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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

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EDITORIAL

Antimicrobial Resistance: Urgency for Containment

The discovery of antibiotics transformed our world by making previously incurable illness treatable and allowing medical procedures like operations and chemotherapy to be performed safely. Millions of lives have been saved and well-being radically improved. But our time with these drugs is running out due to antimicrobial resistance globally. Antimicrobial resistance is a natural microbial survival mechanism; however, the overuse and misuse of antimicrobials has increased the rate of resistance development and spread resulting financial burden in public health. Antimicrobial resistance (AMR) threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi resulting a growing and alarming global public health threat.

Inappropriate and irritational prescribing, dispensing, extensive agricultural and veterinary use and availability of fewer antibiotics. Inappropriate prescribing and incorrectly prescribed antibiotics also contribute to the promotion of resistant bacteria. Studies have shown that treatment indication, choice of agent or duration of antibiotic therapy is incorrect in 30% to 50% of cases. In addition, 30% to 60% of the antibiotics prescribed in intensive care units (ICUs) have been found to be unnecessary, inappropriate or suboptimal. Incorrectly prescribed and used antibiotics have questionable therapeutic benefit and expose patients to potential complications of antibiotic therapy.

Sub-inhibitory and subtherapeutic antibiotic concentrations can promote the development of antibiotic resistance by supporting genetic alterations, such as changes in gene expression, Horizontal Gene Transfer (HGT), and mutagenesis. Changes in antibiotic-induced gene expression can increase virulence, while increased mutagenesis and HGT promote antibiotic resistance and spread. Low levels of antibiotics have been shown to contribute to strain diversification in organisms such as *Pseudomonas aeruginosa*. Sub-inhibitory concentrations of piperacillin and/or tazobactam have also been shown to induce broad proteomic alterations in *Bacteroides fragilis.*

Extensive Agricultural and veterinary use in both the developed and developing world antibiotics are widely used as growth supplements in livestock. The use of antibiotics as growth promoter is banned in Nepal. However, the use of antibiotics without proper culture testing and use of meats without considering residual period have been noted in Nepal. The antibiotics used in livestock increased the risk of antimicrobial resistance that occurs through the following sequence of events: 1) antibiotic use in food-producing animals kills or suppresses susceptible bacteria, allowing antibiotic-resistant bacteria to thrive; 2) resistant bacteria are transmitted to humans through the food supply; 3) these bacteria can cause infections in humans that may lead to adverse health consequences. The agricultural use of antibiotics also affects the environmental microbiome. Up to 90% of the antibiotics given to livestock are excreted in urine and stool, then widely dispersed through fertilizer, groundwater, and surface runoff. While this application accounts for a much smaller proportion of overall antibiotic use, the resultant geographical spread can be considerable.

The development of new antibiotics had been effective at combating resistant bacteria. But antibiotic development is no longer considered to be an economically wise investment of the pharmaceutical industry. Because antibiotics are used for relatively short periods and are often curative, antiboitcs are not as profitable as drugs that treat chronic conditions, such as diabetes, psychiatric disorers or asthma. Because medicines for chronic conditions are more profitable, pharmaceutical companies prefer to invest in them.

The massive increases in trade and human mobility brought about by globalization have enabled the rapid spread of infectious agents, including those that are drug resistant. While developed countries, to a large extent are still able to rely on the latest antimicrobials to treat resistant infections, access to these life-saving drugs is often limited or totally absent in many parts of the world. Urgent coherent, comprehensive and integrated national approach is needed to combat and contain antimicrobial resistance through:

- Development of national antibiotic policy and formulating multi-sectoral national alliances against antimicrobial resistance.

- Study the emergence and spread of antimicrobial resistance and assess accurately its impact on public health.
- Regulating the use of antimicrobial agents both in public and private sectors to prolong and preserve their efficacy.
- Strengthen legislation to prevent the manufacture, sale and distribution of spurious and substandard/not-of standard-quality and poor-quality antimicrobial agents and the sale of antibiotics.
- Promoting behavioral change in prescribers and communities through continuous training, educational campaigns with process and outcome measures for rational use of antimicrobial agents and emphasizing antimicrobial resistance in medical, dental veterinary and pharmacy curricula.
- Build increased capacity for efficient surveillance of antimicrobial resistance and its effective use in modifying antibiotic policy.
- Strengthen diagnostic facilities for microbial diseases to facilitate evidence-based antimicrobial prescription.
- Strengthen infection control practices in health care facilities to reduce the burden of microbial diseases and health-care associated infections.
- Advocate healthy lifestyle, cost-effective and essential immunization and other nonpharmaceutical measures to reduce the disease burden due to microbial diseases.

For comparing antimicrobial resistance Department of Drug Administration (DDA) has been designated the focal point for antimicrobial surveillance as approved National Action Plan on antimicrobial resistance (NAPAMR) that underscores “one health” approach. Surveillance of antimicrobial consumption (AMC) is an important pillar of the National Antimicrobial Resistance Containment Action Plan for Antimicrobial Resistance (2021-2026) in Nepal. Antimicrobial consumption studies carried out from 2016 to 2021 showed total consumption of antibiotics for systemic use (ATC J01) ranged from 81.94 to 109.15 DDD (Daily Defined Dose) per 1000 inhabitants per day DID (2016), 81.94 DID (2017), 109.15 DID (2018) 87.24. Nitroimidazole derivatives (ATC P01AB) accounted for 25% of total consumption, followed by macrolides (ATC J01FA) 15%, third generation cephalosporins (J01DD) and fluoroquinolones (J01MA) at 10%. Systemic use antibacterial accounted for the

largest share (nearly three-fourths during 2018) whereas nitroimidazole (antiprotozoals) accounted for over one-fourth to one-third during the period. The consumption of agents in the WHO access group decreased from 50% in 2016 to 33% in 2021 whereas those in the watch group steadily climbed to 55% within the same time frame.

The laboratory based surveillance for AMR in Nepal started in 1999 with support from USAID and technical assistance from ICDDR B, (International Centre for Diarrhoeal Disease Research/ Bangladesh). with nine participant laboratories monitoring six bacterial pathogens. National Public Health Laboratory (NPHL) is the National Coordinating Center and National reference laboratory for AMR surveillance in human health. The program led by NPHL has expanded to a network of twenty-one laboratories and currently monitors AMR for ten priority bacterial isolates. Similar AMR surveillance in animal health includes collection of AMR data from animals. There are four multisectoral committees to lead and support AMR activities in Nepal. A high level AMR Multisectoral Steering Committee (AMRMSC) chaired by Secretary, MoHP to discuss on policy related issues in AMR, a one health National Technical Working Committee (NTWC) to oversee the approaches and implementation of AMR in the country and to make recommendations on technical issues to AMRMSC and two Technical Working Groups on AMR, one each for human health (TWG-HH) and animal health (TWG-AH) to provide technical and operational inputs to the AMR surveillance including development of guidelines, protocols and SOPs. Ten priority bacterial pathogens included in the National AMR surveillance programme are:

1. *Vibrio cholerae*
2. *Shigella species*
3. *Streptococcus pneumoniae*
4. *Haemophilus influenzae*
5. *Neisseria gonorrhoeae*
6. *Salmonella species*
7. Extended spectrum beta lactamase (ESBL) producing *Escherichia coli*
8. Methicillin resistant *Staphylococcus aureus* (MRSA)

9. *Klebsiella species*

10. *Acinetobacter species*

The significant increase in the consumption of antimicrobial compared to other countries and use of antibiotics in the watch group is of concern. The study showed Nepal needed robust system for antimicrobial containment. The National Action Plan aims to provide a coherent policy framework and priority actions to contain the emergence and spread of AMR, through the following strategic objectives. One of the strategies should be antimicrobial stewardship program to measure the quality of use of these agents and implement systems to improve prescribing.

Everyone needs to act with utmost urgency to avert the AMR crisis. Without integrated action on health policy all the hard-won gains for health will be eroded and diseases that were easy to treat will once again kill a dire and present threat to this generation and generations to come.

