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EDITORIAL

19th International Conference of Drug Regulatory Authorities (ICDRA): Smart Regulation; Delivering Quality assured Medical Products for All

The 19th International Conference of Drug Regulatory Authorities (ICDRA), hosted by India in collaboration with the World Health Organization (WHO), marked a crucial event attracting a large number of delegates from around the globe. This biennial event has become a global platform for the exchange of ideas and collaboration among the world's leading regulatory experts. With the central theme of "Smart Regulation: Delivering Quality Assured Medical Products for All" the conference brought together drug regulatory authorities, policy makers, and experts from around the world to address critical challenges and emerging opportunities in medicine regulation.

The conference underscored the importance of harmonization, collaboration and reliance among regulatory bodies, particularly as the world continues to grapple with the complexities introduced by the COVID-19 pandemic, which accelerated the demand for swift yet safe regulatory responses. The urgency that the pandemic situation created, necessitated the need for rapid approvals, supply chain resilience, and robust pharmacovigilance systems, all of which ICDRA participants explored with an eye toward sustainable practices that balance speed with safety and efficacy.

Participants engaged in thought-provoking discussions, debate and shared potential solutions to these complex yet variegated challenges, highlighting the conference's role as a catalyst for progress. Beyond the scientific program, the ICDRA served as an invaluable networking opportunity for regulatory authorities from different countries. The event provided a space for building relationships, exchanging experiences, and fostering mutual respect. These connections are essential for facilitating future collaboration and enhancing the global regulatory landscape. The pre-ICDRA event also held in the same venue with participation of regulators, industries, civil societies, private experts and more to bring about discussions on the real challenges and opportunities in the medical products sectors and it regulation at the national and international level.

The 19th ICDRA's outcomes are expected to influence global regulatory policies, with a goal of making medicines safer, more effective, and accessible. The conference created a conducive forum of international level and provided a foundation for future regulatory harmonization efforts, shaping a more inclusive and robust framework for global health security.

In conclusion, the 19th ICDRA was a resounding success, bringing together the brightest minds in drug regulation to advance patient safety and public health. The action points identified as the outcome of the conference will help drive the regulatory science further ensuring global aspiration that medicines are safe, effective, and accessible to the patients worldwide.

Narayan Prasad Dhakal
(Director General)
Chief Editor

Scope of the Bulletin

- Pharmaceuticals Stability, quality control formulation, biopharmaceutics
- Policy, legislation, and regulatory control
- Availability and supply
- Administration and dosage
- Choice of therapy, indication, contraindications
- Drug interaction
- Pharmacovigilance, Adverse drug reactions
- Essential drugs

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औषधि पसल/फार्मेसी निरीक्षण :

विवरण	काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
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औषधि मुल्यांकन तथा दर्ता महाशाखा अन्तर्गत मुख्य कार्यहरुः

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2. REGULATORY NEWS

Finasteride

Risk of mood alterations

Canada. Health Canada has alerted health-care professionals that the Warnings, Precautions and Patient Medication Information sections of the Canadian product monographs for finasteride (Propecia® and Proscar®) have been updated with the risk of mood alterations including depressed

mood, depression, self-harm injury and suicidal ideation.

Finasteride is indicated the treatment and control of prostate gland enlargement (benign prostatic hyperplasia), and for the treatment of male pattern hair loss (androgenetic alopecia).

There have been post-marketing reports of serious psychiatric symptoms in patients treated with finasteride that sometimes continued after treatment discontinuation. Mood alterations including depressed mood, depression, self-harm injury, suicidal ideation, as well as worsening of pre-existing depression have been reported in patients treated with finasteride.

It is recommended that all patients be screened for suicidal ideation, self-harm, and depression and/or associated risk factors before treatment initiation. Clinical monitoring of all patients for signs and symptoms of psychiatric disorders should continue throughout treatment and afterward.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Pseudoephedrine

Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Europe. The PRAC of the EMA has recommended new measures for medicines containing pseudoephedrine to minimise the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). PRES and RCVS are rare conditions that can involve reduced blood supply to the brain, potentially causing serious, life‑threatening complications. With prompt diagnosis and treatment, symptoms of PRES and RCVS usually resolve. The recommendation has been also endorsed by the Committee for Medicinal Products or Human Use (CHMP) of the EMA.

Pseudoephedrine is a stimulant that is often used as a decongestant in people who have a cold or allergies. Several pseudoephedrine containing products are available as over-the counter (OTC) medicines.

The PRAC reviewed evidence including post marketing safety data, which showed that pseudoephedrine is associated with risks of PRES and RCVS.

The product information will be updated to include the risks and the new measures to be taken. Pseudoephedrine should not be used in patients with

high blood pressure that is severe or uncontrolled, or with severe acute or chronic kidney disease or failure. Also, health-care professionals should advise patients to stop using these medicines immediately and seek treatment if they develop symptoms of PRES and RCVS such as severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures and visual disturbances

Source: WHO Pharmaceuticals Newsletter No.2, 2024

Promethazine hydrochloride injection

Risk of severe chemical irritation and damage to tissues

United States. US FDA is alerting health care professionals of labelling updates intended to further reduce the risk of severe chemical irritation and damage to tissues from intravenous administration of promethazine hydrochloride injection. Promethazine hydrochloride injection is indicated to help manage certain allergic reactions, motion sickness, postoperative nausea and vomiting, and as a sedative or adjunct to analgesics.

