NEWS FROM INTERNATIONAL REGULATORY AGENCIES

MONTELUKAST – Antagonist of leukotriene receptor. Risk of neuropsychiatric adverse events.

(TGA, Australia. April 2, 2013)

In its latest newsletter on medicines safety, Australia drug regulatory agency published a reminder about the possibility of occurrence of neuropsychiatric adverse events in children, adolescents and adults treated with montelukast. Said events include suicide ideation, depression, agitation, aggressive behavior and hallucination, among others.

http://www.tga.gov.au/hp/msu-2013-02.htm#montelukast

Since 2006, the National Pharmacovigilance System has received only one report of a neuropsychiatric adverse event (irritability) in a montelukast-treated subject.

INCIVO (TELAPREVIR) – Antiviral for the treatment of chronic hepatitis B – Risk of serious skin reactions.

(ANSM, France. April 8, 2013)

Manufacturer Janssen has spread out a letter containing information for health professionals to warn about the risk of serious skin reactions in telaprevir-treated patients (Incivo) following the report of two cases of toxic epidermal necrolysis in Japan (one of them fatal).

Suggestions are as follows:

. Immediately suspending the intake of telaprevir if any serious skin reaction occurs.

. Following the recommendations about the handling of skin rash mentioned in the patient information leaflet.

. Patients are advised to see their doctor in case of presenting with a new skin reaction or worsening of an existing one.

http://ansm.sante.fr/S-informer/Informations-de-securite-Lettres-aux-professionnels-de-sante/Incivo-Telaprevir-Prise-en-charge-des-reactions-cutanees-severes-Lettre-aux-professionnels-de-sante

ANMAT recommends following the guidelines mentioned above.

Incivo is included in a Risk Management Plan; which is informed in the patient information leaflet. In addition, ANMAT develops a "Rash Educational Program for Prescribers" that includes educational material with a summary of dermatologic reactions as well as prevention and treatment algorithms outlined in a pocket-size triptych flyer.

NILOTINIB – Anti-neoplastic drug – Risk of atherosclerosis.

(Health Canada, Canada. April 12, 2013)

Manufacturer Novartis Pharmaceuticals Canada, Inc. together with Canada regulatory agency published a safety announcement to warn about the risk of occurrence of conditions related to atherosclerosis in subjects treated with nilotinib (Tasigna). Adverse events that include artery occlusive disease, coronary and carotid artery stenosis and strokes were reported in nilotinib-treated patients. Manufacturer Novartis carried out a review of cases from its data base and identified 277 cases of atherosclerosis between 2005 and 2013.

http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/26659a-eng.php

ANMAT recommends that the public:

. Monitor atherosclerosis signs during treatment with nilotinib.

. Monitor cholesterol and blood sugar levels after starting treatment with nilotinib and periodically later on.

To date, the National Pharmacovigilance System has received two reports of adverse events related to atherosclerosis (vascular disease and stroke) in 2012 and two reports (under review) of increased plasma cholesterol in 2011 in subjects treated with nilotinib.

Holders of marketing authorizations of nilotinib-containing products are being reminded to keep updated information in patient information leaflets.

STRONTIUM RANELATE– Osteoporosis treatment– Risk of acute myocardial infarction and use restrictions.

(EMA, European Union, April 26, 2013)
(AEMPS, Spain. April 24, 2013)

The European Pharmacovigilance Risk Assessment Committee has recommended the review of the benefit-risk balance of strontium ranelate. Likewise, said committee recommended that patients at a high risk of ischemic heart disease should not use the drug.

On its part, Spain drug regulatory agency recommends restricting the use of strontium ranelate to patients with severe osteoporosis and at a high risk of fracture and not starting treatment in patients at a high risk of ischemic heart disease.

http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/04/WC500142507.pdf

http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/seguridad/2013/NI-MUH_FV_11-2013-ranelato-estroncio.htm

To date, the National Pharmacovigilance System has not received any report of suspected ischemic heart disease associated to the use of strontium ranelate.

ANMAT reminds companies marketing medicinal products containing strontium ranelate as an active ingredient to keep updated information in patient information leaflets.

If you would like to report a suspected adverse event to the Pharmacovigilance Department, click on the following link:

http://www.anmat.gov.ar/farmacovigilancia/Notificar.asp

THALIDOMIDE – Immunemodulatory drugs – Risk of hematologic malignancies.