Bharat Bhattarai
(Director General)
Chief Editor

1. आ.व. २०७८/७९ मंसिर देखि माघ महिनासम्मको प्रगति विवरण

अनुगमन, मुल्यांकन तथा कानुन कार्यान्वयन महाशाखा अन्तर्गत मुख्य कार्यहरु:

औषधि पसल/फार्मेसी निरीक्षण :

विवरण	काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
दोस्रो त्रैमासिक लक्ष्य	४५०	१२५	१२५	१२५	८२५
दोस्रो त्रैमासिक प्रगति	४१६	१६०	१२३	९४	७९३
दोस्रो त्रैमासिक प्रगति प्रतिशत	९२	१२८	९८	७५	९६.१२

उद्योग निरीक्षण :

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दोस्रो त्रैमासिक प्रगति	२४	१	०	०	२५
दोस्रो त्रैमासिक प्रगति प्रतिशत	१२०	१००	०	०	९६.१५

औषधि मुल्यांकन तथा दर्ता महाशाखा अन्तर्गत मुख्य कार्यहरुः

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योजना, समन्वय तथा व्यवस्थापन महाशाखा अन्तर्गत मुख्य कार्यहरु

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2. REGULATORY NEWS

Cefoperazone

Risk of bleeding and hypoprothrombinemia

Saudi Arabia. The Saudi Food & Drug Authority (SFDA) has requested that health-care institutions stop supplying cefoperazone products (Cefobid®) due to the risk of bleeding, and has also advised health-care professionals to prescribe safer alternative antibiotics.

Cefoperazone is indicated for the treatment of a wide range of infections including respiratory tract infections, peritonitis and bacterial septicemia.

Results of several published studies suggest that cephalosporin antibiotics including cefoperazone is associated with the risk of bleeding via inhibiting vitamin K metabolism, which can lead to hypoprothrombinemia.

The SFDA reviewed published literature and post-marketing data to evaluate the potential risk of hypoprothrombinemia and bleeding with cefoperazone use. The SFDA found that the current evidence indicates an increased risk of hypoprothrombinemia and bleeding with the use of cefoperazone compared to other safer therapeutic alternatives that are available in Saudi Arabia for the same indications. Serious and fatal cases of bleeding have been reported with the use of cefoperazone worldwide.

The evaluation of the benefit- risk profile of products containing cefoperazone showed that the potential risks outweigh the benefits.

Reference:

Safety Alerts, SFDA, 14 June 2021 (www.sfda.gov.sa)

Source: WHO Pharmaceuticals Newsletter No.4, 2021

COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19)

1.Risk of capillary leak syndrome (CLS)

Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that people who have previously had capillary leak syndrome (CLS) must not be vaccinated with COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) and that CLS should be added to the product information as a new adverse drug reaction.

CLS is a very rare, serious condition that causes fluid leakage from small blood vessels, resulting in swelling in the arms and legs, low blood pressure and low albumin level.

COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) is a vaccine for preventing COVID- 19 in people aged 18 years and older.

The PRAC carried out an in- depth review of six cases of CLS in people who had received the vaccine.

Health-care professionals should be aware of the signs and symptoms of CLS and of its risk of recurrence in people who have previously been diagnosed with the condition.

People who have been vaccinated with the vaccine should seek immediate medical assistance if they experience rapid swelling of the arms and legs or sudden weight gain in the days following vaccination.

Reference:

EMA, 11 June 2021 (www.ema.europa.eu)

2.Risk of Guillain-Barre syndrome (GBS)

Europe. The PRAC has recommended a change to the product information for COVID- 19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) to include a warning on Guillain- Barre syndrome (GBS).

The PRAC has assessed all the available evidence including cases reported and data from the scientific literature, but at this stage the data neither confirms nor rules out a possible association with the vaccine.

Health-care professionals should be alert to signs and symptom of GBS to allow early diagnosis and supportive care and treatment.

People taking the vaccine are advised to seek immediate medical attention if they develop weakness and paralysis that can progress to the chest and face.

Reference:

EMA, 9 July 2021 (www.ema.europa.eu)

Source: WHO Pharmaceuticals Newsletter No.4, 2021

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.

Reference:

Safety Alerts, SFDA, 20 June 2021 (www.sfda.gov.sa)

Source: WHO Pharmaceuticals Newsletter No.4, 2021

Sunitinib

Potential risk of interstitial lung disease

Saudi Arabia. The SFDA has made a request to update the product information for sunitinib containing products (Renis®, Sutexa®, Sutent®) to include interstitial lung disease as an adverse event.

Sunitinib is indicated to treat gastrointestinal stromal tumor, metastatic renal cell carcinoma and pancreatic neuroendocrine tumors.

The SFDA has reviewed the published literature and post marketing data on the potential risk of interstitial lung disease with the use of sunitinib. The SFDA identified 115 spontaneous case reports of interstitial lung disease with the use of sunitinib in the WHO database.

The SFDA advised health-care professionals to **discontinue sunitinib therapy if a patient developed interstitial lung disease.**

Reference:

Safety Alerts, SFDA, 15 June 2021 (www.sfda.gov.sa)

Source: WHO Pharmaceuticals Newsletter No.4, 2021

Tofacitinib

Risk of cardiovascular events and cancer

Europe. The PRAC has recommended an update to the product information for tofacitinib (Xeljanz®) to include a new recommendation for its use due to the risk of cardiovascular events and cancer.

Tofacitinib is indicated to treat adults with moderate to severe rheumatoid arthritis. The PRAC reviewed the data from a recent study conducted in patients who were 50 years of age or older with at least one additional cardiovascular risk factor.
The PRAC advises health-care professionals that tofacitinib should only be used in patients over 65 years old, patients who are current or past smokers, patients with other cardiovascular risk factors and patients with other malignancy risk factors, if no suitable treatment alternative is available.

Reference:
EMA, 11 June 2021 (www.ema.europa.eu)
Source: WHO Pharmaceuticals Newsletter No.3, 2021

Pembrolizumab (genetic recombination)

Risk of fulminant hepatitis and hepatic failure

Japan. The MHLW and the PMDA have announced that the package insert for pembrolizumab (Keytruda®) should be revised to include the risk of fulminant hepatitis and hepatic failure as adverse drug reactions.

Pembrolizumab is indicated to treat certain types of cancers such as malignant melanoma, unresectable advanced non- small cell lung cancer and relapsed classical Hodgkin lymphoma.

A total of 29 cases of fulminant hepatitis or hepatic failure have been reported in patients treated with pembrolizumab in Japan in the last three years, including five cases for which a causal relationship between the drug and event was reasonably possible. A total of 18 patient mortalities, including three cases of which a causal relationship was assessed to be reasonably possible have been reported.

Patients should be carefully monitored through periodical hepatic function tests.

Reference:
Revision of Precautions, MHLW/PMDA, 15 June 2021 (www.pmda.go.jp/english/)
Source: WHO Pharmaceuticals Newsletter No.4, 2021

3. SAFETY OF MEDICINES

Prednisone

Risk of steroid withdrawal symptoms

New Zealand. The Medsafe has warned of cases of steroid withdrawal symptoms, such as, shaking, sweats, fatigue, puffy face and swollen legs, after taking high-dose prednisone for infective exacerbations of asthma.

Prednisone is a corticosteroid that is indicated for treatment of several conditions such as arthritis, blood disorders, breathing problems and severe allergies.

Prednisone dosing should be determined on a case by case basis taking into consideration the condition being treated and its severity. Generally, prednisone should be used at the lowest effective dose and for the shortest duration.
Prolonged use of prednisone can result in suppression of the hypothalamic-pituitary-adrenal axis. Abrupt cessation or a too- rapid withdrawal of prednisone may cause symptoms of adrenal insufficiency such as abdominal pain, nausea, diarrhea and hypotension.

