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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

GOOD REGULATORY SYSTEM: BACKBONE FOR QUALITY PHARMACEUTICALS

A fundamental role of government is to protect and promote the health and safety of the public by delivering quality health care. Quality pharmaceuticals, with assured safety and therapeutic efficacy are the need and target of the health system. Beside these the availability and affordability of quality pharmaceutical also come into play, in order to strengthen the health care system of any country. The consequences of substandard and falsified medical products can be life threatening and this is a concern, as users of medical products are not usually in a position to judge their safety, quality and efficacy. The interests and safety of the public therefore must be entrusted to a regulatory body which ensures that only products in legal trade are available and marketed products are safe, perform as claimed and are of assured quality. Regulatory systems play a key role in assuring the quality, safety and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public outcomes and innovation.

The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological as well as social change in the context of limited financial and human resources. The importance of robust regulatory systems was recognized by the Sixty-Seventh World Health Assembly and the endorsed resolution WHA 67.20 on regulatory system strengthening for medical product. The resolution notes that “effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes”, that “regulators are an essential part of the health

workforce" and that "inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products".

A sound legal framework, adoption of international norms and standards and recruitment and development of competent human resource along with Good Regulatory Practices (GRP) are necessary to ensure "good regulatory oversight". Good regulatory practices (GRP) is a set of principles and practices that are applied to the development, implementation and maintenance of regulatory instruments including laws, regulations and guidelines in order to achieve a public health policy objective in the most efficient way. The ultimate aim of GRP is to serve and protect public health and patients' interests, with respect for all applicable ethical principles.

In any health care setting, the regulatory system encompasses regulatory framework composed of laws, regulations and guidelines which are adapted by regulatory institution represented by national regulatory authority (NRA), the national control laboratory, pharmacovigilance centre(s), research ethics committee(s) and others equipped with essential human and financial resources, infrastructure and equipment and information management systems. GRP covers and addresses overall regulatory system. GRP is based on nine core principles legality, consistency, independence, impartiality, proportionality, flexibility, clarity, efficiency, transparency.

Department of Drug administration is striving at adopting Good Regulatory Practice (GRP) along with Good Reliance Practices (GRepP). However, regulatory institutions require strong political and governmental backup, along with sufficient, sustainable financial resources and competent human resources and organizational communication (inter/intra) and collaboration. Department of Drug Administration is working on regulatory system strengthening and is in the process of evaluating the regulatory systems as mandated by WHO resolution 67.20 on Regulatory System Strengthening for

medical products through The Global Benchmarking Tool (GBT). GBT represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems. GBT tools provide methodology to regulate regulatory frameworks and regulatory functions in order to monitor progress and achievements so far to. Areas of improvement and strengths can be identified by the regulatory authority, which play pivotal role in formulation and implementation of an institutional development plan (IDP) to address the loop hole and gaps and to build upon strength.

DDA with support of WHO has carried out self-benchmarking from 8 February to 10 March with GBT assessment tools to evaluate the regulatory framework and the component regulatory functions through a series of sub-indicators that are grouped to nine cross-cutting categories or themes. The accessed themes and their implementation status are National Regulatory System (NS)-57%, Registration and Marketing Authorization (MA) - 49%, Vigilance (VI) – 30%, Market Surveillance and Control (MC)- 35%, Licensing Establishments (LI)- 66%, Regulatory Inspection (RI)- 78%, Laboratory Testing (LT)-56%, Clinical Trial Oversight (CT)- 43% and NRA Lot Release (LR)- 0%. The self-assessment has identified strengths and areas for improvement in nine themes and also assessed the maturity level in each theme. The implementation status suggested Nepal to be at low maturity level of 1 in each theme.

One of the key gaps identified in the benchmarking tools is the requirement of strong legal framework and guidelines for the different processes. To roll on with the regulatory strengthening activities DDA has initiated the revision of Drug act and carried out studies for restructuring the department of drug administration which is the utmost requirement for the regulatory strengthening. Revision of Medicine Policy is also on the way which would address the overall regulatory reforms and vision for safe, effective and quality medicine for the public.

Thus, systemic approach and strong administrative and political commitment are needed for strengthening the regulatory system which in line with the GBT assessment findings suggests that there is urgent need to formulate an institutional development plan (IDP) to build upon the strengths and address the identified gaps prioritizing the IDP interventions and plan the monitoring process and achievements.

Bharat Bhattarai
(Director General)
Chief Editor

१. आ.व. २०७८/७९ प्रगति विवरण

अनुगमन, मुल्यांकन तथा कानुन कार्यान्वयन महाशाखा अन्तर्गत मुख्य कार्यहरु:

औषधि पसल/फार्मेसी निरीक्षण :

विवरण	काठमाडौं	विराटनगर	वीरगंज	नेपालगंज	जम्मा
बार्षिक लक्ष्य	१८००	५००	५००	५००	३३००
बार्षिक प्रगति	१८५८	६५७	५०६	६४२	३६६३
बार्षिक प्रगति प्रतिशत	१०३	१३१	१०१	१२८	१११

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बार्षिक लक्ष्य	७०	५	१२	५	९२
बार्षिक प्रगति	७२	३	८	५	८८
बार्षिक प्रगति प्रतिशत	१०३	६०	६७	१००	९५.६५

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- औषधि सम्बन्धी कानूनलाई संशोधन र एकीकरण गर्ने सम्बन्धमा व्यवस्था गर्न बनेको विधेयकको प्रारम्भिक मस्यौदा बनाई स्वास्थ्य तथा जनसंख्या मन्त्रालयमा पेश गरेको।
- SEARN (South East Asia Regulatory Network) को नेपालको लागि कार्य समूह (Working Group) गठन गरेको।
- औषधि उत्पादन कुशल अभ्यास संहिता, २०७८(पहिलो संसोधन) मस्यौदा तयार गरेको।
- औषधिको मुल्य समायोजनको लागि मूल्य अनुगमन समितिको वैठक बसेको एवं मूल्य निर्धारण कार्यविधि/कार्यप्रक्रिया आवश्यक निर्णयको लागि मन्त्रालयमा पठाइएकोमा पून पेश गर्न निर्देशन भएको।

2. REGULATORY NEWS

Antiepileptic drugs

Risk of major congenital malformations and neurodevelopmental disorders in children exposed in-utero

Ireland. The Health Products Regulatory Authority (HPRA) has announced that the product information for antiepileptic drugs (AEDs) (including phenytoin, phenobarbital, carbamazepine, pregabalin and valproate) are to be updated based on the latest evidence of risks associated with in-utero exposure to AEDs. For some medicines in this class, use during pregnancy has been associated with major congenital malformations (MCMs) and neurodevelopmental disorders in children exposed in-utero.

AEDs are indicated for the treatment of various forms of epilepsy with some having additional indications in other therapeutic areas such as psychiatry.

A summary of the recent review includes:

- Phenytoin, phenobarbital and carbamazepine have an approximate 2-3 fold risk of MCMs compared to the general population. Study findings on the risk of neurodevelopmental disorders are contradictory and a risk cannot be excluded based on available evidence at this time.
- Pregabalin monotherapy: available data show that if used in the first trimester, it is associated with a slightly higher risk of MCMs compared to women not using pregabalin, or those using lamotrigine or duloxetine.
- Valproate: epidemiological data have demonstrated that use of valproate monotherapy during pregnancy is associated with an approximate 11% (4-5 fold) risk of MCMs and up to 30-40% for risk of neurodevelopmental disorders in children exposed in-utero.

When prescribing AEDs for a woman of childbearing potential for any indication, health-care professionals should fully consider and discuss what is known about the potential risks associated with in-utero exposure, as well as any recommendations concerning contraception and pregnancy planning, including actions to take in the event of a suspected or confirmed pregnancy.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Ceftriaxone

Potential risk of hepatitis and encephalopathy

Australia. The Therapeutic Goods Administration (TGA) has announced that the product information for ceftriaxone has been updated to include a warning about hepatitis and encephalopathy as potential adverse events.

Ceftriaxone is a broad spectrum cephalosporin antibiotic indicated for the treatment of pneumonia, skin, urinary tract, and other infections.

