Vigilance - News

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In this Edition:

I: Editorial

Pharmacovigilance of vaccines against pandemic influenza (H1N1) 2009 in Switzerland

Vaccinations against pandemic (H1N1) 2009 influenza are currently underway. In Switzerland three vaccines are available: Celtura®, Focetria®, and Pandemrix® [1].

In this Editorial, the Vigilance Unit takes the opportunity to review surveillance principles and specific activities in the Unit to monitor the safety of vaccines against pandemic influenza (H1N1) 2009 in Switzerland.

An increased number of reports is expected

In general, with large-scale use of a medication or vaccine, an increased number of suspected adverse events reports is normal and expected for two main reasons. Firstly, the high public profile will stimulate awareness to submit suspected adverse event reports (called the Weber effect); secondly, the absolute number of reports rises in proportion to the increased use of a medication in the population. As an example, if an expected adverse event reporting rate is about 0.01% of doses given, Swissmedic would expect 10 reports if 100,000 individuals are given the drug and 100 reports if a million are given this drug, only based on the expected reporting rate.

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The „PaniFlow“ online-reporting system

In collaboration with WHO and the international drug monitoring program in Uppsala [2], Swissmedic developed an online reporting system called “PaniFlow” for suspected adverse events following vaccination against pandemic influenza (H1N1) 2009. Currently over 300 reports have been entered into PaniFlow. The response to PaniFlow indicates the commitment of and acceptance by health care professionals to report suspected adverse events by an accessible online system. The PaniFlow database provides the Vigilance Unit real-time analysis of reports of suspected adverse events [3].

The Vigilance Unit activities for pandemic influenza vaccines are summarised:

1. Review of each suspected adverse event report that is serious or medically important.
2. A weekly open-access report summarising the analysis of suspected adverse drug events in the Swissmedic PaniFlow database [4].
3. Sharing information and participating in international safety monitoring of pandemic influenza (H1N1) 2009 vaccines.

It is important to note that a lack of information from clinical studies is not equivalent to a contraindication to use. Most drugs and vaccines, including pandemic influenza vaccines, are not formally studied in certain populations such as pregnant women prior to being licensed. Postmarketing surveillance using a spontaneous reporting system such as PaniFlow is important to monitor the safety of the drug or vaccine in different populations and in identifying any potential rare adverse events.

Assessing causality of an adverse event following vaccination

An adverse event that follows a vaccination does not necessarily indicate a causal association between the two events. Safety concerns about an event following vaccination may be raised by the media during the time that Swissmedic is verifying and investigating the case and before its completed assessment. Several events, such as death, pregnancy loss, or Guillain-Barré Syndrome have a known background incidence rate. This means the adverse event or disease occurs at an expected rate in the general population in the absence of drug exposure. A helpful review was recently published and provided background rates of certain diseases that would be of special interest during a vaccination campaign against pandemic influenza (H1N1) 2009 [5].

For further information, visit the main page of the Swissmedic Pandemic Portal www.swissmedic.ch/pandemieportal.asp.

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1. Current Product Information for Celtura®, Focetria® and Pandemrix® is available at http://www.swissmedic.ch/marktueberwachung/00091/01046/01079/index.html?lang=en
2. *The* Uppsala Monitoring Centre www.who-umc.org
3. Information and access to PaniFlow is available at http://www.swissmedic.ch/marktueberwachung/00091/01046/01047/index.html?lang=en
4. Swissmedic Vigilance Report (updated weekly) is available at http://www.swissmedic.ch/marktueberwachung/00091/01046/01055/index.html?lang=en
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II: Flash: Signals relating to the safety of medicines from the Swiss database of the Vigilance Unit

PHARMACOVIGILANCE:

Venous thromboembolism from oral contraceptives

In May 2009 the Swiss media extensively discussed the story of a young woman who suffered a central lung embolism with severe hypoxic brain damage while taking a combined oral contraceptive (COC) containing drospirenone; however, the reports were somewhat incomplete and facts were distorted. Subsequently Swissmedic has repeatedly and systematically published accurate information, presenting the most important facts about the risk of venous thromboembolism (VTE) together with statistics on spontaneous reports of cases in Switzerland in connection with hormonal contraceptives.

