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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

CONTENTS

Page No.

EDITORIAL

Medicine Pricing: Pricing Needs, International trends and Challenges in Nepal

In open market, economic reasoning suggests that in "perfect markets" willing buyers and sellers be left to transact their business without government interference as the market will lead to the optimal price. However, the necessary conditions for a perfect market are rarely met in case of pharmaceutical market and plagued by market failure. The main forms of market failure in pharmaceutical markets are information imbalance, failure of competition, Externalities and Equity. Due to these market failure in pharmaceuticals Government involvement in the pharmaceutical pricing is more extensive than in markets for most other goods. Not only the extent of government intervention matters but also the form of intervention. Governments can inform, regulate, mandate, finance and provide as various forms of interventions.

Access to safe, quality-assured, effective and affordable medicine is the basic rights of human. Unaffordable prices for medicines have become one of the major concerns and challenge for quality healthcare systems and patients all over the world. Rise in price has resulted in increasing pressure on governments and individuals to be able to afford essential medicines resulting high out of pocket expenditure. Higher and increasing medicine pricing has become the problem for both high and Low and middle economic countries (LMICs). Equitable access to essential medicines and other medical technologies depends on affordable pricing and effective health financing. Promoting fair prices and cost-effective interventions is central to the achievement of universal health coverage. However, Medical, public health, and economic texts do not provide a standard definition of a fair price for medicines. Medicine pricing include the characteristics intrinsic to the product, market and transaction at a point in time and the perceptions of consumers and suppliers. Price is based on several factors, including production costs, profit margins, economic value, and prices of related goods.

In dealing with the problem, most high-income have policies directed at pricing and purchasing with national pricing or purchasing strategy except USA where organizational and institutional policies are common. LMICs

including Nepal have less regulated pharmaceutical markets than high-income countries and some LMICs are price acceptors, meaning they pay whatever price the pharmaceutical company specifies. It is difficult to regulate the price of medicine due to multi-dimensional nature of the pharmaceutical pricing and purchasing mechanisms. Pharmaceutical pricing is a function of medicine price, volume of medicines consumed and the interaction between these two variables. The pharmaceutical market comprises three main submarkets: community based over the counter (OTC) medicines, hospital medicines for inpatients and prescription medicines for outpatients.

Community based over the Counter medicine (OTC)

In most countries regardless of high or low and middle income, the OTC submarket is relatively free market, which is largely self-regulated. It is characterized by well-known medicines that have been on the market for a relatively long time. Demand for OTC medicine is patient determined, with or without prescriber influence. OTC medicines are often non-reimbursable and financed through patients' out of pocket expenses, potentially making patient decisions price sensitive. Governments usually leave the pricing of non-reimbursable OTC medicines to market forces. OTC medicines, governments may indirectly impact on the price of these medicines.

Hospital medicines for inpatients

Expenditure on medicines in the hospital submarket is generally subsumed within the total hospital budget. Typically, the range and type of medicines used in hospitals are subject to the policies of hospital drug and therapeutic committees. Medicines may be purchased either through direct negotiation with manufacturers or by tender, often resulting in a discounted price or rebates. In most high-income countries, medicine prices in hospitals are frequently not subject to government purchasing or pricing policies. However, in some jurisdictions including many LMICs, governments fund hospitals and thus policies may impact on purchasing.

Prescription medicines for outpatients

The prescription medicine outpatient submarket often accounts for the largest proportion of a nation's total pharmaceutical expenditure and is often financed within the national budget in high-income countries. In most European countries outpatient medicines represent 75–84% of total pharmaceutical expenditure, of which 50–80% may be reimbursed by public

health insurance or social security systems. As the dominant purchaser, most European governments have pharmaceutical benefit arrangements in this submarket. In contrast, in LMICs, most payments are out-of-pocket (OOP). This changes the power that can be wielded by the government from being the dominant purchaser to a weak regulator. The weak power wielded by LMICs' governments is compounded by the fact that in poor resource settings of LMICs, laws and regulations may exist but are often poorly enforced and implemented. The lack of reliable healthcare information systems in LMICs also contribute to their poor implementation, monitoring and evaluation of health interventions in general and pharmaceutical pricing and purchasing policies in particular.

Different countries practice different and multiple pricing mechanism for medicine pricing some of the pricing mechanisms are: -

Internal Reference Pricing (IRP)
Internal Reference Pricing (IRP) is the practice of setting or negotiating medicine prices by referencing prices of medicines within the country that are identical, similar, or therapeutically equivalent.

External Reference Pricing (ERP)
External Reference Pricing (ERP), commonly known as International Reference Pricing, is a price control mechanism whereby a government considers the price of a medicine in other countries to inform or establish a price in its own country.

Special Pricing Agreements
Special Pricing Agreements (SPAs), a type of innovative agreement for payers and pharmaceutical companies to align on value, speed to market, and/or risk, are legal contracts between the government and the manufacturer.

Pharmacoeconomic Evaluation
Pharmacoeconomic Evaluations (PEs) often involve a cost-effectiveness analysis (CEA) to examine the value of medicines, usually defined in terms of its consequences (e.g., Quality-adjusted Life Years (QALYs) gained) relative to its cost. Other types of PE include cost-minimization, and cost-benefit analysis. PE is particularly useful for identifying value for money of a medicine, which most countries use to inform their subvention decisions and

some countries use to determine drug prices.

Cost Plus Pricing

Cost Plus Pricing is a cost-based method for setting prices of medicines, where the production costs, research and development (R&D), administrative costs, overheads and profit, and promotional expenses are summed to determine the reimbursed price.

Price maintenance premium (PMP)

Price Maintenance Premium is a policy which awards one or multiple premiums to prices of drugs should they meet certain criteria. This strategy aims to incentivise manufacturers to launch in a certain country because it allows them to recuperate larger returns on investment.

Tendering and Negotiations

Tendering is a process whereby the government engages manufacturers to submit quotations for a particular contract, usually in a competitive bidding process. It usually takes place towards the end of the pricing process, once the government has determined an initial price to reference the bids, and is often used to reduce prices of medicines that have existing competition in the market. It simultaneously works as a procurement strategy to aid supplier and volume decisions for certain medicines and typically relies on some form of negotiation.

The use of different techniques by different countries for medicine pricing varies according the perspective of regulators, purchasers and payers and also with the country with whom the medicine is being purchased and its geographic proximity, economic similarity, historical links, the availability of price information, public health status, level of public health insurance.

Medicine Pricing and Challenges in Nepal

Drug act 1978 section 26 has empowered to fix price of medicine but section 26 of this Act has been appointed to commence on 16 November 1992 (the Nepal Gazette dated 16 November 1992). It states the Department of Drug Administration may, if it deems necessary, fix the price of any drug, by obtaining approval of the Government of Nepal. However, the provision of those medicine that have been fixed the price shall be published in the Nepal Gazette was inserted by the Second Amendment of the act in November 2000. No other legal framework of medicine pricing exists.

Before the Drug Act 1978, almost all the drugs were imported and marketed from India and the pricing was as per the Indian market and the trend continue even after the establishment of Department of Drug Administration through Drug Act. Nepal Chemist and Druggist Association (NCDA) was the professional organization for the import and/or distribution and sales of medicine and NCDA as a part of their professional duty was watchdog to look for the differences in the price between Indian and Nepalese market. After 80s national manufacturers came into the scene and the previous pricing dynamics changed.

In November 1993 Price fixation committee was formulated through ministerial decision and in
March 1995 the committee fixed the price of 8 items representing large volume parenteral. Later 4 items including paracetamol suspension and tablet was added in the price fixation in June 1997. The committee was later reformed and renamed as Price monitoring committee in September 2007. The committee is still functional and the committee fixed and revised the price 21 medicines on different dates the last price fixation was on June 2012. In August 2015, prices of 96 medicines was published in Nepal Gazette including some antimicrobials, diabetic, cardiac and some anticancer drugs. Since then, the prices of medicines have not been reviewed.

Issues of medicine pricing in Nepal

- Lack of pharmaceutical policy and legal framework regarding pricing.
- Lack of Strategic positioning of national pharmaceutical industry by Government.
- Pricing decision as a political agenda rather than technical issues.
- Most of the imported drugs are from India so independent pricing without the consideration of Indian market will affect the availability of some critical medicines.
- Dependency of API, Excipient, machineries, technology and packaging.
- Lack of diversification of national manufacturers.
- Small market size and meager export potential.
- Unethical market scenario.

- Lack of strong pricing mechanism in social insurance system.
- No dynamic Price Control mechanism.
- Higher out of pocket payment for medicine.
- Lack of established Continual Drug supply chain management Practices.
- Insufficient National treatment protocol/guideline.
- Lack of Drug and Therapeutic committee and treatment guideline in most of the hospital settings.
- Shortage of technical expertise in Pharmacoeconomics both in the regulatory and pharmaceutical industry.

Pricing in fact is a complex process and involves the multiple facets. Pricing of medicines should be balanced with the space to grow the pharmaceutical industry; assurance of affordable quality assured products in the market and ethical market. In nutshell Nepal being a small market, which is predominant by Indian market the external reference pricing cannot be ignored for effective supply chain management. India in fact have well defined policy and structure and has been carrying out effective price control with regards to the generic drugs. So, external reference pricing should be the predominant strategy.

Also, the COVID-19 pandemic led to the increase in prices of critical care drugs due to significant disruptions to normal supply chains as well as cost increases for raw materials including transportation which impacted on smaller markets like Nepal. And India banning the export of certain essential drugs including Remdesivir during the pandemic made it hard for the availability of medicines to the patients in need.

In Conclusion, the government, pharmaceutical manufactures, importers and players in supply chain should promote price transparency and accountability with public centered responsibility for resilient healthcare system.