The TGA reviewed evidence published in the literature and international and national postmarked adverse event data. There were 52 reports of hepatitis and related symptoms and three reports of encephalopathy for patients treated with ceftriaxone. Health-care professionals should be aware of reports of encephalopathy particularly in the elderly with severe renal impairment or central nervous system disorders. Suspension of treatment with ceftriaxone should be considered if encephalopathy is suspected.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Metformin

Permitting use in pregnancy

United Kingdom. The MHRA has announced that the product information for metformin is to be updated to permit its use during

pregnancy and the periconceptional phase as an addition or an alternative to insulin, if clinically needed. Metformin is indicated for the treatment of type-2 diabetes, and good blood glucose control in pregnancy reduces the risk of congenital abnormalities, pregnancy loss, pregnancy induced hypertension, preeclampsia, and perinatal mortality. A review was conducted using new safety data from a study investigating immediate and longer-term effects of metformin in-utero exposure on children born to pregnant women with pre-existing diabetes. The results of the study were reassuring, with no safety signals of concern identified for use of metformin in pregnancy relating either to those who were pregnant or their baby.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Nifedipine

Risk of pulmonary oedema when used in pregnancy

Australia. The TGA has announced that the product information for nifedipine products has been updated to provide new information about the risk of acute pulmonary oedema when used as a tocolytic agent (inhibiting myometrial smooth muscle contractions) for the treatment of preterm labor in pregnancy. Nifedipine is a calcium channel blocker and indicated for the management of chronic stable angina pectoris and vasospastic angina pectoris (Prinzmetal's angina, variant angina) due to coronary heart disease and the treatment of hypertension. Nifedipine is contraindicated in pregnancy and during lactation. The TGA reviewed four adverse event reports involving offlabel use of nifedipine in pregnancy. The risk was higher in cases of multiple pregnancy (twins or more), with an intravenous administration route or concomitant use of beta-2 agonists

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Pregabalin

Risk of severe respiratory depression

Ireland. The Health Products Regulatory Authority (HPRA) has announced that the product information for pregabalin-containing medicinal products will be updated to include a warning on respiratory depression and to add it as a possible adverse reaction with unknown frequency, following the conclusions of the PRAC.

Pregabalin-containing medicinal products are indicated for the treatment of neuropathic pain in adults, as adjunctive therapy in adults for specific forms of epilepsy and for generalized anxiety disorder in adults.

The PRAC reviewed safety data and concluded that pregabalin is associated with reports of respiratory depression in the absence of concomitant therapy with opioids or other central nervous system (CNS) depressants, in patients with and without other risk factors for respiratory depression.

Healthcare professionals should be advised that patients with risk factors (compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants and older age (> 65 years)) may be at higher risk of experiencing respiratory depression with pregabalin and dose adjustment may be necessary. Patients taking the medicine should be advised to contact their doctor if they experience trouble breathing or have shallow breaths and not to drink alcohol while taking pregabalin.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Tetanus, diphtheria and pertussis (Tdap) vaccine

Risk of Guillain-Barré syndrome

Republic of Korea. The MFDS has updated the product information for tetanus, diphtheria and pertussis (Tdap) vaccine (Boostrix®) to

include the risk of Guillain-Barré syndrome (GBS). Tdap vaccine is indicated for booster immunization against tetanus, diphtheria and pertussis in individuals aged 10 years and older. The KIDS reviewed one report, which suggested a causal link between Tdap vaccine administration and GBS, and other information from a foreign regulatory authority and a medical database. Healthcare professionals should be aware of the signs and symptoms of GBS in patients with recent vaccination history.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Tramadol

Risk of urinary retention

India. The NCC-PvPI, IPC has advised the CDSCO to revise the PIL for tramadol to include urinary retention as an adverse drug reaction. Tramadol is indicated for the treatment of moderate to severe pain, diagnostic procedures and surgical pain. NCC-PvPI, IPC reviewed seven reports of tramadol-associated urinary retention and a causal relationship between them was found.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Hydroxychloroquine or chloroquine, and macrolide antibiotics

Interaction: Increased risk of cardiovascular events with co-administration

United Kingdom. The MHRA has announced that the product information for hydroxychloroquine, chloroquine and macrolide antibiotics (azithromycin, erythromycin or clarithromycin) will be revised to include the increased risk of cardiovascular events and cardiovascular mortality if hydroxychloroquine or chloroquine is taken with a macrolide antibiotic.

Hydroxychloroquine is indicated for treatment of rheumatoid arthritis, systemic lupus erythematosus, and dermatological conditions. Chloroquine is indicated for malaria prophylaxis or treatment and other indications.

A review was conducted following the results of an observational study which shows that co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events (including angina or chest pain and heart failure) and cardiovascular mortality. Health-care professional should carefully consider the benefits and risks before prescribing macrolide antibiotics to patients being treated with hydroxychloroquine or chloroquine.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Amoxicillin

Potential risk of aseptic meningitis

Canada. Health Canada has announced that the product safety information for amoxicillin-containing products will be updated to include the potential risk of aseptic meningitis. Amoxicillin is an antibiotic indicated for the treatment or prevention of certain bacterial infections. Products may contain amoxicillin alone or in combination with other antibiotics. Health Canada reviewed the available information by searching national and international databases, and the published literature. Twenty-one case reports of aseptic meningitis in adult patients receiving amoxicillin containing products were obtained and all of them were found to be possibly or probably linked with the use of the amoxicillin-containing products. The review concluded that there may be a link between amoxicillin-containing products and the risk of aseptic meningitis.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Chloramphenicol

Recommended dose considering risk of reproductive toxicity

New Zealand. The Medsafe has announced that the product information for chloramphenicol eye drops will be updated to include dosing recommendations for children aged under two years. The recommended dose is one drop in the affected eye(s) four times daily for five days.

Chloramphenicol eye drops are indicated for the treatment of infections of the eye. Some products contain boron in the excipients (boric acid and borates), which could be associated with reproductive toxicity (based on animal studies).

The Medicines Adverse Reactions Committee considered that the relevance of the animal data to humans is uncertain. Although human studies have not shown reproductive toxicity, they were not sufficiently robust to rule out this risk. The paediatric dose, reflecting the conventional dosing regimen for children, is associated with a boron exposure below the threshold of concern for reproductive toxicity.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Statins

Removal of contraindication for pregnant women

USA. The US Food and Drug Administration (FDA) has requested revisions to the information in the prescribing information for the entire class of statin medicines about use in pregnancy. These changes include removing the contraindication against using these medicines in all pregnant patients.

Statins are a class of medicines that have been used to lower low-density lipoprotein cholesterol (LDL-C) in the blood. Medicines in the statin class include atorvastatin, fluvastatin, lovastatin, pitavastatin,

pravastatin, rosuvastatin, and simvastatin.

It was concluded that contraindicating these drugs in all pregnant women is not appropriate because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients.

Healthcare professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy. Patients taking statins should notify their healthcare professionals if they become pregnant or suspect they are pregnant. Those who require statins after giving birth should not breastfeed and should use alternatives such as infant formula.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

3. SAFETY OF MEDICINES

Alcohol-based hand sanitizer
Risk of eye injury

USA. The US Food and Drug Administration (FDA) has issued a warning about exposure of hand sanitizer to the eyes (through splashing or touching the eyes after use). Exposure in the eye can result in serious injury, including severe irritation and damage to the surface of the eye.

Hand sanitizers are over-the- counter (OTC) used to reduce virus and bacteria on hands.

Eye exposure to hand sanitizer has been reported in all age groups; however, it has occurred most often in children. Such eye injuries have become much more frequent, likely due to the marked increase in the use of alcohol-based hand sanitizer during the COVID-19 pandemic.

Consumers and caregivers should avoid touching eyes after applying alcohol-based hand sanitizer to hands. Adults should always supervise young children using alcohol-based hand sanitizers, especially around some dispensers which often are at children's eye level and can splash. If alcohol- based hand sanitizer does accidentally splash or get in the eyes, the eyes should be thoroughly rinsed under gentle running water for 15 to 20 minutes.

Reference:

MedWatch, US FDA, 11 February 2022 (link to the source within www.fda.gov)

Source: WHO Pharmaceuticals Newsletter No.2, 2022

Bevacizumab

Potential risk of Fournier's gangrene

Saudi Arabia. The SFDA has released a potential safety signal concerning Fournier's gangrene associated with the use of bevacizumab.

Bevacizumab is a monoclonal antibody inhibiting VEGF-A and indicated for the treatment of non-small cell lung cancer and other cancers.

The SFDA reviewed 35 case reports, nine of which supported the association, and the literature.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Cefuroxime

Potential risk of Kounis syndrome

Saudi Arabia. The SFDA has released a potential safety signal concerning Kounis syndrome associated with the use of cefuroxime.

Cefuroxime is cephalosporin antibacterial drug indicated for the treatment of infectious diseases caused by sensitive bacteria.

The SFDA reviewed 11 case reports, three of which supported the association, and the literature.

Source: WHO Pharmaceuticals Newsletter No.1, 2022.