Reference:
Prescriber Update, Medsafe, June 2021 (www.medsafe.govt.nz/)
Source: WHO Pharmaceuticals Newsletter No.4, 2021

Retinoid medicines (Oral)

Pregnancy prevention and risk of psychiatric adverse events

United Kingdom. The MHRA has announced the publication of a new guidance on remote consultations for pregnancy prevention in women of childbearing potential. The document also provides guidance on monitoring for signs of psychiatric reactions in patients taking oral retinoid medicines.

Oral forms of the retinoid medicines such as isotretinoin, alitretinoin and acitretin are indicated to treat severe dermatological diseases that are resistant or unresponsive to standard therapies.

Psychiatric adverse events have been reported in patients taking oral retinoids and they are under review.

The guidance aims to remind health-care professionals of the need to implement the pregnancy prevention programme and monitor all patients taking oral retinoids.

Remote consultations should occur with at least the same frequency as the usual clinic consultations, to allow adequate monitoring of mental health and other potential adverse events.

Reference:
Drug Safety Update, MHRA, 7 July 2021 (www.gov.uk/mhra).

Source: WHO Pharmaceuticals Newsletter No.4, 2021

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

Increased risk of postpartum hemorrhage

New Zealand. The Medsafe has announced that the results of a review of observational studies has shown that there is a small increased risk of postpartum hemorrhage when selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) are used during the month up to delivery in pregnant women.

SSRIs and SNRIs are antidepressants indicated for several symptoms such as depression and anxiety disorder.

In March 2021, the Medicines Adverse Reactions Committee (MARC) reviewed the risk of postpartum hemorrhage when SSRIs (citalopram, escitalopram, fluoxetine, sertraline and paroxetine) and SNRIs (venlafaxine) are used during the month up to delivery, and considered that an increased risk of postpartum hemorrhage was biologically plausible.

Health-care professionals are reminded to continue to consider the benefits of treating depression for the pregnant women.

Reference:
Prescriber Update, Medsafe, June 2021 (www.medsafe.govt.nz/)
Source: WHO Pharmaceuticals Newsletter No.4, 2021

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.

Amiodarone and rivaroxaban AND gastrointestinal haemorrhage

Annette Rudolph

Summary

A signal regarding the interaction between amiodarone and rivaroxaban resulting in gastrointestinal haemorrhage was detected during a screening of VigiBase, the WHO global database of individual case safety reports (ICSRs) in autumn 2020. Up to 6 December 2020 VigiBase contained 24 unique reports of gastrointestinal haemorrhage resulting from the combined use of amiodarone and rivaroxaban. Most patients were elderly with a median age of 74 years (range 34 – 91 years). In five cases (20.8%) reduced renal function was reported, potentially influencing rivaroxaban's exposure.

The antiarrhythmic drug amiodarone and its active metabolite act as moderate inhibitors for a series of CYP enzymes as well as P-gp and therefore have the potential for PK interactions with various drugs. The oral factor Xa inhibitor rivaroxaban is metabolised hepatically via the cytochrome P450 (CYP) enzymes 3A4 and 2J2 and is eliminated renally, via P-gp-mediated secretion. Its pharmacokinetic (PK) profile carries the risk for the development of dose-dependent toxicity when administered to patients suffering from hepatic or renal impairment or to patients receiving CYP enzyme inhibiting drugs concomitantly.

Introduction

Amiodarone is an antiarrhythmic drug used for conversion and prevention of supraventricular arrhythmias, like atrial fibrillation (AF)1,2. Its antiarrhythmic effect is based on a prolongation of the heart's action potential by inhibition of voltage- gated potassium and calcium channels. Amiodarone is poorly bioavailable after oral administration. After intravenous injection it is strongly

protein-bound with an extremely long plasma half-life (20-100 days). Amiodarone undergoes extensive hepatic metabolism, mainly via the CYP enzyme 3A4 and several others. In vitro experiments have shown that amiodarone and its active metabolite are moderate inhibitors for a series of CYP enzymes as well as P-gp and therefore carry the potential for PK interactions with various drugs (2,3).

Rivaroxaban is an orally bioavailable, highly selective factor Xa inhibitor, blocking the intrinsic as well as the extrinsic pathway of the blood coagulation cascade. It is indicated for prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery, treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults (4). After oral administration, rivaroxaban reaches maximal serum concentrations (tmax) after two to four hours.

Elimination of rivaroxaban occurs through a dual pathway: two thirds of the administered dose undergo hepatic metabolism via the CYP enzymes 3A4 and 2J2. The remaining third is eliminated renally via P-gp-mediated secretion1,4. Elimination half-time (t1/2) is seven to eleven hours4,5. The summary of product characteristics (SmPC) advises the cautious use of rivaroxaban in patients suffering from renal impairment as well as in patients receiving comedications inhibiting both CYP3A4 and P-gp due to potential PK interactions4. Due to its pharmacodynamic (PD) properties, the risk for all kinds of hemorrhages is increased under rivaroxaban therapy (4).

Reports in VigiBase

The potential signal “amiodarone – interaction with rivaroxaban causing gastrointestinal (GI) haemorrhage” was identified during a screening of VigiBase, in autumn 2020.

Up to 6 December 2020, VigiBase contained 24 unique ICSRs reporting the MedDRA preferred term (PT) “gastrointestinal haemorrhage” in patients receiving rivaroxaban and amiodarone as suspected and/or interacting drugs and these were subjected to in-depth assessment. All cases were classified as serious. In three cases (12.5%) a fatal outcome was reported. Reports were sent from five different countries (United States of America (USA), Switzerland, France,

Canada, and Belgium), with most of the reports (n = 18; 75.0%) from the USA. Information on the daily dose for amiodarone and rivaroxaban was available in 19 and 12 cases, respectively. Patients received on average 19.0 mg rivaroxaban (range 15-20 mg/d) and 233.3 mg amiodarone (range 200-400 mg/d) daily. This is in line with the therapeutic doses recommended in the SmPCs (2,4). Table 1 gives an overview of the 24 assessed case reports.

Table 1. Overview of case details

Case	**Age/ Sex**	**Drugs**	**Reactions (MedDRA preferred terms)**	**Time-to-onset (GI haemorrhage)**	**Additional information**
1	63/F	Amiodarone (S) Rivaroxaban (I)	Gastrointestinal haemorrhage Drug interaction	Unknown Unknown	
2	71/F	Amiodarone (S) Rivaroxaban (I) Acetylsalicylic acid (I)	Gastrointestinal haemorrhage Drug interaction	Unknown Unknown	
3	-/-	Amiodarone (S) Rivaroxaban (S) Ibrutinib (S) Acetylsalicylic acid (S) Fluconazole (S) Warfarin (S) Enoxaparin (S) Diltiazem (S)Fish oil (S) Verapamil (S) Tocopherol (S) Apixaban (S) Nicotinic acid (S) Clopidogrel (S) Ticagrelor (S)	Gastrointestinal haemorrhage Contusion Cerebral haemorrhage Haematoma Epistaxis	Unknown Unknown	
4	-/-	Amiodarone (S) Rivaroxaban (S)	Gastrointestinal bleeding	Approx. 10 days Approx. 10 days	

5	66/ M	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S) Tamsulosin, Hydromorphone, Prednisone, Methocarbamole, Metoprolol, Salbutamol, Furosemide, Oxycodone, Simvastatin, Tiotropium, Lorazepam, Fluticasone/Salmeterol, Gabapentin, Clonazepam, Lisinopril (C)	Gastrointestinal haemorrhage	Approx. 2 months Approx. 2 months	
6	91/F	Amiodarone(S) Rivaroxaban (S)	Gastrointestinal haemorrhage Rectal haemorrhage Melaena Drug interaction Anemia	5 days 5 days	
7	85/ M	Amiodarone (S) Rivaroxaban (S) Dabigatran (S) Acetylsalicylic acid (S) Enoxaparin (S) Furosemide, Pantoprazole, Metoprolol, Zolmitriptan (C)	Gastrointestinal haemorrhage Haematuria Fall Acute kidney injury Haemorrhage intracranial	Unknown 2 years	
8	62/ M	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S)	Blood loss anemia Gastrointestinal haemorrhage	Unknown 6 months	Predisposing factors: liver cirrhosis Removal of benign colon polyp (10/12/2015)
9	73/F	Amiodarone (S) Rivaroxaban (S)	Gastrointestinal Haemorrhage Swelling (amiodarone) Weight increase (amiodarone)	Unknown 2 weeks	