FDA recommends healthcare professionals administer promethazine hydrochloride injection by deep intramuscular administration instead of intravenous administration. If promethazine hydrochloride injection must be administered intravenously, health care professionals should review and follow the updated information in the labelling to dilute promethazine hydrochloride injection and administer by intravenous infusion to reduce the risk of severe tissue injury.

FDA has required that manufacturers update their prescribing information for promethazine hydrochloride injection to include new safety information and update the carton labelling and container labels with the corresponding information.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Valproate

Potential increased risk of neurodevelopmental disorders in children

1.Europe. The PRAC of EMA is recommending precautionary measures for the treatment of male patients with valproate medicines. These measures are to address a potential increased risk of neurodevelopmental disorders in

children born to men treated with valproate during the 3 months before conception. Neurodevelopmental disorders are problems with development that begin in early childhood, such as autism spectrum disorders, intellectual disability, communication disorders, attention deficit/hyperactivity disorders and movement disorders.

Valproate medicines are used to treat epilepsy, bipolar disorders and, in some EU countries, migraine.

The PRAC recommends that valproate treatment in male patients is started and supervised by a specialist in the management of epilepsy, bipolar disorder or migraine. Doctors should inform male patients who are taking valproate about the possible risk and discuss the need to consider effective contraception, for both the patient and their female partner. Valproate treatment of male patients should be reviewed regularly to consider whether it remains the most suitable treatment, particularly when the patient is planning to conceive a child. In reaching its conclusion, the PRAC reviewed data from a retrospective observational study carried out by companies that market valproate and data from other sources, including non-clinical (laboratory) studies and scientific literature, and consulted patients and clinical experts.

The retrospective observational study used data from multiple registry databases in Denmark, Norway and Sweden and focused on birth outcomes in children born to men who were taking valproate or taking lamotrigine or levetiracetam (other medicines to treat conditions similar to those treated with valproate) around the time of conception. The results of the study suggest there may be an increased risk of neurodevelopmental disorders in children born to men taking valproate in the 3 months before conception.

The data showed that around 5 out of 100 children had a neurodevelopmental disorder when born to fathers treated with valproate compared with around 3 out of 100 when born to fathers treated with lamotrigine or levetiracetam. The study did not investigate the risk in children born to men who stopped using valproate more than 3 months before conception.

The possible risk in children born to men treated with valproate in the 3 months before conception is lower than the previously confirmed risk in

children born to women treated with valproate during pregnancy. It is estimated that up to 30 to 40 out of 100 preschool children whose mothers took valproate during pregnancy may have problems with early childhood development, such as being slow to walk and talk, being intellectually less able than other children, and having difficulty with language and memory.

The potential risk of neurodevelopmental disorders and the precautionary measures will be reflected in updates to the product information and educational material for valproate medicines.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Fluoroquinolone antibiotics

Further restrictions for use due to risk of disabling and potentially long-lasting or irreversible side effects

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has updated indications for systemic (by mouth, injection, or inhalation) fluoroquinolone antibiotics. It has been suggested that they must only be used in situations when other antibiotics, that are commonly recommended for the infection, are inappropriate, as they can cause long-lasting (up to months or years), disabling and potentially irreversible side effects, sometimes affecting multiple body systems and senses.

Fluoroquinolone antibiotics are a group of medicines that kill bacteria and have an important role in treating certain life-threatening infections. They include ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin.

Restrictions to the use of fluoroquinolones were introduced in 2019 to minimize the risk of these reactions. In 2023 the MHRA reviewed the effectiveness of these measures in the UK and has taken additional action to further minimise the risk.

Situations in which other antibiotics are considered to be inappropriate and a fluoroquinolone may be indicated include:

• there is resistance to other first-line antibiotics recommended for the infection

• other first-line antibiotics are contraindicated in an individual patient

• other first-line antibiotics have caused side effects in the patient requiring

treatment to be stopped
• treatment with other first-line antibiotics has failed
Source: WHO Pharmaceuticals Newsletter No.3, 2024

Acetazolamide
Risks of choroidal effusion and choroidal detachment
Europe. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) has recommended updating the product information for acetazolamide to include the risks of choroidal effusion and choroidal detachment (decrease in vision or pain in the eyes due to accumulation of fluid in the vascular layer of the eye behind the retina).
Acetazolamide is an inhibitor of carbonic anhydrase and is indicated for the treatment of glaucoma.
Cases of choroidal effusion/detachment have been reported after the use of acetazolamide. Symptoms include acute onset of decreased visual acuity or ocular pain and can occur within hours after initiation of acetazolamide treatment. If choroidal effusion/detachment is suspected, acetazolamide should be discontinued as rapidly as possible
Source: WHO Pharmaceuticals Newsletter No.1, 2024

