025.

Distribution of reports received by reporting source

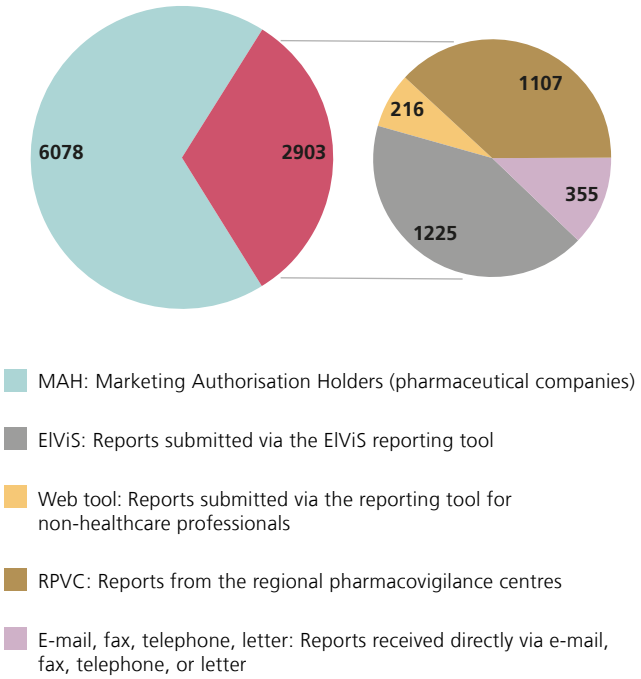

Figure 2: Reports received by source
In turquoise: Reports from Marketing Authorisation Holders (MAH)
In red: Reports received directly by Swissmedic or the Regional Pharmacovigilance Centres (RPVC)

Information on affected patients

The age of the affected individuals in the suspected case reports ranged from 0 to 100 years, with a median age of 59 years. In 1,929 reports, no information on age or age group was provided.

See Figure 3 and Figure 4 for the number of reports by age group and sex, respectively.

Number of reports by age group

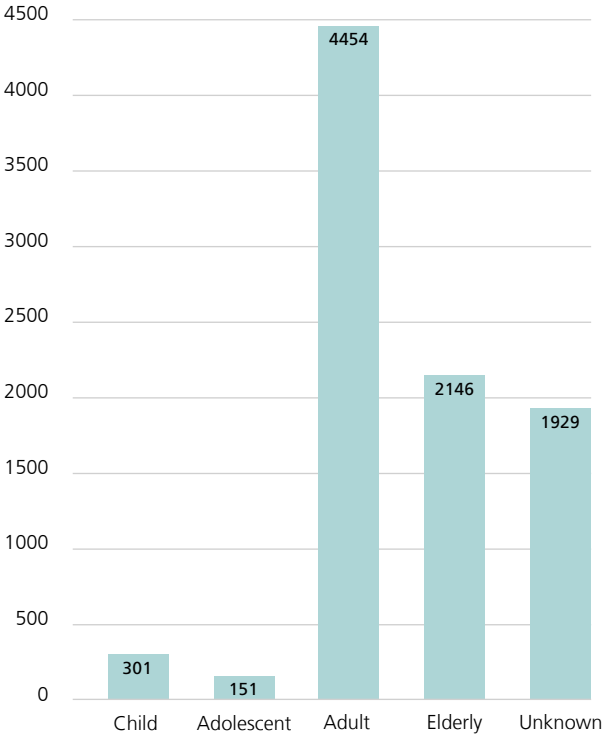

Figure 3: Reports by patient age group

Number of reports by sex

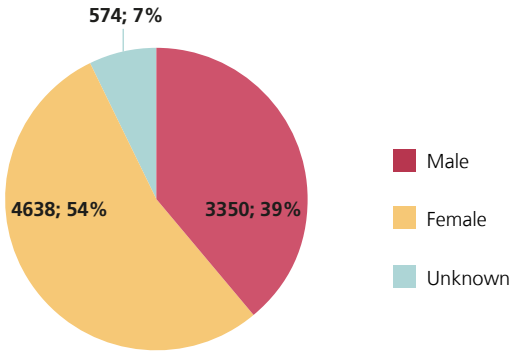

Figure 4: Reports by sex of affected patients

Information on suspected and interacting medicinal products

Reports of suspected adverse drug reactions typically list one or more medicinal products that are suspected of having caused the reaction or being involved in an interaction.

