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EDITORIAL

AI IN MEDICINE REGULATION: OPPORTUNITIES, CHALLENGES AND IMPACTS

Artificial Intelligence (AI) refers to machine-based systems that employ algorithms to meet human-defined goals through predictions, recommendations, or decisions. AI's applications are expanding across various sectors, including healthcare, where it enhances clinical care, manufacturing, research, and regulatory processes. In recent years, regulatory bodies have issued key guidelines on AI in medicine regulation. USFDA published a discussion paper on AI in drug manufacturing in 2023 and a draft on AI for use in making regulatory decisions in January 2025. The European Medicines Agency (EMA) released its final reflection paper on the use of AI in the medicinal product life cycle in September 2024. In the UK, the MHRA launched the "AI Airlock" sandbox in 2024 to pilot regulatory approaches. WHO issued regulatory considerations on AI in 2023 and guidance on large models in 2024.

AI can assist regulatory authorities in medicine regulation in areas like dossier assessment, pharmacovigilance, quality control, policy making etc. With Natural-language processing programs, AI can analyze large volume of data that are present in regulatory submissions, health records, literature etc. This can be beneficial for human reviewers to further evaluate the documents as it reduces review time. It can help regulatory authorities to make faster and more reliable regulatory decisions. In pharmacovigilance, AI can identify trends and interpret findings fast enabling early risk identification for timely intervention if necessary. AI tools can detect substandard or falsified medicines by analyzing product images, packaging etc. AI tools can determine the abnormal pattern suggesting data integrity issues related to batch manufacturing, analytical reports, stability reports etc. AI can predict how a new regulation might affect public health outcomes and to evaluate different policy options to reach to the most suitable regulatory policy assisting regulatory authorities in evidence and risk-based decision making.

AI system development, its validation, and its regular maintenance require significant amount of financial resources. Many AI systems are opaque and generate hard to explain outcomes. Even though an AI interprets that there might be potential risk with the drug, regulatory authority still needs to justify this to manufacturers or to other stakeholders. If routine review tasks are automated, human expertise can decline. Regulatory staff might become overly reliant on algorithmic outputs, reducing their ability to catch unusual but critical issues not foreseen by the model. Utilization of patient records, or adverse-event

information, in cloud-based AI systems will expose sensitive health information to cyber-based vulnerabilities like cyber-attacks. Countries need to analyze these risks and benefits of using AI and make an informed decision regarding the use of AI.

AI can help patients to get faster access to new treatments and sooner detection of safety issues. However, if not properly designed it may fasten the approval of drugs with significant risk to patient and may delay the approval of good ones. AI in the approval process can expedite regulatory reviews for the pharmaceutical industry. Faster and more predictable decision-making by regulatory authorities may encourage pharmaceutical industries for more research and development.

It is necessary for regulatory authorities to ensure regulatory preparedness before implementing AI to increase the benefits and reduce potential harms. Regulatory authorities must develop strong data systems by digitalizing all manual records, along with access to health records with interoperable systems. Availability of skilled professionals is also crucial before implementing AI. Algorithms shall be used to analyze data and highlight potential issues but final decisions shall be made by human experts. AI models used in regulatory review process must be open to professional review. Key performance metrics such as sensitivity, specificity etc. should be disclosed. AI models must be regularly updated. Regulatory authorities with limited resources can gain from working together. For example, regional groups of regulatory authorities could purchase AI tools jointly, harmonize standards and can have joint training for professionals. Clear communication with the public is important. Explaining how AI is useful in regulatory review process and safeguarding public health is important. It will help to build public trust. Alignment with global regulatory guidelines (guidelines from WHO, ICH members, WHO listed authorities) for use of AI in medicine regulation is important.

In conclusion, AI can be used to perform regulatory functions more efficiently. There are certain challenges like cost, data privacy, transparency, over-reliance on machines. Legal frameworks, strong data systems and skilled human resources are essential for the implementation of AI. With clear guidelines and careful oversight, AI can be a valuable tool to strengthen medicine regulation and protect public health.

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
लक्ष्य	७५०	३७५	३७५	३७५	१८७५
प्रगति	८०३	५११	४०८	५७३	२२९५
प्रगति प्रतिशत(%)	१०७	१३६.२	१०८.८	१५२	१२२.४

उद्योग निरीक्षण :

विवरण	काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
लक्ष्य	६०	४	९	४	७७
प्रगति	४५	४	७	६	६२
प्रगति प्रतिशत (%)	७५	१००	७७.७८	१५०	८०.५२

औषधि मुल्यांकन तथा दर्ता महाशाखा अन्तर्गत मुख्य कार्यहरुः

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2. REGULATORY NEWS

Amphotericin B (lipid formulations)
Risk of hyperkalemia Europe.

The PRAC of the EMA has recommended updating the product information for amphotericin B (lipid formulations, AmBisome® and Abelcet®) to include the risk of hyperkalemia. PRAC has also agreed that no further action is deemed warranted at this stage for non-lipid amphotericin B (Fungizone®), of which product information already includes the risk of hyperkalaemia. Amphotericin B is an antifungal medication used for serious fungal infections and leishmaniasis. Lipid formulations and non-lipid amphotericin B products are not equivalent in terms of pharmacodynamics, pharmacokinetics and dosing and so the products should not be used interchangeably without accounting for these differences.

The updated product information for lipid formulations of amphotericin B states:

Cases of hyperkalemia (some of them leading to cardiac arrhythmias and cardiac arrest) have been reported. Most of them occurred in patients with renal impairment, and some cases after potassium supplementation in patients with previous hypokalemia.

Therefore, renal function and laboratory evaluation of potassium should be measured before and during treatment. This is particularly important in patients with pre-existing renal disease, who have already experienced renal failure, or in patients receiving concomitant nephrotoxic medications.

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Azithromycin

Rare risk of cardiovascular death

Australia. The Therapeutic Goods Administration (TGA) has updated warning about the risk of sudden cardiovascular death to the Product Information (PI) and Consumer Medicine Information (CMI) documents for azithromycin.

Azithromycin is indicated for mild to moderate infections in adults, including upper and lower respiratory tract infections, as well as uncomplicated skin and skin structure infections, among others.

Azithromycin already carried a warning of ventricular arrhythmias associated with prolonged QT interval. The update describes an increased short-term risk of cardiovascular death with azithromycin compared to other antibacterial drugs, including amoxicillin. This risk is rare but appears to be greater during the first 5 days of azithromycin use.

The new warning also advises that healthcare professionals should consider a

screening ECG in patients' event and updated warnings by the Food and Drug Administration in the US. It is important to note that the Committee observed that the information in the observational studies was insufficient to establish or exclude a causal relationship between acute cardiovascular death and azithromycin use due to inconsistent results between studies. at high risk of a prolonged QT, based on their medical history or ongoing medical treatments.

The update was made following a recommendation from the Australian Advisory Committee on Medicines. This was based on the Committee's review of published literature including observational studies, the seriousness of the adverse event and updated warnings by the Food and Drug Administration in the US.

It is important to note that the Committee observed that the information in the observational studies was insufficient to establish or exclude a causal relationship between acute cardiovascular death and azithromycin use due to inconsistent results between studies.

Source: WHO Pharmaceuticals Newsletter No.5, 2024

Chlorhexidine (cutaneous use)

Risk of persistent corneal injury and significant visual impairment

Europe. The PRAC of the EMA has recommended updating the product information for chlorhexidine for cutaneous use, indicated for skin disinfection, and relevant combination products to include the risk of persistent corneal injury and significant visual impairment. Chlorhexidine is an antiseptic and disinfectant, which is used for skin disinfection before surgery. Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant. The updated product information for the relevant chlorhexidine products state:

This product must not come into contact with the eye.

• Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area.

• Extreme care must be taken during application to ensure that this product does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure.

• If this product comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought**.**

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Fezolinetant

Risk of liver injury

United States. The US FDA has added a warning about the risk of liver injury to the existing warning about elevated liver function test values and required liver function testing in the prescribing information for fezolinetant (Veozah®).