Bharat Bhattarai
(Director General)
Chief Editor

1. आ.व. २०७८/७९ श्रावन देखि कार्तिक महिनासम्मको प्रगति विवरण

अनुगमन, मुल्यांकन तथा कानुन कार्यान्वयन महाशाखा अन्तर्गत मुख्य कार्यहरु:

औषधि पसल/फार्मेसी निरीक्षण :

विवरण	काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
पहिलो त्रैमासिक लक्ष्य	६००	१६५	१६५	१६५	१०९५
पहिलो त्रैमासिक प्रगति	४२५	१९७	१२६	१४५	८९३
पहिलो त्रैमासिक प्रगति प्रतिशत	७१	१००	७६	८८	८२

उद्योग निरीक्षण :

विवरण	काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
पहिलो त्रैमासिक लक्ष्य	१७	१	४	१	२३
पहिलो त्रैमासिक प्रगति	२२	०	०	१	२३
पहिलो त्रैमासिक प्रगति प्रतिशत	१००	०	०	१००	१००

औषधि मुल्यांकन तथा दर्ता महाशाखा अन्तर्गत मुख्य कार्यहरु:

सि.न.	कार्य विवरण	संख्या
१.	नयाँ उत्पादन अनुज्ञापत्र प्रदान	२१८
२.	उत्पादन अनुज्ञापत्र नवीकरण	१६०२
३.	बजार बिक्रि वितरण प्रमाणपत्र प्रदान	२२६

सि.न.	कार्य विवरण	संख्या
४.	बजार बिक्रि वितरण प्रमाणपत्र नवीकरण	१२४७
५.	पैठारी सिफारिसपत्र प्रदान	४४०
६.	पैठारी सिफारिसपत्र नवीकरण	५४१७
७.	विदेशी औषधि उद्योग दर्ता	१५
८.	नयाँ विदेशी औषधि दर्ता	१३२

		काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
९.	नयाँ फार्मेसी दर्ता	४४१	१३९	१५०	१७०	९००
१०.	फार्मेसी नबिकरण	२५३५	१४०७	७४९	९१७	५६०८
११.	फार्मेसी रद्ध	१४७	४०	२	६१	२५०
१२.	फार्मेसीमा संशोधन	४८७	१०२	०	१२६	७१५
१३.	व्यवशायी प्रमाणपत्र दर्ता	४	७	०	०	११
१४.	व्यवशायी प्रमाणपत्र नबिकरण	४५९	९९	२४	१३४	७१६

योजना, समन्वय तथा व्यवस्थापन महाशाखा अन्तर्गत मुख्य कार्यहरु

सि.न.	कार्य विवरण	संख्या
१.	लागु तथा मनोद्विपक औषधिहरुको सिफारिश (पटक)	२५
२.	Uppsala Monitoring Centre मा ADR Reporting गरिएको संख्या	३
३.	औषधि मुल्यांकन समितिको बैठक संख्या	३
४.	औषधि मुल्यांकन समितिको बैठकबाट औषधिको बिशेष सिफारिस गरिएका औषधिको संख्या	३

सि.न.	कार्य विवरण	संख्या
५.	जोखिममा आधारित बजारिकृत औषधिको नमूना संकलन तथा विश्लेषणको लागि पठाएको	१६
६.	औषधि सूचना प्रवाह	२७
७.	ड्रग बुलेटिन प्रकाशन	१

अन्य कार्यहरु :

- औषधि दर्ता नियमावली तेस्रो संसोधन २०७७ मा उल्लेखित अत्यावश्यक औषधि र आकस्मिक तथा जीवनरक्षक औषधिहरुको सुची परिमार्जन गरि National Emergency, Lifesaving & Critical Care Medicine List र Orphan and Neglected Tropical Disease List को मस्यौदा बनाई पेश गरेको।
- अत्यावश्यक औषधिको राष्ट्रिय सूची [National List of Essential Medicine (NLEM)] छैठौं संशोधन, २०२१ प्रकाशन र वितरण गरेको।
- Guideline for Risk-Based Post-Marketing Quality Surveillance of Medicines in Nepal मस्यौदा तयार गरेको।
- MNCH and FP औषधिहरुको Pre-qualification purpose को लागि प्रारम्भिक audit गरेको।
- औषधि उत्पादन कुशल अभ्यास संहिता ,२०७८(पहिलो संसोधन) मस्यौदा तयार गरेको।

2. REGULATORY NEWS

Hydrocortisone

Risk of acute adrenal insufficiency in children when switching from tablets to granules

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that the product information for hydrocortisone granules (Alkindi®) will be updated following a report of an infant developing severe adrenal insufficiency when switched from hydrocortisone soluble tablets to hydrocortisone granules.

Hydrocortisone granules are indicated for replacement therapy of adrenal insufficiency in infants, children and adolescents.

Parents or carers should be advised to observe the child carefully in the first week after the switch. Also, the prescriber should instruct parents and carers what to do if the child develops any symptoms of adrenal insufficiency such as tiredness, floppiness, temperature instability, headache or vomiting.

If a child requires additional dosing during the first week after the switch, an increase in the daily dose of hydrocortisone granules should be considered.

Source: WHO Pharmaceuticals Newsletter No.2, 2021

In Nepal: Health care professionals are warned of the risk of acute adrenal insufficiency in children when switching from tablets to granules with the use of Hydrocortisone.

Pregabalin

Risk of severe respiratory depression

United Kingdom. The MHRA has announced that the product information for pregabalin (Lyrica®) will be amended to include new warnings for respiratory depression.

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain with partial seizures and for generalized anxiety disorder in adults.

Use of pregabalin with opioid medicines or other central nervous system (CNS)

depressant medicines has been previously associated with reports of respiratory failure, coma and deaths.

A recent European review considered reports of severe respiratory depression thought to be related to the action of pregabalin alone on the CNS.

Similar warnings are already in place for gabapentin (Neurotonin®) and other gabapentinoids medicines.

Health-care professionals should consider whether adjustments are necessary for patients at higher risk of respiratory depression including those with compromised respiratory function and aged older than 65 years.

Source: WHO Pharmaceuticals Newsletter No.2, 2021
In Nepal: Health care professionals are warned of the risk of severe respiratory depression with the use of Pregabalin.

Salbutamol

Risk of shock and anaphylaxis
Japan. The MHLW and the PMDA have announced that the package insert for salbutamol (Venetlin®, Sultanol®) should be revised to include the risk of shock and anaphylaxis as adverse drug reactions.

Salbutamol is indicated for relief of symptoms associated with airflow obstruction and bronchospasm.

A total of three cases of shock or anaphylaxis have been reported in Japan in the last three years, one of which was assessed to have a possible causal relationship between the drug and event. No patient mortalities have been reported.

Patients should be carefully monitored and if any abnormalities are observed, administration of salbutamol should be discontinued and appropriate measures should be taken.

Source: WHO Pharmaceuticals Newsletter No.2, 2021
In Nepal: Health care professionals are warned of the risk of shock and anaphylaxis with the use of Salbutamol.

Sofosbuvir

Potential risk of severe cutaneous adverse reactions (SCAR)
Canada. Health Canada has announced that they will be working with the

manufacturer to update the safety information for sofosbuvir to include the risk of Stevens– Johnson syndrome (SJS).

Sofosbuvir is indicated to treat chronic hepatitis C virus infection.

Health Canada reviewed the potential risk of severe cutaneous adverse reactions (SCAR) with the use of sofosbuvir. This was triggered by an update to the product safety information made by the EMA.

The safety review focused on specific types of SCAR: SJS and toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM) and bullous dermatitis (BD).

Health Canada reviewed 13 foreign reports from available information in the Canada vigilance database, international databases and published literature.

The conclusion of the review was that there may be a link between the use of sofosbuvir and the risk of SJS.

Source: WHO Pharmaceuticals Newsletter No.2, 2021

In Nepal: Health care professionals are warned of the risk of cardiovascular event and infantile hypertrophic pyloric stenosis (IHPS) with the use of Erythromycin.

Levothyroxine (tablet)

Risk of related to aggravating thyroid symptoms when switching between different products

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that the product information for levothyroxine is being updated to include the risk of aggravating thyroid symptoms when switching between different levothyroxine products (tablets).

Levothyroxine is indicated for the control of hypothyroidism. In the UK, prescribing of levothyroxine is usually generic, so patients may switch between different levothyroxine products according to what is available at their local pharmacies.

From 2015 to 2019, the MHRA received 335 reports of the thyroid condition being aggravated or ineffectiveness of the levothyroxine product following substitution with another. Associated symptoms were mostly consistent with hypothyroidism

or hyperthyroidism and included fatigue, headache, malaise, anxiety, palpitation, nausea myalgia and dizziness. The underlying causes for the symptoms experienced after switching between products are generally unclear.

Generic prescribing of levothyroxine remains appropriate for the majority of patients and the licensing of these generic products is supported by bioequivalence testing.

If a patient reports persistent symptoms of their condition being aggravated when switching between different levothyroxine products, health-care professionals should consider consistently prescribing a specific product known to be well tolerated by the patient. Also, if symptoms or poor control of thyroid function persist, prescribing an oral solution formulation of levothyroxine should be considered.

Source: WHO Pharmaceuticals Newsletter No.3, 2021
In Nepal: Health care professionals are warned of the risk of related to aggravating thyroid symptoms when switching between different products with the use of Levothyroxine (tablet).

Olanzapine

Potential risk of somnambulism

Saudi Arabia. The SFDA has requested that the product information for olanzapine containing products (Olazine®, Olenza®, Zolan®) is updated to include a potential risk of somnambulism (sleepwalking) as an adverse drug reaction.

Olanzapine is indicated for treatment of schizophrenia and bipolar disorder including mixed or manic episodes.

The SFDA reviewed published literature and post marketing data on the potential risk of sleepwalking associated with olanzapine use. The SFDA identified 64 spontaneous case reports of somnambulism with olanzapine use in the WHO database, reported between 1999 and May 2021. Most reported cases were from the United States. Among these cases, 32 cases were reported as serious cases.

Source: WHO Pharmaceuticals Newsletter No.4, 2021
In Nepal: Health care professionals are warned of the Potential risk of somnambulism with the use of Olanzapine.

Remdesivir

Risk of sinus bradycardia

Europe. The PRAC has recommended a change to the product information for remdesivir (Veklury®) to include sinus bradycardia as an adverse drug reaction.

Remdesivir is indicated to treat COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen.

The PRAC reviewed available data on rare reported cases of bradycardia in patients treated with remdesivir as well as data from clinical trials and the scientific literature.

The PRAC concluded that a causal relationship between the use of remdesivir and the event is reasonably possible and recommended the revision of the product information.

The majority of the events of sinus bradycardia resolved a few days after the treatment with remdesivir was discontinued.

Source: WHO Pharmaceuticals Newsletter No.4, 2021

In Nepal: Health care professionals are warned of the risk of sinus bradycardia with the use of Remdesivir.

Sertraline

Potential risk of microscopic colitis

Australia. The TGA has announced that the PI for sertraline containing products (Zoloft® and generics) have been updated to include the potential risk of microscopic colitis.

Sertraline is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of obsessive compulsive disorder, social phobia and premenstrual dysphoric disorder.

The TGA received six cases of microscopic colitis suspected to be related sertraline (up until 20 May 2021).

Diarrhea is listed as a common adverse reaction with sertraline. If diarrhea is severe or prolonged, microscopic colitis should be considered.

Source: WHO Pharmaceuticals Newsletter No.4, 2021

In Nepal: Health care professionals are warned of the potential risk of microscopic

colitis with the use of Sertraline.

Tamoxifen

Contraception duration extended

Australia. The TGA has announced that the duration of contraception after finishing tamoxifen treatment has been extended from two months to nine months.

Tamoxifen is a selective estrogen receptor modulator and indicated for the treatment of breast cancer.

Tamoxifen is contraindicated in pregnancy and the possibility of pregnancy should be excluded before treatment is started.

A small number of reports of spontaneous abortions, birth defects and foetal deaths have occurred following the use of tamoxifen, although no causal relationship has been established.

Women should be informed about the potential risks to the foetus if they become pregnant while taking tamoxifen or within nine months of finishing treatment.

Source: WHO Pharmaceuticals Newsletter No.4, 2021
In Nepal: Health care professionals are warned of the Contraception duration extended with the use of Tamoxifen.

3. SAFETY OF MEDICINES

Propofol

Risk of green breast milk

New Zealand. The Medsafe has announced that the CARM received a report of a patient who expressed green breast milk post-surgery after using propofol as an anesthetic agent.