10	83/F	Amiodarone (S) Rivaroxaban (S) Sertraline (S) Nadolol, Pantoprazole, Vitamin D nos, Vitamins nos, Febofibrate, Furosemide, Alprazolam, Cyanocobalamin, Fluticasone (C)	Dyspnoea Gastrointestinal haemorrhage Melaena Gastritis Haematemesis Vomiting	1 year 3 years	Predisposing factors: Solitary kidney
11	74/F	Amiodarone (S) Rivaroxaban (S) Enoxaparin (S) Dabigatran (S) Acetylsalicylic acid (S) Prednisolone, Hydrochlorothiazide, Nicotinic acid, Multivitamin, Lisinopril, Ketorolac, Atenolol, Ibuprofen (C)	Gastrointestinal haemorrhage	Unknown 20 days	
12	63/ M	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S)	Gastrointestinal haemorrhage Off label use Pulse absent Acute respiratory distress syndrome Product use issue	Unknown Unknown	
13	74/F	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S) Valsartan, Diltiazem, Pravastatin (C)	Gastrointestinal haemorrhage Myocardial infarction Haemorrhagic stroke Haemoptysis Epistaxis	Unknown 5 days	
14	85/ M	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S) Allopurinol, Lorazepam, Insulin, Furosemide, Ibuprofen, Acetaminophen/Hydrocodon, Nortryptilin, Omeprazole, Potassium, Sennosoid (C)	Acute kidney injury Blood blister Haemorrhage Gastrointestinal haemorrhage Petechiae Haematuria	Unknown 2 months	

15	60/ M	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S)	Anaemia Gastrointestinal haemorrhage	Unknown 2 months	
16	75/F	Amiodarone (I) Rivaroxaban (I) Clopidogrel (I) Acetylsalicylic acid (I)	Overdose Gastrointestinal haemorrhage Ecchymosis	2 months 2 months	Predisponen factors: Pyelonephritis secondary to diabetes mellitus II Elevated rivaroxaban plasma concentrations at admission (500 ng/mL) Light to moderate renal insufficiency (age- dependent) (61 mL/min CKD-EPI)
17	74/ M	Amiodarone (S) Rivaroxaban (S) Acetylsalicylic acid (S) Macrogol 3350, Carvedilol, Simvastatin, Ramipril (C)	Gastrointestinal haemorrhage Blood loss anaemia	Unknown Unknown	
18	89/ M	Amiodarone (S) Rivaroxaban (S) Clopidogrel (S) Acetylsalicylic acid (S) Vitamin D, Iron, Finasterid, Nicotinic acid, Ramipril, Rosuvastatin, Tamdulosin,Trimetoprim/Sulfamethoxazole, Lycopene (C)	Gastrointestinal haemorrhage Iron defficiency anaemia Diverticulum Small intestinal haemorrhage	Unknown Unknown	
19	-/-	Amiodarone (S) Rivaroxaban (S)	Gastrointestinal haemorrhage Errosive oesophagitis	Unknown Unknown	

20	87/F	Amiodarone (I) Rivaroxaban (I) Torasemide, Enalapril, Ipratropium, Salbutamol, Spironolactone, Pramipexole, Insulin degludec, Pantoprazole (C)	Gastrointestinal haemorrhage Melaena Drug interaction	30 days 15 days	Predisposing factors: hepatic cirrhosis, renal insufficiency (GFR ca. 40 mL/min)
21	77/F	Amiodarone (S) Rivaroxaban (S) Venlafaxine (S),Oxazepam, Atrovastatin, Spironolactone, Zolpidem, Rimenidine, Furosemide, Olmesartan, Nicardipine, Macrogol 3350/Potassium/Sodium bicarbonate/Sodium sulfate (C)	Gastrointestinal haemorrhage Shock haemorrhagic	9 days 9 days	Initial creatinine clearance (52 mL/min), decreased dramatically within 10 days (21 mL/min)
22	34/F	Amiodarone (I) Rivaroxaban (S)	Gastrointestinal haemorrhage Gingival bleeding	16 days 16 days	Predisposing factors: Haemophilia A
23	72/ M	Amiodarone (I) Rivaroxaban (I) Acetylsalicylic acid (I) Metoprolol, Rosuvastatin, Loperamide, Pantoprazole, Diphenhydramine/Lorazepam (C)	Gastrointestinal haemorrhage Melaena Dyspnoea Asthenia Blood loss anemia	years months	Predisposing factors: GI haemorrhage 6 years before event onset, chronic renal insufficiency grad III secondary to diabetes mellitus type II
24	78/F	Amiodarone (S) Rivaroxaban (S)	Optic atrophy Atrial fibrillation Haemoglobin decreased Gastrointestinal haemorrhage	year months	

Among the 24 cases, 12 patients were female and nine male with a median age of 74 years (range 34– 91 years). In three cases information on patients'sex and age was missing. In five cases (20.8%) the MedDRA PT "Drug interaction" was specifically co- reported. In eight cases (33.3%) rivaroxaban and amiodarone were the only two reported drugs (including one case with concomitant hepatic and renal impairment, and one case with underlying haemophilia). In five cases (20.8%) reduced renal function was reported, potentially influencing rivaroxaban's plasma concentrations (see Table 1).

Patients received a median of three suspected/interacting drugs (range two to 19). Fourteen reports included co-medications that, in addition to rivaroxaban, had anticoagulant or antiplatelet activity. Acetylsalicylic acid was listed in all fourteen reports and in five of these one or more other antiplatelet agents (clopidogrel, ticagrelor) or anticoagulants (warfarin, enoxaparin, apixaban, dabigatran) were also listed as shown in Table 1.

Analysing the concomitant drugs, in total 12 substances had PD interaction potential, anotherfour substances had PK interaction potential and one substance (ticagrelor) had PK as well as PD interaction potential with rivaroxaban6,7. A data- driven exploration of the reports pinpointing features using vigiPoint8 revealed an unexpectedly frequent reporting of nicotinic acid as a concomitantly administered drug (12.9% (three ICSRs) in cases reporting GI haemorrhage with rivaroxaban and amiodarone in combinations (foreground) vs 0.3% in cases reporting GI haemorrhage with rivaroxaban (background 1) and 0.0% in cases reporting GI haemorrhage with amiodarone (background2)).

Literature and Labelling

Labelling

Rivaroxaban:

According to the Summary of Product Characteristics (SmPC) of Xarelto® (rivaroxaban), limited clinical data suggest that rivaroxaban plasma concentrations are significantly increased (approximately 44-64%) in patients suffering from severe renal impairment (creatinine clearance 15- 29 mL/min), resulting in increased PD effects (4, 9).

The FDA's SmPC of rivaroxaban therefore advises to regularly assess patient's

renal function and possibly adjust the dose accordingly9. Furthermore, a formal contraindication for the use of rivaroxaban in patients suffering from hepatic disease is imposed, as it has been associated with a clinically relevant bleeding risk4.

The SmPC advises also against the use of rivaroxaban in patients being concomitantly treated with azole-antimycotics or HIV protease inhibitors, since substances that are strong inhibitors of both CYP3A4 and P-gp may increase rivaroxaban plasma concentrations to a clinically significant degree resulting in an increased risk for bleeding. Inhibitors of only one of the rivaroxaban elimination pathways either CYP3A4 or P-gp – are expected to increase rivaroxaban plasma concentrations to a lesser extent. Advice on the use of weak to moderate inhibitors of CYP3A4 and P-gp, such as amiodarone, is absent. The SmPC warns, however, specifically against co-treatment with dronedarone, a less lipophilic successor substance of amiodarone, in patients receiving rivaroxaban therapy, due to limited available clinical data4.