Fezolinetant is a nonhormonal prescription medicine approved to reduce the frequency and severity of moderate to severe hot flashes caused by menopause. The medicine is in a drug class called neurokinin 3 (NK3) receptor antagonists. It works to restore the balance between estrogen hormones and a brain chemical called neurokinin B (NKB) by blocking the activities of the NK3 receptor, which plays a role in the brain's control of body temperature.

The FDA made this update after reviewing a post marketing report of a patient with elevated liver function test values and signs and symptoms of liver injury after taking the medicine for about 40 days. The FDA also added new recommendations for patients and health care professionals about increasing the frequency of liver function testing, adding monthly testing for the next 2 months after starting fezolinetant, and then at months 3, 6, and 9 of treatment as already recommended. The updated prescribing information also instructs patients to stop the medicine immediately and contact the health care professional who prescribed the medicine if signs and symptoms of liver injury occur.

Source: WHO Pharmaceuticals Newsletter No.5, 2024

17-hydroxyprogesterone caproate (17-OHPC)

Suspension of marketing authorisations

Europe. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) has recommended the suspension of the marketing authorisations for medicines containing 17- hydroxyprogesterone caproate (17-OHPC).

17-OHPC is a synthetic progestogen (steroid hormone that acts like progesterone). In some EU countries, 17-OHPC medicines are authorised as injections to prevent pregnancy loss or premature birth in pregnant women. They are also authorized for the treatment of various gynaecological and fertility disorders, including disorders caused by a lack of progesterone.

The PRAC reviewed the results of a large population-based study, which looked at the risk of cancer in people who had been exposed to 17-OHPC in the womb, over a period of about 50 years from the time they were born. Data from this study suggest that these people might have an increased risk of cancer compared

with those who were not exposed to the medicines. However, the PRAC noted that there was a low number of cancer cases in the study and that the study had some limitations, such as limited information on risk factors for cancer. The PRAC therefore concluded that the risk of cancer in people exposed to 17-OHPC in the womb is possible, but cannot be confirmed due to uncertainties.

In addition, the review considered new studies which showed that 17-OHPC is not effective in preventing premature birth; there are also limited data on its effectiveness in other authorised uses.

In view of the concern raised by the possible risk of cancer in people exposed to 17- OHPC in the womb, together with the data on the effectiveness of 17-OHPC in its authorised uses, the PRAC considered that the benefits of 17-OHPC do not outweigh its risks in any authorised use. The Committee is therefore recommending the suspension of the marketing authorisations for these medicines. Alternative treatment options are available.

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Codeine (oral solution)

Reclassified to prescription-only medicine

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that codeine oral solution (also known as codeine linctus) is to be reclassified from a pharmacy-only medicine to a prescription-only medicine (POM) owing to the risk of dependence, addiction, and overdose.

Codeine oral solution is authorised for the treatment of dry coughs in adults and children aged 12 to 18 years without breathing difficulties. Codeine is converted into morphine by the liver enzyme CYP2D6. For those who are ultra-rapid metabolisers of codeine, the risk of opioid toxicity is increased.

Recent safety information has revealed that codeine oral solution is being used recreationally for its opioid effects (known as “Purple Drank”), rather than for its intended use as a cough suppressant. This carries a serious risk of addiction and overdose which can be fatal.

All market authorisation holders (MAH) are in the process of updating their product licences to reflect the change to POM. To avoid any stockpiling, all existing codeine oral solution stock should now be treated as POM.

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Preparations containing brimonidine tartrate

Risks of serious corneal opacity

Japan. The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have issued a

notification instructing the marketing authorization holders (MAHs) to revise PRECAUTIONS on the package insert of the preparations containing brimonidine tartrate to include risk of serious corneal opacity. Preparations containing brimonidine tartrate include brimonidine tartrate, brimonidine tartrate/timolol maleate, brimonidine tartrate/brinzolamide, and ripasudil hydrochloride hydrate/brimonidine tartrate, which are used for the treatment of glaucoma and ocular hypertension in patients who have not responded sufficiently to other anti-glaucoma drugs. The MHLW and PMDA received a total of 19 cases, of which 11 cases have been confirmed where a causal relationship between the preparations containing brimonidine tartrate and the event was reasonably possible. In addition, among cases of serious corneal opacity, especially for the cases in which corneal opacity spread from the peripheral part of the cornea to the central part in a fan-like pattern developing into the central part of the cornea (pupillary area), it is known that the opacity part becomes scarred even after discontinuation of the preparations, resulting in poor visual prognosis. Special attention should be paid to these cases. If corneal infiltration or corneal neovascularisation is observed as a prodromal symptom, it is important to discontinue administration of the preparations and to administer steroid eye drops at that time. Therefore, ophthalmologists must monitor the presence or absence of findings such as corneal infiltration or corneal neovascularisation through periodic medical examinations. If any findings of prodromal symptoms or corneal opacity are observed, ophthalmologists are encouraged to take appropriate measures.

Source: WHO Pharmaceuticals Newsletter No.5, 2024

Ivacaftor, lumacaftor, tezacaftor, elexacaftor

Risk of depression

Ireland. The Health Products Regulatory Authority (HPRA) has announced that the product information for ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symkevi®), and elexacaftor /tezacaftor/ ivacaft or (Kaftrio®) has been updated to include a new warning on the risk of depression following recommendation from the EMA's PRAC.

Ivacaftor, lumacaftor, tezacaftor and elexacaftor are cystic fibrosis transmembrane conductance regulator (CFTR) modulators, and their products are indicated for the treatment of cystic fibrosis.

The recommendation follows a review of the available data on the risk of depression and related events, including cases from spontaneous reports in post-marketing surveillance, some with a close temporal relationship and a positive de-challenge and re-challenge, and based on which the PRAC considered that a causal relationship is at least a reasonable possibility.

Depression (including suicidal ideation and suicide attempt) has been reported in

patients, usually occurring within three months of treatment initiation and in patients with a history of psychiatric disorders. In some cases, symptom improvement was reported after dose reduction or treatment discontinuation.

Patients and caregivers should be alerted to the need to monitor for depressed mood, suicidal thoughts, or unusual changes in behaviour, and to seek medical advice immediately if these symptoms present.

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Topiramate

Introduction of new safety measures

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has concluded that topiramate is now contraindicated in pregnancy and in women of childbearing potential unless the conditions of a Pregnancy Prevention Programme are fulfilled.

Topiramate is indicated for the prophylaxis of migraine and for the treatment of epilepsy. It is available as tablets, a liquid oral solution and as capsules that can be swallowed whole or sprinkled on soft food.

Following a comprehensive review of the safety of antiseizure medications in pregnancy, including topiramate, MHRA concluded that the use of topiramate during pregnancy is associated with significant harm to the unborn child (both from the confirmed risks of congenital malformations and low birth weight and the potential risk of neurodevelopmental disorders). As a result, new restrictions are being introduced. Topiramate is now contraindicated in women of childbearing potential unless they meet the conditions of the Pregnancy Prevention Programme (for all indications), during pregnancy for migraine prophylaxis, and during pregnancy for epilepsy unless no other suitable treatment is available**.**

Source: WHO Pharmaceuticals Newsletter No.4, 2024

3.SAFETY OF MEDICINES

Eribulin mesylate

Risk of teratogenicity and other reproductive adverse events

South Africa. The SAHPRA has reminded health-care professionals about the risk of teratogenicity and other reproductive adverse events associated with the use of eribulin mesylate (Halaven®). Eribulin mesylate is a genotoxic anticancer medicine indicated for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease.

Eribulin mesylate is also indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease. The SAHPRA has advised health-care professionals that eribulin mesylate may cause teratogenicity and other reproductive adverse events (embryotoxicity, mutagenicity, spontaneous abortions and foetal deaths) due to its genotoxic nature. In males, eribulin mesylate may cause DNA damage in the sperm, potentially resulting in adverse events in the embryo or foetus of a female sexual partner. In females, eribulin mesylate may directly affect the embryo or foetus; or may cause DNA damage in the oocytes. To minimise the risk of drug-induced heritable DNA damage and to ensure that genomic integrity of gametes at the time of conception is maintained, female patients of childbearing potential using eribulin mesylate and female sexual partners, (with childbearing potential) to male patients receiving this product are generally advised to use highly effective contraception during treatment and for an adequate period following the end of treatment**.**

Source: WHO Pharmaceuticals Newsletter No.5, 2024

Bisoprolol

Potential risk of hyperkalaemia

Saudi Arabia. The Saudi Food & Drug Authority (SFDA) has released a safety signal concerning use of bisoprolol and potential risk of hyperkalaemia.