In consultation with its Human Medicines Expert Committee (HMEC), Swissmedic is analysing the latest data and studies on the risk of VTE when taking COC. Health professionals an the general public were informed in October this year about the results of the analysis, its recommendations and the measures being taken [1]. According to two studies published by the BMJ in August, the risk of VTE when taking COC containing drospirenone is directly related to second- and third-generation COC, i.e. the risk is somewhat higher than previously assumed, therefore Swissmedic launched a review of preparations containing drospirenone. The most important results of the new studies should be reflected in their information leaflets, especially the results regarding the relative risk in comparison with second- and third-generation COC, and the absolute risk (i.e. the incidence of VTE among the preparations). The review has not yet been completed.

In the course of the discussion, the question was again raised as an example of the significance of spontaneous reports in the case of a very well known risk that has been described in a large number of epidemiological studies. It was important to explain to the media, the general public and politicians concerned what spontaneous reporting cannot do: it is not a systematic register of adverse drug reactions, nor is it intended to be. Therefore, spontaneous reports do not allow for any statements to be made about how often adverse drug reactions occur and cannot make comparative statements. Comparative (epidemiological) studies must be conducted for that purpose. In the case of well known risks, spontaneous reports are an important resource in compiling major new aspects of these risks or factors that are not commonly considered in everyday practice. The prerequisite is that these factors are well documented. In the case of COC, the detailed analysis of all spontaneous reports on VTE and COC in Switzerland provided us with the following information:

→ In almost 40% of reported cases, there was at least one risk factor for VTE. This percentage could be higher because a fairly strict benchmark was set for the presence of a predisposition and in some reports there were no unequivocal indications of risk factors. The detailed case history regarding risk factors, which is taken again during screening investigations, is conclusive. Among the best known of these – previous or family history of VTE, obesity, age – reference is made also to the reports of VTE occurring in women on COC after long-haul flights. For the last factor, it is quite possible to implement preventive measures.

→ It is still challenging to detect pulmonary embolism at an early stage. Warning symptoms, if there are any, are often non-specific. The most common symptoms include reduced lung function, but dyspnoea and syncope are also important. Pleural symptoms and signs in young women should also specifically raise the question

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about whether they are on COC, and pulmonary embolism should be included in the differential diagnosis.

→ And, finally, an appreciable percentage of women have an increased risk, especially of arterial complications, if they smoke and are taking COC.

The debate in the media brought a rare, yet potentially serious risk back into the minds of consumers. Swissmedic intends to publish an update on this issue based on spontaneous reports at least annually on its website and to remind people about the precautions that should be taken. We hope that this information will help consumers make an informed decision about contraception, in consultation with their doctors, and take into account the benefits and risks, so that safety measures may be optimized.

References:

[1]De Geyter et al. (2009) Venöse Thromboembolien unter kombinierten oralen Kontrazeptiva – aktueller Stand.
published in: Pharmajournal 2009; 21:4-6
Schweizerische Ärztezeitung 2009; 43:1654-57 [in German]
http://www.swissmedic.ch/aktuell/00003/01108/index.html?lang=en

SSRI – risk in newborns: How many publications have raised safety?

The main indication for selective serotonin reuptake inhibitors (SSRI) and a few related medications with slightly different modes of action is depression.

The group include the active compounds fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram, but others such as venlafaxine, mirtazapine, reboxetine, nefazodone and bupropion are also used and are similarly effective.

In the past, fluoxetine achieved inordinate success, almost seen as a fashionable preparation [even receiving literary 'honours' such as *Listening to Prozac®*, *Le bonheur sur ordonnance*, *Glück auf Rezept*]. Some preparations containing this active compound became veritable blockbusters, generating billions in revenue in the pharmaceutical industry.

The pendulum then swung in the opposite direction, from more or less 'cosmetic pharmacology' towards greater caution, since the publication in the past few years of some articles about side effects, with particular focus on the risks of congenital abnormalities in newborns. There is a scientifically plausible background that with the very common or off-label use of a drug, even rare side effects may be detected.

Even medical professionals find it challenging to grasp the overall status of SSRI risks. For this reason, the following are the most important sources of information published over the past few years, and including a recent publication in 2009:

- 2005: *„Newer antidepressants in pregnancy and rates of **major malformations:** a meta-analysis of prospective comparative studies",* Pharmacoepidemiol Drug Saf 2005; 14: 823-827
- 2006: *„Selective Serotonin-Reuptake Inhibitors and Risk of **Persistant Pulmonary Hypertension** of the Newborn",* N Engl J Med 2006; 354:579-87
- 2007: *"First-Trimester Use of Selective Serotonin-Reuptake Inhibitors and the Risk of **Birth Defects**",* N Engl J Med 2007; 356: 2675-83
- 2007: *"Use of Selective Serotonin-Reuptake Inhibitors in Pregnancy and the Risk of **Birth Defects**",* N Engl J Med 2007; 356: 2684-92
- 2007: *"**Delivery Outcome** in Relation to Maternal Use of Some Recently Introduced Antidepressants"*, J Clin Psychopharmacol 2007; 27: 607-613
- 2007: *"Effects of Antenatal Depression and Antidepressant Treatment on Gestational Age at Birth and Risk of **Preterm Birth**",* Am J Psychiatry 2007; 164: 1206-1213

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- 2008: *"Paroxetine and fluoxetine in pregnancy: a prospective, multicentre, controlled, observational study",* Br J Clin Pharmacol 2008; 66: 695-705
- 2009: *"Selective serotonin reuptake inhibitors in pregnancy and* ***congenital malformations:*** *population based cohort study",* BMJ 2009; 339: b3569

These publications adopted different study designs (retrospective, prospective, meta-analysis) and used different data sets. What these articles have in common is that none could evaluate all the above-mentioned suspected risk factors concurrently, mainly due to the low incidence of some events of interest. Furthermore, only **live births** were taken into account. No potential influences of SSRIs on miscarriages were either investigated or discussed. If we take the combined number of pregnancies or births into account, there are practically no data on how or whether *in utero* exposure has any influence on the subsequent development of the fetus. However, 'no data' here also means 'no negative data'.

The following are the **main results** and conclusions, in the same order as listed above:

1) The rate of malformations was comparable in non-exposed babies. There was no cluster or any particular malformation that was more common. The malformations observed – ventricular septal defect, hypospadias, cleft palate – also occur naturally.
2) Adjusted odds ratio = 6.1 for PPHN (persistent pulmonary hypertension of the newborn) with maternal SSRIs exposure after the 20th week of gestation, in comparison to matched controls. However, no association was found with SSRIs taken before the 20th week of gestation and no association with non-SSRI antidepressant drugs at any time during pregnancy.
3) For the SSRI group as a whole there was no increase in craniosynostosis, omphalocele, or heart defects. With some SSRIs a few specific defects occurred more commonly than expected, however they remained infrequent. "The absolute risks are small."
4) No association between SSRI used in early pregnancy and congenital heart defects. In comparison with controls, increased anencephaly (OR 2.4), craniosynostosis (OR 2.5) and omphalocele (OR 2.8).
5) No increased incidence of stillbirths or congenital anomalies and no difference between SSRIs and (selective) noradrenaline reuptake inhibitors. No evidence of teratogenicity.
6) Birth weight and Apgar scores were not affected by either antidepressants or untreated depression, although SSRIs administered prenatally were associated with lower gestational age at birth or preterm birth. The influence of depression per se was excluded.
7) In comparison with the control group, slightly lower birth weight and earlier gestational age at birth (i.e. consistent with study 6). Transient all-cause complications in full-term babies were 20%. Congenital anomalies increased by a factor of 2. However, the authors expressly point out that ventricular septal defect, for example, was considered as a 'major anomaly', even if the defect later spontaneously closed.
8) Sertraline and citalopram, but not paroxetine or fluoxetine (all with comparable numbers of births under investigation, in the hundreds) were associated with septal defects. This risk was even higher with the use of various SSRIs or when medication was changed. No association between SSRIs and non-cardiac malformations.

On the whole, the cardiac malformations in SSRI-exposed infants that occurred more frequently than in non-exposed infants were not serious and often resolved spontaneously. Furthermore, studies with a small number of cases relative to the increase in incidence levels should be viewed with great caution. The absolute numbers are very small. There are no indications of teratogenic risks or chromosomal mutations.

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When considering “congenital malformations”, one should not automatically construe these to be only severely malformed or nonviable babies.

Swissmedic is conducting an ongoing review for this substance group, and also after provisional completion of this review, we will continue to monitor any further developments.

Intelence® tablets, active substance etravirine – severe skin reactions and systemic hypersensitivity reactions

The preparation is licensed for the treatment of HIV-1 infections in combination with other antiretroviral medicines in adults who have already received antiretroviral therapy.

The warning originates from Canada and is based on postmarketing reports. In one case a toxic epidermal necrolysis (TEN) occurred, resulting in death. Several other cases involved severe systemic reactions, sometimes with liver involvement and even organ failure. To date, a total of six suspected adverse drug reactions (ADRs) have been reported for etravirine in Switzerland, two of which were in connection with the reactions mentioned here, but none with a fatal outcome. Both these cases involved skin reactions requiring hospitalization and one of these two cases was diagnosed as DRESS syndrome (drug rash with eosinophilia and systemic symptoms) with liver involvement.