Azacitidine
Risk of cutaneous vasculitis
Europe. The PRAC of the EMA has recommended updating the product information for azacitidine injectable formulations to include the risk of cutaneous vasculitis (inflammation of blood vessels in the skin which may result in rash).
Azacitidine is a type of cancer chemotherapy drug and is indicated for the treatment of myelodysplastic syndromes and chronic myelomonocytic leukaemia. Oral dosage form and injectable formulations are available, of those injectable formulations are subject to this safety update.
Having considered evidence in EudraVigilance and literature, the PRAC has agreed that a causal relationship between azacitidine injectable formulations and cutaneous vasculitis is at least a reasonable possibility.
Source: WHO Pharmaceuticals Newsletter No.2, 2024

Pembrolizumab and atezolizumab

Potential risk of aplastic anaemia

Canada. Health Canada has announced that the product information for pembrolizumab (Keytruda®) and atezolizumab (Tecentriq®) is to be updated to include the potential risk of aplastic anaemia, as well as for the other products in the immune checkpoint inhibitors (ICIs) drug class that are not currently labelled for this risk (Bavencio®, Imfinzi®, Jemperli® and Libtayo®), to include the risk of aplastic anaemia.

Pembrolizumab (Keytruda®) and atezolizumab (Tecentriq®) are anti-cancer agents belonging to a class of drugs called ICIs. They are authorized for sale to treat different types of cancers.

Triggered by safety information received from the manufacturers and published cases in the scientific literature, Health Canada reviewed information from the Canada Vigilance database and published literature. Health Canada reviewed 12 cases (1 Canadian and 11 international) of aplastic anaemia in patients receiving Keytruda. Of those 12 cases, 1 was found to be probably linked to the use of Keytruda, 9 (1 Canadian) were found to be possibly linked, 1 was unlikely to be linked and 1 could not be assessed. Health Canada reviewed 2 international cases of aplastic anaemia in patients receiving Tecentriq. Both cases were found to be possibly linked to the use of Tecentriq. Health Canada also reviewed 9 articles published in the scientific literature reporting cases of aplastic anaemia with the use of Keytruda or Tecentriq. The evidence reviewed further supports the link between the risk of aplastic anaemia and the use of Keytruda or Tecentriq.

Source: WHO Pharmaceuticals Newsletter No.1, 2024

Pegfilgrastim, filgrastim, lenograstim

Potential risks of myelodysplastic syndrome and acute myeloid leukemia

Japan. The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the product information for pegfilgrastim, filgrastim, and lenograstim will be updated to include the potential risks of myelodysplastic syndrome and acute myeloid leukemia.

Pegfilgrastim, filgrastim, and lenograstim are recombinant granulocyte colony-stimulating factors, a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells and release them into the bloodstream, and are indicated for the prevention of chemotherapy-induced febrile neutropenia.

An observational study performed in the US has reported an increased risk of myelodysplastic syndrome or acute myeloid leukemia in patients with breast or lung cancer who were treated with pegfilgrastim or filgrastim in conjunction with chemotherapy. Although the causal relationship of these medicines to myelodysplastic syndrome or acute myeloid leukemia is not clear, patients should be carefully monitored after administration of the medicines.

Source: WHO Pharmaceuticals Newsletter No.2, 2024

3.SAFETY OF MEDICINES

Nirmatrelvir/ritonavir

Risk of serious and potentially fatal adverse reactions

Europe. The PRAC of EMA has reminded health-care professionals of the risk of serious and potentially fatal adverse reactions with nirmatrelvir/ritonavir (Paxlovid®) when used in combination with certain immunosuppressants that have a narrow safe dosage range (where small changes in the dose can lead to serious adverse reactions), due to drug-drug interactions reducing the body's ability to eliminate these medicines.

Nirmatrelvir/ritonavir is a medicine used for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe. The immunosuppressants concerned are called calcineurin inhibitors (tacrolimus, ciclosporin) and mTOR inhibitors (everolimus, sirolimus), which reduce the activity of the immune system. They are used for treating certain autoimmune disorders or for preventing the body from rejecting transplanted organs.

Nirmatrelvir/ritonavir should only be given with tacrolimus, ciclosporin,

everolimus or sirolimus if close and regular monitoring of their blood levels is possible, to reduce the risk of drug-drug interactions causing serious reactions. Health-care professionals need to consult with a multidisciplinary group of specialists to manage the complexity of taking these medicines together.

The PRAC reviewed all available evidence, including reports of serious adverse reactions, some of which were fatal, resulting from drug-drug interactions between nirmatrelvir/ritonavir and these immunosuppressants. In several cases, blood levels of these immunosuppressants increased rapidly to toxic levels resulting in life-threatening conditions. Therefore, the PRAC agreed on a direct health-care professional communication (DHPC) to remind health-care professionals of the risk of these interactions, which is known and already described in the product information for this medicine.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Vitamin B12 (hydroxocobalamin, cyanocobalamin)
Risk of cobalt sensitivity reactions

United Kingdom. The MHRA is reminding healthcare professionals the risk of cobalt sensitivity reactions in patients being treated for vitamin B12 deficiency. Cobalt sensitivity reactions typically present with cutaneous symptoms of chronic or subacute allergic contact dermatitis.