Table 1 lists the medicinal products that were most frequently reported as "suspected" or "interacting" in 2025. The 10 most frequently mentioned medicinal products are listed by chemical, therapeutic or pharmacological category using the ATC classification system.

Table 1: Ranking of the most frequently mentioned medicinal products

ATC code	Classification	Number
L01XC	Monoclonal antibodies	640
L04AA	Selective immunosuppressants	455
L01XE	Protein kinase inhibitors	380
N02BB	Pyrazolones	314
L04AC	Interleukin inhibitors	271
H02AB	Glucocorticoids	232
N05AX	Other antipsychotics	226
N03AX	Other antiepileptics	221
B03AC	Iron parental preparations	219
L01FF	PD-1/PDL-1 inhibitors	210

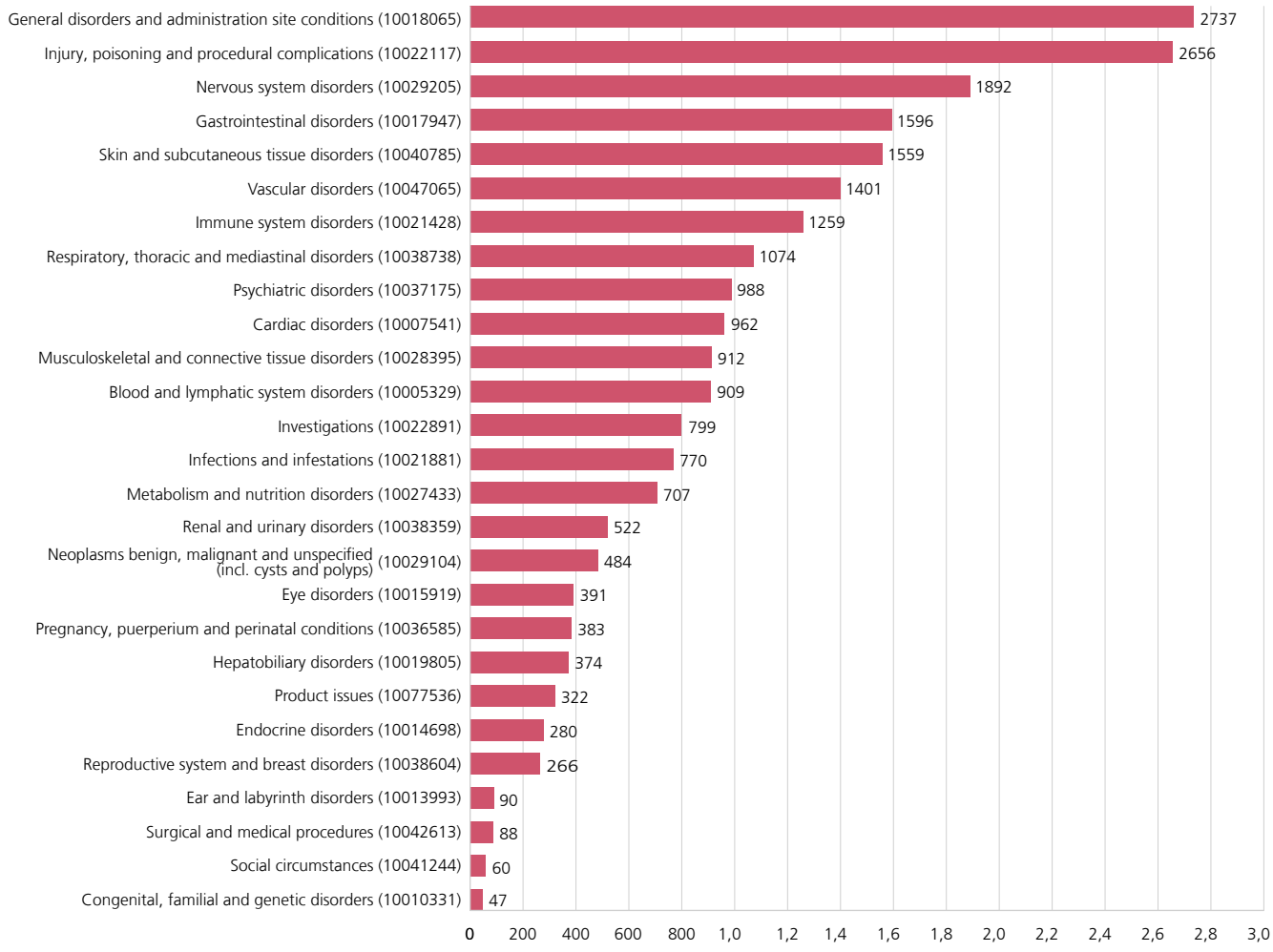

Figure 5: Number of reported reactions by affected organ system (based on MedDRA System Organ Classes [SOC])

Information on reported reactions

Of the initial reports, 59% (n=5,280) were classified as serious by the reporter. A higher relative proportion of serious reports is generally expected as a result of legal reporting requirements.