One known ADR that is mentioned in the Patient Product Information was a high incidence of mostly maculopapular rashes with self-limiting progression and a relatively high incidence of Stevens-Johnson syndrome (SJS, a synonym of erythema multiforme major). SJS usually starts on the mucous membranes and, similar to TEN, is a severe skin reaction with blistering lesions over the entire body, but the risk of death is lower than TEN. Both types of severe skin reactions are rare and can be caused by a large number of different medications, as well as by infections. TEN is particularly common in children where it is associated with staphylococcal infections. The exact causal mechanisms are largely unclear.

In terms of systemic hypersensitivity, which without any further specification was already known and mentioned in the Patient Product Information, the degree of severity and in particular the possibility of liver failure in the reported cases were new findings.

Further to these reports, a Healthcare Professional Communication was published in Canada. In the meantime the Patient Product Information was also adapted in the USA and in October 2009 in Switzerland. The warning it contains is particularly important: that Intelence® should be ceased immediately in the event of signs of a severe skin reaction or hepatitis. Fever or mucosal lesions are the first important signs, in addition to other non-specific symptoms such as generalised malaise, muscle pain, limb pain, and elevated liver enzyme levels.

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HAEMO-VIGILANCE:

Introduction of pathogen inactivation procedures (PI) in Switzerland

Bacterial contamination of thrombocyte concentrations (TC) is one of the major risks of transfusion (1, 2). Haemovigilance data from Switzerland show that at minimum, between 1:12,000 and 1:20,000 of transfused TC are contaminated with bacteria (3). International vigilance data reveal a comparable level of risk (4). Up until now, it was not entirely possible to avoid this risk, on account of the properties of the product itself. Transfusing pathogenic bacteria can cause transfusion reactions with varying degrees of severity and in extreme cases may even lead to death. Swissmedic recorded two deaths as a result of a transfusion with bacterially contaminated TC in 2005, and one death in 2009.

According to the current state of knowledge, this can be avoided by the use of pathogen inactivation procedures. In the past few years these procedures have been the focus of transfusion medicine research. Swissmedic recently authorized the first procedure for pathogen inactivation in Switzerland, under the brand name Intercept. This procedure involves the addition of amotosalen (a psoralen) to individual thrombocyte concentrations, which causes irreversible covalent bonding between DNA double strands by means of intercalation during subsequent UV illumination. This causes any agents present in the product (viruses, bacteria, parasites, or DNA-containing human cells) to lose the ability to replicate. Psoralen residues and breakdown products are absorbed in an additional stage of the process before the TC is released for transfusion. Other procedures for inactivating pathogens in blood components are currently the subject of further scientific investigations. The due diligence laid down in Article 3 of the Swiss Law on Therapeutic Products requires that measures available to avoid transfusion-associated bacterial infections be applied nationwide and for all patient groups.

The Swiss Red Cross Blood Transfusion Service is developing a plan for a nationally coordinated roll-out of the pathogen inactivation procedure. Swissmedic is supporting these efforts so that a known risk that is inherent in the product can be eliminated in the future.

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3) Swissmedic Haemovigilance annual reports, available at: http://www.swissmedic.ch/marktueberwachung/00159/00160/00437/index.html?lang=en
4) SHOT Annual Reports http://www.shotuk.org

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VETERINARY MEDICINES VIGILANCE:

„Cats are not small dogs!!"

The assumption by many cat owners - that cats and small dogs can be treated using the same medication - costs many cats their lives throughout the world every year. Many cases involve the erroneous application of insecticides containing the active compound permethrin, which are only licensed for use on dogs.

One common mistake concerns preparations containing high permethrin concentrations in the range of 500 to over 700 mg per millilitre. Permethrin is the most common pyrethroid insecticide used in veterinary medicine. In most mammals these compounds have a wide safety margin: permethrin is only marginally resorbed after oral application and is quickly hydrolyzed (Kühnert, 1991). The dermal LD_{50} is in the range of 1 to 1.5 g/kg (Ungemach, 2003). Detoxification of pyrethroids in mammals occurs through hydrolysis and oxidation (Meyer, 1999). The compounds are subsequently made water-soluble by sulfation or glucuronidation (IPCS/INCHEM, 1996; Meyer, 1999) and eliminated from the body. This latter stage may explain the increased sensitivity of cats to permethrin. Due to a species-specific glucuronidation defect, it is very difficult for cats to eliminate the compound via this metabolic pathway (Richardson, 2000). The intensive cleaning behaviour of cats plays an additional role, leading to repeated oral intake.