Empagliflozin

Risk of ketoacidosis and Fournier's gangrene

New Zealand. The Medsafe has announced that empagliflozin is associated with the risk of ketoacidosis and Fournier's gangrene (necrotising fasciitis of the perineum).

Empagliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitors and is used for the treatment of type two diabetes mellitus. The CARM received three reports of ketoacidosis and two reports of Fournier's gangrene following initiation of empagliflozin.

For the risk of ketoacidosis, healthcare professionals are advised to consider stopping empagliflozin temporarily during an acute illness, particularly if patients are unwell, febrile or vomiting and not eating.

Empagliflozin should also be temporarily stopped before undergoing medical procedures or surgery. For the risk of Fournier's gangrene, patients should be advised to seek immediate medical attention if they experience pain, tenderness, redness or swelling of the genital or perineal area, particularly with associated fever or malaise.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Finasteride

Potential risk of diabetes mellitus

Saudi Arabia. The SFDA has released a potential safety signal concerning diabetes mellitus associated with the use of finasteride.

Finasteride is a 5α-reductase inhibitor and indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

The SFDA reviewed 62 case reports, two of which supported the association, and the literature.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Propylthiouracil and carbimazole

Use in pregnancy

Australia. The TGA has announced that the pregnancy category for both propylthiouracil (PTU®) and carbimazole (Neo-Mercazole®) is being changed from being suspected of harmful effects on the human

foetus by the pharmacological effects to the being associated with an increased incidence of human foetal malformations.

Propylthiouracil is an antithyroid drug indicated for the treatment of hyperthyroidism or prior to surgery or radioactive iodine therapy in these patients

Carbimazole is also an antithyroid drug indicated for hyperthyroidism. It is used as a definitive therapy for the induction of a permanent remission in either primary or secondary thyrotoxicosis. It is also used in preparation for thyroidectomy before and after radioactive iodine treatment. The risks relating to congenital abnormalities in neonates are known for these medicines.

The TGA reviewed reported cases of congenital abnormalities for propylthiouracil and carbimazole in the postmarketing setting.

Healthcare professionals should be advised that propylthiouracil and carbimazole should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Source: WHO Pharmaceuticals Newsletter No.1, 2022

Paclitaxel

Caution for medication error

United Kingdom. The MHRA has requested health-care professionals to take caution not to confuse Paclitaxel formulations with nabpaclitaxel.

Nab-paclitaxel indicated for the treatment of certain cancers of the breast, pancreas, and lung. Paclitaxel is indicated for the treatment of cancers of the ovary, breast, and lung, and advanced AIDS-related Kaposi's sarcoma. They have different indications, pharmacokinetics, dosages, and preparation and administration instructions; therefore, they are not interchangeable.

Although the UK has not received a case report to suggest harm has occurred in the countries due to a mix-up of these paclitaxel formulations, errors in dosing or administration could have potential consequences for clinical response and increased toxicity or adverse reactions.

Health-care professionals should make a clear distinction between paclitaxel formulations when prescribing, dispensing, administering, and communicating about these medicines. The use of brand names is advised for nabpaclitaxel formulations.

Source: WHO Pharmaceuticals Newsletter No.2, 2022

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.

Tocilizumab and gastric perforation

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Summary

Tocilizumab (TCZ), a humanized monoclonal antibody acting as an interleukin6 (IL-6) receptor antagonist, belongs to an important group of biological agents that has revolutionized the anti-inflammatory therapy of rheumatoid arthritis (RA). However, drugs that block IL-6 are reported to be associated with increased risk of gastrointestinal (GI) perforation, mainly intestinal. Gastric perforation associated with TCZ was identified as a potential signal in a screening of VigiBase, the WHO global database of individual case safety reports. As of March 2020, there were 20 unique patients (compared with 3 expected), from 9 countries, reporting gastric perforation with TCZ as a suspected medicine, in VigiBase. These cases occurred with a time to onset ranging from 0.5 to 36 months (median 5 months); 17/20 (85%) were considered as serious, 1 with a fatal outcome. The indication (known in 18 patients) for TCZ treatment was RA in 16 and temporalis arthritis, or giant cell arthritis (GCA), in two patients. The outcome was unknown for 7 patients, 11 patients recovered or were recovering, including four where a surgical procedure was reported, and two did not recover, including the fatal case. Known risk factors for gastric perforation existed in 10 patients, including co-mobilities or a history of GI disorders,

smoking; and concomitant treatment with methotrexate (MTX), rituximab, steroids, NSAIDs, or a combination of these. There seemed to be more patients with a high body weight than with a low body weight, when information was available. Considering the seriousness of this reaction, it would be prudent to recommend close monitoring of patients when treated with TCZ, in particular those with risk factors for GI perforation as well as those with a high body weight, as its dose is determined by the patient's total body weight.

Introduction

Tocilizumab (TCZ) is a humanized monoclonal antibody that acts as an interleukin6 (IL-6) receptor antagonist. Thus, it is an immunosuppressive and interleukin repressive medicine, indicated for adult treatment of severe active and progressive rheumatoid arthritis (RA), especially in combination with methotrexate (MTX),[1] and giant cell arteritis (GCA).[2], [3] TCZ is often given to patients responding inadequately or being intolerant to previous therapy with disease-modifying anti-rheumatic drugs or tumour necrosis factor (TNF) antagonists.[4] Further, it can be given as monotherapy in case of intolerance to, or inappropriate continued treatment with glucocorticoids or MTX. TCZ reduces progression rate of joint damage and improves physical function when given in combination with MTX. It is also indicated for treatment of juvenile idiopathic polyarthritis in patients from two years of age who have not responded to previous MTX treatment. More recently, TCZ has been discussed and tested as an alternative treatment for COVID19 patients with a risk of cytokine storms, since it has been suggested that IL-6 is one of the most important cytokines in the storms.[5]

Gastrointestinal (GI) perforation is a hole in the wall of GI tract which could include the oesophagus, stomach, small intestine and large intestine. Underlying causes of GI perforation may be gastric ulcers, duodenal ulcers, appendicitis, GI cancer, diverticulitis,

inflammatory bowel disease, and use of medicines such as NSAIDs. Surgical intervention is usually required for haemostasis, and closure of perforation and conservative treatment is indicated only in selected patients who are clinically stable.6

Gastrointestinal perforation is mentioned in both the EMA and FDA labelling. However, the labelling is focused on intestinal perforation, and as a complication of diverticulitis. This was why gastric perforation was identified as a potential signal in a screening of VigiBase.

The objective of this study was to analyze the pattern and clinical features of gastric perforation associated with TCZ in the VigiBase cases, and to assess the causality alongside literature findings.

Reports in VigiBase

A clinical review of reports with gastric perforation (PT) associated with TCZ retrieved from VigiBase up to March 2020 was performed.

VigiBase contained 20 unique patients reporting gastric or stomach perforation with TCZ as a suspected or interacting medicine, compared with 3 expected. Table 1 shows the patients' demographics and their characteristics. The reports came from nine countries (Japan (5), USA (5), Colombia (3), Austria (2), and 1 each from UK, Ireland, Greece, Portugal and Hungary). The indications of TCZ, available for 18 patients, were RA (n=16) and GCA (n=2). There were 13 females, 6 males and one gender information missing, which reflect the population treated under the indications. Their ages ranged from 37 to 83 years (median: 61 years). When reporter category information was available, most reports came from physicians (n=16). Of the 20 cases, 17 (85%) were serious, including 4 lifethreatening and one with a fatal outcome. In 11cases (55%) there were narratives, although some of these were considered not informative.

In addition to gastric perforation, seven patients had co-reported reactions such as acute coronary syndrome, pulmonary embolism, cerebrovascular accident, neutropenia, transaminases increased, respiratory or urinary tract infections, while some patients had multiple co-reported reactions. TCZ was the only suspected drug in 15 patients (75%),. In the remaining five cases the co-reported suspected drugs included MTX, prednisolone, hormones (unspecified) and celecoxib, and two of these patients, on NSAIDs or steroid, no gastroprotection (such as antacids) was mentioned. Where information was provided, 12 patients were taking concomitant medications.

TCZ dosing information was available for eight patients: the mean dose, corresponding to fourweekly intervals, was 7.9 (SD 1.1; median 8.0) mg/kg, ranging from 6.0 to 10.0 mg/kg, based on the highest dose if different doses had been given. When information was available (n=9), the mean body weight was 80 kg (SD 24; median 89), ranging from 49 to 114 kg (49, 52, 53, 75, 88, 90, 98, 100 and 114 kg, respectively).