Propofol is indicated for induction and maintenance of general anesthesia in adults and children. It has been reported that propofol may discolor urine. Internationally, there are other case reports of green breast milk following administration of propofol. Health-care professionals are reminded to check the data sheet for information on breastfeeding following administration of propofol. Risk of green breast milk New Zealand. The Medsafe has announced that the CARM received a report of a patient who expressed green breast milk post-surgery after using propofol as an anesthetic agent. Propofol is indicated for induction and maintenance of general anesthesia in adults and children. It has been reported that propofol may discolor urine.

Internationally, there are other case reports of green breast milk following administration of propofol. Health-care professionals are reminded to check the data sheet for information on breastfeeding following administration of propofol.

Source: WHO Pharmaceuticals Newsletter No.2, 2021

In Nepal: Health care professionals are warned of the risk of green breast milk with the use of Propofol.

Clopidogrel

Potential risk of hypertension

Saudi Arabia.

The SFDA has released a potential safety signal concerning hypertension associated with the use of clopidogrel.

Clopidogrel is indicated for use in adult patients suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease. In 2020, the SFDA reviewed all the evidence available on the association between clopidogrel

and hypertension following an ICSR sent to the Saudi National Pharmacovigilance Centre.

Causality assessment of this case was associated with a positive dechallenge and was considered to be probable. In the WHO global database of ICSRs (VigiBase), 357 ICSRs were found for this drug/adverse drug reaction combination as of September. 2020.

The SFDA's investigation concluded that the current available evidence from assessment of the ICSRs might support a relationship between clopidogrel and hypertension. 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.3, 2021
In Nepal: Health care professionals are warned of the potential risk of hypertension with the use of Clopidogrel.

Amitriptyline

Potential risk of drug reaction with eosinophilia and systemic symptoms Saudi Arabia.
The Saudi Food and Drug Authority (SFDA) has released a potential safety signal about drug reaction with eosinophilia and systemic symptoms (DRESS) associated with the use of Amitriptyline.
Amitriptyline is a tricyclic antidepressant with sedative properties.

In 2021, the SFDA reviewed all the evidence available on the association between amitriptyline and DRESS after receiving an individual case safety report (ICSR).

The SFDA's investigation concluded that the current available evidence from assessment of the ICSRs might support a relationship between amitriptyline and DRESS. This potential 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.3, 2021
In Nepal: Health care professionals are warned of the potential risk of drug reaction with eosinophilia and systemic symptoms with the use of Amitriptyline.

Donepezil

Potential risk of QT prolongation

Saudi Arabia.

The SFDA has released a potential safety signal concerning QT prolongation associated with the use of donepezil.

Donepezil is indicated for symptomatic treatment of mild to moderately severe Alzheimer's dementia.

The SFDA has comprehensively reviewed all relevant data and evidence to evaluate this risk, which includes case-report analysis, data mining of the WHO global database of ICSRs, and relevant evidence from the literature. A total of 132 ICSRs were found globally in the WHO database of ICSRs in December 2020. Casualty assessments were made on a selection of good quality reports.

More than half of the selected ICSRs were assessed to have a supportive association (seven probable and 14 possible). Statistical data mining of reports in VigiBase showed that the number of observed cases was more than expected.

Multiple articles in the literature supported this association, and included evidence of a class effect and a published case-report for donepezil.

Health-care professionals should be aware of this potential risk and monitor any signs or symptoms in treated patients.

Source: WHO Pharmaceuticals Newsletter No.3, 2021

In Nepal: Health care professionals are warned of the potential risk of QT prolongation with the use of Donepezil.

Fluoroquinolones

Risk of heart valve regurgitation

Singapore. The Health Sciences Authority (HSA) has announced that the use of systemic fluoroquinolones is associated with a small increased risk of heart valve regurgitation.

Fluoroquinolones are indicated to treat infections such as acute sinusitis and acute bronchitis. There are seven systemic fluoroquinolones used in Singapore:

ciprofloxacin, ofloxacin, norfloxacin, lomefloxacin, levofloxacin, moxifloxacin and pefloxacin. Fluoroquinolones are known to increase the risk of collagen related disorders such as tendonitis, tendon rupture, and aortic aneurysm and dissection.

In September 2020, the EMA concluded that fluoroquinolone use may increase the risk of heart valve regurgitation, and as a result the EMA recommended that the existing warning on aortic aneurysm and dissection in the package inserts of systemic and inhaled fluoroquinolone-containing products should be expanded to include heart valve regurgitation.

The HSA has not received any local reports of heart valve related disorders associated with fluoroquinolone.

Health-care professionals are advised to take into consideration the risk when prescribing systemic fluoroquinolones and the availability of other therapeutic options for patients with pre-existing risk factors such as heart valve diseases, connective tissue disorders, hypertension or rheumatoid arthritis.

Source: WHO Pharmaceuticals Newsletter No.3, 2021
In Nepal: Health care professionals are warned of the risk of heart valve regurgitation with the use of Fluoroquinolones.

Theophylline

Potential risk of encephalopathy
Saudi Arabia.
The SFDA has released a potential safety signal concerning encephalopathy associated with the use of theophylline.

Theophylline is indicated for the treatment of the symptoms and reversible airflow obstruction associated with chronic asthma and other chronic lung diseases.

In 2021, the SFDA reviewed all the evidence available on the association between theophylline and encephalopathy following an ICSR sent to the Saudi National Pharmacovigilance Centre.

The SFDA's investigation concluded that further investigation to confirm this risk is needed, and health-care professionals should be aware of this potential adverse reaction.

Source: WHO Pharmaceuticals Newsletter No.3, 2021

In Nepal: Health care professionals are warned of the potential risk of encephalopathy with the use of Theophylline.

Colchicine

Risk of fatality if overdose

New Zealand.

The Medsafe has issued a warning reminding the public of the high risk of fatality with colchicine overdose and that there are no effective treatments available for severe colchicine poisoning.

Colchicine is indicated for the treatment of acute gout when nonsteroidal anti-inflammatory drugs are contraindicated, ineffective or not tolerated.

Although colchicine has a narrow therapeutic index with the well-defined separation between therapeutic and toxic doses, some clinical guidelines may refer to unapproved dosing schedules for colchicine.

From January 2016 to January 2021, the National Poisons Centre (NPC) received 56 cases related to colchicine poisoning.

The main reasons of the poisoning were child exploratory behavior, therapeutic error and intentional self-poisoning.

Health-care professionals should communicate with patients about the importance of storing medicines out of sight and reach of children and ensure patients know when and how to take colchicine.

Source: WHO Pharmaceuticals Newsletter No.4, 2021

In Nepal: Health care professionals are warned of the risk of fatality if overdose with the use of Colchicine.

4. Signal

A signal is defined by WHO as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

Levetiracetam and Hypokalaemia

Mónica Tarapués, Ecuador

Summary

Levetiracetam is considered a remarkable antiepileptic drug due to its mechanism of action, which is unrelated to the Na+ channels or to GABAergic transmission. Few interactions are described for this drug due to its minimal hepatic metabolism; however, sixty-six percent of its elimination depends on the renal function. Drug induced hypokalaemia is a hazardous reaction that could lead, in the worst cases, to death. A screening of VigiBase, the WHO global database of individual case safety reports, identified disproportionate reporting of the MedDRA Preferred Term (PT) "Hypokalaemia" with levetiracetam. A selection of the cases with a completeness score above 0.60 was made to analyse drug–reaction association patterns. A consistent time to onset and a biological plausibility support this signal. Through this analysis, it seems reasonable to consider the association between hypokalaemia and levetiracetam use. Currently, only the product information from Canada warns of hypokalaemia as an adverse reaction to levetiracetam, but all clinicians should be aware of this adverse event.

Introduction

In December 1999, levetiracetam was approved in the United States (US) as an antiepileptic drug for the treatment of adults with partial seizures, and approval by the European Union (EU) followed in September 2000. Around 2005, oral tablets and solutions were approved for children, and in 2006, it began to be used for the treatment of status epilepticus. At the time of writing, levetiracetam is indicated for the treatment of epilepsy in adults, adolescents, children, and infants. It is a pyrrolidone derivative (S-enantiomer of α-ethyl-2- oxo-1-pyrrolidine acetamide), chemically unrelated to existing antiepileptic active substances. Regarding its mechanism of action, it is well known that the

interaction is between levetiracetam and the synaptic vesicle protein 2A. In this way, it does not exhibit the classical action of other antiepileptic drugs because there is no effect on voltage dependent Na+ channels or GABAergic transmission. (1)

Hypokalaemia is a common and sometimes serious electrolyte imbalance. Its presence can aggravate the baseline clinical conditions of patients. The hypokalaemia categories are well known: mild with plasma levels of >3.0–3.5 mmol/L generally asymptomatic; moderate 2.5–3.0 mmol/L its symptoms are cramping, malaise, myalgia, weakness; and severe < 2.5 mmol/L associated with electrocardiogram changes (including ST segment depression, U-wave elevation, T-wave inversion), arrhythmias and paralysis. Drug-induced hypokalaemia could be associated with a decrease in potassium intake, or with increased potassium shifting (transcellular shifts). This electrolyte disbalance is commonly associated with diuretics, β2-receptor agonists drugs, corticosteroids, some antimicrobials, or high doses of insulin (2).

Reports in VigiBase

During 2017, the MedDRA Preferred Term "hypokalaemia" was highlighted for the drug levetiracetam in VigiBase, the WHO global database of individual case safety reports. This combination was kept under review in order to gather more cases. As of 15 September 2019, in an updated and extended search in the database, there were 74 reports of this drug–adverse drug reaction (ADR). Seventeen cases were suspected as duplicates; therefore, 57 were considered. Due to the high number of cases, an analysis of the reports with a completeness score over 0.6 was undertaken. In the present case series, 23 cases were evaluated.

The reports came from eight countries. Eleven patients were female, the other eleven were male, and gender was not specified in one report. The age was recorded in twenty-one patients. Ten out of twenty-one were adults, nine were elderly, one was aged 5, and one a new-born. More than half of the cases were submitted by physicians (sixteen reports). In fourteen cases the ADR was considered as serious, mainly because of prolonged hospitalization (eight cases), or concomitant medically important conditions (five cases). One case was reported as serious because the patient died. The summary of case characteristics is set out in Table 1.

Levetiracetam was the unique suspected drug in 14 reports, the therapeutic

indication being epilepsy (focal seizures, convulsions, partial seizures with secondary generalization). The time to onset was mentioned in eighteen reports, in seventeen cases a range from the same day up to two months was given. In one case the patient experienced the ADR after two years of treatment. Half of the patients had a time to onset around ten days after starting levetiracetam. The route of administration was mentioned in twenty reports, the more frequent being oral route (ten reports), followed by intravenous (nine) and transplacental (one). In the case of the transplacental route, it seems according to the narrative text that exposure of the new-born was during the pregnancy span. Regarding the concomitant medicines, hydrocortisone was reported as a co-suspected drug in two cases, however, in one report, the starting date was given in the same timeframe as levetiracetam. Lacosamide was also mentioned as co-suspected in two other cases, within the same timeframe as levetiracetam. In four reports the use of proton pump inhibitors such as esomeprazole (one as co suspected and another one as concomitant) and pantoprazole (two cases as concomitant) was mentioned.