Reactions reported in suspected case reports are classified according to the internationally recognised terminology Medical Dictionary for Regulatory Activities (MedDRA), enabling their assignment to specific system organ classes (SOCs).

In 2025, a total of 22,599 reaction entries and 3,129 unique reactions were reported. On average, approximately 2.5 reactions were reported per case. Figure 5 shows the number of reported reactions by MedDRA system organ class, and Table 2 presents the most frequently reported preferred terms (PTs) of the most common suspected/interacting drug classes. Most reports related to off-label-use (n=613) were submitted by MAHs.

Table 2: Most frequently reported preferred terms (PTs) of the most common suspected/interacting drug classes

ATC code	Classification	Most commonly reported reaction
L01XC	Monoclonal antibodies	Off label use, malignant neoplasm progression, Toxicity to various agents
L04AA	Selective immunosuppressants	Off label use, headache, fatigue
L01XE	Protein kinase inhibitors	Off label use, malignant neoplasm progression, diarrhoea
N02BB	Pyrazolones	Agranulocytosis, pancytopenia, neutropenia
L04AC	Interleukin inhibitors	Off label use, drug ineffective, disease progression
H02AB	Glucocorticoids	Off label use, drug ineffective, gestational diabetes
N05AX	Other antipsychotics	Urinary retention, constipation, aggression
N03AX	Other antiepileptics	Dizziness, off label use, nausea
B03AC	Iron parental preparations	Dyspnea, pruritus, erythema
L01FF	PD-1/PDL-1 inhibitors	Colitis, hepatitis, pneumonitis

Information on the Swissmedic website

Pharmacovigilance in the spotlight

Learning from adverse reaction reports – cases from pharmacovigilance

24.04.2026
Hepatic and pulmonary side effects after the long-term administration of low-dose methotrexate

06.02.2026
Jarisch-Herxheimer reaction during antibiotic treatment of spirochaetal infections

06.01.2026
Phosphonorm® administered instead of Phoscap capsules

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

12.09.2025
Drug-induced aseptic meningitis

07.08.2025
Drug-induced taste disorders

27.06.2025
Spironolactone and persistent hoarseness – a hormonally induced side effect

02.05.2025
Finasteride and persistent side effects

Reporting of ADRs by healthcare professionals

Explainer video

swissmedic

Safety Update – product information updates

Since November 2025, Swissmedic provides a monthly overview of product information updates in the **Safety of Medicines newsletter**. This monthly overview provides information about selected active substances or active substance groups whose Information for healthcare professionals has been or will be updated with new safety-related information.

The new safety-related information is currently available in German, French, and Italian.

Subscribe to the **Safety of Medicines newsletter** to receive the overview Safety Update – product information updates monthly

Safety Update May 2026

Active susbstance(s)	New safety information	Updated section	(Direct) Healthcare Professional Communication (D)HPC
GLP-1 receptor agonists	Dysgeusia	Undesirable effects	–
Irinotecan	Mucosal inflammation	Undesirable effects	–
Metformin	Use in patients with mitochondrial diseases (MELAS syndrome, MIDD) is not recommended. If signs suggestive of MELAS or MIDD, metformin must be discontinued immediately and diagnostic evaluation initiated.	Special warnings and precautions for use	–
Metronidazole	Hearing disorders/hearing loss (including sensorineural hearing disorders), tinnitus	Undesirable effects	–
MVA-BN (smallpox, mpox, vaccinia vaccine)	Myocarditis, pericarditis	Undesirable effects	–
Pirtobrutinib	Women of childbearing potential: effective contraception during treatment and for at least 1 month after the last dose	Pregnancy and breast-feeding	–
Rocuronium	Hypersensitivity reactions with rocuronium as well as with the sugammadex–rocuronium complex	Undesirable effects	–
Semaglutide	Non-arteritic anterior ischaemic optic neuropathy (NAION): In the event of sudden vision loss, an ophthalmological examination should be performed; if NAION is confirmed, treatment with semaglutide should be discontinued.	Special warnings and precautions for use, Undesirable effects	–
Sugammadex	Hypersensitivity reactions with sugammadex as well as with the sugammadex–rocuronium complex	Undesirable effects	–
Vorasidenib	Hepatotoxicity: drug-induced liver injury (DILI), autoimmune hepatitis, hepatic necrosis, acute hepatitis, increased blood bilirubin, liver failure	Special warnings and precautions for use, Undesirable effects	–