Bisoprolol is a cardio-selective beta1-blocker, a medication used to manage hypertension and congestive heart failure.

The SFDA has detected this signal and reviewed all the evidence available. The Saudi National database showed 103 reported domestic cases while the WHO VigiBase resulted in 278 international cases. Author extracted the top 30 cases with the highest completeness score (1.0) for further evaluation and applied the WHO-UMC causality assessment criteria. Among them, 24 cases were probably or possibly

linked to this medicine.

Disproportionality has been estimated using Information component (IC= 3.7), which showed a positive statistical association. In addition, one article reported a class effect on beta blocker with the hyperkalaemia risk.

The SFDA's investigation concluded that the current available evidence from assessment of the ICSRs, data mining and literature might support a relationship between bisoprolol and hyperkalaemia. This signal needs further investigation to confirm the risk, and health-care professionals should be aware of this potential adverse reaction**.**

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Glatiramer acetate

Risk of anaphylactic reactions

Europe. The PRAC of the EMA has concluded that glatiramer acetate is associated with anaphylactic reactions, which may occur shortly following administration of glatiramer acetate even after months up to years after initiation of treatment. Cases with a fatal outcome have been reported. Initial symptoms of anaphylactic reactions may overlap with symptoms of post-injection reaction and could potentially lead to a delay in the identification of an anaphylactic reaction.

Glatiramer acetate is authorized for the treatment of relapsing forms of multiple sclerosis.

The PRAC has agreed a direct healthcare professional communication (DHPC) to inform healthcare professionals about this risk and to recommend that patients and/or caregivers be advised of the signs and symptoms and to seek emergency care in the event of an anaphylactic reaction. If such a reaction occurs, treatment with glatiramer acetate must be discontinued.

Source: WHO Pharmaceuticals Newsletter No.5, 2024

Glucagon-like peptide-1 (GLP-1) receptor agonists

Potential risks of suicidal thoughts and thoughts of self-harm not supported

Europe. The PRAC of the EMA has concluded that the available evidence does not support a causal association between the Glucagon-Like Peptide-1 (GLP-1) receptor agonists – dulaglutide, exenatide, liraglutide, lixisenatide and semaglutide – and suicidal and self-injurious thoughts and actions.

GLP-1 receptor agonists are used to treat type 2 diabetes and some are also

authorised for weight management under certain conditions in adults who are obese or overweight.

The review started in July 2023, following case reports of suicidal thoughts and thoughts of self-injury from people using liraglutide and semaglutide medicines, and in November 2023 the committee requested additional data from the marketing authorisation holders for these medicines.

Additionally, the committee analysed the results of a recent study, based on a large database of electronic health records, which investigated the incidence of suicidal thoughts in patients with overweight and type 2 diabetes mellitus treated with semaglutide or other non GLP-1 receptor agonists for diabetes or overweight. The study found no causal association between the use of semaglutide and suicidal thoughts.

Another study was conducted by EMA, based on electronic health records, which examined the risk of suicide-related and self-injury-related events in people with type 2 diabetes mellitus. The results did not support a causal association between the use of GLP-1 receptor agonists and this risk.

After reviewing the available evidence, the PRAC considered that no update to the product information is warranted.

Source: WHO Pharmaceuticals Newsletter No.4, 2024

Warfarin

Risk of drug interactions with tramadol

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has reminded healthcare professionals that taking warfarin and tramadol together can cause harmful drug interactions, which can raise the International Normalised Ratio (INR), and result in severe bruising and bleeding, which in some patients could be fatal.

Warfarin is a coumarin derived vitamin K antagonist used for prevention and treatment of blood clots. Warfarin has a low therapeutic index, which means care is required when taking co-prescribed medicines due to the possibility of interactions that could lead to an increased risk of bleeding. Tramadol is a non-selective opioid analgesic, which acts as an agonist at the mu, delta and kappa opioid receptors.

The MHRA has received a report following the death of a patient who died from a bleed on the brain, following concurrent treatment with warfarin and tramadol.

The MHRA has advised healthcare professionals to ask patients about all the medicines that they are currently taking when prescribing warfarin, and be aware of

the risk of increased INR when warfarin and tramadol are used together, with a risk of major bruising and bleeding which could be life-threatening.
Source: WHO Pharmaceuticals Newsletter No.5, 2024

Steroids (topical)
Introduction of new labelling on potency
United Kingdom. The MHRA announced that over the coming year, topical steroids will be labelled with their potencies to aid correct selection and to simplify the advice to patients requiring multiple steroid products of differing potencies. These will be labelled "mild steroid", "moderate steroid", "strong steroid", and "very strong steroid". Topical corticosteroids are used for treatment of skin conditions such as eczema, psoriasis, and atopic dermatitis. They are available in four different levels of potencies from mildly potent, moderately potent, potent and very potent. Topical steroids can rarely lead to serious side effects such as thinning of the skin, adrenal suppression or very rarely Cushing's syndrome, due to systemic absorption. The incidence of these more serious side effects is linked to the amount, potency and duration of use of the topical steroid. Patients have also reported experiencing a less well understood group of side effects that has been termed "Topical Steroid Withdrawal Reactions". Health-care professionals should advise patients on the amount of product to apply, how often, where to apply it and when to stop treatment when prescribing or dispensing topical steroids. Patients, particularly those who require prolonged use or are using very potent topical steroids, should be advised to look for these effects and seek prompt medical attention if they occur.
Source: WHO Pharmaceuticals Newsletter No.4, 2024

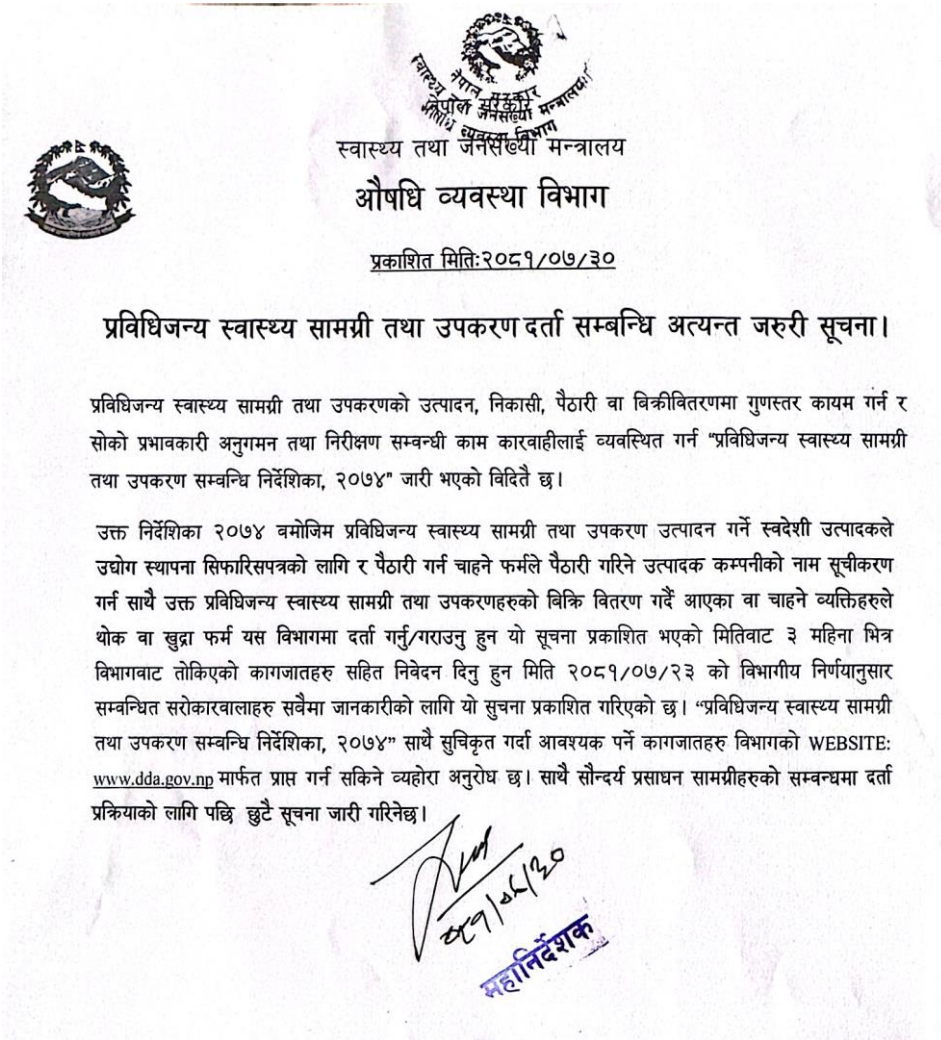
Pegfilgrastim
Potential risks of SJS and TEN not supported
Canada. Health Canada's safety review did not find sufficient evidence to support a link between the use of pegfilgrastim (Neulasta®) and the risks of Stevens-Johnson syndrome (SJS), a serious disorder of the skin and mucous membranes, and toxic epidermal necrolysis (TEN), a severe form of SJS.
Pegfilgrastim is recombinant granulocyte colony-stimulating factors and is indicated for the prevention of chemotherapy-induced febrile neutropenia.
Health Canada has been monitoring the potential risks of SJS and TEN with the use of pegfilgrastim since the EMA's labelling update for pegfilgrastim in 2020. At that