Hypokalaemia was described as the single ADR in eleven cases. Hypomagnesemia was reported in four cases as a co-reported reaction, and in two of these cases, the starting dates mentioned were the same as hypokalaemia. Likewise, three reports mentioned diarrhoea, two during the same time period as hypokalaemia. The plasmatic level of potassium concentrations was registered in fourteen cases, with a range of 2.2 – 3.3 mmol/L, in all cases the levels being reported after the levetiracetam was started.

Levetiracetam was withdrawn from three patients and the dose reduced in another one, all these being reported as recovered. In ten patients the dose was not changed, and of these, four were described as recovered, another four as recovering, one as not recovered, and for the last one the outcome was unknown. Sixteen cases had a narrative; in seven of these a supplement of potassium was mentioned. One patient died; this was an elderly person (aged 83), with co-reported ADRs pneumonia, atrial fibrillation, tachycardia, hypoproteinaemia, hypoalbuminemia, and blood lactate dehydrogenase increased, but there was no narrative. It is difficult to attribute the fatal outcome to the hypokalaemia.

Literature and Labelling

The literature suggests that levetiracetam is widely used due to high tolerability comparing favourably with other antiepileptic drugs used in epilepsy, and because it can be used when other drugs are contraindicated or patients have a refractory condition to other antiepileptics. (1)

Sixty-six percent (66%) of levetiracetam is excreted unchanged by glomerular filtration in the kidney, with subsequent tubular reabsorption, as well as its primary metabolite (ucb L057). The plasma half-life of levetiracetam across studies is 6 to 8 hours, however the labelling mentions it could be greater in subjects with renal impairment and in the elderly, primarily due to impaired renal clearance. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore a 50% reduction of the daily maintenance dose is recommended when the creatinine clearance is <60 mL/min/1.73m2.(3,4)

The Summary of Product Characteristics (SPC) of levetiracetam in the US and Europe does not list hypokalaemia as an ADR. However, the SPC in Canada mentions hypokalaemia as an ADR observed in the post-marketing surveillance. (5–8)

In the literature, a case report published in 2014 from Turkey described a 23-year-old man where hypokalaemia was found during routine blood tests six weeks after taking 500 mg levetiracetam twice daily. After the nephrology consultation, his hypokalaemia (3.1 mmol/L; normal: 3.5–5.5 mmol/L) and hypomagnesaemia (0.56 mmol/L; normal: 0.75–1.30 mmol/L)) were considered to be associated with levetiracetam; it was withdrawn and the electrolytes returned to normal after two weeks.(9) In 2015 a publication from Greece described hypokalaemia and hypomagnesemia associated with levetiracetam in two patients. A 90 year-old female patient had received levetiracetam 500 mg twice daily intravenously; two days later a low plasma level of potassium and magnesium were identified (2.4 mmol/L, and 0.58 mmol/L, respectively). The other patient was a 79 year-old female who had been administrated levetiracetam at 1 gr twice daily intravenously, and three days later the level of potassium was 2.4 mmol/L and magnesium 1.35 mg/dL. Despite the potassium supplement at the hospital, the patients did not fully recover, and consequently levetiracetam was withdrawn.(10) In 2018, another case from Turkey described a 34 year-old woman who was admitted to hospital after attempting to commit suicide. In the laboratory test hypokalaemia (3.1 mEq/lt) and hypomagnesemia

(1.2 mg/dl) were observed; the patient was taking 2500 mg/day levetiracetam for epilepsy although the duration of treatment was not described.(11) These publications suggest that the hypokalaemia observed could be due to a transcellular shift mechanism, an unknown side effect of the levetiracetam, given that they ruled out other potential causes such as metabolic alkalosis or gastrointestinal losses. (9–11)

Discussion and Conclusion

In this case series, it is difficult to rule out other potential causes as there is a lack of information regarding the baseline condition of the patients. However, the association should be considered, given the high suspicion of the reporters and the fourteen reports where levetiracetam was the only drug mentioned. On the other hand, diarrhoea – another potential cause – was only mentioned in two cases. It is worth noting that the time to onset in most cases (twelve patients out of twenty-three) was within ten days after starting levetiracetam.

Regarding other drugs that can be associated with hypokalaemia, corticosteroids, and methylxanthines are strongly associated with drug-induced hypokalaemia and other electrolyte imbalances.(2) In one patient, hydrocortisone and theophylline were reported as co-suspected drugs. However, levetiracetam was used in the same temporal sequence of these drugs, and for that reason it is not possible to rule out their potential association with hypokalaemia.

Magnesium deficiency exacerbates potassium wasting by increasing distal potassium secretion. However, hypomagnesemia alone does not necessarily cause hypokalaemia.(12) In this case series, four patients had hypomagnesemia, but in two cases the starting dates were unknown and in the other two cases, they had the same starting date as hypokalaemia, making the analysis of the potential causal relationship between hypomagnesaemia and hypokalaemia difficult. Then again, there are several reports regarding the association of proton pump inhibitors and hypomagnesemia.(13,14) Esomeprazole was mentioned as a co-suspected drug for hypokalaemia and hypomagnesemia in one patient. This potential interaction needs further analysis in large studies.

In a prospective study of 32 children in Greece (18 females, 14 males, mean age 5.94 ± 4.1 years, range 1- 15 years) being treated with levetiracetam for the onset of epilepsy, no statistical differences were observed in the alteration of serum sodium, potassium, and magnesium from two to six months with the use

of levetiracetam.(15) However, the authors point to the small number of patients studied as a major limitation of their study, and suggest that the young age of patients may have played a protective role in the prevention of electrolyte imbalance. Following clinical trials made in this age group, levetiracetam has been authorized for use in children, and is therefore considered a safe therapeutic option for this group of patients.(16) However, our sample has two patients under 18 years old, even one case of a new-born patient with hypokalaemia.

In the twenty-three patients, only four had their dose of levetiracetam reduced or withdrawn, and these patients were reported as recovered. However, some patients started with the potassium supplement, such as in three cases reported as recovered, despite no change in the dose of levetiracetam, nor withdrawal. In the same way, in two other patients in whom the action with levetiracetam was reported as unknown, the outcome was reported as recovered. It is important to consider the treatment received for this ADR, and whether patients would have an asymptomatic hypokalaemia; the dechallenge as an outpatient could be difficult to identify and report, because the levels of potassium could return to normal two to four weeks after withdrawal, and the reporter might not have had this information at the time that they sent the report.

The biological plausibility comes through a transcellular shift imbalance of potassium, as discussed in the case reports.(9–11) This hypothesis goes in tandem with the alterations of the potassium homeostasis described as a cause of drug-induced hypokalaemia.(17,18) A previous signal regarding acute renal failure associated with levetiracetam was published in 2016 by Uppsala Monitoring Centre; this ADR is already mentioned in the US SPC as an ADR identified in post-marketing surveillance, and in the EU SPC as having a rare frequency.(19) The occurrence of renal adverse effects seems reasonable, based on to levetiracetam pharmacokinetics.

In conclusion, patients being treated with levetiracetam should be closely monitored for changes in their potassium levels. Our analysis, and the available evidence based on the pharmacokinetics of the drug, suggest a potential causal relationship between levetiracetam and hypokalaemia. Current product information for levetiracetam does not sufficiently inform physicians about electrolyte imbalance, and the product labelling may need to be revised worldwide since the Canadian SPC already includes hypokalaemia as an ADR identified in post-marketing (6).

Table 1. Summary characteristics of 57 case reports in VigiBase of hypokalaemia in association withLevetiracetam in VigiBase

Characteristic	**23 cases with high completeness score(above 0.6)**	**34 cases with low completeness score(less than 0.59)**
Age (median / range)	57 years / 0* - 90 years	45 years / 5 – 87 years
Patient sex distribution	11 female / 11 male / 1 unknown	21 female / 13 male
Geographical spread	India (n=7), Germany (n= 4), Italy (n=3), Japan (n=3), Greece (n=2), France (n=2), USand Ireland (n=1 each)	US (n=17), Germany (n=6), United Kingdom n=2 and Italy, Korea, Japan, Turkey, Denmark,France, Hungary, Belgium , Ireland (n= 1 each)
Reporter types	16 physicians; 4 pharmacists; 3 other health professionals	17 physicians; 3 pharmacists; 9 other health professionals; 2 consumers; 3 unknown
Single suspect drug	14 reports	9 reports
Single reported drug	7 reports	4 reports
Category of hypokalaemia	3 reported as mild, 7 reported as moderate, 4reported as severe, 9 reports unknown	5 reported as mild, 1 reported as severe, 28 reports unknown
Time-to-onset	Mentioned in 18 reports with a median of 10days 12 reports after 1 to 10 days, 3 reports after 11 to 20 days, 2 report after 60 days, 1 report after 2 years	Mentio ned in 2 reports 30 and 60 days
Withdrawn/recovered	1 report with dose reduced, 3 reports with drugwithdrawn and all with reaction abated 8 reports with dose not	1 report with drug withdrawn and the reactionabated

	changed and reactionabated or in recovering	

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Source: WHO Pharmaceuticals Newsletter No.3, 2021

5. आ.व. २०७७/७८ मा Recall गरिएका औषधिहरुको विवरण

S. No.	Brand Name	Batch No	Mfg Date	Expiry Date	Manufacturer
1	Ben-A 400 Tablet (Albendazole)	T05980 59	Aug-18	Aug-21	ACME Laboratories, Dhaka, Bangladesh
2	Routin 10 Tablet (Rosuvastatin)	ROT 06	Dec-18	Nov-20	CTL Pharmaceuticals Pvt LTd., Bhaktapur
3	Alcox 250 Capsule (Cloxacillin)	BC104 8	Oct-18	Sep-20	Leben Laboratories Pvt Ltd, India
4	Eloz-100 Capsule (Itraconazole)	058023	Sep-20	Aug-20	Maruti Pharma Pvt Ltd, Bara
5	Eloz-100 Capsule (Itraconazole)	058025	Apr-19	Mar-21	Maruti Pharma Pvt Ltd, Bara
6	Eloz-200 Capsule (Itraconazole)	ELC-18007	Sep-18	Aug-20	Maruti Pharma Pvt Ltd, Bara
7	Eloz-200 Capsule (Itraconazole)	ELC-18009	Nov-18	Oct-20	Maruti Pharma Pvt Ltd, Bara
8	Aciloc 25mg/ml Injection (Ranitidine)	19075	Nov-19	Oct-22	Cadila Pharmaceuticals, India
9	Safe Hand 200 ml (Ethyl alcohol IP 80% v/v, in water soluble base)	GSH-001	Apr-20	Mar-21	Prime Pharmaceuticals Pvt.Ltd., Nepal
10	Hand Rub Instant Hand Sanitizer, 1 Ltr. (Ethyl Alcohol 75%, Glycerin 1.45%, Hydrogen Peroxide 0.125%, Distilled water 21.8%)	001	Jun-20	May-22	Himalayan Sherpa Herbs Pvt. Ltd., Nepal
11	Alexofen-120 Tablet (Fexofenadine Hydrochloride Tablets USP)	ALE 33	Dec-19	Nov-21	CTL Pharmaceuticals Pvt LTd., Bhaktapur,Nepal