Permethrin is normally present in preparations as a racemate and the isomers differ with regard to their biotransformation speed and their toxicity. The *trans*-isomer is eliminated more quickly and is therefore probably less toxic than the *cis*-isomer (IPCS/INCHEM, 1996; EMEA, 2000). In addition, it has been shown that the cis/trans-isomer ratio influences the lethal dose. In mice, a 75/25 cis/trans mixture by oral administration is more than five times more lethal than a mixture with the opposite 25/75 isomer ratio (LD_{50} 310 mg/kg BW vs. 1620 mg/kg BW; IPCS/INCHEM, 1996). In the products licensed as spot-on veterinary medicines in Switzerland, the ratio is 40/60 in favour of the *trans*-isomer (manufacturer's data). This type of mixture presents an LD_{50} of 400 mg/kg in rats after oral application (EMEA, 2000).

Cases of permethrin poisoning have been reported in cats from Switzerland. Every year several cases are also reported to the Swiss Toxicological Information Centre (STIZ) in Zurich. Two examples are described below. In the first case a full pipette containing 744 mg permethrin as a spot-on preparation was administered directly onto the skin of a 12-month-old female house cat weighing 4 kg. The animal was presented to a veterinary surgeon with "CNS disturbances, convulsions, salivation and diarrhoea" (wording of the report). After washing the animal with a shampoo, the application area was additionally treated with alcohol. The cat was also given diazepam for two days, and recovered. At the time of this report the animal was in convalescence. Another cat was given two pipettes of a spot-on preparation by its owner. This cat was administered a total of 2.5 g permethrin because the product was registered for dogs weighing between 10 and 25 kg! The animal was presented with "cramps, apathy and salivation" (wording of the report) and sedated with diazepam. At the time this report was submitted the animal's state of health could no longer be determined. However, it is doubtful whether a cat could survive such a high dose of permethrin. In general the following symptoms of permethrin poisoning in cats are described in the literature: muscle tremors, hyperexcitability, hypersalivation, vomiting, depression, ataxia, epileptic episodes, anorexia and, in the event of delayed treatment or massive exposure, death (Meyer, 1999). The latency period up to the development of symptoms can vary between a few minutes and as much as three days (ASPCA, 2000).

Although the dangers of such erroneous applications are well known to practising veterinarians, the poisoning and death of cats occurs with alarming regularity worldwide be-

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cause the preparations are not normally applied by veterinarians but by the pet owners themselves (Keck, 2003; Dyer, 2004; ASPCA, 2005). A study recently published in France looked specifically into this issue (Delhaye, 2008). Around 475 cases of permethrin poisoning in cats are reported every year in France, including about 8% considered life-threatening. In comparison with sales by veterinary surgeons, the frequency of erroneous applications was six times higher when the preparations were bought in a pharmacy and as much as 13-fold higher when they were bought in a pet shop or a supermarket. Out of 139 specifically investigated cases, 88% of the wrongly treated cats recovered (123 cases), while 10 animals died and 6 had to be put down. A comparison between the products sold as sprays and spot-on's showed that the latter led more often to serious outcomes due to the high concentrations of the active ingredient. This problem has also been described in Australia; in a recent survey the reasons given for mistakenly applying the products included the following: cost (treating both dogs and cats in the same household); wrong or incomplete advice given in pharmacies, supermarkets or pet shops (the compound was described as suitable and safe for cats); confusion with preparations for cats (which are also sold as spot-on products but contain other active ingredients); or use despite clear warnings from the veterinarian or the pharmacist (personal communication). The last reason makes it clear that regulatory measures are at best only partially effective. The study by Delhaye mentions that despite improvements to warnings, in the form of pictograms and warning messages, the number of erroneous applications of these preparations in France did not decrease. The labels of all of the concerned products contain clear warnings in Switzerland as well, with the danger described in the form of both warning messages and pictograms. Each preparation carries the unequivocal contraindication 'Not to be used on cats' and all related spot-on preparations also carry a pictogram with a cat crossed over. The appropriate emergency treatment (wash with liquid detergent) is described in the package information sheet (Tierarzneimittelkompendium der Schweiz [Swiss Veterinary Medicines Compendium], 2009). Delhaye also recommends restricting sales of the preparations to outlets that can guarantee competent advice, i.e. primarily veterinarians. In Switzerland these preparations cannot be sold in either pet shops or supermarkets because they are in restricted sales categories. There are currently three spot-on products, two sprays and one shampoo containing permethrin licensed by Swissmedic on the market. All of them are licensed exclusively for dogs: the sprays and shampoo in sales category E (free sales), two spot-on products in sales category B (prescription only) and one spot-on product in category C (sale with professional medical advice in pharmacies). However, sprays and shampoos present a considerably lower risk as they contain lower concentrations of permethrin (20 mg per ml for the sprays, 10 mg per ml for the shampoo). There have been no reports pertaining to these preparations since the introduction of the reporting obligation for adverse drug reactions to veterinary medicines.