time, it was determined that Health Canada would continue to monitor the potential risks due to the small number of cases reported. In 2023, following additional cases of SJS or TEN reported by the manufacturer, Health Canada initiated a safety review.

Health Canada's review of 10 cases of SJS and/or TEN in patients receiving pegfilgrastim could not conclude whether pegfilgrastim played a role in the SJS and TEN because all cases reviewed included a combination of other drugs previously known to be associated with the development of SJS and TEN and were missing information to support a reliable association. In addition, review of the scientific literature did not identify any cases of SJS or TEN associated with the use of pegfilgrastim. Health Canada's review of the available information did not find sufficient evidence to support a link between the use of pegfilgrastim and the risks of SJS and TEN. It was determined that no updates are needed for the product information at this time.

Source: WHO Pharmaceuticals Newsletter No.4, 2024

4. REGULATORY NOTICES



स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मितिः२०८१/०७/३०

प्रविधिजन्य स्वास्थ्य सामग्री तथा उपकरण दर्ता सम्बन्धि अत्यन्त जरुरी सूचना।

प्रविधिजन्य स्वास्थ्य सामग्री तथा उपकरणको उत्पादन, निकासी, पैठारी वा बिक्रीवितरणमा गुणस्तर कायम गर्न र सोको प्रभावकारी अनुगमन तथा निरीक्षण सम्बन्धी काम कारवाहीलाई व्यवस्थित गर्न "प्रविधिजन्य स्वास्थ्य सामग्री तथा उपकरण सम्बन्धि निर्देशिका, २०७४" जारी भएको विदितै छ।

उक्त निर्देशिका २०७४ बमोजिम प्रविधिजन्य स्वास्थ्य सामग्री तथा उपकरण उत्पादन गर्ने स्वदेशी उत्पादकले उद्योग स्थापना सिफारिसपत्रको लागि र पैठारी गर्न चाहने फर्मले पैठारी गरिने उत्पादक कम्पनीको नाम सूचीकरण गर्न साथै उक्त प्रविधिजन्य स्वास्थ्य सामग्री तथा उपकरणहरुको बिक्रि वितरण गर्दै आएका वा चाहने व्यक्तिहरुले थोक वा खुद्रा फर्म यस विभागमा दर्ता गर्नु/गराउनु हुन यो सूचना प्रकाशित भएको मितिवाट ३ महिना भित्र विभागवाट तोकिएको कागजातहरु सहित निवेदन दिनु हुन मिति २०८१/०७/२३ को विभागीय निर्णयानुसार सम्बन्धित सरोकारवालाहरु सबैमा जानकारीको लागि यो सुचना प्रकाशित गरिएको छ। "प्रविधिजन्य स्वास्थ्य सामग्री तथा उपकरण सम्बन्धि निर्देशिका, २०७४" साथै सुचिकृत गर्दा आवश्यक पर्ने कागजातहरु विभागको WEBSITE: www.dda.gov.np मार्फत प्राप्त गर्न सकिने व्यहोरा अनुरोध छ। साथै सौन्दर्य प्रसाधन सामग्रीहरुको सम्बन्धमा दर्ता प्रक्रियाको लागि पछि छुटै सूचना जारी गरिनेछ।

२०८१/०८/३०

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०८१/०९/२५

औषधिपुरक सामग्रीहरुको विक्रिवितरण सम्बन्धि अत्यन्त जरुरी सूचना

फर्माकोपियामा उल्लेख भएका र उपचारमा प्रयोग हुने भिटामिन तथा खनिज (**Vitamin, Calcium, Iron, Magnesium** जस्ता **minerals** र **micronutrient**) मिश्रित फर्मास्युटिकल बनावट (ट्याब्लेट, क्याप्सुल, झोलहरु) का औषधिहरु न्युट्रास्युटिकल्सका नाममा र औषधि मिश्रित आइन्मेंट, क्रिमहरु सौन्दर्य प्रशाधन सामग्रीका नाममा आयात गरी बिक्री वितरण भैरहेको भन्ने विषयमा जनगुनासाहरु आइरहेको र बजार अनुगमन तथा निरीक्षणका क्रममा विभागमा दर्ता नभएका त्यस्ता किसिमका औषधिहरु चिकित्सकको सिफारिसमा पुर्जा मार्फत औषधि पसलहरुबाट बिक्री वितरण भैरहेको पाइएको छ। निरिक्षणका क्रममा नेपाल सरकारबाट मिति २०४९/११/१८ मा प्रतिबन्धित भिटामिन तथा खनिज समिश्रण समेत भेटिएकोमा विभागबाट यस्ता कानून विपरीतका कार्यहरुको विरुद्धमा विभिन्न समयमा सम्बन्धित अदालतमा मुद्दा दायरभै विभागको मागदावी बमोजिम आदेश समेत प्राप्त भएको छ। साथै, समान प्रकृतिको मुद्दा सम्मानित सर्वोच्च अदालतमा समेत विचाराधीन रहेको छ। यस विभागबाट पटक पटक सूचना जारी गरी कानून विपरित कार्य नगर्न/नगराउन सम्बन्धित सरोकावाला निकाय तथा सम्बन्धित व्यक्ति समेतलाई जानकारी गराउँदै आईरहेको विदितै छ।

यस विभागमा दर्ता भएका औषधिहरुसंगको सक्रिय तत्व र ब्रान्ड नामसँग दुरुश्त मिल्दोजुल्दो हुने र देखिने गरि न्युट्रास्युटिकल्स तथा सौन्दर्य प्रशाधनका नाममा यस विभागमा दर्ता नै नगरी आयात गरी औषधि पसल मार्फत उपलव्ध गराउँदा चिकित्सक तथा स्वस्थकर्मी र बिरामीहरुलाई समेत भ्रम सिर्जना भएको अवस्था छ। विभागको स्वीकृति विना आयात भएका यस प्रकारका औषधिको सुरक्षितता, गुणस्तरियता र मूल्य सार्थकता (Value for money) एकिन नहुने हुँदा जनस्वास्थ्यमा समेत प्रतिकुल असर पर्ने जोखिम सृजना भएको छ।

औषधि ऐन, २०३५ र सो अन्तर्गत बनेका नियमावली अनुसार औषधि बिक्री वितरण गर्न प्रमाणपत्र लिएको व्यक्तिले ऐनको दफा ८(क) बमोजिम विभागमा दर्ता रहेको औषधि मात्र बिक्री-वितरण गर्नुपर्ने कानूनी व्यवस्था रहेतापनि माथि उल्लेखित विभागमा दर्ता नभएका र नेपाल सरकारबाट प्रतिबन्धित औषधिहरु समेत बिक्री वितरण भइरहेको पाइएकोले यस्ता औषधिहरुको बिक्री वितरण अविलम्ब रोक्नुहुन सम्बन्धित सबैको जानकारीको लागि यो सूचना पुनः प्रकाशित गरिएको छ। यस सूचनाको अवज्ञा गरी त्यस्ता उत्पादनहरु निरिक्षणको क्रममा बिक्री वितरण गरेको पाइएमा कानून अनुसार जफत तथा औषधि ऐन, २०३५ बमोजिम कारवाही हुने छ।

