DRUG BULLETIN OF NEPAL (DBN)

December-March 2018 Vol 29 No. 2 Mangsir-Falgun 2075

2018

GOVERNMENT OF NEPAL
MINISTRY OF HEALTH AND POPULATION
DEPARTMENT OF DRUG ADMINISTRATION

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

EDITORIAL

Medicines regulation: a life cycle approach

Drugs Act, 2035 section (5) gives Department of Drug Administration (DDA) a broad mandate to implement the objectives of the act mainly to protect and promote public health. DDA thus obliged to protect patients against ineffective or harmful medicines, consequences of untreated disease due problem with access and availability and enrich the people with rational information on medicines. The first objective leads DDA into a gatekeeper functions thus obliging to apply stringent standards of medicines assessment and even denying marketing authorization if deemed necessary. The second and third objectives require DDA to support and enable drug development and promote rational information dissemination so that patient have access to safe, effective and quality medicines as early as possible with appropriate and unbiased information.

To achieve these broader objectives, approaches of regulation throughout the products life must be in place. The pharmaceutical product life cycles can be broadly classified into; pre approval, approval and post approval phases. Regulatory measures should be developed and must be applied throughout the product life cycle. The regulatory life cycle of the product can be as follows:

Pre approval phase

The legislative requirements are shaped into guidance, codes and directives in transparent manner as to make transparent and unambiguous. Drug consultative committee, drug advisory committee and various committees are set and engaged for scientific advice, setting newer requirements to address safety, quality and efficacy of the product. Efforts have been made to facilitate regulatory submissions, addressing confusions or grievances with transparent formats on dossiers, good practice guidelines, standard operating procedures on online submissions etc. further work is desired in many issues including development of guidance and standard procedures on clinical trials, bioequivalence study, pricing etc.

Approval phase

Once the product is developed the applicant applies for product license as well as marketing authorization. Though Nepal often relies on approvals of stringent regulatory authority or on the pharamcopoeial references, evaluation on the dossier has been started. Drug regulators at this stage should evaluate administrative and prescribing information, nonclinical, clinical and quality data. DDA has adopted a practical approach of accepting dossier in Common technical document (ICH prescribed format) or WHO prescribed format or as prescribed by DDA (mentioned in the medicines registration guidance 2073). At this stage regulators check progress of the dossier evaluation, anticipate questions, prepares answer/reply to the expected questions, clarify the questions, plan meetings/ hearing with the applicant if needed, negotiate and identify post approval commitments including product information/labeling requirements. The approval must be founded on reliable scientific evidences. For this to be in place applicants require product development, manufacturing and testing capacity at par and should be made accountable before according marketing approval.

Post approval phase

Nepal's regulatory system encompasses the control of post approval phase of the drug product. The facility handling sales, storage and distribution of the pharmaceutical products must have license to do so issued form DDA. The law prescribes the requirement of arrangement for conducting such functions as well as personnel who can handle them. And codes on sales and distribution has been issued with do's and don'ts for such firms so that product quality is maintained upto the expected expiration date as well as to facilitate compliance. Post approval commitments are often intimated as a precondition to issue marketing authorization are also needed to be followed. Enforcement in this connection is desired and must be taken as a serious violation of the commitment. After approval of the product various adverse effects, side effects might be noted than were observed during phase 3 clinical trials, which might require variations on the labelling, indications so and so forth. This it is considered as one of the main elements on pharmaceutical lifecycle approach. Drug act requires renewal of the licenses; thus, any variation or post approval commitment are tracked during this stage also. Disincentives of the post approval commitments have often lead to violation of such commitment thus DDA has made mandatory to get approval of any variation including price

changes. National pharmacovigilance center receives adverse drug action reporting, which is currently being supported by 11 regional centers and is uploaded to global database run by WHO collaborating center the Uppsala monitoring center. DDA is strengthening this system to support regulatory decisions as well. This year upto second quarter DDA has issued 39 recalls which suggests the impact of the storage, transport and handling of medicines on quality beside manufacturing practices. Good practices in manufacture, sales and distribution are the minimum requirements to be observed for safeguarding quality of the product. DDA has issued codes on good manufacturing practices and good practices in sales and distribution as mandatory requirement for manufacturer and those involved in sales and distribution.

In conclusion, medicines are perhaps the most highly regulated commodities than any other products available for mass consumption. However regulatory system of one country, place of phases does not guarantee the quality, efficacy and safety of the product. A medicines regulatory agency requires strong and motivated human resources who can deliver the function diligently and efficiently, besides the harmonization of requirements and control measures across the countries in case of transshipped products.

Product that was developed well and formulated well cannot be the only testimony of assured quality of product, the product life cycle phase beginning form development, approval, to post approval until it reaches to the patient must be regulated in order to assure the product quality, efficacy and safety. The consideration of product life cycle regulation can thus help fulfill the legislative mandate of protection and promotion of the public health.

Narayan Prasad Dhakal
Chief Editor

REGULATORY NEWS

Analytical Method validation

Drug category rules, 2043 lists few pharmacopoeias that are applicable for test procedures of medicines within Nepal. In-house method had been previously allowed by Department of Drug Administration (DDA) for molecules whose monographs have not been enlisted in the listed pharmacopoeia. An analytical method validation committee has been formed by DDA which forwards proposed analytical methods for approval from the Drug advisory committee (DAC). Till now seventeen methods have been approved from DAC which are for the following drugs.

क्र.सं.	औषधिको नाम र बनोट	सक्रिय तत्व	Reference	Analytical Method No
1	Diacerin Capsule	Diacerin	IP2014/IH	Dia 073/074/AP002
2	Rabeprazole capsule	Rabeprazole	IP2014/IH	Rabe 073/074/AP003
3	Desloratadine tablets	Desloratadine	USP2015/IH	Des 073/074/AP004
4	Esomeprazole Capsule	Esomeprazole	IP2014/IH	Esmo 073/074/AP005
5	Amlodipine and telmisartan tablets	Amlodipine /Telmisartan	IP2014/IH	AmloTelmi 073/074/AP001
6	Amlodipine and Atorvastatin tablets	Amlodipine / Atorvastatin	IP2014/IH	AmloAtor 073/074/AP006
7	Cefdinir Dispersible tablets	Cefdinir	USP2015/IH	Cefdi 073/074/AP007
8	Fexofenadine Hydrochloride suspension	Fexofenadine	USP2015/IH	Fex 073/074/AP008
9	Levocetirizine Dihydrochloride Syrup	Levocetrizine	USP2015/IH	Lev 073/074/AP009
10	Sofosbuvir tablet	Sofosbuvir	IH	Sof 073/074/AP010

11	Paracetamol and Ibuprofen suspension	Paracetamol / Ibuprofen	IH	Ibu ParS 073/074/AP011
12	Linagliptin tablets	Linaglipptin	IH	Lina 073/074/AP012
13	Metronidazole and Diloxanide Furoate tablets	Metronidazole/ Diloxanide Furoate	IP	Metr Dilo 073/074/AP013
14	Amiloride and Frusemide Tablets	Amiloride/ Frusemide	IH	Ami Fru 073/074/AP013
15	Metformin and Glimepiride tablets	Metformin/ Glimepiride	IP	Met Gli 073/074/AP015
16	Metformin and Sitagliptin	Metformin/ Sitagliptin	IP	Met Sit 073/074/Ap016
17	Febuxostat Tablets	Febuxostat	IH	Febu 073/074/AP017

New approved molecules

The drug evaluation committee within DDA is responsible for studying the quality, safety, efficacy, cost-effectiveness etc. of new molecules that have not been registered in the department and not been published in any listed pharmacopoeias. The committee makes a decision based on the study whether to forward the molecules to DAC or not. The DAC, based on the report/recommendation from the drug evaluation committee makes a decision to approve or reject those drugs for registration. In this fiscal year 2074/75 three molecules have been approved for registration within DDA by DAC which are as follows:

1. **Rivaroxaban** which is a factor Xa inhibitor, an anticoagulant

2. **Sevelamer carbonate** which is a phosphate binder useful in hyperphosphataemia in patients undergoing dialysis.