12	Calcigen-F Tablet (Calcium Carbonate BP eq to Elemental calium 500 mg and Colecalciferol BP 250 IU))	CVD3-110	Feb-22	Jan-22	Nova Genetica Pvt.Ltd., Nepal
13	Calcigen-F Tablet (Calcium Carbonate BP eq to Elemental calium 500 mg and Colecalciferol BP 250 IU))	CVD3-109	Feb-22	Jan-22	Nova Genetica Pvt.Ltd., Nepal
14	Trace-100 Capsule (Itraconazole Capsules)	ICC-10	Mar-19	Feb-21	Nova Genetica Pvt.Ltd., Nepal
15	ACLOV 200 Tablet (Acyclovie Tablets)	AV1-0119	Jan-19	Dec-20	Lomus Pharmaceuticals Pvt.Ltd., Nepal
16	ENVAS 2.5 Tablet (Enalapril Maleate Tablets IP)	JK 19004	Jun-19	May-21	Cadila Pharmaceuticals Limited , India
17	Rabi 20 Tablet (Rabeprazole Tablets IP)	RBT9039	Feb-19	Jan-21	Qmed Formulations Pvt.Ltd., Bhaktapur, Nepal
18	Acifix Tablet (Rabeprazole Sodium 20 mg Tablets IP)	TAC2-015	Aug-19	Jul-21	Curex Pharmaceuticals Pvt.Ltd., Kavre, Nepal
19	MLT 10 Tablet (Montelukast Tablet IP)	TML1-009	Nov-19	Oct-21	Curex Pharmaceuticals Pvt.Ltd., Kavre, Nepal
20	Proton-P Tablet (Pantoprazole Sodium Delayed Release Tablet USP 40 mg)	0781	Jan-20	Dec-21	Reliance Formulation Pvt.Ltd., India
21	FEXHIST Oral Suspension (Fexofenadine Hydrochloride Oral Suspension)	LFH76001	Aug-19	Jul-21	Prime Pharmaceuticals Pvt.Ltd., Nepal
22	Gastogel Suspension Oral Suspension ()	GSL 7051	Jun-20	May-23	Bhaskar Herbaceuticals Pvt.Ltd., Nepal

23	Lipilage-10 Tablet (Atorvastatin Tablets IP)	LIP 28	Jul-19	Jun-21	CTL Pharmaceuticals Pvt.Ltd., Nepal
24	Irgonol-200 Capsule (Intraconazole Capsules)	JY19002	Jul-19	Jun-21	Magnus Pharma Pvt.Ltd.,Nepal
25	Inox Capsule (Intraconazole Capsules BP)	INC 947	Feb-20	Jan-22	Amtech Med.Pvt.Ltd., Nepal
26	Inox Capsule (Intraconazole Capsules BP)	INC 946	Nov-19	Oct-21	Amtech Med.Pvt.Ltd., Nepal
27	Itac Capsule (Intraconazole Capsules)	IT1902	Aug-19	Jul-21	Biogain Remedies Pvt.Ltd.,Nepal
28	Syntran-200 Capsule (Intraconazole Capsules BP)	FSYC 67002	Oct-19	Sep-21	Arya Pharmalab Pvt.Ltd., Nepal
29	ACTICET Tablet (Ibuprofen Paracetamol Tablets IP)	ACT67012	Mar-20	Feb-23	Arya Pharmalab Pvt.Ltd., Nepal
30	Clean Well Instant Hand Sanitizer, 500 ml (Ethyl Alcohol 70% w/v)	FAHS20	Apr-20	Mar-21	Arya Pharmalab Pvt.Ltd., Nepal
31	Clean Well Instant Hand Sanitizer, 100 ml (Ethyl Alcohol 70% w/v)	AAHS27	Apr-20	Mar-21	Arya Pharmalab Pvt.Ltd., Nepal
32	Dabur (Instant Hand Sanitizer, 75 ml) (Ethyl Alcohol 80% v/v, Glycerin 1.45 v/v, Hydrogen Peroxide 0.125 % v/v, Purified Water q.s)	NB00005	Jun-20	May-21	Dabur Nepal Pvt.Ltd., Nepal
33	Dabur (Instant Hand Sanitizer, 1 litre) (Ethyl Alcohol 80% v/v, Glycerin 1.45 v/v, Hydrogen Peroxide 0.125 % v/v, Purified Water q.s)	NB00005	Jun-20	May-21	Dabur Nepal Pvt.Ltd., Nepal

34	Neolore Injection (Lorazepam Injection IP)	NA5791	Feb-19	Apr-22	Neon Laboratories Limited., Bosar Road, Unit 401404, M.S.
35	Syno-Pill Tablet (Combipack of Mifeprostone Tablets IP and Misoprostol Tablets IP)	E0S2HTA012	Aug-20	Jul-22	Synokem Pharmaceuticals Limited, India
36	Aflam Oral Suspension (Ibuprofen and Paracetamol Suspension)	ALL913	Oct-19	Sep-21	Amtech Med.Pvt.Ltd., Nepal
37	Wormout Oral Suspension (Albendazole Oral Suspension USP)	LAD76005	May-20	Apr-22	Prime Pharmaceuticals Pvt.Ltd., Nepal

6. आ.व. २०७७/७८ मा Hand Sanitizer को नमुना संकलन गरि परीक्षण गर्दा Methanol मिश्रित तथा न्यून गुणस्तरका Hand Sanitizer को विवरण

S. No.	Brand Name	Batch No	Mfg Date	Expiry Date	Reason for Non-compliance	Manufacturer
1	Gloria Dew Cosmetics Instant Hand Sanitizer	03	Mar-20	Mar-22	contains methanol	Nepal Kayakalpa Udhyog, Nepal
2	Hygiene Spray, Instant Hand Sanitizer Original 50 ml	NM	May-20	Apr-23	contains methanol	Hygiene Soap amd Chemical Pvt.Ltd., Nepal

3	Suryamukhi Advance Hand Sanitizer 500 ml	06	Aug-20	Jul-23	contains methanol	Suryamukhi Herbal Products., Nepal
4	Aerosoft Hand Sanitizer Refreshing Gel 300 ml	NM	Apr-20	Apr-22	contains methanol	Search Chem Cum Herbal Products, Nepal
5	Advanced Hand Sanitizer with Vitamin E, 100 ml	HS - 06	Aug-20	Jul-22	contains methanol	Adhar Chemicals & Food Industry Pvt.Ltd., Nepal
6	Opekal Non-washing antibacterial Soluation 120ml	NM	May -20	May-22	contains ethanol (68% v/v)	Guangzhou Obopekal Fine Chemical Co.Ltd., Guangzhou, China
7	Sasa Instant Hand Sanitizer 50ml	NM	Mar-20	Feb-23	contains ethanol (13.78%v/v) and methanol (39.434%v/v)	Samapada Heathcare Pvt.Ltd., Nepal
8	Pamacare Instant Hand Sanitizer 60ml	252	Jul-20	Jun-22	contains ethanol (66% v/v)	RL Crop India, Valsad, India

9	Unicare Instant Hand Sanitizer 65 ml	UN H50 1	Mar-20	Feb-23	contains ethanol (55% v/v)	Shreenath Herbal & Cosmetic Industry (P.)., Ltd, Nepal
10	Herbaltree Hand Rub 500ml	273	Aug-20	Jul-23	Contains Methanol (62% v/v)	Shivika Cosmeceuticals India Pvt.Ltd., India
11	Kum Hand Sanitizer 5 Ltr.	03	Mar-20	Feb-22	Contains Isoporpyl Alcohol (25 % v/v)	R. Chemical & Packaging Industries, Nepal
12	Clean Hand Sanitizer 5 lit.	03	Mar-20	Feb-22	Contains Methanol (8% v/v), Ethanol	R. Chemical & Packaging Industries, Nepal
13	Instant Hand Sanitizer Gel, 5 ltr.	01	Aug-20	Jul-22	Contains Methanol (72% v/v)	Kumkum Herbal Industries Pvt.Ltd., Nepal
14	Kumkum Instant Hand Sanitizer Gel 500ml	01	Jul-20	Jun-22	Contains Methanol (52% v/v)	Kumkum Herbal Industries Pvt.Ltd., Nepal
15	Instant Hand Sanitizer Original , 1 ltr Gel 5 Litre	OA-08	Jun-20	Jan-22	Contains Methanol (75 % v/v)	Om Arogya Healthcare Pvt.Ltd., Nepal

16	Sadhana Instant Hand Sanitizer, 5 Lit.	05	Aug-20	Aug-22	Contains Methanol (41 % v/v),	Sudhana Suppliers, Nepal
17	Drone Hand Sanitizer, 500 ml	05	Sep-20	Aug-22	Contains Methanol (32 % v/v), Ethanol (9% v/v), Isopropyl Alcohol (31 % v/v), pH: 9.51	Kalika Soap and Chemicals Pvt.Ltd., Nepal
18	Drone Hand Sanitizer, 500 ml	05	Sep-20	Aug-22	Contains Methanol (33 % v/v), Ethanol (10% v/v), Isopropyl Alcohol (32 % v/v), pH: 9.45	Kalika Soap and Chemicals Pvt.Ltd., Nepal
19	Aerosoft Instant Hand Sanitizer, 5 Ltr.	SI5L 202008	Aug-20	Aug-22	contains methanol (47%)	Susankya Industries Pvt.Ltd., Kathmandu,Nepal

7. REGULATORY NOTICES

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

कोभिड-१९ खोपको आपतकालीन प्रयोग अनुमति प्रदान गरिएको सम्वन्धमा

Oxford University बाट विकसित भएको AstraZeneca AB को AstraZeneca AZD1222 (ChAdOx1 nCoV-19 Corona Virus Vaccine(Recombinant)) (COVID-19 Vaccine AstraZeneca) खोपलाई विश्व स्वास्थ्य संगठनले आपतकालीन प्रयोगको लागि सुचिकृत गरिसकेको र नेपालमा कोभिड-१९ विरुद्ध सो खोपको आपतकालीन प्रयोगका लागि औषधि (तेस्रो संशोधन) अध्यादेश, २०७७ को दफा ९क, र औषधि वा खोपको आपतकालिन प्रयोग सम्बन्धी (पहिलो संशोधन) संहिता, २०७८ को दफा ४क., दफा ११ (च) बमोजिम मिति २०७८/०३/१५ को विभागीय निर्णयानुसार कोभ्याक्स सुविधामार्फत नेपाल सरकारलाई प्राप्त भएको AstraZeneca को खोपको आपतकालीन प्रयोगका लागि अनुमति प्रदान गरिएको व्यहोरा सम्वन्धित सबैको जानकारीका लागि अनुरोध छ ।

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

कोभिड-१९ खोपको आपतकालीन प्रयोग अनुमति प्रदान गरिएको सम्वन्धमा

Janssen-Cilag International NV, Belgium को Janssen AD26COV2.S Vaccine लाई विश्व स्वास्थ्य संगठनले आपतकालीन प्रयोगको लागि सुचिकृत गरिसकेको र नेपालमा कोभिड-१९ विरुद्ध सो खोपको आपतकालीन प्रयोगका लागि औषधि (तेस्रो संशोधन) अध्यादेश, २०७७ को दफा ९क, २०७७ र औषधि वा खोपको आपतकालिन प्रयोगसम्बन्धि (पहिलो संशोधन) संहिता, २०७८ को दफा ४क., दफा ११ (च) बमोजिम मिति २०७८/०३/१६ को विभागीय निर्णयानुसार कोभ्याक्स सुविधामार्फत नेपाल सरकारलाई प्राप्त भएको Janssen AD26COV2.S खोपको आपतकालीन प्रयोगका लागि अनुमति प्रदान गरिएको व्यहोरा सम्वन्धित सबैको जानकारीका लागि अनुरोध छ ।