०८/१९/२५

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

नेपाली सदकीर

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रदेश स्तरमा हुने फार्मेसी (औषधि) पसल दर्ता प्रमाणपत्र नवीकरण तथा व्यवसायी मान्यता प्राप्त कार्ड नविकरण सम्वन्धि जरुरी सूचना ।

यस विभागले सालवसाली रुपमा फार्मेसी (औषधि पसल) दर्ता प्रमाणपत्र नवीकरण तथा प्रत्येक पाँच पाँच वर्षमा व्यवसायी मान्यता प्राप्त कार्डको नवीकरण गर्दै आईरहेको व्यहोरा विदितै छ।

उल्लेखित कार्यमा हुने खर्चलाइ मितव्ययी बनाइ सेवाग्राहीहरुको माग तथा सुविधालाई ध्यानमा राखी विभागको कार्यलाइ सेवाग्राही मैत्री बनाउन निम्न वमोजिमको मिति र स्थानमा फार्मेसी पसल दर्ता प्रमाणपत्र नविकरण र व्यवसायी मान्यता प्राप्त कार्ड नवीकरण गर्ने जस्ता सेवा प्रदान गर्न यस विभागवाट टोली खटिने हुँदा गण्डकी प्रदेश अन्तर्गत संचालनमा रहेका थोक तथा खुद्रा औषधि पसलका संचालक तथा व्यवसायीहरुको जानकारीको लागि मिति २०८१/०९/२४ को निर्णय वमोजिम यो सूचना प्रकाशन गरिएको छ।

निम्नः

स्थानः स्वास्थ्य मन्त्रालय, गण्डकी प्रदेश, कास्की, पोखरा।

मितिः २०८१/१०/०६ आइतवार देखि २०८१/१०/११ शुक्रवार सम्म, कार्यालय समय भित्र ।

संपर्कः- फा.अ. मणिराज श्रेष्ठ, ९८४३६९८३३०

शाखा अधिकृत

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

औषधि व्यवस्था विभाग

प्रदेश स्तरमा हुने फार्मेसी (औषधि) पसल दर्ता प्रमाणपत्र नवीकरण तथा व्यवसायी मान्यता प्राप्त कार्ड नविकरण सम्वन्धि जरुरी सूचना ।

यस विभागले सालवसाली रुपमा फार्मेसी (औषधि पसल) दर्ता प्रमाणपत्र नवीकरण तथा प्रत्येक पाँच पाँच वर्षमा व्यवसायी मान्यता प्राप्त कार्डको नवीकरण गर्दै आईरहेको व्यहोरा विदितै छ।

उल्लेखित कार्यमा हुने खर्चलाइ मितव्ययी वनाइ सेवाग्राहीहरुको माग तथा सुविधालाई ध्यानमा राखी विभागको कार्यलाइ सेवाग्राही मैत्री वनाउन निम्न वमोजिमको मिति र स्थानमा फार्मेसी पसल दर्ता प्रमाणपत्र नविकरण र व्यवसायी मान्यता प्राप्त कार्ड नवीकरण गर्ने जस्ता सेवा प्रदान गर्न यस विभागवाट टोली खटिने हुँदा लुम्विनी प्रदेश अन्तर्गत संचालनमा रहेका थोक तथा खुद्रा औषधि पसलका संचालक तथा व्यवसायीहरुको जानकारीको लागि मिति २०८१/११/०५ को निर्णय वमोजिम यो सूचना प्रकाशन गरिएको छ।

निम्नः

स्थानः वुटवल उप महानगरपालिका वडा नं. ८ को कार्यलय भवन, लुम्विनी प्रदेश, वुटवल।
मितिः २०८१/११/११ आइतवार देखि २०८१/११/१५ विहिवार सम्म, कार्यालय समय भित्र ।
संपर्कः- फा.अ. मणिराज श्रेष्ठ, ९८४३६९८३३०

२०८१/११/५
शाखा अधिकृत

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रतिजैविक औषधिहरुको खपत विवरण सम्बन्धि सूचना

प्रकाशित मिति : २०८१/११/२२

उपरोक्त विषयमा यस विभागबाट प्रतिजैविक औषधिहरुको खपत विवरण सम्बन्धित उत्पादक तथा आयातकर्ताहरुबाट संकलन गरि **WHO** को Global Antimicrobial Resistance and Use Surveillance System **(GLASS)** मा **2023** सम्मको विवरण पेश भएको व्यहोरा जानकारी गराईन्छ। साथै आगामी दिनमा पनि निरन्तर रुपमा सोको वार्षिक विवरण समयमा नै उपलब्ध गराउनु पर्ने दायित्व रहेको छ।

गत वर्ष जस्तै गरि सन् **2024** मा पनि प्रतिजैविक औषधिहरुको प्रयोग तथा खपत विवरण विभागले तयार गरेको ढांचामा सो विवरण **ddaamcreporting@gmail.com** ईमेलमा मिति २०८१/१२/०१ गते भित्र यथासिघ्र पेश गर्नु अनुरोध गरिन्छ।

साथै विश्व पशु स्वास्थ्य संगठन **(WOAH)** मा **Reporting** गर्ने प्रयोजनका लागि नेपाली औषधि उत्पादक तथा आयातकर्ताले सन् **2022, 2023** र **2024** को पशुपन्छीमा प्रयोग तथा खपत भएका प्रतिजैविक औषधिहरुको खपत विवरण पशु सेवा विभागले तयार गरेको ढांचामा मिति २०८१/१२/०१ गते भित्र **vsdrlktm@gmail.com** ईमेलमा यथासिघ्र पेश गर्नु समेत अनुरोध गरिन्छ।

०८१/११/२२

वरिष्ठ औषधि व्यवस्थापक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मितिः २०८१।११।२५

Atorvastatin 5mg tablet र Empagliflozin 5mg tablet strength का एकल समिश्रणका औषधिहरुको उत्पादन तथा विक्रिवितरण नगर्ने बारे अत्यन्त जरुरी सूचना।

विभागमा दर्ता भएका Atorvastatin 5mg tablet र Empagliflozin 5mg tablet का एकल समिश्रणका औषधिहरुको प्राविधिक अध्ययन गर्दा सो Individual strength हरु USFDA, EMA, PMDA,TGA लगायत innovator को समेत दर्ता रहेको नदेखिएको, उल्लेखित strength sub-therapeutic dose रहेको र सो strength हरुको तथ्यगत विवरणहरु पर्याप्त स्थापित नभएकोले औषधि मूल्यांकन समितिको मिति २०८१/०६/०९ र २०८१/०७/०२ को सिफारिस अनुरुप औषधि सल्लाहकार समितिको मिति २०८१/१०/०३ गतेको ५७ औं बैठकबाट देहाय बमोजिम निर्णय गरी कार्यान्वयन गर्न यस विभागलाई सिफारिस भई आएकोमा मिति २०८१/११/२५ को विभागीय निर्णयानुसार सम्बन्धित सरोकारवाला सबैको जानकारीको लागि यो सूचना प्रकाशन गरिएको छ।

निर्णय:

१. Atorvastatin 5mg र Empagliflozin 5mg tablet strength का एकल समिश्रणका औषधिहरुको नयाँ थप दर्ता नगर्ने र उत्पादन भै वा आयात भै हाल बजारमा उपलब्ध रहेका उक्त औषधिको हकमा निर्णय भएको मितिले बढीमा ३ महिना भित्र बजारबाट फिर्ता गर्ने ।

२. बजारमा मौज्दातमा रहेका यस प्रकारका समिश्रणका औषधिहरुको आधिकारिक विवरण विभागमा पेश गर्ने र सम्बन्धित प्रमाणपत्रहरु, अनुज्ञापत्र र सिफारिसपत्र फिर्ता लिई नियमानुसार रद्द गर्ने।