Hydroxocobalamin and cyanocobalamin are oral and injectable forms of vitamin B12 that are used to treat vitamin B12 deficiency. Endogenous vitamin B12 and these medicines contain a cobalt component.

There is evidence within the literature of cobalt sensitivity reactions occurring following administration of vitamin B12. Additionally, the MHRA received three Yellow Card reports, which report vitamin B12 as a suspect drug and possible allergic reactions to cobalt. Following the MHRA's review, it was considered appropriate to improve awareness that hydroxocobalamin and cyanocobalamin medicines contain cobalt.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Omega-3-acid ethyl esters
Risk of atrial fibrillation
Europe. The EMA is reminding health-care professionals by issuing a Direct Health-care Professional Communication (DHPC) that a dose-dependent increased risk of atrial fibrillation (AF) in patients with established cardiovascular diseases or cardiovascular risk factors who were treated with omega-3-acid ethyl ester medicines compared to those treated with placebo. The observed risk was found to be highest with a dose of 4 g/day.

Medicinal products containing omega-3 ethyl esters are indicated for the reduction of triglyceride levels (hypertriglyceridemia) when the response to diet and other non-pharmacological measures has proved inadequate.

The PRAC assessed data from several systematic reviews and meta-analyses of large randomised controlled trials (RCTs) that overall enrolled more than 80,000 patients mostly with cardiovascular diseases or cardiovascular risk factors and investigated omega-3 fatty acid treatment on cardiovascular outcomes compared with placebo.

Health-care professionals should advise patients to seek medical attention in case of symptoms of atrial fibrillation such as lightheadedness, asthenia, palpitations or shortness of breath. If atrial fibrillation develops, treatment should be permanently discontinued.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Paracetamol
Risk of hepatotoxicity
Ireland. The HPRA has reminded health-care professionals that hepatotoxicity in association with paracetamol may occur even at doses within the normal therapeutic range in patients who are at increased risk. It is important to maintain awareness of any emerging or changing risk factors during treatment with paracetamol.

Paracetamol is recommended for the short-term treatment of the mild to moderate pain such as headache, toothache, musculoskeletal disorders and menstrual pain and for fever associated with cold and flu.

Patients at an increased risk of hepatotoxicity include those who are

underweight, of low body mass index, malnourished, dehydrated, chronic alcoholism or with co-existing renal or hepatic impairment. Those with conditions that may predispose to glutathione deficiency or depletion and those concomitantly taking hepatotoxic drugs are also considered at risk.

Health-care professionals should take into consideration any emerging or changing risk factors (e.g. malnourishment, weight loss, dehydration) and maintain awareness over the course of treatment to any dose adjustment that may be warranted when prescribing or administering paracetamol.

For some patients considered to be at higher risk of hepatotoxicity, a lower starting dose, a reduction in dose and/or a reduced frequency of dosing may be appropriate.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

Chimeric Antigen Receptor (CAR) T cell Immunotherapies
Risk of T-cell malignancy

1.United States. US FDA is investigating serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous Chimeric Antigen Receptor (CAR) T cell immunotherapies.

CAR T cell immunotherapies are human gene therapy products in which the T cell specificity is genetically modified to enable recognition of a desired target antigen for therapeutic purposes.

US FDA has received reports of T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies. Reports were received from clinical trials and/or post marketing adverse event (AE) data sources. US FDA has determined that the risk of T-cell malignancies is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CART cell immunotherapies.

Although the overall benefits of these products continue to outweigh their potential risks for their approved uses, US FDA is investigating the identified risk of T cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action.

Patients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies. In the event that a new malignancy occurs following treatment with these products, contact the manufacturer to report the event and obtain instructions on collection of patient samples for testing for the presence of the Chimeric Antigen Receptor (CAR) transgene.

Source: WHO Pharmaceuticals Newsletter No.3, 2024

4. REGULATORY NOTICES

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि प्रशासन विभागको
तथा जनसंख्या विभाग

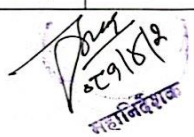
औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८१/०४/०२

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिको नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिलको ब्याच नं.को औषधि न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि उक्त ब्याच नं. का औषधि बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योग तथा तिनका प्रतिनिधिहरुका जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिहरुको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल:

सि.नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादक/ आयातकर्ताको नाम र ठेगाना
1.	**Ofen** **(Aceclofenac Tablets IP)** Each film coated tablets contain: Aceclofenac IP 100mg	O-23	**Mfg. Date:** Apr. 2023 **Exp. Date:** Mar. 2025	**Does not comply as per IP 2022 with respect to assay test performed.**	**उत्पादकको नाम:** **Sumy Pharmaceuticals (P) Ltd.,** Beldia, Gaindakot-13, Nawalparasi, Nepal



नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८१/०५/२१

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिको नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिलको ब्याच नं.को औषधि न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि उक्त ब्याच नं. का औषधि बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योग तथा तिनका प्रतिनिधिहरुका जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिहरुको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल:

सि.नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादक/ आयातकर्ताको नाम र ठेगाना
1.	**AZOL** **(Albendazole Suspension)** Each 10 ml contains: Albendazole USP 400mg	LAZ-048	**Mfg. Date:** Dec. 2022 **Exp. Date:** Nov. 2024	**Does not comply as per IP 2022 with respect to assay performed.**	<u>उत्पादकको नाम:</u> **Curex Pharmaceuticals (P) Ltd.,** Kavre, Nepal

०८१/०५/२१
महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

जडिबुटीजन्य सुगन्धित तेलहरुको खाने र बाह्य प्रयोगको लागि प्रचलनमा रहेका उत्पादनहरुको सूचिकृत सम्बन्धि जरुरी सूचना॥

(प्रकाशित मितिः २०८१/०४/१७)

प्रस्तुत विषयमा औषधि सल्लाहकार समितिको ४२औं बैठकले जडिबुटीजन्य सुगन्धित तेलहरुको खाने र बाह्य प्रयोग सम्बन्धमा Therapeutic Claim नभएका सामान्य उपभोग्य वस्तुका रुपमा प्रचलनमा रहेका उत्पादनहरुको उत्पादन एंव बिक्रीवितरण र प्रयोगलाई (रोग उपचारका लागि नभएको) भन्ने लेवलमा उल्लेख गरी कुनै Therapeutic/Medicinal दावी गर्न नपाउने गरी उपभोक्ताको विवेकमा निर्माता, विक्रेता र उपभोक्ता नै जवाफदेही हुने गरी जनस्वास्थ्यको दृष्टिकोणबाट उक्त उत्पादनहरुको सुरक्षितता एंव प्रभावकारिताका लागि "न्यूनतम मापदण्ड एंव प्रकियाहरु तोकि" सोही बमोजिम वस्तुहरुको सूचिकृत गर्ने एंव पारदर्शी तवरले अभिलेख राख्ने परिपाटी औषधि व्यवस्था विभागले लागू गर्न दिएको परामर्श अनुरुप मिति २०८१/०३/२३ को विभागीय निर्णयानुसार जडिबुटीजन्य सुगन्धित तेलहरुको खाने र बाह्य प्रयोगको लागि प्रचलनमा रहेका उत्पादनहरुको सूचिकृत सम्बन्धित न्यूनतम मापदण्ड, २०८१ स्वीकृत भएकोले सबै सरोकारवालहरुको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै सो मापदण्ड एवं प्रक्रिया पुरा गरी उत्पादकहरुले शर्तहरु पालना गर्ने गरी सूचीकृत गरिने व्यहोरा समेत यसै सूचना मार्फत जानकारी गराईन्छ।

उक्त जडिबुटीजन्य सुगन्धित तेलहरुको खाने र बाह्य प्रयोगको लागि प्रचलनमा रहेका उत्पादनहरुको सूचिकृत सम्बन्धित न्यूनतम मापदण्ड, २०८१: पाना २ विभागको Website मा समेत प्रविष्ट गरिएको व्यहोरा जानकारी गराईन्छ।

०८१/४/१८

महानिर्देशक

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

"अनलाइन औषधि विक्रि वितरण मापदण्ड, २०८१" लागु गर्ने सम्बन्धि सूचना

प्रकाशित मितिः २०८१/०४/२१

नेपालमा औषधिको बिक्रि वितरणमा कुशलता, प्रभावकिरता, गुणस्तरीयता एंव प्रतिस्पर्धा कायम राख्दै जनताको अपेक्षा एवं आकांक्षालाई सम्बोधन गर्ने गरी औषधि विक्रि वितरण संहिता, २०८० जारी भै सकेको विदितै छ । उक्त संहिताको दफा ८ को उपदफा १० बमोजिम "अनलाइन औषधि विक्रि वितरण मापदण्ड, २०८१" को मस्यौदा तयार भई अन्तिम चरणमा रहेकाले मिति २०८०/०४/०९ को विभागीय निर्णयानुसार सार्वजनिक सुझाव संकलन गर्ने उद्देश्यले उल्लेखित मापदण्ड यसै साथ संलग्न गरि यो सूचना प्रकाशित गरिएको छ।

उक्त अनलाइन औषधि विक्रि वितरण मापदण्ड, २०८१ सम्बन्धि उपयुक्त राय/सुझाव भएमा यो सूचना प्रकाशन भएको मितिले दश (१०) दिन भित्र निम्न ढाँचामा विभागको आधिकारिक इमेल ठेगाना info@dda.gov.np मा सुझावहरु पठाउनु हुन समेत सम्बन्धित सरोकारवाला सबैलाई अनुरोध गरिन्छ।

सुझावहरु पेश गर्ने ढाँचा :

सि.नं.	मापदण्डको दफा	मापदण्डमा हुनुपर्ने विषय वा बुँदा

०८१/४/२१
महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
प्रकाशित मितिः २०८१।०४।२१