The time to onset (TTO) was reported for 13 patients, and ranged from 0.5 to 36 months (mean: 10; SD: 11; median: 5).The reaction led to withdrawal of TCZ in seven patients, when information was available. The outcome was reported as recovery for 11 patients, no recovery for 1, fatal for 1, and unknown for 7. Positive dechallenge was reported for four patients and rechallenge for one patient , who had no gastric symptoms reported two weeks after the restart of TCZ, at the time of reporting. Surgery was specifically mentioned in the management of the reaction for four patients.

Where information on the medical history and concomitant medications was available, known risk factors for gastric perforation were reported for 10 patients, including GI disorders, smoking; concomitant treatment with MTX, rituximab, steroids, NSAIDs, or a combination of these.

Table1. Patients' demographics and characteristics of gastric perforations associated with tocilizumab in VigiBase

Case	Age/sex /body weight	Indication / Dose (mg /4 w)	Other suspected (S) or concomitant drugs	Time to onset (months)	Outcome Recovery: Yes/No/ unknown	Co-reported adverse events	Relevant medical history and concomitant medicines
1	-/-/-	Unknown / -	-	Unknown	Unknown	-	-
2	55/F/ 88 kg	RA / -	Calcium carbonate, levothyroxine, losartan, omeprazole, vitamin D nos	Unknown	Unknown	Acute coronary syndrome, UGI haemorrhage	PPI; BW 88 kg
3	53/F/-	RA / 560	-	5	Yes (sequelae)	-	-
4	70/F/-	RA / 400	-	3	Yes (sequelae)	-	-
5	50/F/-	RA / 504	-	36	Yes	-	-
6	37/F/ 98 kg	RA / 780	Etoricoxib leflunomide hydroxychloroquine tramadol	2	Yes, after surgery	-	NSAID, diverticulitis, BW 98 kg
7	-/F/-	RA / -	-	Unknown	Unknown		
8	67/-/-	RA / -	Rituximab (S), beclometasone, budesonide, fluticasone, folic acid, formoterol, furosemide, gabapentin, ipratropium, metformin, MTX, montelukast, pantoprazole, prednisone, ranitidine, salbutamol, salmeterol, simvastatin, sitagliptin, warfarin	Unknown	Unknown	Oesophagitis, pulmonary embolism, tongue ulceration	Steroid high dose, MTX, PPI, rituximab, higher than max dose
9	65/F/-	RA / 400		13	Yes		
10	49/F/ 52 kg	RA / -	DMARDs, NSAIDs	17	Unknown	GI haemorrhage, neutropenia	NSAID
11	55/M/ 90 kg	RA / 680/35-40	Folicacid (S), hydroxychloroquine (S), MTX. Corticosteroids, PPI	27	Yes, after surgery	Transaminases increased, URTI	Smoking, MTX, steroids; PPI; high dose; BW 90 kg
12	58/M/ 49 kg	RA / 400	MTX (S), Prednisol (S), alfacalcidol allpurinol, aspartate calcium, diclofenac, dimeticone, etizolam,	3	Yes	-	MTX, steroids, max dos

Case	Age/sex /body weight	Indication / Dose (mg /4 w)	Other suspected (S) or concomitant drugs	Time to onset (months)	Outcome Recovery: Yes/No/ unknown	Co-reported adverse events	Relevant medical history and concomitant medicines
			iron, lansoprazol, mizoribine, risedronic acid, tacrolimus, zopiclone				
13	46/M/ 100 kg	RA / 800	Diclofenac, leflunomide omeprazole, prednisolone	3	Yes, after surgery	Abscess, (probably tamponated)	NSAID, steroids, PPI, BW 100 kg
14	/F/-	Unknown / -	-	Unknown	Unknown	-	-
15	73/M/ 75 kg	RA / 600	Meloxicam, MTX, PPI	11	Yes, after surgery	-	NSAID, PPI, MTX. No history of GI disorders (ulcers, diverticulosis etc).
16	62/F/ 113 kg	RA / -	Folic acid, metoprolol, oxybutynin, pravastatin, rivaroxaban, omeprazole	Unknown	Unknown	UTI, influenza	(Rivaroxaban), PPI, BW 113.5 kg. Mg/kg unknown.
17	79/M/-	GCATemp .art/-	-	Unknown	No	-	-
18	83/M/-	RA/162/1o r2v =	Hormones (S), iguratimod, Sulfasalazin	8	Yes		
19	76/F/-	Temp.art/ 162/1v (=648?) s.c./i.m.	Prednisone	3	Death	Cerebrovascular accident	Steroids; fatal
20	50/F/ 53 kg	RA /162/2v (= 324 mg?)	Celecoxib (S), prednisolone (S), folic acid, MTX, paracetamol, tramadol	0.5	Yes	-	NSAID, steroids, MTX

BW: Body weight; DMARDs: Disease-modifying antirheumatic drugs; F:Female; GCA: Giant cell arteritis; GI: Gastrointestinal; M: Male; MTX: Methotrexate; NSAIDs: Nonsteroidal anti-inflammatory drugs; PPI: Proton pump inhibitor; RA: Rheumatoid arthritis; TCZ: Tocilizumab; URTI: Upper respiratory tract infection;

Literature and labelling

Tocilizumab (RoActemra) EU summary of product characteristics (SPC) [4]

Posology and method of administration

Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, systemic juvenile idiopathic arthritis (sJIA), juvenile idiopathic polyarthritis (pJIA) or cytokine release syndrome (CRS). TCZ should be administered as an intravenous infusion over one hour.

For RA patients, the recommended posology is 8 mg/kg body weight, given once every four weeks.

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended. Dose adjustments are needed if laboratory abnormalities (liver enzyme abnormalities, low absolute neutrophil count, and low platelet count) are found. No dose adjustment is required in elderly patients >65 years of age, or in patients with mild renal impairment.

Special warnings and precautions for use

Complications of diverticulitis: perforations as complications of diverticulitis have been reported uncommonly with TCZ in RA patients. TCZ should be used with caution in patients with a previous history of intestinal ulceration or diverticulitis. Patients presenting with symptoms potentially indicative of complicated diverticulitis, such as abdominal pain, haemorrhage or unexplained change in bowel habits with fever should be evaluated promptly for early identification of diverticulitis, which can be associated with gastrointestinal perforation.

Adverse drug reactions relevant to the signal are presented in Table 2.

Table2. Adverse drug reactions (relevant to the signal, selected by the authors)

MedDRA System Organ Class	Frequency categories with preferred terms
Infections and infestations	**Uncommon:** diverticulitis
Gastrointestinal disorders	**Common**: abdominal pain, mouth ulceration, gastritis **Uncommon**: stomatitis, gastric ulcer

Gastrointestinal perforation: during the 6-month controlled clinical trials, the overall rate of gastrointestinal perforation was 0.26 events per 100 patient years with TCZ therapy. The overall rate of gastrointestinal perforation was 0.28 events per 100 patient years in the longterm exposure population. Reports of gastrointestinal perforation in patients taking TCZ were primarily reported as complications of diverticulitis including generalized purulent peritonitis, lower gastrointestinal perforation, fistulae and abscess.

Discussion

TCZ, a monoclonal antibody targeting the IL-6 receptor, has been reported to increase the risk of GI perforation.7 The risk for lower GI perforation associated with TCZ was estimated to be more than twice that for anti-tumour necrosis factor agents[8]. In a registry of lower intestinal perforation (LIP), the crude incidence rate of LIP was found to be significantly higher in patients taking TCZ (2.7/1000 person-years), compared with all other treatments (0.2−0.6/1000 person-years).9 In the literature, more data are available for the risk of for lower GI tract perforation. More recently, based on updated data it was reported that, although data are limited, drugs that block IL-6 are associated with a greater increased risk of GI perforation, than other RA therapies[7]. In our current study, 20

patients with gastric perforation in VigiBase were reviewed with a focus on the clinical features. TTO ranged from 0.5 to 36 months (mean 10; median 5). About 2/3 of the patients were females, reflecting the treatment indication of RA where a female to male prevalence ratio of 2-3:1 has been reported[10].

When TCZ (RoActemra) was approved in the EU (2009), the Member States were required to implement an educational pack to inform physicians and patients about the risks of serious infections and complications of diverticulitis[11]. In the summary of the Risk Management Plan (RMP) it was stated that the rate of serious infections appeared to increase with body weight[12].The dose of TCZ is dependant on body weight: 8 mg/kg body weight, given once every four weeks. For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended [13]. In the current study, the mean body weight was about 80 kg. However, no patient weighed 80 kg. Only one patient weighed 75 kg, which was close to the mean body weight, while five patients were heavier (88.2, 90, 98, 100 and 113.5 kg) and three were lighter (49, 52.2 and 53 kg). It would seem that heavier patients are over-represented in this study. It has been reported that chronic dosing using total body weight can lead to drug toxicity in obese adults.14 Although the body composition (lean versus adipose weight) and the body mass index were not reported, it seems prudent to recommend close monitoring of patients, in particular, those with a high body weight when the drug is dosed according to total body weight.