3. **Dabigatran Etexilate** which is an antithrombic agent used in prevention of venous thromboembolism disorders and pulmonary embolism in adults after surgery.

IMPORTANT INFORMATION

Finasteride

Potential risk of serious muscle-related adverse effects.

Health Canada has recommended that manufacturers update the product information for finasteride containing products (Propecia®, Proscar® and generics) to include information about the potential risk of serious muscle-related adverse effects. Finasteride at a dose of 5mg is used to treat and control noncancerous enlargement of the prostate gland (benign prostatic hyperplasia) and for treatment of androgenic alopecia at a dose of 1mg. Health Canada reviewed the potential risk of serious muscle-related adverse events such as rhabdomyolysis, myopathy and muscle disorders such as pain, weakness, atrophy or stiffness. At the time of this review, Health Canada had received 11 Canadian reports of serious muscle-related adverse effects. Four cases were thought to be possibly linked to finasteride use. In three of the four cases individuals recovered after stopping the use of finasteride (the outcome is unknown in the fourth case). There were not enough information to establish a link between finasteride and muscle-related adverse effects in the remaining seven reports.

Three additional cases of serious muscle-related adverse effects with the use of finasteride were reported in the literature. Two cases reported either myalgia with an increase in muscle enzymes, or rhabdomyolysis following the use of finasteride to treat hair loss in men. These patients recovered after they stopped using finasteride. The WHO global database of Individual Case Safety Reports (ICSRs) contained 508 reports of serious muscle-related adverse effects suspected of being linked to the use of finasteride, mostly atrophy, weakness, myalgia and sudden, strong muscle tightening (spasms). There were not enough information in these reports to suggest a causal effect. Health Canada's review of the available information

concluded that the risk of serious musclerelated adverse effects with the use of finasteride cannot be ruled out.

Source: WHO Pharmaceuticals Newsletter No. 4, 2017

In Nepal: Health care professionals are informed of the potential risk of serious muscle-related adverse effects with the use of finasteride.

Loperamide (high dose)

Risk of serious cardiac adverse events.

The National Pharmaceutical Regulatory Agency (NPRA) has updated the package inserts for all products containing loperamide with warnings and safety information related to the risk of serious cardiac adverse events with high doses. Loperamide is an antidiarrhoeal medicine. Between 2000 to December 2016, the NPRA has received 14 reports containing a total of 29 adverse events suspected to be related to loperamide use in Malaysia. More than half the adverse events (15 events, 52%) were related to skin disorders such as rash and pruritus. Other adverse events reported were anaphylaxis, shortness of breath, dizziness, dysaesthesia, face and mouth oedema, nausea, oculogyric crisriskis, stomatitis, and throat tightness. To date, the NPRA has not received any reports of cardiac adverse events related to loperamide use. A search of the WHO global database of Individual Case Safety Reports (ICSRs), VigiBase, identified 7431 individual case safety reports involving loperamide since year 1977. A total of 328 reports involved cardiac disorders such as ventricular tachycardia (60 reports), cardiac arrest (50), and torsades de pointes (46). The NPRA has issued advice to health-care professionals, alerting them to potential risks of cardiac events, susceptible individuals, drug interactions, and management of suspected cardiotoxicity with loperamide use.

Source: WHO Pharmaceuticals Newsletter No. 4, 2017

In Nepal: Health care professionals are informed of the risk of serious cardiac adverse events with the use of loperamide.

Mefloquine

Risk of long-lasting and permanent neurological and psychiatric adverse events.

Health Canada has recommended that the product information for mefloquine should be updated to explain the risk of vestibular damage more clearly. A checklist to assist health-care professionals in deciding whether to prescribe mefloquine to individual patients will be developed to prevent mefloquine from being prescribed to patients who are contraindicated (for example past or ongoing neurological or psychiatric conditions). Mefloquine is a prescription drug to prevent and treat malaria. Health Canada reviewed the potential risk of rare longlasting (lasting for 90 days or more) and permanent neurological and psychiatric adverse events with the use of mefloquine. From 1993 to 30 September 2016, Health Canada has received 27 Canadian reports of adverse events that were potentially long-lasting. In addition, 37 international reports (from databases and published literature) of adverse events included five reports of permanent damage to the vestibular system. The vast majority of the reports (61 out of 64) were deemed to have a possible link between the use of mefloquine and the long-lasting or permanent adverse events. However, insufficient information was available to conclude that mefloquine use was responsible for the adverse event(s) reported. The review also found that some patients were prescribed mefloquine even though the use was contraindicated because they had past or ongoing neurological or psychiatric conditions. The current product information for mefloquine describes the potential for long-lasting neurological and psychiatric adverse events that aligns with the review findings. However, the risk of rare permanent vestibular damage could be more clearly explained.

Source: WHO Pharmaceuticals Newsletter No. 4, 2017

In Nepal: Health care professionals are informed of the risk of long-lasting and permanent neurological and psychiatric adverse events with the use of mefloquine

Sulfasalazine

Risk of Stevens Johnson Syndrome and toxic epidermal necrolysis.

The Pharmacovigilance Program of India, Indian Pharmacopeia Commission (PvPI, IPC) has made recommendations to the Central Drugs Standard Control Organisation (CDSCO) about revising the drug safety label for sulfasalazine to include Stevens-Johnson syndrome and toxic epidermal necrolysis as potential adverse drug reactions. Sulfasalazine is indicated for the treatment of severe rheumatoid arthritis, ulcerative colitis and Crohn's disease. Between 2011 and 2017, PvPI received 15 reports of Stevens Johnson syndrome and seven reports of toxic epidermal necrolysis with sulfasalazine use. The cases were reviewed by Signal Review Panel (SRP)- PvPI, IPC who concluded that there was a strong causal relationship between sulfasalazine and Stevens Johnson syndrome and toxic epidermal necrolysis.

Source: WHO Pharmaceuticals Newsletter No. 4, 2017

In Nepal: Health care professionals are informed of the chance of development of Stevens Johnson Syndrome and toxic epidermal necrolysis with the use of sulfasalazine.

Tramadol

Breastfeeding whilst taking tramadol is not recommended.