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New: FAQs – Questions and answers on the risk management of human medicinal products – with effect from 1st April 2026

Swissmedic is supplementing its existing guidance documents with a structured collection of FAQs on key requirements and procedures relating to the risk management of human medicinal products. In these newly published FAQs, Swissmedic addresses frequently asked questions on drug safety signals, Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs) and related information materials, and Direct Healthcare Professional Communications (DHPCs).

The answers are designed to help marketing authorisation holders and other stakeholders acquire a practical understanding of the requirements, procedures, and expectations relating to risk management.

swissmedic

Healthcare Professional Communications

Some links are available in German only

15.04.2026
DHPC – Spevigo® (spesolimabum)
Verzögerter Neudruck der zuletzt genehmigten Packungsbeilage aufgrund der Übertragung der Zulassung

14.04.2026
DHPC – Kyprolis® (carfilzomibum)
Potentielle sichtbare Partikel nach Rekonstitution

01.04.2026
DHPC – Crysvita (Burosumab)
Risiko einer schweren Hyperkalzämie

20.03.2026
HPC – Lisdexamfetamindimesylat
Kontraindikation für Patienten mit Phäochromozytom

12.03.2026
DHPC – Citrate d'Yttrium (90Y)-YMM-1 (yttrii(90-Y) citras)
Nicht konforme Sterilitätsprüfung nach Freigabe

12.03.2026
DHPC – Rybelsus® / Rybelsus® N (orales Semaglutid)
Vermeidung von Medikationsfehlern aufgrund der Einführung einer neuen Formulierung (Rybelsus® N) mit erhöhter Bioverfügbarkeit

11.03.2026
DHPC – Voxzogo (vosoritidum)
Textfehler auf der Faltschachtel

06.03.2026
DHPC – Keppra® (Levetiracetam)
Risiko für Medikationsfehler aufgrund des Wechsels der Applikationsspritze

18.02.2026
DHPC – Cytosar (cytarabinum)
Diskrepanz Barcode

11.02.2026
DHPC – Irbesartan Spirig HC (irbesartanum)
Textfehler auf der Faltschachtel

28.01.2026
DHPC – Ocrevus® (Ocrelizumab)
Leberschädigung mit Ocrelizumab

23.01.2026
DHPC – Arixtra® (fondaparinuxum natricum)
Ernsthafter Qualitätsmangel im Zusammenhang mit der Nadel der vorgefüllten Spritze

12.12.2025
DHPC – Urapidil Stragen i.v. (urapidilum)
Beschädigtes Originalitätssiegel bei einigen Packungen

04.12.2025
DHPC – Rhophylac® (immunoglobulinum humanum anti-D)
Wichtige Mitteilung – Partikel

21.11.2025
DHPC – DIBASE® 10'000 (cholecalciferolum)
Wichtige Mitteilung zur Vermeidung von Handhabungsfehlern

Announcements

06.05.2026
Swissmedic Journal
Latest edition
Swissmedic Journal April 2026

05.05.2026
Focus on narcotics
A company meeting designed to clarify project-specific issues concerning narcotics

01.05.2026
FAST-Track Pilot-Project
New harmonised procedure between ethics committees and Swissmedic

27.04.2026
Clinical investigations with medical devices
New edition ISO 14155:2026 is available

24.04.2026
Hepatic and pulmonary side effects after the long-term administration of low-dose methotrexate
Learning from adverse reaction reports – cases from pharmacovigilance

23.04.2026
Focus campaign 2026 to review post-market surveillance documentation
Swissmedic will be conducting a focus campaign of the requirements for post-market surveillance of higher-risk medical devices

20.04.2026
Summary report on authorisation – Veklury®
Extension of therapeutic indication (03)

20.04.2026
Summary report on authorisation – Imaavy®
First authorisation

17.04.2026
Sammelmeldungen für in house IVD und in house MEP ab 1. Januar 2027 nicht mehr möglich
Meldungen gemäss Art. 10 IvDV und Art. 18 MepV sind ab diesem Zeitpunkt ausschliesslich als Einzelmeldungen einzureichen.