पशुपन्छी औषधि व्यवसायी मान्यता परीक्षाको नतिजा प्रकाशन भएको सम्बन्धि सूचना।

पशुपन्छी औषधि व्यवसायी मान्यता परीक्षाको काठमाडौं केन्द्रबाट मिति २०८१।०२।१९ गते शनिवारका दिन लिईएको परीक्षामा निम्न रोल नं./सिम्बोल नं. का परीक्षार्थी उत्तीर्ण भएकाले सोको जानकारीको लागि यो सूचना प्रकाशन गरिएको छ। साथै उत्तीर्ण भएका परीक्षार्थीहरुले नतिजा प्रकाशन भएको मितिबाट ४५ (पैतालिस) दिन भित्र नागरिकता सहित शैक्षिक प्रमाणपत्रका प्रमाणित प्रतिलिपि (Notarized Copy) हरू विभागमा बुझाई व्यवसायी प्रमाणपत्र लिनु हुन समेत यसै सूचना मार्फत जानकारी गराईन्छ।

विषय:

उत्तीर्ण भएका परीक्षार्थीको विवरण:

V081-1	V081-2	V081-8	V081-10	V081-11	V081-12
V081-13	V081-14	V081-15	V081-16	V081-27	V081-28
V081-47	V081-50	V081-51	V081-54	V081-64	V081-66
V081-67	V081-71	V081-72	V081-80	V081-83	V081-86
V081-87	V081-88	V081-92	V081-94	V081-96	V081-100
V081-105	V081-110	V081-114	V081-124	V081-133	V081-140
V081-141	V081-145	V081-150	V081-237	V081-320	V081-341
V081-358					

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

विदेशी औषधि उत्पादकको WHO GMP Audit सम्बन्धी अत्यन्त जरुरी सूचना
प्रकाशन मिति : २०८१/०४/२३

यस विभागको चालु आ.व. ०८१/८२ को स्वीकृत वार्षिक कार्यक्रम अनुसार नयाँ औषधि दर्ता एवं गुणस्तर एकिनका लागि विदेशी औषधि उद्योगको WHO GMP Audit गर्न उत्पादकहरुको छनौटका लागि नेपाल सरकार (सचिव स्तर) को मिति २०८१/०४/०४ को निर्णयानुसार मापदण्ड स्वीकृत भएकोले तपशिल बमोजिम मापदण्डमा आधारित इच्छुक पैठारीकर्ता साथै यस अघि निवेदन दिनुभएका निवेदकहरुले समेत आफ्नो निवेदन अद्यावधिक गर्न चाहेमा विभागबाट तोकिएका कागजातहरु सहित यो सूचना प्रकाशन भएको मितिले तीस दिन भित्र विभागमा निवेदन दिनुहुन यो सूचना प्रकाशन गरिएको छ ।

तपशिलः

क्र.स.	उद्योगको विवरण
१.	उद्योगको निरीक्षण हालसम्म पनि नभएको तर विभागमा उक्त उद्योग सुचिकृत रहेको र सो उद्योगको उत्पादनहरु विभागमा दर्ता रहेको तथा बिक्रि वितरण हुँदै आएको तथा उद्योग सुचिकृत रही उद्योगबाट उत्पादित औषधी दर्ता रहेको तर उत्पादकको ठेगाना (साइट) परिवर्तन भएको उद्योग ।
२.	औषधी दर्ता नियमावली २०३८ अनुसूची ४ घ १ र ४ घ २ मा आकस्मिक, जीवन रक्षक, र सघन उपचारमा प्रयोग हुने र अर्फान र बेवारुथा गरिएको रोगको उपचारमा प्रयोग हुने भनि समावेश ।
३.	स्वदेशी उद्योगले उत्पादन नगर्ने पशुपंक्षीको लागि उत्पादित सुइ जन्य औषधि र भ्याक्सिन उत्पादन गर्ने उद्योग ।
४.	Transdermal Drug Delivery System, Liposomal Delivery System, Biologicals (vaccine समेत), Blood and Blood products र Biotechnology प्रविधिमा आधारित औषधि उत्पादन गर्ने उद्योग ।

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

औषधि ऐन २०३५ बमोजिम औषधि खरिद टेण्डर आहवान गर्नुपर्ने सम्बन्धि अत्यन्त जरुरी सूचना !!!