०८१।११।२५

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मितिः २०८१।११।२५

नयाँ औषधि तथा नयाँ समिश्रणहरुको अनुमोदन सम्बन्धि सूचना।

औषधि सल्लाहकार समितिको मिति २०८१/१०/०३ गतेको ५७औं बैठकको निर्णयानुसार निम्न पच्चीस (२५) प्रकारका नयाँ औषधि (New Molecule) साथै औषधिका नयाँ समिश्रणहरु तत्तत रोग एवं रोगको अवस्थामा प्रयोग गर्ने गरि अनुमोदन गरी विभागले अपनाई आएको विधि र प्रकृया पुरा गरी दर्ता गर्न सिफारिस भै आएको व्यहोरा मिति २०८१/११/२५ को विभागीय निर्णयानुसार सम्बन्धित सबैको जानकारीको लागि यो सूचना प्रकाशन गरिएको छ।

S.NO.	Generic Name	Indication(S)
1	Budesonide 0.5 mg and Formoterol Fumarate 20 mcg Respirator Suspension	for regular treatment of asthma, regular long-term treatment of moderate-to-severe COPD, with frequent symptoms and a history of repeated exacerbations in patients aged 6 years and above
2	Budesonide 1.0 mg and Formoterol Fumarate 20 mcg Respirator Suspension	
3	Nepafenac Ophthalmic Suspension 1mg/ml	for the treatment of pain and inflammation associated with cataract surgery in patient aged 10 years and above
4	Itraconazole 130mg Capsules	for the treatment of Blastomycosis (Pulmonary and extrapulmonary), Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis, Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy in patients aged 18 years and above
5	Clofarabine 1mg/ml, 20 ml Vial	for the treatment of Acute lymphoblastic leukaemia (ALL) who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response in patients aged 1 to 21 years
6	Pancrelipase delayed release pellets Equivalent to: Lipase 10000 USP units, Protease 37500 USP units, Amylase 33200 USP units	for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions in patients aged 12 years and above
7	Pancrelipase delayed release pellets Equivalent to: Lipase 25000 USP units, Protease 62500 USP units, Amylase 74700 USP units	
8	Trimipiramine Maleate equivalent to Trimipiramine 10mg/25mg tab	for the relief of symptoms of depression
9	Prasugrel HCL equivalent to prasugrel 10mg tab	for the prevention of atherothrombotic events in adult patients with acute coronary syndrome in patient aged 18 years and above
10	Prucalopride 2mg tablets	for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief in adults aged 18 years and above

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11	Nivolumab 40mg, Injection	for treatment of melanoma, adjuvant treatment of melanoma, non-small cell lung cancer (NSCLC), neoadjuvant treatment of NSCLC, Malignant pleural mesothelioma (MPM), Renal cell carcinoma (RCC), Classic Hodgkin lymphoma (CHL), Squamous cell cancer of the head and neck, Urothelial carcinoma, Mismatch repair deficient or microsatellite instability high colorectal cancer, osophageal squamous cell carcinoma, gastro oesophageal junction or osophageal adenocarcinoma in adults aged 18 years and above
12	Artesunate powder for injection 60mg	for the treatment of severe malaria caused by Plasmodium falciparum, in adults and children
13	Indacaterol 150mcg (as acetate), glycopyrronium 50mcg, mometasone furoate 160mcg	for maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta 2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year in patients aged 18 years and above
14	Ferric carboxymaltose Injection 500mg/10ml, 100mg/2ml, 1000mg/20ml	for the treatment of iron deficiency in adults when oral iron preparations are ineffective or cannot be used in patient aged 14 years and above
15	L-Glutamine powder for oral solution, 5gm in 8gm sachet	to reduce the acute complication of sickle cell disease in adult and pediatric patient 5 years of age and older
16	Carbetocin 100 mcg/ml Injection	for the prevention of uterine atony and postpartum hemorrhage following cesarean section under epidural or spinal anaesthesia in patients aged 18 years and above
17	Aflibercept Injection 40mg per 1ml Injection	for the treatment of patients with Wet Age-related MacularDegeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Retinopathy of Prematurity (ROP) in patients aged 18 years and above
18	Trifarotene 0.005 % cream	for the cutaneous treatment of Acne Vulgaris of the face and/or the trunk in patients from 12 years of age and older
19	Lacosamide Infusion 10mg/ml	as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older
20	Fluticasone Furoate 100mcg & Vilanterol 25mcg powder for inhalation	for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema
21	Desoximetasone 0.05 % cream	for the relief of acute or chronic corticosteroid-responsive dermatoses
22	Ibuprofen Solution for Infusion 400mg/100ml	for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
23	Vortioxetine HCL 5mg/10mg/20mg	for treatment of major depressive episodes including prevention of relapse in adults aged 18 years and above
24	Varenicline Tartarate 0.5mg/1mg	for smoking cessation in adults (tobacco dependence)
25	Dapagliflozin & Metformin (5 mg/ 500 mg,5 mg/ 1000 mg,10 mg/ 500 mg & 10 mg/ 1000 mg) Tablet, Extended Release)	For treatment of type 2 diabetes mellitus

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औषधि व्यवस्था विभाग

प्रकाशित मितिः २०८१।११।२५

औषधिको स्तर निर्धारण सम्बन्धि सूचना।

औषधि सल्लाहकार समितिको मिति २०८१/१०/०३ गतेको ५७ औं बैठकको निर्णयानुसार निम्न चौध (१४) प्रकारका नयाँ औषधि वा नयाँ समिश्रणका औषधिको स्तर अनुमोदन गरी विभागलाई सिफारिस भै आएको व्यहोरा सम्बन्धित सबैको जानकारीको मिति २०८१/११/२५ को विभागीय निर्णयानुसार यो सूचना प्रकाशन गरिएको छ।

S.No.	Product Name	Analytical Profile No.
1.	Fenbendazole Tablets [Vet]	Fenben 080/81/AP 156
2.	Empagliflozin and Linagliptin Tablets	Empa Lina 080/81/AP 157
3.	Fenbendazole Bolus [Vet]	Fenben B 080/81/AP 158
4.	Benfotiamine Capsules	Benfot 080/81/AP 159
5.	Prucalopride Tablets	Prucal 080/81/AP 160
6.	Thiocolchicoside Tablets	Thioco 080/81/AP 161
7.	Tetracycline Bolus	Tetra 080/81/AP 162
8.	(S)- Amlodipine Besylate and Losartan Tablets	S Amlo Losar 080/81/AP 163
9.	Oxytetracycline Bolus	Oxytetra 081/082/AP 164
10.	Bilastine Orodispersible Tablets	Bilas DT 081/082/AP 165
11.	Bilastine Oral Solution	Bilas OS 081/082/AP 166
12.	Oxyclonazide and Levamisole Bolus [Veterinary]	Oxyclo Levami B 081/082/AP 167
13.	Bedaquiline Tablets	Bedaq 081/082/AP 168
14.	Ciprofloxacin HCl Powder [Vet]	Ciprovet 081/082/AP 169

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Reserve Antibiotics अस्पताल फार्मेसीबाट मात्र विक्रिवितरण गर्ने सम्बन्धि अत्यन्त जरुरी सूचना।

प्रतिजैविक औषधिको राष्ट्रिय खपतको विवरणले रिजर्भ समुहका प्रतिजैविक औषधिहरुको खपत बढ्दै गईरहेको, पशुपन्क्षीमा प्रयोग हुने औषधिहरुको प्रयोग सम्बन्धि प्रतिजैविक सर्भिलेन्सको समेत अभाव रहेको, औषधि सिफारिसकर्ता, औषधि बिक्रेता, र प्रयोगकर्तालाई प्रतिजैविक औषधिको वर्गिकरण बारे पर्याप्त ज्ञान नभएकोले त्यस्ता औषधिको अनुचित प्रयोग हुन गई प्रतिजैविक प्रतिरोध बढ्न जाने सम्भावना रहेको छ।