The findings in the present case series are in line with the literature reporting the commonly used concomitant medicines in RA, e.g. MTX, NSAIDs, and corticosteroids, all known to present risks for GI disorders, in particular gastric perforation[7]. As shown in Table 1, in five patients MTX was used, in five cases NSAIDs, and in six cases steroids, including one with higher dose of steroids. In addition, one patient concomitantly used rivaroxaban which is

known to increase the risk of GI bleeding. Therefore, these drugs may also have contributed to the adverse events. In addition, six patients had also concomitantly used PPI, although it is unknown if it was used to prevent or treat GI problems.

Diverticulosis was specifically mentioned for only two patients, one where it was reported present, and another where it was absent. Diverticular inflammation was reported for 0.8% of patients, who underwent colonoscopy but who lacked symptoms or clinical evidence of diverticulitis.[15] Up to 40% of the Western population may have diverticulosis.16 It is unclear if patients with known severe diverticulosis should be excluded from TCZ treatment, or if they should have a colonoscopy before starting TCZ to assess whether they have diverticulosis[17]. It has also been suggested that IL6 blockers should be avoided in patients with a history of diverticulitis, as they are known to increase the risk of subsequent intestinal perforation. the impact of diverticulitis on gastric perforation is unclear.

One patient was a smoker, which could induce pathogenic and carcinogenic processes in the GI tract [18]. This is because active compounds in cigarette smoke can damage GI tract structure through cellular apoptosis induction, and hamper the mucosal cell renewal. Cigarette smoke also interferes with the protective mechanisms of the GI tract through modulating the mucosal immune system, and reducing the mucosa blood flow. In addition, it inhibits the synthesis and release of EGF and polyamines, which reduces mucus secretion, which may compromise the integrity of the mucosal defense.

Eleven patients, when information was provided, had at least one factor that may have contributed to the occurrence of gastric damage, such as concomitant drugs (e.g., MTX, NSAIDs, steroids, rivaroxaban), or conditions (e.g., smoking, high body weight and associated high dose of TCZ). Eight of these patients had more than

one of the factors, suggesting compounded risk for the reaction to occur.

Only four reports specifically mentioned surgery for the ADR. The current treatment of perforated peptic ulcer is surgical repair, although conservative treatment can be adopted in selected patients.[6] It is unclear in our case series whether the perforations without surgery mentioned in the reports were 'microperforation' (see definition of GI perforation[7]) for which surgery is not indicated, or if surgery was performed but not noted in the reports.

Conclusion

Gastrointestinal perforation is an important identified risk of TCZ treatment which may be lifethreatening. However, the current labelling is focused on intestinal perforation, and as a complication of diverticulitis. In VigiBase, cases of gastric perforation have been reported, particularly in patients with high body weight and taking concomitant medications known to cause gastric perforation. Healthcare professionals should be aware of this potential risk and closely monitor patients, in particular those with risk factors for GI perforation, as well as those with high body weight, during treatment with TCZ, which is dosed according to total body weight.

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Source: WHO Pharmaceuticals Newsletter No.1, 2022

५. आ.व. २०७८/७९ मा निलम्बनको कारवाहीमा परेका औँषधि पसलहरुको विवरण

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१	रिभाईभ मेड्स प्रा. लि फार्मेसी युनिट	काठमाडौ म.न.पा-.१८, क्षेत्रपाटी	रिभाईभ मेड्स प्रा . लि फार्मेसी युनिट	सागरिका भट्टराई	०८/२९ /२०७८	०७
२	सहेली मेडिसिन डिष्ट्रब्युटर्स	काठमाडौ म.न.पा-.१८, क्षेत्रपाटी	सहेली श्रेष्ठ	नगेन्द्र प्रासाद बजगाई	०८/२९ /२०७८	०७
३	पशुपति ड्रग डिष्ट्रब्युटर्स	काठमाडौ म.न.पा-.१८, क्षेत्रपाटी	साधुराम ढुङ्गाना	दिव्यश्वरी रानाभाट	०८/२९ /२०७८	०७
४	भिविड मेडिसिन डिस्ट्रब्यूटर्स	काठमाडौ-१८, क्षेत्रपाटी	हरिभक्त बलामी	कुसुम श्रेष्ठ	०८/२९ /२०७८	०७
५	स्वयम्बु आयुर्वेद ड्रग सेन्टर	नरदेवी, काठमाडौं	लोकेन्द्र कुमार भगत	लोकेन्द्र कुमार भगत	०८/२९ /२०७८	०७
६	अन्तरिक्ष मेडिसिन	काठमाडौ १८, क्षेत्रपाटी	जुनेस गौतम	बसन्त राज भण्डारी	०८/२९ /२०७८	०७
७	ज्योतिर्गमय ट्रेड कन्सर्न	काठमाडौ १८, काठमाडौं	रामचन्द्र शर्मा	रितुमाया स्यानताङ	०८/२९ /२०७८	०७
८	सुखायु आयुर्वेदिक फार्मेसी	काठमाडौं-१४, कलंकी काठमाडौं	हृदय नारायण चौधरी	हृदय नारायण चौधरी	०७/१४ /२०७८	०७
९	सभ्यता मेडिकल हल	चन्द्रागिरी-२३, काठमाडौं	सन्तोष कुमार यादव	सन्तोष कुमार यादव	०७/१४ /२०७८	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१०	निर्जल फार्मेसी	काठमाडौं-०४, कलकी	आबास पौडेल	आबास पौडेल	०७/१४/२०७८	०७
११	दिपक फार्मेसी	गोदावरी १४ , ललितपुर	दिपक महत	मन्जु सुवाल	०७/०७/२०७८	०७
१२	युजल फार्मेसी	गोदावरी ०१ . ललितपुर	आङ्ग दावा शेर्पा	आङ्ग दावा शेर्पा	०७/०७/२०७८	२१
१३	नविन फार्मेसी	महालक्ष्मी-१८, ललितपुर	नारायण भट्टराई	नारायण भट्टराई	०८/१६/२०७८	१०
१४	ईजी फर्मा	महालक्ष्मी १६, ललितपुर	मेन कुमारी गोराथोकी	मेन कुमारी गोराथोकी	०८/१६/२०७८	०७
१५	आसीन मेडिकल हल	बुढानिलकण्ठ वडा नं .३, काठमाडौं, कपन	आसिम कार्की	आसिम कार्की	०७/०७/२०७८	०७
१६	राधाकृष्ण पोलिक्लिनिक	बुढानिलकण्ठ , वडा न . ०७ कपन काठमाडौं	अनिता दुवाल	अनिता दुवाल	०७/०७/२०७८	०७
१७	म्हसिका फार्मेसी	बुढानिलकण्ठ , वडा न . १२ कपन काठमाडौं	मयुर श्रेष्ठ	मयुर श्रेष्ठ	०७/०७/२०७८	०७
१८	असम मेडिकल हल	किर्तिपुर-०५, काठमाडौं	सलिना प्रजापती	सलिना प्रजापती	०७/०७/२०७८	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१९	किर्तिपुर सामुदायिक स्वास्थ्य केन्द्र	किर्तिपुर-०९, काठमाडौं	किर्तिपुर सामुदायिक स्वास्थ्य केन्द्र	हरि गोपाल महर्जन	०७/०७ /२०७८	०७
२०	नमस्ते फर्मा	बुटवल, उ.म.न.पा-०८, रुपन्देही	तिलक राज गौतम	तिलक राज गौतम	०८/२० /२०७८	०७
२१	विराट मेडिकल हल	सिदार्थनगर-१३, रुपन्देही	सरस्वती गौतम घिमिरे	सरस्वती गौतम)घिमिरे	०८/२० /२०७८	०७
२२	आयशा फार्मेसी	सिदार्थनगर-०३, रुपन्देही	राम नरेश प्रसाद मल्लाह	राम नरेश प्रसाद मल्लाह	०८/२० /२०७८	०७
२३	विनायक फर्मा	सिदार्थनगर-०३, रुपन्देही	तारा भण्डारी	तारा भण्डारी	०८/२० /२०७८	०७
२४	नुर फार्मेसी	सिदार्थनगर-०३, रुपन्देही	महोम्मद इर्फान पठान	बिन रसाईली	०८/२० /२०७८	०७
२५	गुडवेल फार्मेसी	बुटवल, उ.म.न.पा-०८, रुपन्देही	आशा पाण्डे	बाबुराम सुबेदि	०८/२० /२०७८	०७
२६	निदान फार्मेसी	बुटवल, उ.म.न.पा-०८, रुपन्देही	नम नारायण बेलबासे	नम नारायण बेलबासे	०८/२० /२०७८	०७
२७	रेसु फर्मा	बुटवल, उ.म.न.पा-०६, रुपन्देही	राजीब कुमार पौडेल	राजीब कुमार पौडेल	०८/२० /२०७८	०७
२८	जनकल्याण फार्मेसी	बुटवल, उ.म.न.पा-०८, रुपन्देही	उमेश चन्द्र शर्मा	उमेश चन्द्र शर्मा	०८/२० /२०७८	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
२९	एटोर्मा फार्मेसी	का.म.न.पा-०९, काठमाडौं	बम बहादुर कार्की	बम बहादुर कार्की	०८/२०/२०७८	०७
३०	झोराली फार्मेसी	टोखा-०१, काठमाडौं	कृष्ण प्रसाद घिमिरे	कृष्ण प्रसाद घिमिरे	०६/१७/२०७८	१०
३१	टोखा इमर्जेन्सी मेडिकल हल	टोखा-०४, काठमाडौं	भवानी दाहाल	भवानी दाहाल	०६/१९/२०७८	१०
३२	विर्षना गोर्खाली मेडिकल हल	टोखा-०३, काठमाडौं	बिनय दवाडी	मोनिक श्रेष्ठ	०६/१९/२०७८	०७
३३	सपनातिर्थ फारमेसी	टोखा-०३, काठमाडौं	सुधा पौडेल	पद्धम राज कैनी	०६/१९/२०७८	१४
३४	प्राकृतिक वाईपास फार्मेसी	का.म.न.पा-१६, काठमाडौ.	पुस्कर काफ्ले	गोकर्ण सापकोटा	०६/१९/२०७८	१४
३५	निकाम मेडिकल हल	टोखा न.पा-. १५, काठमाडौं	सुनिता अधिकारी	बाबुराम पराजुली	०६/१९/२०७८	०७
३६	मेडिगोल्ड फार्मेसी	टोखा न.पा-. १२, काठमाडौं	पशुपती गिरी	पशुपती गिरी	०६/१९/२०७८	०७
३७	गान्धि तुलसी मनोहरा कम्युनिटी हेल्थ सेन्टर प्रा.ली . फार्मेसी युनिट	वागेश्वरी मनोहरा-०९, काठमाडौं	गान्धि तुलसी मनोहरा कम्युनिटी हेल्थ सेन्टर प्रा.ली . फार्मेसी युनिट	रोजिना कार्की	०६/०४/२०७८	१४