The Medicines and Medical Devices Safety Authority (Medsafe) has stated that breastfeeding while taking tramadol is not recommended. Small amounts of tramadol are found in breast milk and the effect of this on infants and new-borns is not fully known. Tramadol is used

for moderate to severe pain in adults and children from the age of two years. In New Zealand, the Medicines Adverse Reactions Committee (MARC) reviewed the use oftramadol in children in June 2016. Although very small amounts of tramadol and its active metabolite are found in breast milk, its safety in new-borns and infants has not been studied. There is a theoretical risk of breathing problems in the baby due to the opioid effects of tramadol. The Centre for Adverse Reactions Monitoring (CARM) has received one case report in a one-month-old where exposure to tramadol via breast milk was suspected to have caused a red rash. The baby was reported to have recovered and the rash was not considered severe or serious.

Source: WHO Pharmaceuticals Newsletter No. 4, 2017

In Nepal: Health care professionals are recommended to not allow use of tramadol in breastfeeding women.

Atypical antipsychotics

Potential risk of sleep walking and sleep-related eating disorder.

Health Canada recommends that the product safety information for all atypical antipsychotics should be updated to include risks of sleep walking (SW) and sleeprelated eating disorder (SRED). Atypical antipsychotics are used to treat mental disorders such as schizophrenia, bipolar disorder and depression. Health Canada reviewed the potential risk of SW and SRED with the use of atypical antipsychotics, following the publication of a case report which described these events in a patient treated with ziprasidone. At the time of the review, Health Canada had received a total of 13 unique Canadian reports of SW and SRED suspected to be linked to the use of atypical antipsychotics. In the review it was suggested that of these 13 reports, two cases of sleep disorder were likely to be linked to atypical antipsychotics use. The patients recovered when they stopped the treatment. Six reports, out of 13, were found to have a possible link. Other risk factors such as preexisting conditions,

history of sleep disorders or use of other medications could have contributed to the events; however, a link could not be ruled out. The five remaining reports could not be assessed due to insufficient information. This safety review evaluated information from 413 international reports of SW and SRED suspected to be associated with the use of atypical antipsychotics, but these reports provided limited additional information. In addition, Health Canada found 23 published case reports of SW and SRED suspected to be associated with the use of atypical antipsychotics. In the majority of these reports, patients recovered when they stopped the treatment and in some cases, the events returned when patients resumed the treatment. The drug was taken as recommended and the events appeared to happen more often with higher doses. Overall, the review of these case reports suggested a link between the use of atypical antipsychotics and SW or SRED.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are recommended to be aware of the potential risk of sleepwalking and sleep-related disorder with the use of atypical antipsychotics.

Azithromycin

Risk of acute generalized exanthematous pustulosis.

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for azithromycin (Zithromax®) has been updated to include the risk of acute generalized exanthematous pustulosis as a clinically significant adverse reaction. Azithromycin is an antimicrobial used for a number of bacterial infections caused by strains of genus Staphylococcus, Streptococcus, Pneumococcus, Neisseria gonorrhoeae, Moraxella (Branhamella) catarrhalis, Haemophilus influenzae, Legionella pneumophila, Peptostreptococcus, Prevotella, Chlamydia, and Mycoplasma. One

case of acute generalised exanthematous pustulosis has been reported in Japan. A causal relationship could not be excluded in this case. In addition, the company core datasheet (CCDS) has been updated.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are recommended to be aware of the potential risk of acute generalized exanthematous pustulosis with use of azithromycin.

Combined use of buprenorphine or methadone with benzodiazepines or CNS depressants

Medication management can reduce risks of serious adverse effects.

The US Food and Drug Administration (FDA) has required that drug labels for buprenorphine and methadone medicines (medication assisted treatment, MAT) are updated to include detailed recommendations for minimizing the use of MAT medicines and benzodiazepines together. Medicines containing buprenorphine or methadone as the active ingredient are FDA-approved to treat opioid addiction and dependency. MAT should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), despite the risk of serious adverse effects, as harm caused by untreated opioid addiction usually outweighs risks. Careful medication management by health-care professionals can reduce these risks. The FDA recommended that health-care professionals should take several actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are recommended to take actions and precautions and develop a treatment plan when buprenorphine

or methadone is used in combination with benzodiazepines or other CNS depressants.

Dabigatran

Risk of acute hepatic failure, hepatic function disorder, and jaundice.

The MHLW and the PMDA have announced that the package insert for dabigatran (Prazaxa®) has been updated to include the risks of acute hepatic failure, hepatic function disorder and jaundice as clinically significant adverse reactions. Dabigatran is used to reduce the risk of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation. A total of five cases associated with acute hepatic failure, hepatic function disorder and jaundice have been reported in Japan. Of these, a causal relationship could not be excluded in one case.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are warned of the risk of acute hepatic failure, hepatic function disorder and jaundice with the use of dabigatran.

Doxycycline

Risk of fixed drug eruptions.

The Saudi Food and Drug Authority (SFDA) has updated the summary of product characteristics and patient information leaflet for doxycycline to include the risk of fixed drug eruptions (FDE). Doxycycline is a tetracycline broad-spectrum antibiotic with bacteriostatic characteristics. It is used as treatment or prophylaxis against a wide range of susceptible strains of gram-negative and grampositive bacteria and other microorganisms. The SFDA initiated the investigation based on a signal observed in a published case report

examining potential associations between doxycycline and risk of FDE. As a result, the SFDA reviewed the available evidence related to this safety issue including screening of the WHO global database of Individual Case Safety Reports, VigiBase. In addition, a literature review was conducted. The SFDA concluded that the available evidence suggests a probable association between doxycycline and FDE.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are warned of the possibility of fixed drug eruptions with use of doxycycline.

Hyoscine butylbromide ampoule

Caution of use in patients with pre-existing cardiac conditions.

The Therapeutic Goods Administration (TGA) has updated product information for hyoscine butylbromide (Buscopan®) to include a caution regarding the use of hyoscine ampoules in patients with pre-existing cardiac conditions (for example cardiac failure, coronary heart disease). The Australian product information for hyoscine butylbromide already lists tachycardia, decreased blood pressure and anaphylaxis as potential adverse effects, but the product information has been updated to include a stronger warning in the precautions section because these adverse events can be more serious in patients with cardiac conditions. Monitoring of these patients is advised and emergency equipment and personnel trained in its use must be readily available. Hyoscine butylbromide ampoules, administered by intramuscular or slow intravenous injection, are used to treat gastrointestinal tract, biliary and renal spasms, and are used as a diagnostic in radiology. There are 28 cases describing tachycardia and/or hypotension relating to use of hyoscine butylbromide in the TGA's adverse events database. An additional four cases describe anaphylactic reactions. There is insufficient clinical information provided to determine whether or not these reactions occurred in

people with pre-existing cardiac conditions. None of these cases reported death, cardiac arrest or myocardial infarction.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are warned to use hyoscine butyl bromide with caution in patients with pre-existing cardiac conditions.

Corticosteroids

Rare risk of central serous chorioretinopathy.