The SmPC labels bleeding as the most reported adverse reaction in patients treated with rivaroxaban. Amongst bleeding events, gastrointestinal tract haemorrhages were observed most frequently occurring in 3.8% of cases in one study10. Due to its pharmacological properties, rivaroxaban can cause an increased risk of occult or overt bleeding from any tissue or organ4.

Amiodarone:

Amiodarone and its active metabolite, desethylamiodarone, act as inhibitors of various CYP enzymes as well as the P-gp, resulting in increased exposure to their substrates1,2. Though only a limited number of in vivo DDI have been reported, a potential for other interactions should be anticipated in relation to amiodarone (11).

Importantly to consider is amiodarone’s long half- life. Therefore, effects resulting from PK interactions may be observed months after discontinuation of amiodarone therapy (1).

According to the SmPC of amiodarone, thrombocytopenia, potentially increasing the risk of haemorrhagic events, is labelled as a very rare adverse reaction (2).

Literature

A series of four published case reports describes patients experiencing increased anticoagulation parameters and/or haemorrhagic events after co-treatment with rivaroxaban and amiodarone, in one case even weeks after amiodarone cessation (1).

The four case reports describe three male and one female patient, aged 71 to 88 years old, who were admitted to the hospital due to experiencing haemorrhagic events (pulmonary haemorrhage, intracerebral mass bleeding, and cardiac tamponade) (12–14) or elevated INR (1). In two cases the adverse reactions resolved after withdrawal of rivaroxaban (1,12) in one case rivaroxaban as well as amiodarone were withdrawn and the patient recovered14, and in one case the patient's death was reported as outcome13. In one case the patient's renal function was reported to be impaired (eGFR = 50 mL/min)1.

Discussion

In the 24 assessed ICSRs reporting GI haemorrhage in combination with amiodarone and rivaroxaban as suspected or interacting drugs, amongst the 79 reported concomitant drugs, 17 substances were found to have PK and/or PD interaction potential6.

The potential DDI between amiodarone and rivaroxaban was identified and labelled by the reporter in only five cases. A possible reason for this circumstance might be missing awareness/labelling. Furthermore, amiodarone's long half-life might impede recognition of the potential DDI.

Nicotinic acid was co-reported with an unexpected frequency in cases of GI haemorrhage following concomitant use of amiodarone and rivaroxaban.

In the SmPC of nicotinic acid as well as in published case reports the potential to cause decreased platelet counts and coagulopathy are discussed, mentioning that the exact mechanism of action of nicotinic acid is not yet explored15–20.

The assessed reports also raise awareness of concomitant prescribing of anticoagulant and antiplatelet medicines as there are few indications for their combined use. In 15 cases patients received additional substances with antithrombotic activity. Most were "elderly patients" (≥ 65 years old). Advanced

age is a known risk factor for bleeding events associated with anticoagulation.

Furthermore, it is known that renal function decreases with advancing age. For five patients impaired renal function was specifically reported. A series of four published literature case reports indicates that the potential DDI in real-world clinical practice warrants attention (1, 12–14).

According to the European public assessment report (EPAR) Risk Management Plan (RMP) from 201821, potential risks of rivaroxaban treatment of patients with severe renal impairment (creatinine clearance < 30 mL/min) as well as patients being co-treated with systemic inhibitors of CYP3A4 or P-gp - other than azole antimycotics and HIV-protease inhibitors were identified as “missing information”. In 2013, the EMA’s Pharmacovigilance Risk Assessment Committee (PRAC) recommended an updating of the European SmPC of rivaroxaban regarding the sections “Contraindications” and “Interactions”22. It was recommended to include a series of potential DDI, amongst them amiodarone, to be mentioned for cautious concomitant use. Based on preclinical and clinical data that did not show a significantly increased clinical risk the market authorisation holder did not consider including amiodarone in section 4.5.

Haemorrhage being a known risk associated with rivaroxaban, the identification of a possible interaction with another medicine, such as amiodarone, resulting in an increased risk of haemorrhagic events is inevitably confounded.

However, although several of the assessed cases as well as the published case reports include confounding factors, such as the use of concomitant medications and underlying organ dysfunctions, the case series supports the hypothesis of a clinically relevant potential interaction between amiodarone and rivaroxaban and suggests particular caution for co-prescription in patients predisposed to rivaroxaban-related haemorrhage through age, co- morbidities and other medicines that also increase the risk through PK or PD mechanisms. . The decision to consider co-prescribing amiodarone and rivaroxaban is an opportunity to review the patient’s medicines especially where multiple antithrombotic medicines are being prescribed.

There are clinical indications for dual antiplatelet/anticoagulant therapy but de-

prescribing of an unnecessary antiplatelet medicine may be appropriate in some cases (23).

Conclusion

Due to their overlapping indication field and their clinical significance, amiodarone and rivaroxaban could commonly be used concomitantly or close in time in clinical practice. The observed concomitant treatment of patients with multiple drugs potentially increasing the risk for haemorrhagic events via PK and/or PD interactions with rivaroxaban and amiodarone constitutes a concern for their use in real-world clinical practice. Caution when attempting concomitant use of amiodarone and rivaroxaban should be advised, recommending benefit/risk exploration on an individual patient basis, particularly in vulnerable patients.

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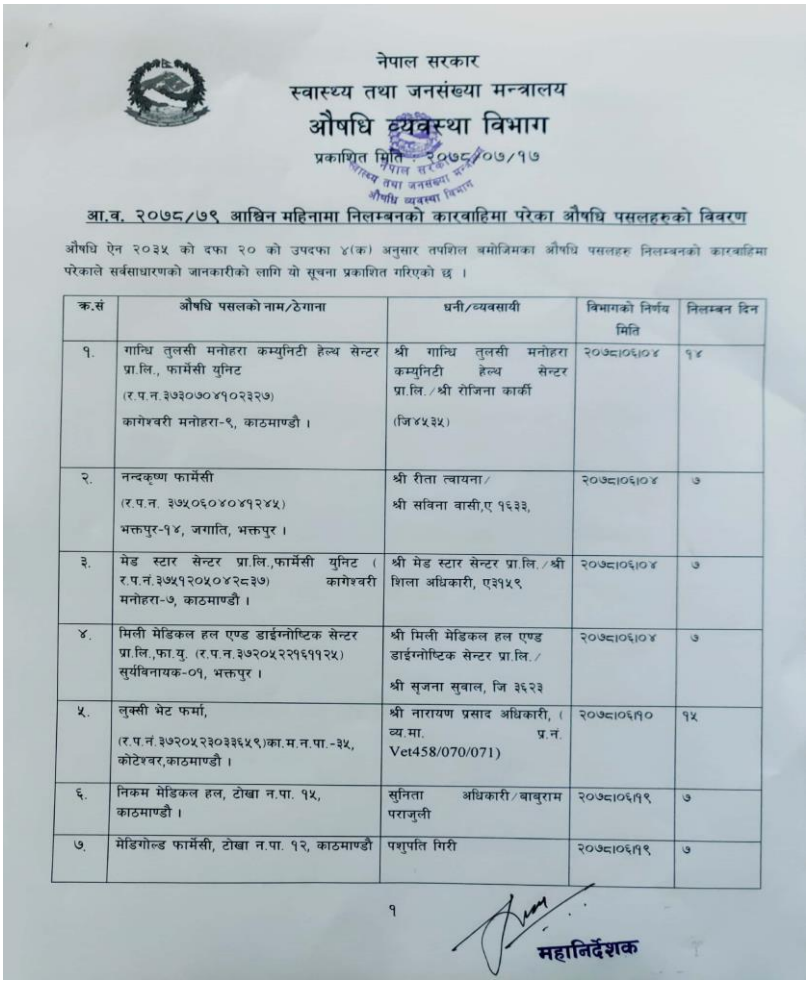
5. REGULATORY NOTICES



नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
प्रकाशित मिति : २०७८/०७/१७

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 बासी,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.न. 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