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
३८	मेडि स्टार सेन्टर प्रा.लि . फार्मेसी युनिट	कागेश्वरी मनोहरा-०७, काठमाडौं	मेडि स्टार सेन्टर प्रा.लि . फार्मेसी युनिट	सिला अधिकारी	०६/०४ /२०७८	०७
३९	नन्दकृष्ण फार्मेसी	भक्तपुर-१४, जगाति, भक्तपुर	रिता त्वायना	सबिना वासी	०६/०४ /२०७८	०७
४०	मिली मेडिकल हल एण्ड डाईग्नोष्टिक सेन्टर, प्रा.ली . फार्मेसी युनिट	सुर्यविनायक-०१, भक्तपुर	मिली मेडिकल हल एण्ड डाईग्नोष्टिक सेन्टर, प्रा.ली . फार्मेसी युनिट	सिर्जना सुवाल	०६/०४ /२०७८	०७
४१	दिर्घायु मेडिको फर्मा	बनेपा-०६, काभ्रे	गंगा कायस्ठ	नवराज सिग्देल	०७/०७ /२०७८	०७
४२	स्माइल केयर फार्मेसी	बनेपा-०७, काभ्रे	पवन अधिकारी	सुमित्रा राजथला	०७/०७ /२०७८	०७
४३	कम्युनिटी वेलनेस सेन्टर प्रा.ली . फार्मेसी युनिट	बनेपा-०७, काभ्रे	कम्युनिटी वेलनेस सेन्टर प्रा.ली फार्मेसी युनिट	प्रज्ञा शर्मा	०७/०७ /२०७८	०७
४४	स्याउला वासःपास	पनौती-०५, काभ्रे	आजु अवा	दिक्षा सैजु	०७/०७ /२०७८	०७
४५	ध्रुवतारा भेटेरिनरी सेन्टर	पनौती-०६, काभ्रे	पवन कुमार के.सी.	पवन कुमार के.सी.	०७/०७ /२०७८	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
४६	बिराज औषधि पसल	मुग्लु-१०, काभ्रे	बिराज औषधि पसल	अपिल मिजार	०७/०७ /२०७८	०७
४७	जनसेवा फार्मेसी	मण्डन देउपुर-०६, काभ्रे	सोरता देबी भगत	रश्मिता तिमीलसिना	०७/०७ /२०७८	२१
४८	सिंगटि मेडिकल हल	बिगु- ०४, दोलखा	कृष्ण बहादुर थापा	सन्तोष कुमार सुवेदी	०३/२९ /२०७९	२१
४९	श्रेष्ठ फार्मेसी	भिमेश्वोर - ०६ , दोलखा	संजय श्रेष्ठ	एलिना श्रेष्ठ	०३/२९ /२०७९	२१
५०	मिल्ती फार्मेसी	मन्थली १३, रामेछाप	कुमार बिक्रम कार्की	बसन्त राज निरौला	०३/२९ /२०७९	०७
५१	रामेछाप सामुदायिक हस्पिटल) फा यु	मन्थली -०२, रामेछाप	रामेछाप सामुदायिक हस्पिटल प्रा.लि.	तेजराम खत्री	०३/२९ /२०७९	२१
५२	दीपसोन फार्मेसी	कगेश्वोरी मनहरा- १, काठमाडौं	प्रमिला तामाङ	जस्मिता महर्जन	०३/२९ /२०७९	०७
५३	शिव शक्ति होमिओ फार्मेसी	मन्थली -०२, रामेछाप	श्याम नारायण लाल	श्याम नारायण लाल	०३/२९ /२०७९	२१
५४	क्षितिज मेडिसिन सप्लायर्स	मन्थली -०४, रामेछाप	मोहन कुमार श्रेष्ठ	रमेश कुमार श्रेष्ठ	०३/२९ /२०७९	०७
५५	सेती देवी मेडिकल हल	मन्थली -०१, रामेछाप	केदार कुमार खत्री	केदार कुमार खत्री	०३/२९ /२०७९	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
५६	अर्किड मेडिकल हल	गोकुलगंगा - ०१, रामेछाप	डबल काजी तामाङ	सुना तामाङ	०३/२९ /२०७९	२१
५७	टेक केयर फार्मेसी	गोकुलगंगा - ०२, रामेछाप	प्रेम लाल प्रधान	प्रेम लाल प्रधान	०३/२९ /२०७९	०७
५८	सगरमाथा फार्मेसी	उमाकुण्ड- ०२, रामेछाप	शम्भु प्रसाद चौधरी थारु	शम्भु प्रसाद चौधरी थारु	०३/२९ /२०७९	०७
५९	डीमिक्सा फार्मेसी	उमाकुण्ड- ०२, रामेछाप	मेनुका न्यौपाने	दिपक दाहाल	०३/२९ /२०७९	०७
६०	गौरीशंकर मेडिकल हल	चरीकोट, दोलखा	बिमल श्रेष्ठ	बिमल श्रेष्ठ	०३/२९ /२०७९	०७
६१	हाम्रो गौरीशंकर पोलिक्लिनिक	भिमेश्वोर - ०६ , दोलखा	सन्तोष श्रेष्ठ	सन्तोष श्रेष्ठ	०३/२९ /२०७९	२१
६२	ओली भेट सेन्टर	भिमेश्वोर - ०१ , दोलखा	सिता भट्टराई	सिता भट्टराई	०३/२९ /२०७९	०७
६३	खोज आयुर्वेदिक फर्मा	भिमेश्वोर - ०५ , दोलखा	कमल प्रसाद चौलागाईं	कमल प्रसाद चौलागाईं	०३/२९ /२०७९	२१
६४	खाडी चौर फार्मेसी	बलेफी -०७, सिन्धुपाल्चोक	रामेश्वर कार्की	योगेन्द्र थापा	०३/२९ /२०७९	३०
६५	जेविन फार्मेसी	कालिन्चोक - ०३, दोलखा	जीवनाथ दुलाल	जीवनाथ दुलाल	०३/२९ /२०७९	२१
६६	दोलखा मेडिको	भिमेश्वोर - ०३ , दोलखा	सुन्दर प्रकाश खड्का	निस्मा खड्का	०३/२९ /२०७९	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
६७	सितगंगा फार्मेसी	सितगंगा - ०४ , अर्घाखाँची	केशव भट्टराई	प्रदिप चौधरी	०३/२९ /२०७९	०७
६८	रश्मी फार्मेसी	सन्धिखर्क - ०६, अर्घाखाँची	बसन्त कुमार रोकाय	बसन्त कुमार रोकाय	०३/२९ /२०७९	०७
६९	वेदना फार्मेसी	सन्धिखर्क - ०१, अर्घाखाँची	निम बहादुर राना मगर	विजय बहादुर कुमाल	०३/२९ /२०७९	०७
७०	कुन्ता फार्मेसी	सन्धिखर्क - ०१, अर्घाखाँची	धमेन्द्र श्रेष्ठ	धमेन्द्र श्रेष्ठ	०३/२९ /२०७९	२१
७१	लुम्बिनी भेट सेन्टर	सन्धिखर्क - ०२, अर्घाखाँची	बिनोद गैरे	बिनोद गैरे	०३/२९ /२०७९	०७
७२	फर्मेसिया नेपाल	चन्द्रागिरी न.पा .११ , काठमाडौं	मो एकवाल परोहा	मो एकवाल परोहा	०३/२९ /२०७९	०७
७३	सत्यता फार्मेसी	चन्द्रागिरी न.पा .१५ , काठमाडौं	सुदिप अधिकारी	ज्वाला पुडासैनी	०३/२९ /२०७९	०७
७४	मेड पोईन्ट मेडिको	चन्द्रागिरी न.पा .११ , काठमाडौं	सविन मानन्धर	कविता भण्डारी	०३/२९ /२०७९	२१
७५	किरण फार्मेसी	महालक्ष्मी न.पा.१ , ललितपुर	नविना घिमिरे	नविना घिमिरे	०३/२९ /२०७९	२१
७६	सरिता मेडिकल हल	ललितपुर म.न.पा .०९, ललितपुर	जितेन्द्र प्रसाद राउत	जितेन्द्र प्रसाद राउत	०३/२९ /२०७९	२१