The MHRA has provided advice to health-care professionals on the risk of central serous chorioretinopathy (CSCR) with local as well as systemic administration of corticosteroids. Corticosteroids are indicated for a wide variety of indications in the treatment or suppression of inflammatory and allergic disorders, commonly including: • asthma and allergic rhinitis • systemic inflammatory disorders, for example, rheumatoid arthritis • skin conditions, for example, eczema CSCR is a rare adverse effect that occurs with all formulations and has been described after local administration of corticosteroids via inhaled and intranasal, epidural, intraarticular, topical dermal and periocular routes. Although blurred vision is a symptom of CSCR, it is also an established adverse effect of steroid treatment. The causes of blurred vision are various and can also include cataract and glaucoma. The MHRA has recommended that patients are provided with guidance to report any vision problems or disturbances. If a patient has received treatment with local administration of a corticosteroid and presents with visual symptoms, referral to an ophthalmologist should be considered.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are advised that if a patient has received treatment with local administration of a corticosteroid

and presents with visual symptoms, referral to an ophthalmologist should be considered.

Desloratadine

Potential risk of QT interval prolongation: not enough evidence.

Health Canada has carried out a safety review to look at the potential risk of QT interval prolongation with the use of over-the-counter (OTC) desloratadine-containing products. This safety review was triggered by a signal publication in the WHO Pharmaceuticals Newsletter No.2, 2015, describing cases of abnormal heart rhythm suspected to be associated with the use of loratadine and desloratadine. Desloratadine is used to relieve symptoms of seasonal allergy or allergy caused by pollen or dust (hay fever). At the time of the review, Health Canada had received 10 Canadian reports of abnormal heart rhythm suspected to be associated with desloratadine use. Of these, one case was further assessed. The review of this case found a possible link between desloratadine and abnormal heart rhythm. However, other factors such as concomitant medicines may have played a role. The remaining nine reports were excluded from further review because the test results to confirm the abnormal heart rhythm were not available. In addition, Health Canada reviewed 13 international reports of abnormal heart rhythm suspected to be associated with the use of desloratadine that were provided by the manufacturer. Of these, four reports were further assessed. A link between these four reports and abnormal heart rhythm could not be established due to other factors that may have played a role such as: concomitant medicines, underlying heart conditions, and administration of higher than recommended doses of desloratadine. A search in the WHO database of Individual Case Safety Reports, VigiBase identified 35 cases of abnormal heart rhythm suspected to be associated with desloratadine use. A link between the use of desloratadine and the abnormal heart rhythm could not be established, as there was not enough information in the reports to draw conclusions. Published

scientific studies have shown that desloratadine is not associated with abnormal heart rhythm in humans. WHO Pharmaceuticals Newsletter No. 5, 2017 • 11 Safety of Medicines Health Canada's review of the available information did not establish a link between the use of desloratadine and abnormal heart rhythm.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

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

Ketamine

Risk of severe liver injury with repeated and/or prolonged high-dose use.

The ANSM has received reports of serious liver injury potentially related to the repeated and/or prolonged use of high dose ketamine. The ASNM has reminded healthcare professionals that good practice recommendations for use of ketamine should be implemented. It is essential to observe the recommended dosages and monitor the liver function closely. Ketamine is indicated as an anaesthetic agent, alone or in combination with other anaesthetics. Ten cases of serious liver injuries, including four cases leading to liver transplantation, have been reported by healthcare professionals since 2014. These are cholestatic type cholangitis, which may be linked to the repeated and/or prolonged administration of ketamine.

Source: WHO Pharmaceuticals Newsletter No. 5, 2017

In Nepal: Health care professionals are warned of the potential risk of severe liver injury with repeated and/or prolonged high-dose use of ketamine.

SIGNAL

SGLT-2 inhibitors and genital pruritus

A non-serious event with the potential for noncompliance and/or discontinuation

Dr Rebecca E Chandler, Uppsala Monitoring Centre

Summary

Sodium glucose cotransporter-2 inhibitors (SGLT- 2i) are members of a relatively new class of oral antidiabetic agents which are used in the treatment of type 2 diabetes mellitus as monotherapy or in combination with other agents. Itching in the genital area is a common non-serious adversereaction for these types of drugs which was known at the time of approval. A joint UMC/Lareb signal detection sprint performed in October 2016, highlighted reports from patients that were retrieved from VigiBase, the WHO global database of individual case safety reports, which revealed that often patientsstop taking these medications because of this adverse event.

A 71 year old female with a history of type 2 diabetes and hypertension was initiated on empagliflozin. The patient was treated for cystitis approximately one month after starting therapy. Also, the patient experienced non-serious events of thrush, burning in the urogenital area, redness in the urogenital area, blistering in the urogenital area and hypoglycaemia. In the course of five days the itching increased up to intolerability. Therapy for the event of cystitis was antibiotics and antifungal cream; therapy of the symptoms in the urogenital area included unspecified ointments without success and a mild-cortisone containing ointment which helped slightly. Empagliflozin was discontinued.

A 60 year old female experienced severe itching, soreness, and reddening of the genital area and an inability to sit while on therapy with dapagliflozin. The patient was diagnosed with candidal mycosis and treated with antifungal cream. The cream did not bring improvement and the patient discontinued dapagliflozin “on her own” in response to the events.

Introduction

Sodium glucose cotransporter-2 inhibitors (SGLT-2i) are members of a relatively new class of oral antidiabetic agents. Three medicines in this class, dapagliflozin, canagliflozin and empagliflozin, are currently marketed for use in the treatment of type 2 diabetes mellitus as monotherapy or in combination with other agents.

SLGT-2i work by inhibiting glucose reabsorption in the kidney and thereby promoting urinary excretion of glucose. Studies have revealed that SGLT-2i have beneficial effects on blood glucose levels, but also they reduce blood pressure and induce weight loss. Given that the action of these agents is independent of both insulin secretion and insulin action, another benefit of these agents is a lower risk of hypoglycaemia.

Given their mechanism of action, one of the major safety concerns for the SLGT-2i is an increased risk of genital infections caused by high levels of glucose in the urine. This safety concern is common enough that it was observed in clinical trials and has been fairly well characterised. Genital infections are largely fungal in nature, manifesting as mycotic vulvovaginitis in females and mycotic balanitis in males. Such infections have been estimated to affect 5-10% of patients using SGLT-2i and are more common in premenopausal women, patients with a history of genital infections, and obese patients. There was no evidence of a relationship between the incidence of genital infections and the amount of glycosuria observed in the clinical trials. Furthermore, rates of infections are highest in the first few months of treatment.

Reports in VigiBase

During a joint UMC/Lareb signal detection sprint with a focus on patient reports, a total of 99 individual case safety reports which included the MedDRA preferred term (PT) 'pruritus genital' for dapagliflozin, canagliflozin and empagliflozin were identified in VigiBase, the WHO global database of individual case safety reports as of 6 November 2016.

Forty-eight reports of pruritus genital (48.5%) have been received for dapagliflozin, 31 (31.3%) for canagliflozin and 20 (20.2%) for empagliflozin.

67.7% of the reports have been described events in females, 28.3% of the reports for males.

40.4% of the reports originated from the Americas, 36.4% from Europe, and 23.2% from Asia.

The most commonly co-reported MedDRA PT were genital burning sensation (9.1%), pollakiuria (7.1%) and dysuria (5.1%).