खुद्रा फार्मेसी मार्फत रिजर्भ समुहको औषधिको विक्रिवितरणले सोको अनुचित प्रयोग हुन सक्ने र सो बाट प्रतिजैविक प्रतिरोध बढ्न जाने भएकोले उपचारको लागि उपयुक्त औषधि उपलब्ध नभई उपचार प्रभावकारी नहुने हुँदा रिजर्भ समुहको औषधिको समुचित नियमन र प्रयोग गर्न औषधि सल्लाहकार समितिको मिति २०८१/१०/०३ गतेको ५७ औं बैठकबाट देहाय बमोजिम निर्णय गरी कार्यान्वयन गर्न यस विभागलाई सिफारिस भई आएकोमा मिति २०८१/११/२५ को विभागीय निर्णयानुसार सम्बन्धित सरोकारवाला सबैको जानकारीको लागि यो सूचना प्रकाशन गरिएको छः

निर्णयः

१. प्रतिजैविक प्रतिरोध राष्ट्रिय कार्ययोजना २०८०/८१-८४/८५ (NAP-AMR) मा उल्लेख भए सरह राष्ट्रिय अत्यावश्यक औषधि सूचीमा रिजर्भ समूहका प्रतिजैविक औषधिहरु चिकित्सकको सिफारिसमा अस्पतालको फार्मेसीबाट मात्र विक्रिवितरण गर्ने ।

२. अस्पताल फार्मेसीले प्रतिजैविक औषधिको खपत विवरण वार्षिक रुपमा अभिलेख राख्ने।

३. राष्ट्रिय अत्यावश्यक औषधि सूचीमा सूचिकृत रिजर्भ समूहका प्रतिजैविक औषधिहरु बाहेक अन्य प्रतिजैविक प्रतिरोध औषधिहरुलाई दर्ता गर्दाका बखत विभागले एक्सेस (access), अवेर (aware) र रिजर्भ (reserve) समूहमा वर्गीकरण गरी दर्ता गर्ने ।

पुनश्चः राष्ट्रिय अत्यावश्यक औषधि सूचीमा (NLEM, 6th Edition) सूचिकृत रिजर्भ समूहका प्रतिजैविक औषधिहरु देहाय अनुसार रहेका छन्:

Reserve group antibiotics		
S.No.	Antibiotics	Strength/Dosage Form
1.	Meropenem	Powder for Injection: 500mg, 1gm (as trihydrate) in vial)
2.	Polymyxin B	Powder for Injection: 500,000 IU in vial
3.	Piperacillin + Tazobactam	Powder for Injection: 2gm (as sodium salt) +250mg (as sodium salt); :4gm (as sodium salt) + 500mg (as sodium salt) in vial
4.	Vancomycin	Powder for Injection: 250mg (as hydrochloride) in vial
Complementary List		
5.	Colistin	Powder for Injection: 1 million I.U. (as colistimethate sodium) in vial
6.	Linezolid	Injection for intravenous administration: 2mg/ml in 300ml bag; Powder for Oral Liquid: 100mg/5ml, Tablet: 400mg, 600mg

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औषधिजन्य सामग्रीहरुको विज्ञापन तथा प्रयोग सम्वन्धि जरुरी सूचना

सामाजिक संजालका फेसबुक, टिकटक लगायतका माध्यम मार्फत मधुमेह, मोटोपन, **Prostate, Uric acid, Thyroid,** यौनशक्ति बढाउने, क्यान्सर जस्ता रोग समेत निको पार्ने भनि दावी गरिएका औषधिजन्य पदार्थहरूको विधुतीय संजाल **(Online Platform)** मार्फत भ्रमात्मक विज्ञापन गरी अनियन्त्रित विक्री भएको पाइएकोमा विभागको ध्यानाकर्षण भएको छ।

यस विभागमा दर्ता नभएका साथै उक्त उत्पादनहरूको कुनै प्रमाणित वैज्ञानिक आधार समेत नभएको देखिन्छ। प्रयोगशालाहरुको रिपोर्टका आधारमा यस प्रकारका औषधिहरु र तिनका समिश्रणहरुको प्रयोगबाट मानवीय स्वास्थ्यमा थप जटिल समस्या देखिने गरेको प्रमाण एवंम् तथ्यहरु पाइएको छ। उदाहरणका लागि **Garcinia Cambogia** को प्रयोगबाट **Lead Poisoning, Severe Abdominal Pain, Constipation** जस्ता सामान्य देखि गम्भीर किसिमका असर प्रतिअसरहरू विरामीमा देखिने गरेको पाईएको छ। यौनशक्ति बढाउने दावी सहित बजारमा ल्याइएका कतिपय उत्पादनहरुमा यौन दुर्वलता हटाउन प्रयोग हुने औषधि सिल्डेनाफिल **(Sildenafil)** को समिश्रण रहेको भेटिएका छन्। सोको अत्यधिक प्रयोगबाट मानव स्वास्थ्यमा हानि पुऱ्याउनुका साथै मृत्यु समेत हुन सक्दछ।

तथ्यहिन र भ्रमात्मक विज्ञापनका आधारमा औषधि तथा औषधिजन्य सामग्रीका रुपमा प्रयोग हुँदा/गर्दा सर्वसाधारण उपभोक्ताहरूमा नकारात्मक असर पर्नुका साथै जनधनको क्षति समेत हुने हुँदा यस्ता प्रकारका उत्पादनहरु औषधिसँग मिल्दोजुल्दो नाम राखी औषधिकै रुपमा प्रचार प्रसार, सिफारिस, ओसारपसार एवंम् विक्रिवितरण साथै प्रयोग भए गरेको पाईएकोले यस प्रकारका औषधि ऐन, २०३५ विपरितका काम/कारवाही नगर्न/नगराउनु हुन सर्वसाधारण महानुभाव तथा सरोकारवालाहरु सबैमा जानकारीका लागि यो सूचना प्रकाशित गरिएको छ।

२०८१/१२/२१
महानिर्देशक

स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना
प्रकाशित मितिः २०८२/०१/३१

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	उत्पादकको नाम र ठेगाना
1.	**Dopan-DSR** **Each Capsule contains:** Pantoprazole Sodium sesquihydrate IP eq. to pantoprazole 40mg (as enteric coated pellets) & Domperidone IP 30mg (as sustained release pellets)	DPSC-3301	**Mfg. Date:** Aug. 2023 **Exp. Date:** Jul. 2025	**Does not comply** as per IP 2022 with respect to **assay test** performed.	**उत्पादकको नामः** **Siddhartha Pharmaceuticals Pvt. Ltd.** Madhawaliya, Tilottama-15, Rupandehi, Nepal
2.	**Pandom-DSR** **Each Capsule contains:** Pantoprazole Sodium sesquihydrate IP eq. to pantoprazole 40mg (as enteric coated pellets), & Domperidone IP 30mg (as prolonged release pellets)	PAC-24052	**Mfg. Date:** Apr. 2024 **Exp. Date:** Mar. 2026	**Does not comply** as per IP 2022 with respect to **assay test** performed.	**उत्पादकको नामः** **Supreme Healthcare Pvt. Ltd.** Lipanimal-8, Bara, Nepal.
3.	**Pantafast-DSR** **Each Capsule contains:** Pantoprazole Sodium sesquihydrate IP eq. to pantoprazole 40mg (as enteric coated pellets) & Domperidone IP 30mg (as sustained release pellets)	PFDC 01041	**Mfg. Date:** Apr. 2024 **Exp. Date:** Mar. 2026	**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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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८२/०२/०६

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 औषधिको 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	उत्पादकको नाम र ठेगाना
1.	**Povine** Povidone Iodine IP 10%w/v (Available Iodine 1%w/v) Purified water q.s.	LPS5-023	**Mfg. Date:** May. 2024 **Exp. Date:** Apr. 2026	**Does not comply** as per IP 2022 with respect to **assay test** performed.	<u>उत्पादकको नाम:</u> **Curex Pharmaceuticals Pvt. Ltd.** बनेपा-१० काभ्रेपलाञ्चोक, नेपाल

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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८२/०२/२६

यस विभागमा प्राप्त औषधिका नमुनाहरु श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिल बमोजिमका ब्याच नं. को औषधिहरु न्यून गुणस्तर भएको पाइएकोले उक्त बनावट (Dosage Form) भएको औषधि, औषधि ऐन, २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि 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 सबैमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