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
७७	न्यु केयर पोली क्लिनिक प्रा लि फा. यु	ललितपुर म.न.पा .०८, ललितपुर	न्यु केयर पोलिक्लिनिक प्रालि.	इन्दु लम्साल	०३/२९ /२०७९	२१
७८	युनिक फर्मा	ललितपुर म.न.पा.१६, ललितपुर	रघु नाथ श्रेष्ठ	रघु नाथ श्रेष्ठ	०३/२९ /२०७९	०७
७९	ओम आरोग्य हेल्थ केयर प्रा लि) फा यु	महालक्ष्मी न.पा.४, ललितपुर	ओम आरोग्य हेल्थकेयर प्रा.लि.	एलिशा बन्जाडे	०३/२९ /२०७९	०७
८०	पबी फर्मा	का.म.न.पा. ३१, काठमाडौं	आशिका पौडेल	बाबुराम पौडेल	०३/२९ /२०७९	२१
८१	जेम्स फार्मेसी	ललितपुर म.न.पा .२३, ललितपुर	-	-	०३/२९ /२०७९	०७
८२	बहरवा फार्मेसी	मध्यपुर ठिमी-०३, भक्तपुर	रेजु प्रजापति	पुनम प्रजापति	०३/२९ /२०७९	०७
८३	पाण्डे मेडिकल हल	भक्तपुर-०२	प्रमिता पाण्डे	प्रमिता पाण्डे	०३/२९ /२०७९	०७
८४	केयर हेल्थ पोलीक्लिनिक	भक्तपुर-०७	केयर हेल्थ पोलिक्लिनिक	अनिल श्रेष्ठ	०३/२९ /२०७९	०७
८५	जेनिथ फर्मा	भक्तपुर-०२	प्रमोद खरेल	प्रमोद खरेल	०३/२९ /२०७९	०७
८६	सुधा आयुर्वेद फार्मेसी	का.म.न.पा.३ ५ , काठमाडौं	सुधा श्रेष्ठ	सुधा श्रेष्ठ	०३/२९ /२०७९	०७
८७	एन्टीक फार्मेसी	का.म.न.पा.३ २ , काठमाडौं	मोजिका श्रेष्ठ	सुमिरा श्रेष्ठ	०३/२९ /२०७९	२१

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
८८	लालुपाते मेडिकल सेन्टर	का.म.न.पा.३२, काठमाडौं	राजा राम कार्की	सविना घिमिरे	०३/२९/२०७९	०७
८९	सुक्रिम फार्मेसी	का.म.न.पा.३२, काठमाडौं	सुमित्रा कुमारी तामांग	सुमित्रा कुमारी तामांग	०३/२९/२०७९	०७
९०	उपेन्जु फार्मेसी	का.म.न-.१५, काठमाडौं	अन्जु थापा	रोजिना थापा	०३/२९/२०७९	०७
९१	बन्जारा आयुर्वेद फर्मा	का.म.न-.३४, काठमाडौं	पूजा बजार	पूजा बजार	०३/२९/२०७९	०७
९२	शिव शेखर फार्मेसी	काठमाडौं-१०	विनोद अधिकारी	विनोद अधिकारी	०३/२९/२०७९	०७
९३	सुवेदी आयुर्वेद मेडिकल हल	काठमाडौं-१०	कृष्ण सुवेदी	कृष्ण सुवेदी	०३/२९/२०७९	०७
९४	रोहण फर्मा	का.म.न-.३१, काठमाडौं	प्रशाल अधिकारी	प्रशाल अधिकारी	०३/२९/२०७९	०७
९५	सराकारी पोलीक्लिनिक प्रा.लि.	काठमाडौं	-	-	०३/२९/२०७९	०७
९६	कुशल ड्रग डिस्ट्रीव्युटर	काठमाडौं	सपना कुमारी जोशी	सपना कुमारी जोशी	०३/२९/२०७९	०७
९७	हेल्दी फार्मेसी प्रा.लि.	काठमाडौं-३१	चन्दा कर्मचार्य	चन्दा कर्मचार्य	०३/२९/२०७९	०७
९८	युजल फार्मेसी	काठमाडौं-०९	डिल्ली राज पैनी	प्रतिक्ष्या घिमिरे	०३/२९/२०७९	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
९९	ज्वलंता फर्मा	काठमाडौं-०९	बालकृष्ण कर्मचार्य	अन्जना श्रेष्ठ	०३/२९/२०७९	२१
१००	इक्शा फार्मेसी	काठमाडौं-३४	मिना राई	सुनिल श्रेष्ठ	०३/२९/२०७९	०७
१०१	रोजल कामख्या फार्मेसी	काठमाडौं-०९	राजु कार्की	सनम घलान	०३/२९/२०७९	०७
१०२	विक्स फर्मा	क.म.न.पा ०१, काठमाडौं	संजय कुमार मण्डल	मनिष पाण्डे	०३/२९/२०७९	०७
१०३	के.वि. फर्मा प्रा.लि	काठमाडौं-२९	के.वि. फर्मा, प्रा.लि.,	निर्मला कलौनी	०३/२९/२०७९	२१
१०४	एभर युथ फार्मेसी	काठमाडौं-३०	सावित्री देवी	प्रबिना तामांग	०३/२९/२०७९	०७
१०५	ताहाचल फर्मेसिया प्रा.लि.	काठमाडौं-१२	ताहाचल फर्मेसिया प्रा.लि.	बाल कृष्ण न्यौपाने	०३/२९/२०७९	०७
१०६	सितापाइला संगम आयुर्वेदिक औषधालय	काठमाडौं-०४	भुपेन्द्र कुवर छेत्री	भुपेन्द्र कुवर छेत्री	०३/२९/२०७९	०७
१०७	आरोहण भेट फर्मा	काठमाडौं-१६	सादुराम ढकाल	सादुराम ढकाल	०३/२९/२०७९	०७
१०८	काङमी फार्मेसी	काठमाडौं-१३	श्रीकान्त राई	मालती बस्नेत	०३/२९/२०७९	०७
१०९	रिलायन्स फर्मा	ललितपुर-२६	फुल बाबु यादव	हर्षेन्द्र राज बज्राचार्य	०३/२९/२०७९	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
११०	आदि श्री फर्मा	चापागाउँ-०६, ललितपुर	रचना सिंह हमाल	सिता घिमिरे	०३/२९/२०७९	०७
१११	घिमिरे आयुर्वेदिक फर्मा	ललितपुर-२५	रत्न राज घिमिरे	रत्न राज घिमिरे	०३/२९/२०७९	०७
११२	चोगा घणेश फार्मेसी	भक्तपुर-०१, सल्लाघारी	कविता सिल्पकार	कविता सिल्पकार	०७/१५/२०७८	१५
११३	म्हसिका फार्मेसी	बुढानिलकण्ठ-१२, कपन, काठमाण्डौं	मयुर श्रेष्ठ	मयुर श्रेष्ठ	०७/०७/२०७८	०७
११४	नवबिल फर्मा	काठमाण्डौ-.०९, काठमाण्डौ.	अनोज बाबु श्रेष्ठ	अस्मिता श्रेष्ठ	०८/१२/२०७८	०७
११५	ऐट्रोमा फार्मेसी	बुढानिलकण्ठ-०९, कपन, काठमाण्डौं	सबिना तामाङ्ग	सबिना तामाङ्ग	०६/१७/२०७८	०७
११६	आसमान फार्मेसी	बुढानिलकण्ठ-०६, कपन, काठमाण्डौं	गौरी नारायण श्रेष्ठ	गौरी नारायण श्रेष्ठ	११/०४/२०७८	१५
११७	सहारा पोलिक्लिनिकए ण्ड डायग्नोष्टिक सेन्टर प्रा.लि., फार्मेसी युनिट	काठमाडौं-३२	सहारा पोलिक्लिनिक एण्ड डायग्नोष्टिक सेन्टर प्रा.लि.	जानकी कुमारी साउद	०३/२९/२०७९	०७
११८	जुभेन्टास फार्मेसी	काठमाडौं-३२	सुजिता मानन्धर	सुजाता मानन्धर	०३/२९/२०७९	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
११९	निकास फार्मेसी	कोटेश्वर-३२,काठमाडौं	नरेन्द्र बहादुर अधिकारी	नरेन्द्र बहादुर अधिकारी	०३/२९/२०७९	१५
१२०	अनुश्री मेडिको	काठमाडौं-३१	अनोज कार्की	अनोज कार्की	०३/२९/२०७९	०७
१२१	हेर्बल आयुर्वेद फर्मा	काठमाडौं-३४	विष्णु गौतम	विष्णु गौतम	०३/२९/२०७९	०७
१२२	दिव्यज्वती फार्मेसी	काठमाडौं-३१	सुनिल गौतम	सुनिल गौतम	०३/२९/२०७९	चेतावनी सहित सचेत गरिएको
१२३	सहयोगीनगर फार्मेसी	काठमाडौं-३२	मनोज कुमार महत्तो	मनोज कुमार महत्तो	०३/२९/२०७९	०७
१२४	आराभ फार्मेसी	काठमाडौं-३२	जितेन्द्र कुमार शाह	रचना सापकोटा	०३/२९/२०७९	०७
१२५	प्रज्वल फार्मेसी	कोटेश्वर-३२, काठमाडौं	पार्वती खत्री	पार्वती खत्री	०३/२९/२०७९	०७
१२६	फर्पिंग पोलिक्लिनिक एण्ड हेल्थ केयर प्रा.लि., फार्मेसी युनिट	दक्षिणकाली-०५, काठमाडौं	फर्पिंग पोलिक्लिनिक एण्ड हेल्थ केयर प्रा.लि.	काजी श्रेष्ठ	०३/२९/२०७९	०७
१२७	रिदम फर्मेसिया	दक्षिणकाली-०१, काठमाडौं	शिला न्यौपाने	शिला न्यौपाने	०३/२९/२०७९	चेतावनी सहित सचेत गरिएको
१२८	क्षितिज मेडिकल स्टोर	का.म.न-.१४, काठमाडौं	कृष्ण महर्जन	कृष्ण महर्जन	०३/२९/२०७९	०७