प्रकाशित मितिः २०८१/०५/०६

औषधि ऐन २०३५ को दफा (१०) मा औषधि बिक्रि वितरण गर्ने व्यक्तिले आफ्नो नाम र पसल वा फर्म औषधि व्यवस्था विभागमा दर्ता गर्नुपर्नेछ भन्ने व्यवस्था रहेको सबैलाई विदितै छ।

औषधि खरिदको टेण्डर आहवान गर्दा Bidding Document को शर्तमा औषधि व्यवस्था विभागमा दर्ता भएको फर्मले मात्र टेण्डरमा सामेल हुन पाउने बारे केही सरकारी तथा गैरसरकारी अस्पतालहरुले यस विभागमा दर्ता नभएको फर्मसँग समेत औषधि खरिद गरेको जानकारी विभिन्न निकायबाट विभागमा प्राप्त भएको छ।

तसर्थ औषधि ऐन, २०३५ को दफा (१०) र दफा (१०)(क) लाई कार्यन्वयन गर्नको निम्ति सम्पूर्ण संस्था (निजि/सरकारी) ले <u>औषधि खरिदको टेण्डर आहवान गर्दा अनिवार्य रुपमा **Bidding Document** को शर्तमा औषधि व्यवस्था विभागमा दर्ता भएको फर्मले मात्र टेण्डरमा सामेल हुन पाउने स्पष्ट व्यवस्था राख्नु हुन</u> मिति २०८१/०४/२४ गतेको विभागीय निर्णयानुसार सम्पूर्ण सरोकारवाला निकाय लगायत (निजि/सरकारी) संघ संस्थाको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

०८१/५/६

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
प्रकाशित मिति: २०८१/०६/२२

"आयुर्वेद औषधिको कुशल उत्पादन अभ्यास संहिता सम्वन्धि जरुरी सूचना"

औषधि दर्ता नियमावली २०३८ को नियम ११ बमोजिम औषधि उत्पादन प्रयोजनको लागि औषधि उत्पादन संहिता, २०४१ लागू भएकोमा औषधि उत्पादनमा नयाँ प्रविधिहरुको विकास भए सँगै औषधि उत्पादन प्रक्रिया, अभ्यासहरु समेत परिमार्जन हुँदै जाने भएकोले औषधि उत्पादन संहितालाई समेत समय सापेक्ष रुपमा परिमार्जन गर्न नेपाल सरकार, माननीय मन्त्री स्तर (मिति २०७२/०९/०२) निर्णयानुसार औषधि उत्पादन कुशल अभ्यास संहिता, २०७२ स्वीकृत भै कार्यान्वयन भएको अवस्था छ।

हालको औषधि उत्पादन कुशल अभ्यास संहिता, २०७२ मा आयुर्वेदिक र परम्परागत औषधिहरुको उत्पादन असल अभ्यास बारेमा स्पष्ट व्यवस्था नभएकोले आयुर्वेदिक औषधिको कुशल उत्पादन अभ्यास संहिता तयार भएको छ। प्रस्तुत मस्यौदामा उपयुक्त राय/सुझाव भएमा यो सूचना प्रकाशन भएको मितिले पन्ध्र (१५) दिन भित्र निम्न ढाँचामा विभागको आधिकारिक इमेल ठेगाना **info@dda.gov.np** मा सुझावहरु पठाउनु हुन मिति २०८१/०६/२२ को विभागीय निर्णयानुसार सम्बन्धित सरोकारवालाको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

सुझावहरु पेश गर्ने ढाँचा :

सि.नं.	संहिताको दफा	संहितामा हुनुपर्ने विषय वा बुँदा

पुनश्चः सो आयुर्वेदिक औषधिको कुशल उत्पादन अभ्यास संहिताको मस्यौदाः पाना १८ यसै साथ संलग्न गरिएको छ।

०८१/०६/२२

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति: २०८१/०६/२३

"Guideline for the safe Disposal Of unwanted Pharmaceuticals" सम्वन्धि जरुरी सूचना

नेपालमा उत्पादित वा आयात भै विक्रिवितरण/प्रयोग भएका औषधि तथा औषधिजन्य सामग्रीको प्रयोग पश्चात वा म्याद गुज्रिएका/गुणस्तर नभएका त्यस्ता उत्पादनहरुको उचित व्यवस्थापन गर्न चुनौतीपूर्ण हुन्छ। प्रयोगमा नआउने/नहुने औषधि तथा औषधि जन्य सामग्रीहरुको उपयुक्त तवरबाट व्यवस्थापन गर्न साथै सोवाट उत्पन्न हुने जोखिमलाई न्यूनीकरण गर्न विभागवाट "Guideline for the safe Disposal Of unwanted Pharmaceuticals" सम्वन्धि कार्यविधिको मस्यौदा तयार भएको छ। प्रस्तुत कार्यविधिको मस्यौदामा उपयुक्त राय/सुझाव भएमा यो सूचना प्रकाशन भएको मितिले पन्ध्र (१५) दिन भित्र निम्न ढाँचामा विभागको आधिकारिक इमेल ठेगाना **info@dda.gov.np** मा सुझावहरु पठाउनु हुन मिति २०८१/०६/२२ को विभागीय निर्णयानुसार सम्बन्धित सरोकारवाला सबैमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

सुझावहरु पेश गर्ने ढाँचा :

क्र. स.	कार्यविधिको बुँदा नम्वर	कार्यविधिमा हुनुपर्ने विषय वा बुँदा

पुनश्चः **"Guideline for the safe Disposal Of unwanted Pharmaceuticals"** सम्वन्धि कार्यविधिः पाना २४ यसै साथ संलग्न गरिएको छ।

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औषधि व्यवस्था विभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८१/०५/२५