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/०४/२९

यस विभागमा प्राप्त सूचनाका आधारमा निरीक्षण अनुगमनको क्रममा बजारमा बिक्रि बितरणमा रहेका तपसिल अनुसारका औषधिमा labelling error भएको पाइएकोले सो औषधि प्रयोग नगर्न/नगराउनुहुन र साथै सो औषधिको बिक्रि बितरण अबिलम्ब रोक्का राखी सम्बन्धित आपूर्तिकर्तालाई फिर्ता गर्न सम्पूर्ण सरोकारवालाहरुलाई सुचित गरिन्छ ।

तपसिल:

उत्पादनको नाम	उत्पादकको नाम र ठेगाना	ब्याच नः/उत्पादन मिति/म्याद सकिने मिति	कारण
Uzoline - 1000 (Cefazolin for Injection USP 1000 mg and Sterilized water for injections BP 5 ml)	Umedica Laboratories Pvt. Ltd., plot no: 221, G.I.D.C., Gujarat, India	Batch no: V30041 Mfg. Date:05/2020 Exp. Date: 04/2023	Labelling error

२०८०।०१।२८

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०५/३१

आ.व. २०७८/७९ श्रावन महिनामा निलम्बनको कारवाहिमा परेका औषधि पसलहरुको विवरण

औषधि ऐन २०३५ को दफा २० को उपदफा ४(क) अनुसार तपशिल बमोजिमका औषधि पसलहरु निलम्बनको कारवाहिमा परेकाले सर्वसाधारणको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ ।

क्र. सं.	औषधि पसलको नाम/ठेगाना	धनी/व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१।	श्री प्रविन मेडिकल हल, का.म.न.पा.-२६,काठमाडौं	श्री प्रविन श्रेष्ठ (ए १३७)	२०७८।०३।२७	१५
२।	श्री भाजुरत्न फर्मा प्राइभेट लिमिटेड (र.प.नं. ७००१) विरगंज-१३,(हाल विरगंज महानगरपालिका वडा नं.१४) पर्सा	शेखर प्र. श्रेष्ठ (११०६/०४७/४८), महेश्वर हाडा (३०७०/०५४/०५५)	२०७८।०४।०१	९०
३।	नतुन फर्मा, र.प.न. ३७०५२३०३५२४८ गोकर्णेश्वर - ०९, आरुवारी, काठमाण्डौ ।	श्री गंगाराम पाण्डे व्य.मा.प्र. ३८५८।०५४।५५	२०७८।०४।२८	२१
४।	चौलागाई फर्मा, र.प.न. ३७२०५२३०३२९४९ गोकर्णेश्वर-१२, काठमाण्डौ ।	श्री बलराम शर्मा	२०७८।०४।२८	१५
५।	सर्वोच्च मेडिकल हल, र.प.न. ३७७०९०१०६१३१४ गोकर्णेश्वर-०९, काठमाण्डौ ।	श्री कृष्ण ठाकुर बरही (धनी) श्री विन्दु वि.क. (व्यवसायी/ए ७९६२)	२०७८।०४।२८	१५
६।	ग्रिसा फार्मेसी ३७५०९०८०६४२५९ गोकर्णेश्वर-०६, तिनचुलि काठमाण्डौ ।	श्री गिता शाहि (धनी) श्री मञ्जु वडाल (व्यवसायी/ए २९५८)	२०७८।०४।२८	१५

५/३१
महानिदेशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०५/३१

आ.व. २०७८/७९ श्रावन महिनामा निलम्बनको कारवाहिमा परेका औषधि उद्योगको विवरण

औषधि ऐन २०३५ को दफा २० को उपदफा ४(क) अनुसार तपशिल बमोजिमका औषधि उद्योगहरु निलम्बनको कारवाहिमा परेकाले सर्वसाधारणको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ ।

क. सं.	औषधि पसलको नाम/ठेगाना	विभागको निर्णय मिति	निलम्बन दिन
१	श्री प्राकृतिक हर्बास्युटिकल्स प्रा.ली, गोदावरी-१०, चापागाउँ, ललितपुर	२०७८।०४।२७	३०

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०५/२३

Pfizer-BioNTech COVID-19 mRNA (COMIRNATY) खोपको आपतकालीन प्रयोग अनुमति प्रदान गरिएको सम्वन्धमा

Pfizer-BioNTech COVID-19 mRNA (COMIRNATY) खोपलाई विश्व स्वास्थ्य संगठनले आपतकालीन प्रयोगको लागि सुचिकृत गरिसकेको र USFDA बाट उक्त खोपको BLA APPROVAL (BL 125742/0) प्रदान भएको र नेपालमा कोभिड-१९ विरुद्ध सो खोपको आपतकालीन प्रयोगका लागि औषधि (तेस्रो संशोधन) अध्यादेश, २०७७ को दफा ९क, २०७७ र औषधि वा खोपको आपतकालिन प्रयोग सम्बन्धि (पहिलो संशोधन) संहिता, २०७८ को दफा ४क., दफा ११ (ग) बमोजिम मिति २०७८/०५/२३ को विभागीय निर्णयानुसार कोभ्याक्स सुविधामार्फत नेपाल सरकारलाई उपलब्ध हुने भनिएको Pfizer-BioNTech COVID-19 mRNA Vaccine (COMIRNATY) खोपको आपतकालीन प्रयोगका लागि अनुमति प्रदान गरिएको व्यहोरा सम्वन्धित सबैको जानकारीका लागि अनुरोध छ।

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०५/३०

Moderna COVID-19 mRNA खोपको आपतकालीन प्रयोग अनुमति प्रदान गरिएको सम्वन्धमा

Moderna COVID-19 mRNA खोपलाई विश्व स्वास्थ्य संगठनले आपतकालीन प्रयोगको लागि सुचिकृत गरिसकेको र USFDA बाट उक्त खोपको Emergency Use Authorization (EUA) प्रदान भएको र नेपालमा कोभिड-१९ विरुद्ध सो खोपको आपतकालीन प्रयोगका लागि औषधि (तेस्रो संशोधन) अध्यादेश, २०७७ को दफा ९क, २०७७ र औषधि वा खोपको आपतकालिन प्रयोग सम्बन्धि (पहिलो संशोधन) संहिता, २०७८ को दफा ४क. र दफा ११ (ग) बमोजिम मिति २०७८/०५/३० को विभागीय निर्णयानुसार COVAX FACILITY बाट Cost Sharing आधारमा नेपाललाई उपलब्ध हुने भनिएको Moderna COVID-19 mRNA Vaccine खोपको आपतकालीन प्रयोगका लागि अनुमति प्रदान गरिएको व्यहोरा सम्बन्धित सबैको जानकारीका लागि अनुरोध छ ।

०७८।५।३०
महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था बिभाग

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरूरी सूचना

प्रकाशित मितिः २०७८/०६/१३

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

तपसिलः

सि. न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	LEVOSAFE-500 (Levofloxacin 500mg Tablets IP)	LVT11017	Jan-2021/ Dec-2022	Does not Comply to IP 2018 with respect to Dissolution Test	Qmed Formulation Pvt. Ltd., Chhaling-5, Bhaktapur, Nepal
2.	ZEFIX-100 (Cefixime 100 mg Dispersible Tablets IP)	ZX 0220	Nov-2020/ Oct-2022	Does not Comply to IP 2018 with respect to Disintegration Test	Lomus Pharmaceuticals Pvt. Ltd., Gothatar, Kathmandu, Nepal

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

औषधिको मूल्य सम्बन्धी प्रकाशित समाचार सम्बन्धमा विभागको विज्ञप्ति

औषधिको मूल्य बृद्दी सम्बन्धी केहि Online पत्रिकामा हालै प्रकाशित समाचार प्रति विभागको गम्भीर ध्यानआकर्षण भएको छ । सो समाचार गलत र भ्रमपूर्ण रहेकोले देहाएको तथ्यबाट अवगत हुन सर्वसाधारण तथा सबै सरोकारवालाहरुमा अनुरोध छ ।

१. औषधि ऐन, २०३५ को दफा २६ मा विभागले आवश्यक देखेमा नेपाल सरकारको स्वीकृति लिई औषधिको मूल्य निर्धारण गर्न सक्ने व्यवस्था रहेकोमा हालसम्म विभिन्न ९६ प्रकारका औषधिहरुको मिति २०७२/०४/१८ मा नेपाल राजपत्रमा प्रकाशित गरी तथा २१ प्रकारका औषधिहरुको प्रक्रिया पुरा गरी विभिन्न मितिमा राष्ट्रिय दैनिकमा सार्वजनिक सूचना प्रकाशित गरि मूल्य निर्धारण गरिएको छ । सो बाहेक नेपाल सरकारले अन्य कुनै औषधिहरुको मूल्य निर्धारण गरेको छैन ।

२. औषधिको मूल्य निर्धारण गर्दा औसत (Mean), मध्यम (Median) तथा सम्बन्धित देशको सन्दर्भ मूल्य (Reference Price) समेतलाई आधार मानी बजारमा आधारित भई मूल्य निर्धारण गर्ने बिधि तयार गरी लागू गर्न औषधि परामर्श परिषदको १४ औ बैठकले सिफारिस गरको छ । सोहि मर्म अनुसार हुने गरि विभागले दर्ता र नविकरण गर्दै आएको छ ।

३. नेपाल सरकारले मूल्य निर्धारण गरेका बाहेक अन्य औषधिहरुको मूल्य स्वयं उत्पादकहरुले नै निर्धारण गर्दै औषधि बजारीकरण भई आएकोमा सोलाई नियन्त्रण गर्न र औषधिको मूल्यलाई पारदर्शी, बैज्ञानिक तथा तथ्यमा आधारित बनाउन विभागले मिति २०७४/१२/१२ को मूल्य अनुगमन समितिको बैठकले सिफारिस गरे बमोजिम त्यस्ता औषधिहरुको सिफारिसपत्र तथा प्रमाणपत्रहरुको नबिकरण गर्दा अधिकतम खुद्रा मूल्य वृद्धि भएको अवस्थामा मूल्य निर्धारण कार्यबिधि स्वीकृत भई लागू नभएसम्म साबिकको अधिकतम खुद्रा मूल्यमा १०% भन्दा नबढ्ने गरी नियन्त्रण गर्ने प्रक्रिया अबलम्बन गरी आएकोछ ।

४. कुनै पनि औषधिको मूल्य सम्बन्धित देशको सन्दर्भ मूल्य (Reference Price) मूल्यभन्दा बढी अधिकतम खुद्रा मूल्य कायम गर्न अनुमति दिएको छैन ।

५. विभागले सुनियत राखी अपनाई आएको बिधिलाई तथ्यको रामरी अध्ययन नगरी गलत र भ्रमपूर्ण सामाचार सम्प्रेषण भएकोले सो समाचार यथार्थ परक नरहेकोले औषधिको मूल्य सम्बन्धमा कोहि कसैलाई केहि बुझ्नु परेमा औषधि व्यवस्था विभागमा सम्पर्क गर्नहुन अनुरोध छ । साथै विभागमा आधिकारीक रुपमा बुझेर मात्र यथार्थ समाचार सम्प्रेषण गर्न समेत सम्बन्धित सबैलाई अनुरोध छ ।

२०८०/०६/१९

सन्तोष के.सी.