Twenty-three of the reports were received from consumers or non-health professionals (eight of which were classified as "serious") and 25 were received from physicians (none of which were classified as "serious"). Furthermore, fifty-four (54.5%) of the reports documented that the drug was discontinued secondary to the reported adverse drug reactions.

Literature and Labelling

The summary of product characteristics for each of these products notes that most genital infections were mild to moderate and only rarely resulted in discontinuation. The patient information leaflet notes only that genital infections are common to very common and manifest with irritation, itching, unusual discharge or odour. There is no information provided to the patient to seek medical consultation for treatment of these infections.

Discussion and Conclusion

The aim of communication is to highlight that some events can be characterised as nonserious in the clinical trial setting but may manifest in the post marketing period as severe events which have a large enough impact on the quality of life for the patient that discontinuing the medication is necessary.

Additionally, more guidance by drug developers or regulators on how to manage these effects may be necessary to ensure that patients who receive benefit from taking the medications are able to remain compliant with them.

Source: WHO Pharmaceuticals Newsletter No. 3, 2017

REGULATORY NOTICES

आ.ब. २०७४/०७५ को दोश्रो चौमशिक सम्म बिभागबाट निलम्बन गरिएको औषधि पसलको सुची

सि.न.	फार्मेसीको नाम	धनि/व्यवसायीको नाम	ठेगाना	निलम्बन अबधि	निर्णय मिति
१	साई सेवा फार्मेसी	अशोक कुमार श्रेष्ठ	भरतपुर-१० चितवन	२१ दिन	४/१७/२०७४
२	साक्षी मेडिकल हल	युगमणि काफ्ले	भरतपुर-७,चितवन	७ दिन निलम्बन	४/१७/२०७४
३	ओएसीस मेडिकल हल	समिर भट्टराई	देबचुली-१३, नवलपरासी	७ दिन निलम्बन	४/१७/२०७४
४	राजु मेडिकल हल	शोभा शर्मा	देबचुली-१३ नवलपरासी	७ दिन निलम्बन	४/१७/२०७४
५	रिलाईफ फर्मा	सगर बहादुर शाक्य	बर्दघाट-७, नवलपरासी	२१ दिन निलम्बन	४/१७/२०७४
६	संजीवनी सामुदायिक स्वास्थ्य फार्मेसी युनिट	प्रदिप पोडेल	शिबराज-६,चन्द्रौटा, कपिलबस्तु	७ दिन निलम्बन	४/१७/२०७४
७	सिर्जना फर्मा	सिर्जना पाण्डे	विरपुर-९, चन्द्रौटा, कपिलबस्तु	२१ दिन निलम्बन	४/१७/२०७४
८	बासुदेब भेट फर्मा	हरिभक्त अधिकारी	कालिका न.प-८, चितवन	१५ दिन निलम्बन	४/१७/२०७४
९	तेजाबी मेडिको फर्मा	बिष्णु कडेल	कावासोती-८, नवलपरासी	१५ दिन निलम्बन	४/१७/२०७४
१०	बिनिता आयु फार्मेसी	बिनिता डुम्रे	नया बेलहानी-८, नवलपरासी	१५ दिन निलम्बन	४/१७/२०७४
११	अर्पित फार्मेसी	शेषकान्त अधिकारी	गैडाकोट-२, नवलपरासी	१५ दिन निलम्बन	४/१७/२०७४
१२	तेजस आयुर्वेदिक मेडिकल हल	अन्जु श्रीवास्तब	कपिलबस्तु-४, तैलिहवा, कपिलबस्तु	१५ दिन निलम्बन	४/१७/२०७४
१३	जनता फार्मेसी	सुभेन्द्र प्रसाद यादब	शिबराज-६,चन्द्रौटा, कपिलबस्तु	१५ दिन निलम्बन	४/१७/२०७४
१४	मनु मेडिकल हल	लक्ष्मण बहादुर खत्री	मध्यबिन्दु-१०, नवलपरासी	७ दिन निलम्बन	४/१७/२०७४
१५	पर्बत फार्मेसी	ऋषिराम चौधरी	दुम्कीबास-१, नवलपरासी	७ दिन निलम्बन	४/१७/२०७४
१६	पवन फार्मेसी	सन्तोष कुमार शुक्ला	कपिलबस्तु-१,तौलिहवा, कपिलबस्तु	७ दिन निलम्बन	४/१७/२०७४
१७	शुभारम्भ मेडिकल हल	सबिता कुमारी दाहाल (पौडेल)	का.म.न.पा-९, कालिमाटीडोल, काठमान्डौ	६० दिन निलम्बन	४/२३/२०७४
१८	क्रिसब मेडिकल हल	बसन्त राज निरौला	का.म.न.पा-१०, शंखमुल, काठमान्डौ	२१ दिन निलम्बन	४/२९/२०७४
१९	काठमान्डौ न्युरो फार्मेसी	राजन श्रेष्ठ	किर्तिपुर न.पा-९, काठमान्डौ	१५ दिन निलम्बन	४/१७/२०७४
२०	उपचार मेडिकल हल	प्रदीप कुमार श्रेष्ठ	का.म.न.पा-९, काठमाडौँ	१५ दिन निलम्बन	४/२९/२०७४
२१	बियाँका फार्मेसी	विनायक कुमार श्रेष्ठ	का.म.न.पा-३, काठमाडौँ	२१ दिन निलम्बन	५/५/२०७४
२२	कोशना मेडिकल सेन्टर	कोपिला पाण्डे	का.म.न.पा-१६, काठमान्डौ	१५ दिन निलम्बन	५/२५/२०७४