17.04.2026
Summary report on authorisation – Kerendia®
Extension of therapeutic indication (01)

15.04.2026
Implementation of the adjustments from the EU ADRA project
Adjustments for veterinary medicinal products with antimicrobial active substances according to the results of the ADRA project in the EU

14.04.2026
Summary report on authorisation – Vocabria®
Extension of therapeutic indication (01)

10.04.2026
Summary report on authorisation – Qalsody®
First authorisation

10.04.2026
Summary report on authorisation – Agamree®
First authorisation

10.04.2026
Summary report on authorisation – Minjuvi®
Extension of therapeutic indication (01)

09.04.2026
Swissmedic Journal
Latest edition
Swissmedic Journal März 2026

01.04.2026

New: FAQs – Questions and answers on the risk management of human medicinal products

Swissmedic is supplementing its existing guidance documents with a structured collection of FAQs on key requirements and procedures relating to the risk management of human medicinal products

01.04.2026

Fassung 12.2 der Europäischen Pharmakopöe in Kraft

Der Institutsrat hat die Fassung 12.2 der Europäischen Pharmakopöe auf den 1. April 2026 in Kraft gesetzt

31.03.2026

Summary report on authorisation – Lynkuet®

First authorisation

30.03.2026

The registration obligation for IVD devices in swissdamed replaces the notification obligation by 1st July 2026

The registration of devices according to Art. 90 IvDO will become mandatory in swissdamed as of July 1, 2026, with a transition period until December 31, 2026

30.03.2026

The registration obligation for MD-DEVIT devices in swissdamed replaces the notification obligation by 1st July 2026

The registration of MD-DEVIT products according to Art. 108 MedDO will become mandatory in swissdamed as of July 1, 2026, with a transition period until December 31, 2026

30.03.2026

Summary report on authorisation – Lyvdelzi®

First authorisation

30.03.2026

The registration obligation for MD devices in swissdamed replaces the notification obligation by 1st July 2026

The registration of devices, systems, and procedure packs according to Art. 108 MedDO will become mandatory in swissdamed as of July 1, 2026, with a transition period until December 31, 2026

27.03.2026

Summary report on authorisation – Prevenar 20®

Extension of therapeutic indication (01)

26.03.2026

Summary report on authorisation – Yorvipath®

First authorisation

24.03.2026

New guideline «Schweizerische Gute Praxis der Materiovigilance im Spital» (GPMV-Spital)

With the new «Schweizerische Gute Praxis der Materiovigilance im Spital» (GPMV-Spital), Swissmedic is publishing a guideline designed to support hospitals, professionals working there and vigilance contact persons for medical devices in the correct implementation of materiovigilance

24.03.2026

Summary report on authorisation – Carvykti®

Extension of therapeutic indication (01)

23.03.2026

Summary report on authorisation – Zepzelca®

Extension of therapeutic indication (01)

23.03.2026

Summary report on authorisation – Aspaveli®

Extension of therapeutic indication (02)

23.03.2026
Summary report on authorisation – Bylvay®
First authorisation

20.03.2026
Revision of chapters 20 and 21 of the Pharmacopoea Helvetica 13
To clarify the distinction under therapeutic products legislation between manufacture and preparation for administration, Swissmedic decided, with effect from 1 June 2025, to make an urgent amendment to the Good Manufacturing Practice rules for medicinal products in small quantities as stated in the Swiss Pharmacopoeia (Ph. Helv.)

20.03.2026
Summary report on authorisation – Tezspire®
Extension of therapeutic indication (01)

16.03.2026
Summary report on authorisation – BEYONTTRA®
First authorisation

13.03.2026
Protection against designer drugs: Further psychoactive substances prohibited
New synthetic drugs can harbour considerable health risks

13.03.2026
Summary report on authorisation – AYVAKYT®
Extension of therapeutic indication (01)

11.03.2026
Save the date: Regulatory & Beyond 2026
Regulatory & Beyond is back; on 16 November 2026 at the Kursaal, Bern

11.03.2026
Veterinary medicinal products: authorisations and drug safety 2025
Annual overview

09.03.2026
Update of the position paper of Swissmedic and swissethics on decentralised clinical trials (DCTs) of medicinal products
Update of the position paper (new version 4.0)

09.03.2026
Summary report on authorisation – Rinvoq®
Extension of therapeutic indication (06)

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