(IMB, Ireland. April 8, 2013)

Manufacturer Celgene has announced through a letter to health professionals that there is an increased risk of hematologic malignancies in thalidomide-treated subjects. Data from a current study indicate that patients with multiple myeloma receiving combination therapy of thalidomide with melphalan and prednisone may have an increased risk of second hematologic malignancies (acute myeloid leukemia and myelodysplastic syndrome) as compared to those treated with lenalidomide plus dexamethasone.

http://www.imb.ie/EN/Publications/Publications/Thalidomide-Celgene-Thalidomide-Important-Safety-Information-from-Celgene-as-approved-by-the-Irish-Medicines-Board.aspx

To date, the Pharmacovigilance Department has not received any report of second hematologic malignancies in patients with multiple myelomide treated with thalidomide.

Holders of marketing authorizations of thalidomide-containing products are reminded of the importance of keeping updated the information in patient information leaflets.

CALCITONIN – Osteoporosis treatment– Suspension of marketing of intranasal preparations and use restrictions for injectable drugs.
(AEMPS, Spain. April 9, 2013)

Spain drug regulatory agency informed the conclusions of the calcitonin-containing medicines benefit/risk balance review. It was determined that these drug products should only be used in short-term treatments, as new data produced by clinical trials indicate a slight increase of tumor risk associated to prolonged treatments. As other therapy alternatives are available, calcitonin use for osteoporosis treatment is not advised. (See news of July 2012).

The European Commission has recently published its decision to suspend the marketing authorization of intranasal calcitonin preparations and to make updated the technical file and patient information leaflet of injectable preparations.

http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/seguridad/2013/NI-MUH_FV_09-2013-calcitonina.htm

To date, the National Pharmacovigilance System has not received any report of tumors in subjects treated with calcitonin.

NATIONAL NEWS

VOTRIENT (PAZOPANIB) – Tyrosine kinase inhibiting anti-neoplastic agent -Change of liver function monitoring frequency.
(ANMAT. April 9, 2013)

Manufacturer GlaxoSmithKline Argentina S.A. has informed about the update of the section: Warnings and Precautions of Prescribing Information of Votrient drug product. Due to the risk of hepatotoxicity, markers of the liver function are to be monitored more frequently than initially recommended during the first 9 (nine) weeks of treatment.

The following changes will be made on Prescribing Information:

. Monitoring of the liver function prior to starting treatment with pazopanib and at weeks 3, 5, 7 and 9. Later on, monitoring at month 3 and 4 and as per clinical indication. Periodic monitoring should be continued after month 4.

VACCINES

HUMAN PAPILLOMAVIRUS VACCINE (HPV) – "VACCINE AGAINST HUMAN PAPILLOMAVIRUS: RESULTS AFTER ONE YEAR OF ITS INCORPORATION INTO THE NATIONAL VACCINATION SCHEDULE". Revista Argentina de Salud Pública, Vol. 4 – Nº March 14, 2013. Published online.

Results obtained after 13 months of the inclusion of the HPV vaccine in Argentina´s National Vaccination Schedule were published in this article. Since October 2012 to date, the coverage reported amounted to 94.8% for the first dose, 70.4% for the second dose and 39.2% for the third dose.

Likewise, HPV vaccine has been incorporated into the Vigilance System for Events Supposedly Attributable to Vaccination or Immunization (ESAVI) of the National Program for the Control of Immune-preventable Diseases (ProNaCEI) of the national Ministry of Health.

Out of the 690,919 doses of the HPV bivalent vaccine administered in the age group of the year 2000, 82 ESAVI were reported. The rate amounted to 0.72/100. Reports account for 46 mild ESAVI and five serious ones requiring hospitalization; three syncopal episodes; one case of anaphylaxis and one of bronchospasm, all of them with ad integrum recovery.

http://saludinvestiga.org.ar/rasp/articulos/volumen14/44-46.pdf

Every girl aged 11 is to be vaccinated. The number of doses required for an effective vaccination is three: the first dose at 0 time, the second dose: one month after the first one and the third dose: 6 months after the first dose. Vaccination is free of charge in all public vaccination offices and hospitals nationwide.

In Argentina, two HPV vaccines are marketed: Cervarix and Gardasil. The patient information leaflets of both vaccines are available for check at ANMAT Drug Formulary by clicking on:

http://www.anmat.gov.ar/aplicaciones_net/applications/consultas/vademecum/vademecum.asp

Health professionals and users are reminded of the possibility of reporting to the National Pharmacovigilance System on suspected adverse events related to the application of HPV vaccines by clicking on the following link:

http://www.anmat.gov.ar/farmacovigilancia/Notificar.asp