सि.न.	फार्मेसीको नाम	धनि / व्यवसायीको नाम	ठेगाना	निलम्बन अवधि	निर्णय मिति
२३	नेपाल औषधालय	मुरारी नेपाल	मध्यपुर थिमी न.पा.-२, भक्तपुर	३० दिन निलम्बन	५/११/२०७४
२४	बसन्त मेडिकल हल	अन्जु गुरुङ	सुनवल-२,नवलपरासी	१४ दिन निलम्बन	११/६/२०७४
२५	गौतम भेट सप्लायर्स	बिष्णु प्रसाद गौतम	पोखरा उ.प.म.न.पा-१२,कास्की	७ दिन निलम्बन	११/१५/२०७४
२६	दिया मेडिकल हल प्रा.लि फा.यु	दिपेन्द्र रेग्मी	पोखरा ९, कास्की	७ दिन निलम्बन	११/१५/२०७४
२७	बरदान फार्मेसी	चेत बहादुर अधिकारी	सुक्ला गण्डकी-६ खैरेनीटार तनहु	७ दिन निलम्बन	११/१५/२०७४
२८	रा.रा. भेट फर्मा	बबिता पंजियार	पोखरा उ.प.म.न.पा-१२,कास्की	७ दिन निलम्बन	११/१५/२०७४
२९	अनु फार्मेसी	बनबारी दहैत थारु	सुनबल-४,नवलपरासी	१५ दिन निलम्बन	९/११/२०७४
३०	प्रसान्त मेडिकल हल	यदुनन्द पाण्डे	राम ग्राम-३,नवलपरासी	१५ दिन निलम्बन	९/११/२०७४
३१	पर्वत फार्मेसी	अनुराग जि.सी	दुम्कीबास-१,नवलपरासी	१५ दिन निलम्बन	९/११/२०७४
३२	दाउन्ने देवी फार्मेसी	लक्ष्मण भट्टराई	बर्दघाट-४,नवलपरासी	२१ दिन निलम्बन	९/११/२०७४
३३	प्रकृति फार्मेसी	रमेस खनाल	बाङ् गंगा -७,कपिलबस्तु	७ दिन निलम्बन	९/११/२०७४
३४	संकल्प मेडिकल हल	तेज प्रसाद घिमिरे	सितगंगा-४,अर्घाखाँची	१५ दिन निलम्बन	९/११/२०७४
३५	सितगंगा फार्मेसी	केशब भट्टराई	सितगंगा-४,अर्घाखाँची	१५ दिन निलम्बन	९/११/२०७४
३६	त्रिदेब फर्मा	बाबुराम खनाल	स.न.पा-१,अर्घाखाँची	१५ दिन निलम्बन	९/११/२०७४
३७	दिपसन फार्मेसी	बिमला अर्याल	सितगंगा-४,अर्घाखाँची	७ दिन निलम्बन	९/११/२०७४
३८	सोनेक्को फर्मा	उमा श्रेष्ठ	गोदावरी न.पा-५,ललितपुर	२१ दिन निलम्बन	८/१/२०७४
३९	लाफा आयुर्वेदिक फार्मेसी	निल बहादुर थापा	तानसेन न.पा-३,पाल्पा	१४ दिन निलम्बन	८/२८/२०७४
४०	जगत्र देवी भेटनरि	छबिलाल भट्टराई	गल्यांग-३,स्यांजा	७ दिन निलम्बन	८/२८/२०७४
४१	सगरमाथा मेडिको कन्सर्न	शंकर धोज कार्की	पुतलीबजार-१,स्यांजा	७ दिन निलम्बन	८/२८/२०७४
४२	बिजय फर्मा	केशब बहादुर दर्नाल	तानसेन-८,पाल्पा	१४ दिन निलम्बन	८/२८/२०७४
४३	अमृत मेडिकल हल	अमृत बिक्रम श्रेष्ठ	तान्हु-८,पाल्पा	७ दिन निलम्बन	८/२८/२०७४
४४	बिबेक बिशेस फर्मा	बिदुर बिसुराल	का.म.न.पा-१६,काठमाडौँ	७ दिन निलम्बन	११/२२/२०७४
४५	बिबेकानन्द सुस्वास्थ्य	चतुरानन्द प्रसाद यादव	का.म.न.पा-१६,काठमाडौँ	७ दिन निलम्बन	११/२२/२०७४
४६	रियाज फार्मेसी	बिनिष बज्राचार्य	का.म.न.पा-१६,काठमाडौँ	१० दिन निलम्बन	११/२२/२०७४
४७	सिटीजन फार्मेसी	हरिराम मण्डल	का.म.न.पा-१६,काठमाडौँ	७ दिन निलम्बन	११/२२/२०७४
४८	रजत फार्मेसी	रजत श्रेष्ठ	का.म.न.पा-११,काठमाडौँ	१० दिन निलम्बन	११/२२/२०७४
४९	सरिता फार्मेसी	रमेश खनाल	का.म.न.पा-३५,काठमाडौँ	७ दिन निलम्बन	११/२२/२०७४
५०	सारबी फार्मेसी	इन्दिरा मैनाली	काठमाडौँ	७ दिन निलम्बन	११/२२/२०७४

सि.न.	फार्मेसीको नाम	धनि / व्यवसायीको नाम	ठेगाना	निलम्बन अवधि	निर्णय मिति
५१	ओमकाली भेटनरी सेन्टर	कृष्ण प्रसाद सापकोटा	बनेपा न.पा-०८,काब्रेपलान्चोक	२१ दिन निलम्बन	८/२०/२०७४
५२	छिमेकि मेडिकल हल	ऋषिराम सुबेदी	अन्नपूर्ण गाबिस-६,कास्की	२१ दिन निलम्बन	११/१५/२०७४
५३	सयोना फार्मेसी	सम्झना पराजुली	ललितपुर म.न.पा-८, ललितपुर	२७ दिन निलम्बन	९/२५/२०७४
५४	सेफवेय फार्मेसी	हेमन्त पन्त	ललितपुर म.न.पा-९, ललितपुर	४५ दिन निलम्बन	१०/११/२०७४
५५	बिनिष फार्मेसी	महेन्द्र साहु तेली	नागार्जुन न.पा.-२, काठमान्डौ	३० दिन निलम्बन	१०/२/२०७४
५६	लिग लिग पालुंगटार हे.कि. एण्ड मेडी सेल्स पा.लि (फा.यु.)	इश्वर गिरी	पलुंगटार न.पा.-१०, गोर्खा	७ दिन निलम्बन	११/१४/२०७४
५७	थापा मेडिकल हल	बोज बहादुर थापा	सुन्दरबजार-७, लमजुंग	७ दिन निलम्बन	११/१४/२०७४
५८	साक्रित मेडिकल हल	निश्चल जी सि	गोर्खा न.पा-९,गोर्खा	७ दिन निलम्बन	११/१४/२०७४
५९	सुनकोशी मेडिकल हल	ओमप्रकाश साह	भिमेश्वर-१, खुर्कोट, सिन्धुली	७ दिन निलम्बन	८/७/२०७४
६०	चरिकोट मेडिसिन सेन्टर	दिपक दाहाल	काब्रे-३, दोलखा	७ दिन निलम्बन	८/७/२०७४
६१	जिबनशक्ति फार्मेसी	राजाराम श्रेष्ठ	भिमेश्वोर न.पा-१, दोलखा	१५ दिन निलम्बन	८/७/२०७४
६२	खनाल फार्मेसी	राजाराम खनाल	भिमेश्वोर न.पा-१, दोलखा	७ दिन निलम्बन	८/७/२०७४
६३	साहरा सामुदायिक अस्पताल प्रा.लि (फा.यु.)	गीता कुमारी खड्का	मन्थली.न.पा-१, रामेछाप	७ दिन निलम्बन	८/७/२०७४
६४	कृति ड्रग हाउस	कृति बस्नेत	मन्थली न.पा-१३, रामेछाप	७ दिन निलम्बन	८/७/२०७४
६५	पुष्पाश्री फार्मेसी	खुमानन्द सुबेदी	भक्तपुर न,पा.१०, भक्तपुर	२१ दिन निलम्बन	११/२८/२०७४
६६	मेडील्याण्ड फार्मेसी	अन्जना श्रेष्ठ	भक्तपुर न.पा-४, भक्तपुर	२१ दिन निलम्बन	११/२१/२०७४
६७	बासना फार्मेसी	राजेन्द्र बि.क	का.म.न.पा-१६, काठमान्डौ	७ दिन निलम्बन	५/३०/२०७४
६८	प्रगति मेडिको फर्मा	सिताराम देबकोटा	तर्केश्वोर , काठमाडौँ	३० दिन निलम्बन	
६९	मेडिस्को फार्मेसी	सुबास श्रेष्ठ	महालक्ष्मी न.प-१६, ललितपुर	७ दिन निलम्बन	
७०	काक्रेबिहार मेडिकल हल	मिन राज जैसी	महालक्ष्मी न.पा-१६, ललितपुर	१५ दिन निलम्बन	
७१	वेलकम मेडिकल हल	चन्द्र महर्जन	ल.उप.न.पा-१०, ललितपुर	१५ दिन निलम्बन	
७२	साहसी फर्मा	ठाकुर प्रसाद सापकोटा	तर्केश्वोर न.पा.११, काठमान्डौ	७ दिन निलम्बन	
७३	राजधानी मेडिकल हल	अम्बर अलि बसाईन	का.म.न.पा-१३, काठमान्डौ	७ दिन निलम्बन	
७४	दवाडी गोर्खा फार्मेसी	ईश्वर दवाडी	टोखा न.पा-१२, काठमान्डौ	१५ दिन निलम्बन	
७५	मिथिला फर्मा	मेनुका पराजुलि	ल.उप.न.पा-६, ललितपुर	७ दिन निलम्बन	