वरिष्ठ औषधि व्यवस्थापक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०६/०६

औषधिको विशेष सिफारिशको लागि आवेदनसँग संलग्न गर्नुपर्ने कागजातहरुको checklistका सम्वन्धमा

यस विभागले औषधिको बिशेष सिफारिश सम्बन्धि (पहिलो संशोधन) कार्यविधि, २०७७ अनुसार विरामीको उपचारको लागि अति आवश्यक पर्ने औषधिहरुको पैठारी गर्न विशेष सिफारिश मार्फत पैठारी अनुमति प्रदान गर्दै आएकोमा मिति २०७८/०६/०६ को विभागीय निर्णय अनुसार आईन्दा विशेष सिफारिशको लागि आवेदन गर्दा "औषधिको विशेष सिफारिशको लागि आवेदनसँग संलग्न गर्नुपर्ने कागजातहरुको Checklist" र Checklist मा उल्लेख भए अनुसारका कागजात पेश गर्नुहुन र यस अघि आयातकर्ताहरुले विभागमा पेश गरेका आवेदनहरुको हकमा समेत Checklist र सो अनुसारका कागजातहरु अद्यावधिक गर्नुहुन सम्पूर्ण सरोकारवालाहरुको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ ।

०८/०६/०६

संग्लनः

औषधिको विशेष सिफारिशको लागि निवेदनसँग संलग्न गर्नुपर्ने कागजातहरुको Checklist – पाना २

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

फोन नं.: ४७८०२२७, ४७८०४३२
फ्याक्स नं.: ९७७-१-४७८०५७२
पोष्ट बक्स नं.: १००३८

मदन भण्डारी पथ
बिजुलीबजार, काठमाडौं, नेपाल

पत्र सङ्ख्या: ०७८/७९
चनाली नं.:

क्याटलग/ब्रोसर सपिङ्ग विधिबाट सवारी साधन (स्कुटर) खरिद सम्बन्धी सिलबन्दी प्रस्ताव आह्वानको सूचना

प्रस्ताव नम्बरः DDA/CS/01/078-79 **प्रथम पटक प्रकाशन मितिः २०७८/०६/०९**

यस विभागको आ.व. ०७८/०७९ को स्वीकृत वार्षिक कार्यक्रम अनुसार सवारी साधन (स्कुटर थान ३) सार्वजनिक खरिद ऐन, २०६३ को दफा ८ को उपदफा १ को खण्ड "क" को नं. ८ र सार्वजनिक खरिद नियमावली, २०६४ को नियम ३१ (ख) बमोजिम उत्पादक कम्पनी वा त्यसको आधिकारिक विक्रेताहरुबीच मात्र प्रतिस्पर्धा गराउने क्याटलग सपिङ विधिबाट खरिद गर्नुपर्ने भएकोले तपसिल बमोजिम सिलबन्दी प्रस्ताव पेश गर्न सम्बन्धित उत्पादक कम्पनी वा सोको आधिकारिक विक्रेताहरुको जानकारीको लागि यो सूचना प्रकाशन गरिएको छ ।

सि.नं.	साधनको नाम	संख्या	संक्षिप्त विवरण (Brief Specifications)	कैफियत
१.	स्कुटर	३ (तीन)	**Type: Scooter** **Engine: 125 ± 3 cc Capacity** **Power Output: Not less than 8 PS** **Torque Output: Not less than 9.5 N-M** **Transmission: Automatic** **Warranty: Min. 1 Year** **Other Details: As per Technical Specification**	

तपसिल

१. सार्वजनिक खरिद नियमावली, २०६४ को नियम ३१(ख) अनुसारको सवारी साधनको उत्पादक वा अधिकारिक विक्रेताहरुबाट खरिदको लागि उक्त सवारी साधन बिक्री गर्न नेपाल सरकारको सम्बन्धित निकायबाट प्राप्त भएका अनुमतिपत्र, सोको अद्यावधिक नवीकरण भएको पत्र, स्थायी लेखा नम्बर (PAN) तथा मूल्य अभिवृद्धि कर दर्ता प्रमाणपत्र, आ.व. २०७६/७७ सम्मको कर चुक्ता गरेको प्रमाणित कागजात यो सूचना प्रकाशित भएको मितिले सातौं दिन (मिति २०७८/०६/१५) कार्यालय समयसम्ममा यस विभागको कार्यालय कोडः ३७००२३५०१, राजस्व शीर्षक नं. १४२२९ उल्लेख गरी राष्ट्रिय वाणिज्य बैंकको शाखा कार्यालयबाट वा यस विभागको राजस्व काउन्टरमा रु १०००/- तिरी प्रस्ताव सम्बन्धी कागजात लिन सकिनेछ ।

२. प्रस्तावदाताले माथी उल्लिखित कागजातका अतिरिक्त उक्त सवारी साधन सप्लाई गरेको हालसम्मको विस्तृत विवरण, सम्बन्धित कार्य अनुभवको प्रमाणपत्र, उत्पादनको आधिकारिक प्राविधिक स्पेसिफिकेसन, मूल्य, गुणस्तर तथा सुविधा सहितको विवरण (Catalogoe or Brochure) संलग्न राखी सूचना प्रकाशित भएको मितिले आठौं दिन (मिति २०७८/०६/१६) दिनको १२ बजे सम्ममा प्रस्ताव सम्बन्धी कागजात रितपुर्वक भरी, सिलबन्दी गरी दर्ता गरी सक्नुपर्ने छ र यसरी दर्ता हुन आएका सिलबन्दी प्रस्तावहरु सोही दिनको २ बजे यस विभागमा खोलिने छ। रित नपुगी आएका र ढिलो गरी आएका प्रस्ताव उपर कुनै कारवाही गरिने छैन । माथि उल्लेखित दिन सार्वजनिक बिदा परेमा बिदा पछिको कार्यालय खुलेको दिन क्रमश हुनेछ ।

३. यस सूचनामा उल्लेखित बाहेक अन्यको हकमा सार्वजनिक खरिद ऐन, २०६३ तथा सार्वजनिक खरिद नियमावली, २०६४ अनुसार हुनुका साथै कुनै संशोधन भएमा यस विभागको सूचना पाटीमा टाँस गरी जानकारी गराईने छ ।

४. प्रस्ताव सम्बन्धमा थप जानकारीको लागि विभागको फोन नं. ०१-४७८०२२७ मा कार्यालय समयमा सम्पर्क गर्न सकिनेछ ।

महानिर्देशक

महानिर्देशक

Email: dg@dda.gov.np, info@dda.gov.np, inspection@dda.gov.np

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०६/१४

Product Recalls को स्तरीय संचालन प्रक्रिया (Standard Operating Procedure) का सम्बन्धमा

विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका, जोखिमका आधारमा बजारबाट संकलन गरिएका र उजुरीका आधारमा संकलन गरिएका औषधिहरुको नमूना परीक्षण गर्दा त्यस्ता औषधिहरु गुणयुक्त, असरयुक्त, जनसुरक्षित नरहेको/ नभएको तथा अधिकतम खुद्रा मूल्य भन्दा अधिक रहेको पाइएमा ति औषधिहरु औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरी बजारबाट फिर्ता (Recall) गर्ने प्रक्रियालाई अझ व्यवस्थित र पारदर्शी बनाउन विभागले Product Recalls को स्तरीय संचालन प्रक्रिया (Standard Operating Procedure) को मस्यौदा तयार गरि मिति २०७८/०६/१३ मा सरोकारवालाहरुको राय, सुझाव तथा प्रतिक्रियाका आधारमा अन्तिम रुप दिने निर्णय भएकाले यो सूचना प्रकाशन गरिएको छ । यस विषयमा केहि राय सुझाव भए https://bit.ly/3AYh3c1 मार्फत सूचना प्रकाशन भएको मितिले १५ दिन भित्र उपलब्ध गराउनुहुन सम्पूर्ण सरोकारवालाहरुलाई अनुरोध गरिन्छ ।

०६८।०६।१४

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०७/१७

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

आ.व. २०७८/७९ आश्विन महिनामा निलम्बनको कारवाहिमा परेका औषधि पसलहरुको विवरण

औषधि ऐन २०३५ को दफा २० को उपदफा ४(क) अनुसार तपशिल बमोजिमका औषधि पसलहरु निलम्बनको कारवाहिमा परेकाले सर्वसाधारणको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ ।

क.सं	औषधि पसलको नाम/ठेगाना	धनी/व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१.	गान्धि तुलसी मनोहरा कम्युनिटी हेल्थ सेन्टर प्रा.लि., फार्मेसी युनिट (र.प.न.३७३०७०४१०२३२७) कागेश्वरी मनोहरा-९, काठमाण्डौ ।	श्री गान्धि तुलसी मनोहरा कम्युनिटी हेल्थ सेन्टर प्रा.लि./श्री रोजिना कार्की (जि४५३५)	२०७८।०६।०४	१४
२.	नन्दकृष्ण फार्मेसी (र.प.न. ३७५०६०४०४१२४५) भक्तपुर-१४, जगाति, भक्तपुर ।	श्री रीता त्वायना/ श्री सविना वासी,ए १६३३,	२०७८।०६।०४	७
३.	मेड स्टार सेन्टर प्रा.लि.,फार्मेसी युनिट (र.प.नं.३७५१२०५०४२८३७) कागेश्वरी मनोहरा-७, काठमाण्डौ ।	श्री मेड स्टार सेन्टर प्रा.लि./श्री शिला अधिकारी, ए३१५९	२०७८।०६।०४	७
४.	मिली मेडिकल हल एण्ड डाईग्नोष्टिक सेन्टर प्रा.लि.,फा.यु. (र.प.न.३७२०५२२१६११२५) सुर्यविनायक-०१, भक्तपुर ।	श्री मिली मेडिकल हल एण्ड डाईग्नोष्टिक सेन्टर प्रा.लि./ श्री सृजना सुवाल, जि ३६२३	२०७८।०६।०४	७
५.	लुक्सी भेट फर्मा, (र.प.नं.३७२०५२३०३३६५९)का.म.न.पा.-३५, कोटेश्वर,काठमाण्डौ ।	श्री नारायण प्रसाद अधिकारी, (व्य.मा. प्र.नं. Vet458/070/071)	२०७८।०६।१०	१५
६.	निकम मेडिकल हल, टोखा न.पा. १५, काठमाण्डौ ।	सुनिता अधिकारी/बाबुराम पराजुली	२०७८।०६।१९	७
७.	मेडिगोल्ड फार्मेसी, टोखा न.पा. १२, काठमाण्डौ	पशुपति गिरी	२०७८।०६।१९	७