It is currently still unclear what measures could significantly prevent the problem. In Australia, veterinarians were provided with posters for their waiting rooms warning pet owners of the dangers for their cats (Grrinninbear Designs, accessible under www.cve.edu.au). All measures aimed at preventing the problem should be mainly targeted at cat owners, because in general they are the ones applying the preparation. In this sense, making most preparations available on prescription only is no guarantee that they will be used correctly. Among other reasons, the packages often contain sufficient pipettes for several months of treatment and over this time the instructions for use are forgotten or are not even read. Once again it must be stressed: "Read the instructions!"

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III: Information regarding the safety of medicines published on the Swissmedic website

regularly updated	Vigilance for the H1N1 flu vaccines
30.11.2009	Neue Fachinformation Pandemrix [in German]
26.11.2009	Batch recall: Implanon, Implantat [in German]
23.11.2009	International Conference on Harmonisation (ICH) Meeting in St. Louis, USA [in German]
19.11.2009	International operation combats the on-line supply of counterfeit and illegal medicines
16.11.2009	Trend towards antibiotics of the newer generations in veterinary medicine
16.11.2009	HPC: MabThera (Rituximab) [in German]
23.10.2009	HPC: Relenza (Zanamivir) [in German]
22.10.2009	Venöse Thromboembolien unter Antibabypillen : Swissmedic informiert über Abklärungen und erinnert an die Vorsichtsmassnahmen [in German]
15.10.2009	Swissmedic expands its international network - Closer collaboration between Swissmedic and the New Zealand therapeutic products authority
08.10.2009	Pandemische Grippe A(H1N1) 2009 - Meldung vermuteter unerwünschter Wirkungen nach A (H1N1)-Grippeimpfung [in German]
25.09.2009	Risiken der Anti-Baby-Pille: Swissmedic klärt tödliche Lungenembolien ab [in German]
25.09.2009	EMEA-Empfehlung zur Zulassung von Pandemieimpfstoffen - Swissmedic informiert über den Stand der Dinge in der Schweiz [in German]
25.09.2009	Fabrazyme®: Anschlussinformation für die Versorgung während des Lieferengpasses und neue Empfehlungen für die rationierte Verwendung [in German]
24.09.2009	DHPC: Plavix® (Clopidogrel) [in German]
28.08.2009	Illegale Einfuhr von Tierarzneimitteln gefährdet die Gesundheit der Verbraucher [in German]
18.08.2009	Cerezyme®: Anschlussinformation für die Versorgung während des Lieferengpasses und neue Empfehlungen für die rationierte Verwendung [in German]

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22.07.2009	Swissmedic: Performance-enhancing substances in amateur sport are a massive risk to health
18.07.2009	Sicherheitsprofil von Erythrozytenkonzentraten in Abhängigkeit Ihrer Lagerdauer [in German]
16.07.2009	Another sharp increase in illegal imports
01.07.2009	Insulin-Glargin (Lantus®) [in German]
30.06.2009	Swissmedic informiert über das Risiko von Fehlmanipulationen bei Epipen und Anapen [in German]
15.06.2009	International Conference on Pharmaceutical Crime
09.06.2009	Einstellung des Vertriebes von Mercaptyl® [in German]
20.05.2009	Tödlicher Zwischenfall bei einer Bluttransfusion [in German]
	Please find the complete list at the following web address: http://www.swissmedic.ch/aktuell/00003/index.html?lang=en

Report of a suspected adverse drug reaction (ADR)

► **New:** The ADR form can be filled in electronically:

MU101_20_001d_FO Meldung einer vermuteten unerwünschten Arzneimittelwirkung (UAW) [in German]

Contact

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