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकहरुबाट उत्पादित तपसिलको ब्याच नं.को औषधिहरु न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि उक्त ब्याच नं. का औषधिहरु बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योग तथा तिनका प्रतिनिधिहरुका जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिहरुको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल:

सि.नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादक/ आयातकर्ताको नाम र ठेगाना
1.	MONTRIZ SYRUP Each 5ml contain: Montelukast Sodium IP eq. to Montelucast-4mg & Levocetrizine Dihydrochloride IP-2.5mg	MZS0124	**Mfg. Date:** Jan. 2024 **Exp. Date:** Dec. 2025	**Does not comply as per IP 2022 with respect to Description/Physical condition of Sample.**	**उत्पादकको नाम:** **Lomus Pharmaceuticals Pvt Ltd.,** Gothatar, Kathmandu, Nepal.
2.	VOMIZ SYRUP Each 5ml contain: Ondansetron Hydrochloride IP eq. to Ondansetron-2mg	361030	**Mfg. Date:** Feb. 2024 **Exp. Date:** Jan. 2026	**Does not comply as per IP 2022 with respect to Description/Physical condition of Sample.**	**उत्पादकको नाम:** **S.R. Drug Laboratories Pvt. Ltd** Satugal, Kathmandu Nepal.

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महानिर्देशक

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औषधि व्यवस्था विभागको

औषधि फिर्ता (Recall) गर्नेसम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८१/०५/३१

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिको नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिलको ब्याच नं.को औषधि न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि उक्त ब्याच नं. का औषधि बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योग तथा तिनका प्रतिनिधिहरुका जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिहरुको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल:

सि.नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादक/ आयातकर्ताको नाम र ठेगाना
1.	**EVACIP,5ML Eye/ear Drops** Each ml contains: Ciprofloxacin Hydrochloride USP Equivalent to Ciprofloxacin 0.3%w/v Hypromellose BP 0.25%w/v Benzalkonium chloride solution (as Preservative) BP-0.02%v/v Water for injection BP q.s.	ECE221	Mfg. Date: Feb. 2024 Exp. Date: Jan. 2026	Does not comply as per USP 2023 with respect to Sterility test.	उत्पादकको नाम: Everest Parenterals Pvt Ltd., Chhatapipara, Bara, Nepal

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महानिर्देशक

नेपाल सरकार
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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८१/०६/०६

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिको नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिलको ब्याच नं.को औषधि न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि उक्त ब्याच नं. का औषधि बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योग तथा तिनका प्रतिनिधिहरुका जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिहरुको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल:

सि.नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादक/ आयातकर्ताको नाम र ठेगाना
1.	**ARFLOX SUSPENSION** Each 5ml suspension contains: Ofloxacin IP-50mg	AFL 90001	**Mfg. Date:** Apr. 2023 **Exp. Date:** Mar. 2025	**Does not comply** as per IP 2022 with respect to Assay test performed.	उत्पादकको नामः **Arya Pharmalab Pvt Ltd.,** Chhatapipara, Bara, Nepal

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महानिर्देशक

औषधि प्रयोग गर्दा ध्यान दिनुपर्ने कुराहरू:

- मान्यता प्राप्त स्वास्थ्यकर्मीको पूर्जामा मात्र औषधि प्रयोग गर्ने ।
- औषधिको प्रयोग सम्बन्धि पूर्ण जानकारी लिने ।
- औषधिको सेवन तोकिएको समयमा, तोकिए बमोजिमको फरकमा, तोकिएको समयसम्म प्रयोग गर्ने ।
- औषधि बालबच्चाको पहुँचबाट टाढा राख्ने ।
- यदि कुनै औषधि सेवन गर्न भूलेमा सम्झने बित्तिक्कै सेवन गर्ने तर अर्को मात्रा सेवन गर्ने समय नजिक भएमा सेवन नगरी अर्को मात्रा सेवन गर्ने ।
- आफू गर्भवती भएमा सो बारे स्वास्थ्यकर्मीलाई जानकारी दिने ।
- औषधि प्रयोग गर्दा जिउ चिलाएमा, छालामा डाबरहरु आएका, स्वास फेर्न गाह्रो भएमा वा यस्तै अन्य लक्षण देखा परेमा तुरुन्त औषधि प्रयोग गर्न छाडी स्वास्थ्यकर्मीलाई सम्पर्क राख्ने ।

एण्टिबायोटिक औषधि प्रयोग गर्दा मान्यता प्राप्त स्वास्थ्यकर्मीको सल्लाहमा तोकिएको अवधि र समयभित्र प्रयोग गरौं र गराऔं ।

औषधि सम्बन्धि थप जानकरीका लागि तल उल्लेखित ठेगानामा सम्पर्क राख्नुहोला ।

औषधि व्यवस्था विभाग

मदनभण्डारी पथ-४, बिजुलीबजार, काठमाडौं

पोष्ट बक्स नं. १००३८, फोन नं.: (०१)-४७८०२२७/४७८०४३२, फ्याक्स नं. ०१-४७८०५७२

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For further information, please contact:

Government of Nepal

Ministry of Health and Population

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