तपसिलः

सि. नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	**RL 500 ML** (Compound Sodium Lactate Injection IP) Each 100 ml contains: Lactic acid IP 0.24 ml equivalent to Sodium Lactate IP 0.320 gm Sodium Chloride IP 0.60 gm Potassium Chloride IP 0.040 gm Calcium Chloride IP 0.0270 gm Water for injection IP q.s.	**A0581030**	**Mfg. Date:** Oct 2024 **Exp. Date:** Sep 2026	**"Does not comply** as per IP 2022 with respect to sterility test performed"	Lomus Parenterals and Formulation Pvt. Ltd. Chireshwarnath Nagarpalika, Ward No. 1, Dhanusha, Nepal
2	**D5 %, 500 ML** (Dextrose 5 % Injection USP) Each 100 ml contains: Dextrose Anhydrous IP 5 gm Water for injection IP q.s.	**A0181004**	**Mfg. Date:** Nov 2024 **Exp. Date:** Oct 2026	**"Does not comply** as per USP 2024 with respect to sterility test performed"	Lomus Parenterals and Formulation Pvt. Ltd. Chireshwarnath Nagarpalika, Ward No. 1, Dhanusha, Nepal

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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८२/०२/२८

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिको नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट 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 औषधिको 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	उत्पादकको नाम र ठेगाना
1.	**CALCIFER DROPS (Cholecalciferol Oral Solution)** Each ml Contains: Cholecalciferol IP 400 IU	CLLF23012	**Mfg. Date:** 08 Oct 2023 **Exp. Date:** 07 Oct 2025	**Does not comply** as per NML AMV Analytical profile No. Chole.D 078/079AP102 with respect to **assay test**	उत्पादकको नामः **National Healthcare Pvt. Ltd.** Chhatapipra, Bara, Nepal.
2.	**CALCIFER DROPS (Cholecalciferol Oral Solution)** Each ml Contains: Cholecalciferol IP 400 IU	CLLF23014	**Mfg. Date:** 05 Nov 2023 **Exp. Date:** 04 Nov 2025	**Does not comply** as per NML AMV Analytical profile No. Chole.D 078/079AP102 with respect to **assay test**	उत्पादकको नामः **National Healthcare Pvt. Ltd.** Chhatapipra, Bara, Nepal.

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स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति: २०७२/०३/१९

नेपाल सरकार स्वास्थ्य तथा जनसंख्या मन्त्रालय औषधि व्यवस्था विभाग

"नविकरण सम्वन्धि विभागको जरूरी सूचना"

औषधि उत्पादन, संचय, विक्रिवितरण, निकासी/पैठारी र थोक एवं खुद्रा पसल संचालन गर्नुपूर्व विभागवाट ईजाजत/प्रमाणपत्र लिनुपर्ने कानूनी प्रावधान रहेको विदितै छ। विभागवाट जारी भएका अनुज्ञापत्र सिफारिसपत्र, एवं प्रमाणपत्र नविकरण गर्नु पर्ने कानूनी व्यवस्था विपरित केहि उत्पादक, थोक तथा खुद्रा व्यवसायी/धनि एवं आयातकर्ता फर्महरुवाट औषधिको उत्पादन, संचय, विक्रिवितरण, आयात वा पैठारी भए/गरेको पाईएकाले विभागको गंभिर ध्यानाकर्षण भएको छ। यस्ता गैह्रकानूनी काम कारवाही विरुद्द औषधि ऐन,२०३५ र अन्तर्गतका नियमावली बमोजिम कारवाही भैरहेको समेत जानकारी गराईन्छ।

कानूनी व्यवस्था विपरित कुनै अनुज्ञापत्र, प्रमाणपत्र वा सिफारिसपत्र नियममा रहेको व्यवस्था बमोजिमको अवधि भित्र नै नविकरण गर्नु गराउन यो सूचना जारी गरिएको छ। औषधि ऐन,२०३५ र अन्तर्गतका नियम बर्खिलाप उत्पादन विक्रिवितरण, संचय एवं निकाशी/पैठारी गरे/ भएको पाईएमा कानुन बमोजिम भैजाने व्यहोरा जानकारीका लागि सूचित गरिन्छ।

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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८२/०२/३०

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 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 औषधिको 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	उत्पादकको नाम र ठेगाना
1.	**AGLOCEF 1G (Ceftriaxone Injection IP) Each Vial Contains:** Ceftriaxone injection equivalent to Ceftriaxone- 1G	N192403	**Mfg. Date:** May- 2024 **Exp. Date:** Oct- 2026	**Does not comply** as per Indian Pharmacopoeia 2022 with respect to **Sterility test Performed**	आयातकर्ता नाम Shubalabh Pharmalink, Birgunj-4, Parsha Nepal उत्पादकको नाम: Aglowmed Ltd, Mumbai, India.

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औषधि व्यवस्था विभाग

औषधिको विक्रिवितरण रोक्का सम्बन्धी अत्यन्त जरुरी सूचना !!!

प्रकाशित मितिः २०८२/०३/२४

यस विभागमा प्राप्त औषधिका नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिल बमोजिमका ब्याच नं. को औषधि न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १३ बमोजिम औषधिको विक्रि वितरण तत्काल रोक्का राखी, उक्त ब्याचको **Lab Investigation** तथा **Failure/ Root Cause Analysis Investigation Report** लगायतका विस्तृत विवरण ७ (सात) भित्र विभागमा पेश गर्न सम्बन्धित उद्योगलाई र विक्रिवितरण नगर्न तिनका प्रतिनिधिहरुलाई जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

तपसिलः

सि. नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	**Merocef-200 DT** **(Cefixime Dispersible Tablets IP)** **Each uncoated dispersible tablet contains:** Cefixime Trihydrate USP eq. to anhydrous Cefixime-200mg	**MET 050**	**Mfg. Date:** Aug. 2024 **Exp. Date:** Jul. 2026	**"Does not comply** as per IP 2022 with respect to Disintegration test performed"	**Royal Sasa Nepal Pharmaceuticals Pvt. Ltd.,** Chitwan, Nepal.

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औषधिको विक्रिवितरण रोक्का सम्बन्धी अत्यन्त जरुरी सूचना !!!

प्रकाशित मितिः २०८२/०३/१६

यस विभागमा प्राप्त औषधिका नमुना श्री राष्ट्रिय औषधि प्रयोगशालाबाट परिक्षण गर्दा देहायको उत्पादकबाट उत्पादित तपसिल बमोजिमका ब्याच नं. को औषधि न्यून गुणस्तर भएको पाइएकोले औषधि ऐन, २०३५ को दफा १३ बमोजिम औषधिको विक्रि वितरण तत्काल रोक्का राखी, उक्त ब्याचको **Lab Investigation** तथा **Failure/ Root Cause Analysis Investigation Report** लगायतका विस्तृत विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योगलाई र विक्रिवितरण नगर्न तिनका प्रतिनिधिहरुलाई जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त ब्याच नं. उल्लेख भएका औषधिको सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

तपसिलः

सि. नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	**PANTOLOC** **(Pantoprazole Tablets IP)** Each enteric coated tablet contains: Pantoprazole Sodium Sesquihydrate IP equivalent to Pantoprazole 40 mg.	**TPT-129(B)**	**Mfg. Date:** Dec 2024 **Exp. Date:** Nov 2027	**"Does not comply** as per IP 2022 with respect to Dissolution test (Buffer Stage) performed"	**Curex Pharmaceuticals Pvt. Ltd.** Banepa, Kavre, Nepal

२८/०३/२०८२
महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८२/०३/३०

यस विभागमा प्राप्त भएको 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 औषधिको 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	उत्पादकको नाम र ठेगाना
1.	**Povine** **Composition:** Povidone Iodine IP 5%w/v (Available Iodine 0.5%w/v) Purified water q.s.	LP4-157	**Mfg. Date:** Sep. 2024 **Exp. Date:** Aug. 2026	**Does not comply as per IP 2022 with respect to assay test performed.**	उत्पादकको नाम: **Curex Pharmaceuticals Pvt. Ltd.** बनेपा-१० काभ्रेपलाञ्चोक, नेपाल

2082/3/30
निः 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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