Given below are the lists of products frequently encountered in the market and not registered in the DDA.

List of unregistered drugs frequently seized by DDA

S.No.	Name of product
1	Pain neel oil
2	Megavita forte
3	Hhomega
4	Reviz
5	Aurhair
6	Eposoft
7	gracid
8	Pre-out kit
9	Heal cartilage powder
10	Oprazole
11	IPL-72
12	Clobata GM
13	Clear-72
14	Trama
15	Pentate 40 mg
16	Zenegra 100 mg
17	Unicet
18	Cetrovis
19	Vigora 100mg
20	Bilin 500
21	Anther 500
22	Coldfit plus
23	Coldarin
24	Lemolet
25	Ulpan

S.No.	Name of product
26	Joint pro
27	Nimsel
28	Power point 10 ml
29	power point 5 ml
30	पेट सफा
31	Zenegra 100
32	Boroline
33	Gintop
34	Powerpoint gel 50 gm
35	Viagra 100 mg
36	Hair power
37	Clobeta –GM
38	Cerin 50 mg
39	Surya pak hair oil
40	Dabar stress
41	Tramadol 100 mg
42	Pilo mark
43	Trans KT 100 ml
44	Dr. artho oil
45	Rejuage tabs
46	Dorid 10 mg
47	Efin-DT 100 mg
48	केश रक्षक
49	Pain Relief
50	Ortho wing

S.No.	Name of product
51	Relon-U
52	Dr.ortho Spray
53	Unwanted pill
54	Paurush Jiwan cap
55	Ravedna tel
56	Uric acid tea
57	Asthma tel
58	Bikalpa
59	Nirdosh
60	Reviz
61	Ortho king
62	Pain heal
63	Scalpe
64	Dv 60 k
65	Zenegra red 100 mg
66	Joint pro spray 35 ml
67	coldfit plus
68	Panzol 40 mg
69	VGORA OIL
70	SANDAHA OIL
71	Newron 1500
72	ECT
73	BREAST CARE CREAM
74	LONG LAST SPRAY
75	ANTI ALCOHOL
74	DIBYUJ OIL
75	AllCare Massage Oil
76	DICLOGEM
77	Vovirif 100 SR
78	Kymmol-50

S.No.	Name of product
79	Liv Cet 5
80	Ketodoc
81	Terbi X
82	Vigro 100 red
83	Pentorem 40, Pentorem D
84	Megamox CV 625
85	Rabekem 20
86	Ceflox
87	Esprot SG, Micabal OD
88	Xulide

Products containing active ingredients named as Dietary Supplement frequently seized by DDA

1. Multivitamis
2. Supravit
3. Eposoft
4. Megavit Fort Tablets
5. Revitalcare
6. Neurocare
7. Alphacal- M
8. MyoCyst
9. Caldoz
10. Anacal-M
11. 1000-D
12. Stelbone Tablets
13. Revival
14. D-Min
15. Cal2-Z

नेपाल सरकार

स्वास्थ्य मन्त्रालय

औषधि व्यवस्था बिभागको

अत्यन्त जरुरी सूचना

(प्रथम पटक प्रकाशित मितिः २०७४/१२/०९)

औषधि सल्लाहकार समितिको ४० औं बैठकले Ammonium Chloride वा Sodium Citrate वा Guaiphenesin भएका सम्मिश्रणका Cough Expectorant को दर्ता खारेज गर्न र नयाँ दर्ता नगर्न यस विभागलाई परामर्श दिए बमोजिम यस्ता सम्मिश्रणमा नयाँ औषधि दर्ता गर्ने नगरिएको सरोकारवालाहरूमा बिदितै छ । सो परामर्शका आधारमा विभागको मिति २०७४/११/३० को निर्णयानुसार देहाय बमोजिम गर्न गराउनुहुन सम्बन्धित सबैको जानकरिको लागि यो सूचना प्रकाशित गरिएको छ ।

१. **उत्पादनको हकमाः** मौज्दात कच्चा पदार्थहरूबाट निर्णय भएको मितिले बढीमा ९ (नौं) महिनाभित्र उत्पादन गरि बिक्रि वितरण गरि सक्नुपर्ने र तत्पश्चात उत्पादन गर्न पाईने छैन् । सो अवधि पश्चात उध्योगसंग भएको सो उत्पादनसँग सम्बन्धित विभागले जारि गरेको उत्पादन अनुज्ञापत्र तथा बिक्रि वितरण दर्ता प्रमाणपत्र विभागमा अनिवार्य रूपमा पेश गर्नुपर्नेछ । उल्लेखित कच्चा पदार्थहरूको पैठारी सिफरिशपत्रहरूको नवीकरण, परिमाण वृद्धि आदि सबै कार्यहरू निर्णय भएको मितिदेखि नै लागू हुने गरि रोक लगाईएको छ ।

२. **पैठारीको हकमाः** निर्णय भएको मितिदेखि नै लागू हुने गरि थप पैठारी गर्न पाईने छैन । पैठारी भई आएका मौज्दात औषधिहरू निर्णय भएको मितिले बढीमा ९ (नौं) महिनाभित्र बिक्रि वितरण गरि सक्नुपर्ने छ । पैठारीकर्तासँग उक्त उत्पादनहरूसँग सम्बन्धित विभागले प्रदान गरेको औषधि पैठारी दर्ता प्रमाणपत्र (अनुसूची ४ ङ) र औषधि पैठारी सिफारिशपत्र (अनुसूची ७) यस विभागमा अबिलम्ब बुझाउनु पर्ने छ ।

३. **बजार मौज्दातको हकमाः** उल्लेखित औषधिहरूको मौज्दात प्रयोग गर्न मिल्ने म्यादसम्म बजारमा उपलब्ध हुन सक्नेछन् ।