महानिर्देशक

८	एटोर्मा फार्मेसी, र.प.नं. ३७७०४०४०६५८५३, का.म.न.पा- ०६, काठमाण्डौ ।	सविना तमाङ	२०७८।०६।१७	७
९	झोराली फार्मेसी , टोखा न. पा. ०१, काठमाडौं।	श्री कृष्ण प्रसाद घिमिरे	२०७८।०६।१७	१०
१०	टोखा इमर्जेन्सी मेडिकल हल, टोखा न. पा. ०४, काठमाडौं	श्री भवानी दाहाल	२०७८।०६।१७	१०
११	विरसना गोर्खाली मेडिकल हल, टोखा न. पा. ०३, काठमाडौं	श्री विनय दवाडी/मनिक श्रेष्ठ	२०७८।०६।१७	७
१२	सपनातिर्थ फार्मेसी, टोखा न. पा. ०३, काठमाडौं	श्री सुधा पौडेल/पद्म राज कैनी	२०७८।०६।१७	१४
१३	प्राकृतिक बाईपास फार्मेसी, का. म. न. पा. १६, काठमाडौं	श्री पुस्कर काफ्ले/गोकर्ण सापकोटा	२०७८।०६।१७	१४
१४	कालिका फार्मेसी, चाँगुनारायण न.पा. ६, भक्तपुर	श्री दिनेश शाही/सुमिता राई	२०७८।०६।१९	७
१५	सार्थक फार्मेसी, चाँगुनारायण न.पा. ६, भक्तपुर	श्री रमेश मधिकर्मी	२०७८।०६।१९	७
१६	सुवेदी फार्मेसी, भक्तपुर न.पा. -१०, भक्तपुर	श्री बाबुराम सुवेदी	२०७८।०६।१९	७
१७	अनमोल फार्मेसी, भक्तपुर न.पा. -१०, भक्तपुर	श्री शोभा कुम्पारख/रुकेश मचामसी	२०७८।०६।१९	७
१८	सिद्धि फार्मेसी, भक्तपुर न.पा. -१०, भक्तपुर	श्री राज्य लक्ष्मी सुवाल वसुकुला	२०७८।०६।१९	७
१९	खरिपाटी फार्मेसी, चाँगुनारायण न.पा. -०५, भक्तपुर	श्री शैलेन्द्र शाह/गीता लामिछाने	२०७८।०६।१९	७

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

महानिर्देशक

Recommendation from Drug and Therapeutics Committee for Special Permission

Name of the Hospital	
Generic Name, Strength and Dosage form	
Brand Name	
Manufacturer	
Therapeutic Class	
Proposed indications for use	
Dosage schedule	
Quantity required by the hospital	
Previous consumption data	
Principle mode of action	
Average duration of therapy	
Are there prescribing guidelines (Plz attach)	
Drugs already approved for same indications	
Advantages over listed alternatives	
Comparative benefit over existing drug	
Price of a drug	
Cost of therapy	
Cost benefit over existing therapy	
Major ADRs	
Innovator/Equivalency	
References	
Recommendation from the DTC (Plz attach minute)	

Signature:

Name of the authorized person from DTC tof the hospital:

Name of the Hospital:

Address of the Hospital:

Date and Stamp:

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०७/२२

सरकारी तथा निजी अस्पतालको Drug and Therapeutic Committee सम्बन्धि सुचना।

सरकारी तथा निजी अस्पतालहरुले आफ्नो अस्पताल अन्तर्गतका Drug and Therapeutics Committee को सुचिकृत गर्नका लागि तपसिल अनुसारको विवरण पेश गर्नुहुन मिति २०७८/०७/१६ को विभागीय निर्णयानुसार सम्बन्धित सबैको जानकारीका लागि यो सूचना प्रकाशित गरिएको छ । औषधिको सुरक्षितता, प्रभावकारिता, गुणस्तर, उपयोगिता अध्ययनलाई थप पारदर्शी र सहज बनाउन सम्पूर्ण आयातकर्ताले औषधिको विशेष सिफारिशको पत्र पेश गर्दा देहायको "Recommendation from Drug and Therapeutics Committee for Special Permission" बमोजिमको विवरण सहित समितिको minute अनिवार्य रुपमा संलग्न गर्नुहुन जानकारी गराइन्छ ।

तपसिल:

अस्पतालको नाम, ठेगाना :

अस्पतालको किसिम : निजि / सरकारी/ अन्य .....

Drug and Therapeutics Committee को सदस्यको विवरण :

सि.नं.	नाम	पद	अनुभव	ई-मेल	फोन नं.

Drug and Therapeutics Committee को सम्पर्क व्यक्तिको नाम :

अस्पतालको छाप :

२०७८/६/२२
महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०७/१२

विज्ञ सूची दर्ता सम्बन्धी सूचना।

औषधिको विशेष सिफारिश सम्बन्धि (पहिलो संशोधन) कार्यविधि, २०७७ को दफा ३ अनुसार गठन भएको औषधि मूल्याङ्कन समितिमा विज्ञको रुपमा औषधिको सुरक्षितता, प्रभावकारिता, गुणस्तर, उपयोगिता सम्बन्धमा वैज्ञानिक तथा तथ्यपरक अध्ययन गरी आफ्नो राय पेश गर्ने प्रयोजनका लागि सम्बन्धित विषय विज्ञको सूची (Roster) मा समावेश हुन इच्छुक विज्ञहरुबाट तिनै औषधि र चिकित्सा विषय र क्लिनिकल फार्मेसीमा स्नातकोत्तर उपाधि हासिल गरेको) ले पन्ध्र दिन भित्र तपसिल बमोजिमको विवरण संलग्न गरी औषधि व्यवस्था विभाग, बिजुलीबजार, काठमाडौँमा वा info@dda.gov.np मा इमेल मार्फत विवरण पेश गर्नुहुन मिति २०७८/०७/१६ को विभागीय निर्णयानुसार सम्बन्धित सबैको जानकारीका लागि यो सूचना प्रकाशित गरिएको छ ।

तपसिलः

क. नाम तथा विवरणः

१. नाम, थर (देवनागरीमा):-
२. नाम, थर (अङ्ग्रेजीमा):-
३. ठेगानाः-
४. मोबाइल नम्बरः-
५. इमेलः-
६. PAN (Permanent Account Number) :-
७. Health Professional Society सँग आबद्ध भएमा सो को विवरणः-

ख. शैक्षिक उपाधि र योग्यता सम्बन्धी विवरणः

१. विषय विज्ञता (Speciality) :-
२. स्नातकोत्तर तहको उपाधि हासिल गरेको वर्षः-
३. स्नातकोत्तर तह भन्दा माथिको उपाधि हासिल गरेको भए सो विषय :-

ग. हाल कार्यरत संस्था सम्बन्धी विवरणः

१. कार्यरत संस्थाको नाम र ठेगानाः-
२. कार्यरत पदः-
३. कार्यरत अवधिः-

घ. संलग्न कागजातहरुः

१. Curriculum Vitae (CV)

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था बिभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७८/०७/०६

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिको नमुना परिक्षण गर्दा तपसिल बमोजिमको उत्पादकबाट उत्पादित तपसिलको ब्याच न. को औषधि न्यून गुणस्तर भएको पाइएकोले सो 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 सम्बन्धित उद्योगको अधिकारिक आयातकर्ता तथा तिनका प्रतिनिधिहरुको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त औषधि सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिलः

सि.न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	PYRIMIDE (Nimesulide Tablets 100mg)	19130070	Jan-2019/ Dec-2021	Does not comply to Analytical Profile No.: NIMES 075/076/AP051 with respect to Dissolution Test	ALKEM LABORATORIES LTD., Kumrek, Rangpo, East Sikkim, India

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

औषधीको आमउपभोक्तालाई जानकारी

- मान्यताप्राप्त स्वास्थ्यकर्मीको पुर्जा अनुसार मात्र औषधीको प्रयोग गर्नुहोस ;
- औषधीको प्रयोग सम्बन्धि सम्पूर्ण जानकारी लिने जस्तै, औषधि कसरी प्रयोग गर्ने, औषधी घरमा कसरी भण्डारण गर्ने, औषधि सेवनगर्दा खान नहुने खाध तथा अन्य औषधि, कुनै मात्रा छुटेमा के गर्ने, औषधिको नकारात्मक असरहरु (side effects), तथा औषधी प्रयोग गर्दा अपनाउनु पर्ने सावधानीहरु ;
- औषधी बच्चाको पंहुचबाट टाढा राख्नुहोस ;
- आफु गर्भवती भएमा सो को बारे स्वास्थ्यकर्मीलाई जानकारी दिनुहोस ;
- औषधी प्रयोग गर्दा जीउ चिलाएमा, छालामा डाबरहरु आएमा, श्वास फेर्न गाह्रो भएमा वा यस्तै अन्य लक्षण देखा परेमा तुरुन्त औषधी प्रयोग गर्न छाडी स्वस्थाकर्मीलाई सम्पर्क राख्नुहोस ;
- यदि एन्टिबायोटिक औषधी सेवन गर्न लाग्नु भएको छ भने तोकिएको मात्रा र अवधिसम्म प्रयोग गर्नुहोस र गरानुहोस ;
- औषधी खरिद गर्ने औषधि पसलको व्यबसायीको मान्यता प्रमाणपत्र हेर्ने गर्नुहोस ;
- औषधी खरिद गर्दा अनिवार्य बिल लिने बानी गर्नुहोस ।

स्वास्थ्यकर्मी, औषधि सिफारिसकर्ता, औषधी उत्पादक, पैठारिकर्ता तथा व्यबशायीलाई जानकारी

- विभागमा दर्ता नभएका औषधिको बिक्रिवितरण नगर्ने तथा बिल बिजकबिना कुनै पनि औषधिको खरिद बिक्रि नगरौ ;
- चिकित्सकहरुले वा स्वास्थ्यकर्मीहरुले व्यबसायिक मर्यादा र आचरणमा बसी औषधिको सिफारिश गर्ने गरौ र कुनै औषधी कम्पनिबाट कुनै लाभ वा अवसरको सम्झौता गर्नु भएको छ भने पारदर्शी गर्ने गरौ ;
- मूल्य नभएको तथा विभागबाट मूल्य स्वीकृत नभएको औषधीको बिक्रि-बितरण गर्ने नगरौ ;
- उद्योग तथा औषधी वितरकले दिने deal bonus पारदर्शी गर्ने गरौ र यसबाट उपभोक्तालाई लाभान्वित गरौ ;
- Physician sample को दुरुपयोग नगरौं ;
- औषधीको स्तर खुलाई मात्र औषधिको उत्पादन र बिक्रिवितरण गर्ने गरौ ;
- लागू तथा मनोद्विपक र एन्टिबायोटिक औषधिहरुको समुचित प्रयोग गर्ने बानि बसालौ र अरुलाई पनि सिकाउ ;
- औषधि दर्ता भए नभएको जानकारी यस विभागबाट जानकारी लिऔ ;
- थोक बिक्रेताले खुद्रा बिक्रेतालाई कारोबार गर्दा आधिकारिक बिल तथा अद्यावधिक दर्ता रहेको औषधी पसलमा मात्र गर्ने र
- लागु तथा मनोदिपक औषधीहरुको अनिवार्य रुपमा चिकित्सकको सिफारिसको आधारमा पारदर्शी रेकर्ड राखेर मात्र बिक्रि वितरण गर्ने गरौ ।

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

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