१

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/०९/३०

आ.व. २०७८/७९ मङ्सिर 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.	नविन फार्मेसी (र.प.नं. ३७२०५२२२२१००७) महालक्ष्मी-१८, ललितपुर	श्री नारायण भट्टराई (धनी/ व्यवसायी)	२०७८/०८/१६	१० (दश)
२.	ईजी फर्मा (र.प.नं. ३७२०५२२१९३५३७) महालक्ष्मी-१६, ललितपुर	श्री मेन कुमारी गोराथोकी (धनि/व्यवसायी) ए१४८०	२०७८/०८/१६	७ (सात)
३.	नुर फार्मेसी (र.प.नं. ३७५०१०४०७३७२४) सिद्दार्थनगर नगरपालिका-०३, रुपन्देही	श्री मोहम्मद ईर्फान पठान (धनी), रबिन रसाईली (व्यवसायी)	२०७८/०८/२०	७ (सात)
४.	विराट मेडिकल हल सिद्दार्थनगर नगरपालिका-१३, रुपन्देही	श्री सरस्वती गौतम घिमिरे (धनी/ व्यवसायी)	२०७८/०८/२०	७ (सात)
५.	नमस्ते फर्मा, (र.प.नं.३७२०५२३०२४८३१) बुटवल उपनगरपालिका-०८, रुपन्देही	श्री तिलकराज गौतम (धनी/ व्यवसायी)	२०७८/०८/२०	७ (सात)
६.	जनकल्याण फार्मेसी (र.प.नं. ३७२०५२३००५०२६) बुटवल उपनगरपालिका-०८, रुपन्देही	श्री उमेश चन्द्र शर्मा (धनी), श्री बम बहादुर कार्की (व्यवसायी)	२०७८/०८/२०	७ (सात)
७.	विनायक फर्मा सिद्दार्थनगर नगरपालिका-०३, रुपन्देही	श्री तारा भण्डारी (धनी/ व्यवसायी)	२०७८/०८/२०	७ (सात)
८.	गुडवेल फार्मेसी (र.प.नं. ३७६०५२२०६५९१७) बुटवल उपनगरपालिका-०६, रुपन्देही	श्री आशा पाण्डे (धनी), श्री बाबुराम सुवेदि (व्यवसायी)	२०७८/०८/२०	७ (सात)
९.	निदान फार्मेसी (र.प.नं. ३७२०५२३०२५४०४) बुटवल उपनगरपालिका-०८, रुपन्देही	श्री राम नारायण बेलबासे (धनी/ व्यवसायी)	२०७८/०८/२०	७ (सात)
१०.	रेसु फर्मा (र.प.नं. ३७४०३०१०४३२२०) बुटवल उपनगरपालिका-०६, रुपन्देही	श्री राजिव कुमार पौडेल (धनी/ व्यवसायी)	२०७८/०८/२०	७ (सात)
११.	आयशा फार्मेसी (र.प.नं. ३७२०५२३०२३९२१) सिद्दार्थनगर न.पा-०३, रुपन्देही	श्री राम नरेश प्रसाद मल्लाह (धनी/व्यवसायी)	२०७८/०८/२०	७ (सात)
१२.	आशा मेडिको कन्सर्न (र.प.नं.३७६०४२१०३४५३३) पो. म.पा. ११, कास्की	श्री अमृता चौधरी (धनि), श्री गोमा थापा क्षेत्री (व्यवसायी) ए ४६६८	२०७८/०८/२१	७ (सात)
१३.	लिजा फार्मेसी, (र.प.नं. ३७९०४३१०८०५४३) पो.म.न.पा.-०८, कास्की	श्री सुवास अधिकारी (धनी/ व्यवसायी) (ए ८७००)	२०७८/०८/२१	७ (सात)
१४.	संयोग फार्मेसी (र.प.नं. ३७७०५१९०९५७०७) पो.म.न.पा. ११, कास्की	श्री भरत पौडेल (धनी), श्री मेनका तिमिल्सीना (व्यवसायी) (जि ३८२८)	२०७८/०८/२१	७ (सात)
१५.	भगवती मेडिसीन सप्लायर्स (र.प.नं.३७२०५२३०७०२०८) पो.म.न.पा-०९, कास्की	श्री खडानन्द पाण्डे (४१७१/०५४/५५)	२०७८/०८/२१	७ (सात)

महानिर्देशक

क्र.सं	औषधि पसलको नाम/ठेगाना	धनी/व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१६.	शुभ प्रभात फार्मेसी (र.प.नं. ३७२०५२२१९२८२६) पो.म.न.पा.-१७, कास्की	श्री हेमराज बराल (ए२५५१)	२०७८/०८/२१	१४ (चौद्ध)
१७.	दिवश फार्मेसी (र.प.नं. ३७५१०२००३५२२९) पो.म.न.पा. ११, कास्की	श्री बिक्रम चौधरी (धनि), श्री सुदिप तिवारी (व्यवसायी , ए६४४५)	२०७८/०८/२१	२१ (एक्काईस)
१८.	जेडेन गुरुङ सिटि फार्मेसी (र.प.नं. ३७८०४१३०६०७००) पो.म.न.पा.-१०, कास्की	श्री एनिशा श्रेष्ठ (ए ७९२६)	२०७८/०८/२१	७ (सात)
१९.	हेल्थ केयर फार्मेसी (र.प.नं. ३७२०५२२१५५२०३) व्यास-०३, तनहुँ	श्री राजेश क्षेत्री (धनि), श्री आरती पौडेल (च्यवसायी) जि ३५९२	२०७८/०८/२१	२१ (एक्काईस)
२०.	कामना मेडिकल कन्सर्न (र.प.नं. ३७२०५२३०३१५४६) पोखरा-०१, कास्की	श्री कलाधर भण्डारी (५३५५/०५८/५९)	२०७८/०८/२१	२१ (एक्काईस)
२१.	बालाजी मेडिसिन डिष्ट्रिब्युटर्स (र.प.नं. ३७५०४१४०८४१५२) पो.म.न.पा-०९, कास्की	श्री कोपिला घिमिरे (धनि), श्री शैलेस राई (व्यवसायी), ए५९७८	२०७८/०८/२१	७ (सात)
२२.	सिसन फार्मेसी (र.प.नं. ३७४१००८०४२०३३) आँबुखैरेनि-०३, तनहुँ	श्री सिसन कुँवर (ए६०२६)	२०७८/०८/२१	७ (सात)
२३.	समाधान फार्मेसी (र.प.नं. ३७३१०१६१२४४५९) व्यास-०३, तनहुँ	श्री समिम खान (धनि), श्री लेखनाथ लामिछाने (२५१७/०५१/५२)	२०७८/०८/२१	७ (सात)
२४.	शिवम फार्मेसी (र.प.नं. ३७२०५२२१७०८४५) सि.न.पा-०७, रुपन्देही	श्री पंकज कुमार जैसवाल (कलवार), श्री महिमा थापा (व्यवसायी) ए८०५९	२०७८/०८/२१	७ (सात)
२५.	ईश्वर फार्मेसी (र.प.नं. ३७२०५२२२१५९३८) तिलोत्तमा-१५, रुपन्देही	श्री राजेश बुढाथोकी (जि ३४२०)	२०७८/०८/२१	७ (सात)
२६.	लारी मेडिकल सेन्टर (र.प.नं. ३७२०५२३०१४१०२) सि.न.पा-०६, भैरहवा, रुपन्देही	श्री मरुल बदर लारी (५२२०/०५९/५९)	२०७८/०८/२१	२१ (एक्काईस)
२७.	इन्द्राज फार्मेसी (र.प.नं. ३७६०२१९०७२५५१) तिलोत्तमा-०७, रुपन्देही	श्री चन्द्रा सापकोटा, श्री तारा भट्टराई (ए२०७१)	२०७८/०८/२१	७ (सात)
२८.	अल्पाईन फर्मा (र.प.नं. ३७८०४१८०५१६११) सि.न.पा-०७, रुपन्देही	श्री देवेन्द कुमार चौधरी (जि ३२१५)	२०७८/०८/२१	७ (सात)
२९.	एप्पल फार्मेसी (र.प.नं. ३७६०९२७०९२८०३) बु.न.पा.-०६, रुपन्देही	श्री श्याम बराल (ए४९७६)	२०७८/०८/२१	७ (सात)
३०.	बाँसगढि फार्मेसी (र.प.नं. ३७५०४२४०३५८०३) सैनामैना-०८, रुपन्देही	श्री मनोहर कुँवर (४५६०/०५६/५७)	२०७८/०८/२१	७ (सात)
३१.	मेडिम्याक्स फार्मेसी (र.प.नं. ३७७०९०१०७२४२५) सि.न.पा-०७, रुपन्देही	श्री रितु पाण्डे (धनि), श्री बिजय कुमार यादव (जि २२३२)	२०७८/०८/२१	७ (सात)
३२.	जिता फार्मेसी (र.प.नं. ३७३०४३१०८१९५७) तिलोत्तमा न.पा.-०३, रुपन्देही	श्री पित्ताम्बर पाठक (३११५/५३/५४)	२०७८/०८/२१	७ (सात)
३३.	बुद्ध पोलिक्लिनिक कपिलवस्तु प्रा.लि. फा.यु. बुद्धबाटिका-०५, कपिलवस्तु (र.प.नं. ३७४०१०५०७५०२८)	श्री श्रृजना भुसाल (ए५३३२)	२०७८/०८/२१	७ (सात)
३४.	अभिजित मेडिकल हल (र.प.नं. ३७७०९१२०८१७४५) बु.उम.नपा.-०५, रुपन्देही	श्री टिकाराम न्यौपाने (धनि), श्री लक्ष्मी भट्टराई (ए३९११)	२०७८/०८/२१	१४ (चौध)
३५.	विरा ड्रग डिस्ट्रिब्युटर प्रा.लि. का.म.न.पा-१८, काठमाण्डौं	श्री रुपक रावल (धनी), श्री लक्ष्मी खड्का (व्यवसायी)	२०७८/०८/२८	१४ (चौध)
३६.	शिवरेखा फार्मेसी (र.प.न. ३७६०३१५०९०४२१) चन्द्रागिरी-१५, ढुङ्गेअड्डा, काठमाण्डौं	श्री निलम पाण्डेय (धनी/ व्यवसायी) (ए २९४५)	२०७८/	२१ (एक्काईस)