नेपाल सरकार

स्वास्थ्य मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरूको नमुना परिक्षण गर्दा तपसिल बमोजिमका उत्पादकहरूबाट उत्पादित तपसिल ब्याच न. का औषधिहरू न्यून गुणस्तर भएको पाइएकोले ती औषधिहरू औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि बजारबाट तुरुन्त फिर्ता (RECALL) गर्न र सोको विवरण यस विभागमा १५ दिन भित्र पेश गर्न सम्बन्धित उद्योग तथा आयतकर्ता तथा तिनका आधिकारिक प्रतिनिधिहरूको जानकारीको लागि यो सूचना प्रकासित गरिएको छ साथै उक्त औषधिहरू सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न/नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ ।

तपसिल

सि.न.	औषधिको नाम	ब्याच. न	Mfg/ Expiry date	कारण	उत्पादकको नाम र ठेगाना
१.	QUINOTECH-500	QTT627	May-2017/ Apr-2019	Pharmacopoeial claim in blister pack masked with ink	Amtech Med Pvt. Ltd., Nepal.
२.	ACILOC-150	16445	Aug 2016/ Jan 2019	Leak test failed	Cadila Pharmaceuticals Limited, India.
३.	BACITOR-10	EP001	May 2017/ Apr 2019	Non-compliance to BP 2017 wrt avg. fill wt.	National Healthcare Pvt. Ltd.
४.	Mahasudarshan Churna	AL0466	May 2016/ 2 yrs from mfg date	Non-compliance to Ayurvedic Pharmacopoeia wrt microbial test	Dabur India Ltd, India

मितिः २०७४/०८/२७ गते (December 13, 2017) गतेको गोरखापत्र राष्ट्रिय दैनिकमा प्रकाशित सूचना

नेपाल सरकार

स्वास्थ्य मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरूको नमुना परिक्षण गर्दा तपसिल बमोजिमका उत्पादकहरूबाट उत्पादित तपसिल ब्याच न. का औषधिहरू न्यून गुणस्तर भएको पाइएकोले ती औषधिहरू औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि बजारबाट तुरुन्त फिर्ता (RECALL) गर्न र सोको विवरण यस विभागमा १५ दिन भित्र पेश गर्न सम्बन्धित उद्योग तथा आयतकर्ता तथा तिनका आधिकारिक प्रतिनिधिहरूको जानकारीको लागि यो सूचना प्रकासित गरिएको छ साथै उक्त औषधिहरू सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न/नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल

सि.न.	औषधिको नाम	ब्याच. न	Mfg/ Expiry date	कारण	उत्पादकको नाम र ठेगाना
१	Vajrakshar Churna 30 g	3-C	Feb 2016/ Jan 2018	Non compliance to Ayurvedic Pharmacopoeia of India w.r.t. total aerobic microbial count	Shree Baidhyanath Ayurved Bhawan Pvt. Ltd., India
२	Saraswat Churna	8-C	Feb 2016/ Jan 2018		
३	Avipattikar Churna	205	Feb 2016/ Jan 2018		
४	Lavanbhaskar Churna 60 g	260	Aug 2016/ Jul 2018		
५	Sitopaladi Churna 60 g	261	Aug 2016/ Jul 2018		
६	Panchsakar Churna 60 g	188	Jul 2016/Jun 2018		
७	Pushyanug Churna No 1 (Keshar Yukta) 30g	15-B	Jul 2016/ Jun 2018		

मिति २०७४/०९/०५ (December 20, 2017) गतेको गोरखापत्र राष्ट्रिय दैनिकमा प्रकाशित सूचना

नेपाल सरकार

स्वास्थ्य मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरूको नमुना परिक्षण गर्दा तपसिल बमोजिमका उत्पादकहरूबाट उत्पादित तपसिल ब्याच न. का औषधिहरू न्यून गुणस्तर भएको पाइएकोले ती औषधिहरू औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि बजारबाट तुरुन्त फिर्ता (RECALL) गर्न र सोको विवरण यस विभागमा १५ दिन भित्र पेश गर्न सम्बन्धित उद्योग तथा तिनका आधिकारिक प्रतिनिधिहरूको जानकारीको लागि यो सूचना प्रकासित गरिएको छ साथै उक्त औषधिहरू सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न/नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ ।

तपसिल

सि.न.	औषधिको नाम	ब्याच. न	Mfg/ Expiry date	कारण	उत्पादकको नाम र ठेगाना
१.	PANOPAZ IV	N16703	Mar-2017/ Feb-2019	Non-compliance w.r.t wt. variation/ endotoxin test	Aglowmed Ltd. Mumbai, India
२.	PANOPAZ IV	N16704	Jun-2017/ May-2019	Non-compliance w.r.t avg. wt./wt. variation	Aglowmed Ltd. Mumbai, India
३.	AZA-500	AZHT-711	Apr-2017/ Mar-2019	Non-compliance to IP 2014	Alliance Pharmaceuticals Pvt. Ltd. Nepal
४.	SALBO-4	SM2T-1601	Dec-2016/ Nov-2019	Non-compliance to IP 2014	G.D. Pharmaceuticals Pvt. Ltd., Nepal

मितिः २०७४/१०/२० गते (February 03, 2018) गतेको गोरखापत्र राष्ट्रिय दैनिकमा प्रकाशित सूचना

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 बित्तिकै 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 जानकारीका लागि तल उल्लेखित ठेगानामा सम्पर्क राख्नुहोला ।

औषधि व्यवस्था विभाग

मदनभण्डारी पथ-४, बिजुलीबजार, काठमाडौं

पोष्ट बक्स नं. १००३८, फोन नं.: (०१)-४७८०३२७/४७८०४३२, फ्याक्स नं. ०१-४७८०५७२

www.dda.gov.np

औषधि व्यवस्था विभागका शाखा कार्यालय

	कञ्चनबारी, विराटनगर	आइर्सनगर, नेपालगंज	मुरली बजैचा, विरगंज
	०२१-४२०८४६	०८१-५२२०७४	०५१-५२७७५३
E-mail:	biratnagar@dda.gov.np	nepalgunj@dda.gov.np	birgunj@dda.gov.np

For further infomation, please contact:

Government of Nepal

Ministry of Health and Population

Department of Drug Administration (DDA)

Madan Bhandari Path-4, Bijulibazar, New Baneshwor, Kathmandu

Phone:01-4780432,4780227, Fax:01-4780572

E-mail:druginfo@dda.gov.np

ddadirector@dda.gov.np

Website: www.dda.gov.np

National Medicines Laboratory (NML)

Madan Bhandari Path-4, Bijulibazar

New Baneshwor, Kathmandu

Phone:01-4781269, Fax:01-4780664

E-mail:nml@dda.gov.np

DDA Branch Offices

Kanchanbari, Biratnagar

Koshi Zone

Tel/Fax: 021-420849

E-mail: biratnagar@dda.gov.np

Adarshnagar, Surket Road

Nepalgunj, Bheri Zone

Tel/Fax: 081-522074

E-mail: nepalgunj@dda.gov.np

Murali Bagaicha, Birgunj, Parsa

Narayani Zone

Tel/Fax: 051-527753

E-mail:birgunj@dda.gov.np

For: Further information, Please visit www.dda.gov.np

Published by:
Department of Drug Administration
Ministry of Health and Population
Government of Nepal

Designed & Printed at:
Asmi Printing Press, Kathmandu, Ph.: 9851040384