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MEDICINE SAFETY COMMUNICATION

Medicine: Selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs)

RE: Warning on the increased risk of postpartum hemorrhage in patients using SSRIs and SNRIs

Reference is made to the new safety information on selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) published in the WHO Pharmaceuticals Newsletter - N° 04/2021 warning on the increased risk of postpartum hemorrhage when above-mentioned medicines are used during the month of up to delivery in pregnant women.

Further consideration of the Drug Safety Update published by the Medicines and Healthcare Products Regulatory Agency recommending prescribers to consider the risk of postpartum hemorrhage in the context of an individual patient's bleeding and thrombotic risk assessment during the peripartum period and the benefits of antidepressants for the patient's mental health during this time.

Selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) are two different types of antidepressants with which their serotonin (5-HT) reuptake inhibiting effects, they increase synaptic levels of serotonin leading to increased activation of a multitude of specific postsynaptic 5-HT receptors. SSRIs include drugs like Citalopram, Escitalopram, Fluoxetine, Paroxetine, and Sertraline; and SNRIs include Desvenlafaxine, Duloxetine, Levomilnacipran, Milnacipran, and Venlafaxine. SSRIs and SNRIs have proven to be effective for many psychiatric illnesses including several anxiety disorders, bulimia, and dysthymia.

These medicines have been known for some time to increase the general risk of bleeding. There are several potential mechanisms by which SSRIs and SNRIs may increase bleeding. These include direct platelet effects, such as the antagonism of serotonin transporters, thereby impairing platelet aggregation-depletion of platelet serotonin levels; and reduction in platelet count.

Rwanda FDA warns about the increased risk of postpartum hemorrhage when selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) are used by mothers during the month before delivery.

Information to Healthcare professionals

- Observational studies have shown an increased risk of postpartum hemorrhage when selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) are used during the month up to delivery.
- Healthcare professionals are advised to continue considering the benefits of treating depression for the mother with the increased risk of postpartum hemorrhage.
- Healthcare professionals including midwives should continue to enquire about the use of antidepressant medicines, particularly in women in the later stages of pregnancy.
- Pharmacists are encouraged to provide detailed medical information and potential risks to patients and encourage them to report any adverse reaction encountered.

Information to patients

- Patients are warned about the increased risk of postpartum hemorrhage when selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) are used in the month before delivery.
- Patients are advised to report any suspected adverse reaction induced by the use of SSRIs and SNRIs to health professionals or Rwanda FDA.

Information to Marketing Authorization Holders

- Marketing Authorization Holders (MAH) are advised to update the medicine safety information for selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) to include the increased risk of postpartum hemorrhage during the month up to delivery.

Note: Healthcare Professionals and patients are urged to report any suspected serious adverse drug reactions associated with SSRIs and SNRIs, and other medicines to Rwanda FDA by completing ADR/AEFI reporting form accessible on the Rwanda FDA website via the link https://www.rwandafda.gov.rw/fileadmin/user_upload/RwandaFDA/Publications/Pharmacovigilance___Food_Safety_Monitoring/Forms/ADR_AEFI_Reporting_form.pdf and the filled form should be sent to the email: pv_sm@rwandafda.gov.rw

Sincerely,

18/03/2022

Dr. Emile BIENVENU
Director General

References

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