स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०७८/१०/२४

आ.व. २०७८/७९ पौष 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.	इन्द्रेणी औषधि पसल (र.प.नं. ३७७०९९४०४३९१७) पोखरा माहानगरपालिका-उपमहानगरपालिका-१०, कास्की	श्री धुर्व शर्मा (धनि), श्री जीवन खड्का (व्यवसायी) (जि ३७०२)	२०७८/०९/०१	७ (सात)
२.	सेवा फार्मेसी (र.प.नं. ३७४०९०६११३३५९) गल्याङ नगरपालिका-०३, स्याङजा	श्री दुर्गा घिमिरे (धनि), श्री निशा थापा (व्यवसायी), ए १३१०	२०७८/०९/०१	७ (सात)
३.	रुद्र मेडिको फर्मा (र.प.नं. ३७२०५२२२१०३३७) लेखनाथ नगरपालिका-०७, कास्की	श्री खरुद्र रमण रेग्मी (धनि/व्यवसायी) ए२०२९	२०७८/०९/०१	७ (सात)
४.	गल्याङ्ग अस्पताल प्रा.लि. (र.प.नं. ३७३०१२८०७०६२७) गल्याङ्ग नगरपालिका-०३, स्याङजा	श्री तेज कुमार सिंजाली (धनि)	२०७८/०९/०१	७ (सात)
५.	मिशन मेडिकल हल (र.प.नं. ३७२०५२३०७१२१८) निलकण्ठ नगरपालिका-०५, धादिंग	श्री बिष्णु प्रसाद रिजाल (धनि व्यवसायी) (५०४३/०५६/०५७)	२०७८/०९/०१	७ (सात)
६.	कालिगण्डकी भेट सेन्टर (र.प.नं. ३७४१२२९२३४३१७) गल्याङ्ग नगरपालिका-०३, स्याङजा	श्री डिल्लीराम अर्याल (धनि व्यवसायी)	२०७८/०९/०१	७ (सात)
७.	लक्ष्मण भेटेनरी सेन्टर (र.प.नं. ३७२०५२२१८३२५३) जगत्रदेवी गा.वि.स.-०८, स्याङजा	श्री लक्ष्मण तिमिल्सिना (धनि व्यवसायी) (५०७/०७१/०७२)	२०७८/०९/०१	७ (सात)
८.	आचार्य भेटेनरी सेन्टर (र.प.नं. ३७२०५२३०१०००८)	श्री कृष्ण आचार्य, भेट ४५५/०७०/०७१	२०७८/०९/२९	७ (सात)
९	सनराज फार्मेसी (र.प.नं. ३७४११२६६६४९४६) धुनिबेसी-०६, धादिङ	श्री संजिव राज पाण्डे, जि २६६१	२०७८/०९/२९	१४ (चौध)
१०	झा मेडिकल हल (र.प.नं. ३७२०५२२१६४१४५) का.म.पा.-१४, बल्खु, काठमाण्डौं	श्री विवेक लाल झा, जि ८६६	२०७८/०९/२९	२१ (एक्काईस)
११	केयर आयुर्वेद प्रा.लि. (आयुर्वेद फार्मेसी युनिट) (र.प.नं. ३७६०८२२०८२४२५) का.म.पा.-१४, बल्खु, काठमाण्डौं	श्री सरस्वती यादव, AC (B) 912	२०७८/०९/२९	३० (तिस)
१२	सुधचिन्तक क्लिनिक प्रा.लि. (फार्मेसी युनिट) (र.प.नं. ३७६०८०६०४३९४७) धाक्रे-०९, धादिङ	श्री सोफिया शर्मा, ए६६४५	२०७८/०९/२९	२१ (एक्काईस)

	औषधि पसलको नाम/ठेगाना	धनी/व्यवसायी	विभागको निर्णय मिति	विलम्बन दिन
१३	किसान एग्रोभेट (र.प.नं. ३७८०५१६०४३८५१) गजुरी-०२, धादिङ	श्री देवराज श्रेष्ठ	२०७८/०९/२९	७ (सात)
१४	भद्रकाली मेडिकल हल (र.प.नं. ३७२०५२२२०५४४९) गजुरी-०२, धादिङ	श्री कुमार अधिकारी, श्री नवराज बानिया (४६४९/०५७/५७)	२०७८/०९/२९	७ (सात)
१५	मलेखु फार्मेसी (र.प.नं. ३७७०३२६०५३३४४) बेनिघाट रोराङ-०३, धादिङ	श्री कैलाश राज घिमिरे (धनि), श्री रोजिता ढकाल , ए७१९	२०७८/०९/२९	३० (तिस)
१६	आदर्श फार्मेसी (र.प.नं. ३७४०५२१०६३८४७) गजुरी-०१, धादिङ	श्री दिपक डल्लाकोटि (४४७३/०५५/५६)	२०७८/०९/२९	१४ (चौध)

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स्वास्थ्य तथा जनसंख्या मन्त्रालय
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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 आयातकर्तले 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

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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 विज्ञहरु(कम्तिमा 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 गर्नहुन मिति २०७८/०७/१६ को विभागीय निर्णयानुसार सम्बन्धित सबैको जानकारीका लागि यो सूचना प्रकाशित गरिएको छ ।

तपशिल:

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 :-

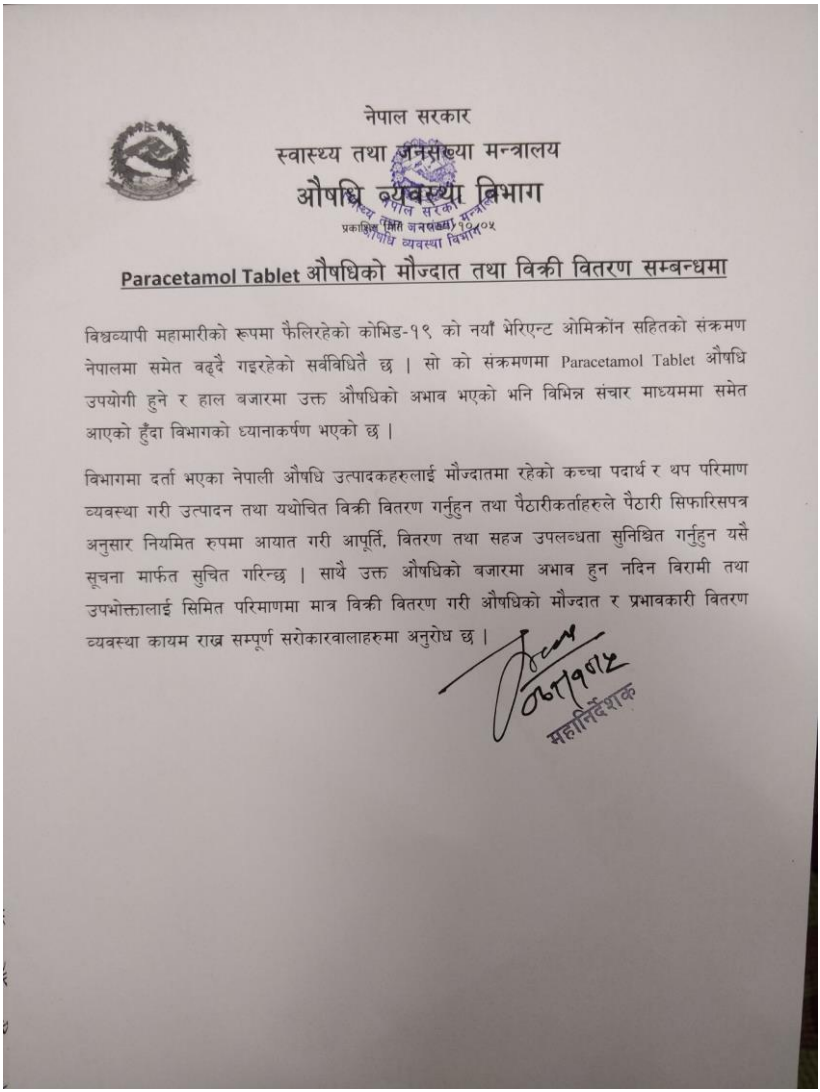
ग. हाल कार्यरत संस्था सम्बन्धी विवरणः

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

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प्रकाशित मिति जनसंख्या १२/०५

Paracetamol Tablet औषधिको मौज्दात तथा विक्री वितरण सम्बन्धमा

विश्वव्यापी महामारीको रूपमा फैलिरहेको कोभिड-१९ को नयाँ भेरिएन्ट ओमिक्रोन सहितको संक्रमण नेपालमा समेत बढ्दै गइरहेको सर्वविधितै छ । सो को संक्रमणमा Paracetamol Tablet औषधि उपयोगी हुने र हाल बजारमा उक्त औषधिको अभाव भएको भनि विभिन्न संचार माध्यममा समेत आएको हुँदा विभागको ध्यानाकर्षण भएको छ ।

विभागमा दर्ता भएका नेपाली औषधि उत्पादकहरुलाई मौज्दातमा रहेको कच्चा पदार्थ र थप परिमाण व्यवस्था गरी उत्पादन तथा यथोचित विक्री वितरण गर्नुहुन तथा पैठारीकर्ताहरुले पैठारी सिफारिसपत्र अनुसार नियमित रुपमा आयात गरी आपूर्ति, वितरण तथा सहज उपलब्धता सुनिश्चित गर्नुहुन यसै सूचना मार्फत सुचित गरिन्छ । साथै उक्त औषधिको बजारमा अभाव हुन नदिन विरामी तथा उपभोक्तालाई सिमित परिमाणमा मात्र विक्री वितरण गरी औषधिको मौज्दात र प्रभावकारी वितरण व्यवस्था कायम राख्न सम्पूर्ण सरोकारवालाहरुमा अनुरोध छ ।

०८/१२/१८

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प्रकाशित मिति : २०७८/१०/०७

पारासिटामोल ५०० एम.जी. चक्की औषधिको सम्बन्धमा विभागको विज्ञप्ति

केहि दिन यता बजारमा Paracetamol 500mg चक्की औषधिको अभाव भनि विभिन्न संचार माध्यममा प्रकाशन भएको समाचार प्रति यस विभागको गम्भीर ध्यानाकर्षण भएको छ । यस विभागमा दर्ता भएका यो औषधि उत्पादन गर्ने उत्पादक एवं थोक तथा खुद्रा फार्मेसीहरुमा अनुगमन गर्दा उत्पादन कार्य सुचारु रहेको एवं बिक्री वितरण कार्य निरन्तर रहेको पाईएको छ । उत्पादकहरूसँग उपलब्ध कच्चा पदार्थ एवं पैठारी परिमाण बारेमा विवरण संकलनको कार्य भइरहेको छ । बजार व्यवस्था कायम राख्ने गरि उपलब्ध एवं थप कच्चा पदार्थको प्रबन्ध मिलाई उत्पादन कार्य सुचारु राख्न एवं बिक्री वितरण कार्य निरन्तर राखी उपलब्धता सुनिश्चीत गर्न समेत विभागले सबै उत्पादक, पैठारीकर्ता एवं बिक्री व्यवसायीहरुलाई निर्देशन दिइसकेको छ ।

अनुगमनका क्रममा विभागबाट आज एक औषधि उत्पादक कम्पनीको स्थलगत निरीक्षण गर्दा उक्त औषधिको कच्चा पदार्थको मौज्दात – १२३७ के.जी (करिब २४ लाख चक्की), बजार बिक्री वितरणको लागि पठाइएको– ४,५९,००० चक्की, उत्पादनका क्रममा रहेको बिस लाख चक्की र प्राप्त हुने क्रममा रहेको कच्चा पदार्थ– १७,००० के.जी (करिब तीन करोड चक्की बनाउन पुग्ने) रहेको विवरण प्राप्त भएको छ । साथै विभागले स्वदेशी औषधि उत्पादकसंग यो औषधि बनाउने आवश्यक कच्चा पदार्थ र तयारी औषधिको विवरण माग गरेकोमा हालसम्म प्राप्त भएको विवरण अनुसार कच्चा पदार्थको मौज्दात १५,७६५.०४ के.जी र सोबाट करिब तिन करोड चक्की उत्पादन हुन सक्ने वस्तुगत आधार र औषधि उत्पादन एवं बिक्री वितरण कार्य निरन्तर एवं नियमित रहेकोले अभाव हुने भ्रममा नपर्न सर्वसाधारणमा हार्दिक अपिल गरिन्छ । साथै, यी कार्यहरुको विभागबाट निरन्तर अनुगमन गरिने र कसैले कृत्रिम अभावको सिर्जना गरे गराएमा प्रचलित कानून बमोजिम कारवाही हुने व्यहोरा समेत अनुरोध छ । यदि कहिँ कतै अभावको सिर्जना रहेको देखिएमा विभागका सूचना अधिकारी (मो.नं- ९७४८३००१०९) वा विभागको आधिकारिक ई-मेल info@dda.gov.np मार्फत सम्पर्क गर्नुहुन समेत अनुरोध गरिन्छ ।

२०७८/१०/०७
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नेपाल सरकार

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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 नगरौ ;
- 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

मदनभण्डारी पथ-४, बिजुलीबजार, काठमाडौं

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औषधि व्यवस्था विभागका शाखा कार्यालय

	कञ्चनबारी, विराटनगर	आदर्शनगर, बेपालगंज	मुरली बजैचा, विरगंज
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E-mail:	biratnagar@dda.gov.np	nepalgunj@dda.gov.np	birgunj@dda.gov.np

For further information, 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:info@dda.gov.np
dg@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, Surkhet 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

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