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१२९	रुम्बा फार्मेसी	दक्षिणकाली-०१, काठमाडौं	प्रतिभा लाखे	प्रतिभा लाखे	०३/२९/२०७९	चेतावनी सहित सचेत गरिएको
१३०	अर्याना मेडिकल हल	काठमाडौं	सन्दिप रायमाझी	सन्दिप रायमाझी	०३/२९/२०७९	१५
१३१	अमृत मेडिकल हल	दक्षिणकाली-०६	सुमित्रा वज्राचार्य	राकेश महर्जन	०३/२९/२०७९	०७
१३२	कुवेर फार्मेसी,	दक्षिणकाली-०६, काठमाडौं	कुवेर फार्मेसी	सुरेन्द्र श्रेष्ठ	०३/२९/२०७९	चेतावनी सहित सचेत गरिएको
१३३	मनमोहन स्मृति सामुदायिक अस्पताल	दक्षिणकाली-०८, काठमाडौं	मनमोहन स्मृति सामुदायिक अस्पताल	उर्मिला वलामी	०३/२९/२०७९	१५
१३४	सुराग फर्मा मिलेनियम	चाल्नाखेल-०५, खहरे, काठमाडौं	राजेश परियार	राजेश परियार	०३/२९/२०७९	१५
१३५	झा मेडिकल हल	का.म.पा.१४, बल्खु, काठमाण्डौ	विवेक लाल झा	विवेक लाल झा	०९/२९/२०७८	२१
१३६	केयर आयुर्वेद प्रा.लि .फा.यु.	का.म.पा.१४, बल्खु, काठमाण्डौ	केयर आयुर्वेद प्रा.लि.	सरस्वती यादव	०९/२९/२०७८	३०
१३७	सुभचिन्तक कलिनिक प्रा.लि .फा.यु.	थाक्रे-०९, धादिङ्ग	सुभचिन्तक कलिनिक प्रा.लि. फा.यु	सोफिया शर्मा	०९/२९/२०७८	२१

सि नं.	पसलको नाम	पसल ठेगाना	धनी	व्यवसायी	विभागको निर्णय मिति	निलम्बन दिन
१३८	आदर्श फार्मेसी	गजुरि-०१, धादिङ्ग	दिपक दल्लाकोटी	दिपक दल्लाकोटी	०९/२९/२०७८	१४
१३९	मलेखु फार्मेसी	बेनिघाट, धादिङ्ग-०३	कैलाश राज घिमिरे	रोजिता ढकाल	०९/२९/२०७८	३०
१४०	भद्रकाली मेडिकल हल	गजुरी-०२, धादिङ्ग	कुमार अधिकारी	नवराज बानिया	०९/२९/२०७८	०७
१४१	किसान एग्रोभेट	गजुरी-०२, धादिङ्ग	देवराज श्रेष्ठ	देवराज श्रेष्ठ	०९/२९/२०७८	०७
१४२	सनराज फार्मेसी	धुनिबेसी-०६, धादिङ	संजिवराज पाण्डे	संजिवराज पाण्डे	०९/२९/२०७८	१४
१४३	आचार्य भेटेरिनरी सेन्टर	धुनिबेसी-०६, धादिङ	श्रीकृष्ण आचार्य	श्रीकृष्ण आचार्य	०९/२९/२०७८	०७

६. आ.व. २०७८/७९ मा National GMP र WHO GMP प्रदान भएका स्वदेशी औषधि उत्पादकहरुको सूची

List of Domestic Manufacturers Awarded with National GMP in 2078/079			
S. No.	**Name of Manufacturer**	**Decision Date**	**Validity**
1.	Genetica Laboratories Pvt. Ltd., Bara	1/6/2079	1/5/2081
2.	Alive Pharmaceuticals Pvt. Ltd	2/10/2079	2/9/2081
3.	Magnus Pharmaceuticals Pvt. Ltd., Bara	1/6/2079	1/5/2081
4.	National Healthcare Pvt. Ltd.	7/5/2078	7/4/2080
5.	Nepal Pharmaceuticals Lab. Pvt. Ltd.	10/26/2078	10/25/2080
6.	Nova Genetica Pvt. Ltd.	1/6/2079	1/5/2081
7.	Ohm Pharmaceuticals Laboratories Pvt. Ltd.	8/3/2078	8/2/2080
8.	Samar Pharma Company Pvt. Ltd., Birgunj	10/26/2078	10/25/2080
9.	Vijayadeep Laboratories Pvt. Ltd.	6/30/2076	6/29/2078
10.	Amtech Med Pvt. Ltd.	2/10/2079	2/9/2081
11.	Florid Laboratories Pvt. Ltd.	4/1/2078	3/30/2080
12.	Supreme Healthcare Pvt. Ltd.	4/26/2078	4/25/2080
13.	Siddhartha Pharmaceuticals Pvt. Ltd., Rupandehi	7/5/2078	7/4/2080
14.	Apple Pharmaceuticals Pvt. Ltd., Rupandehi	10/26/2078	10/25/2080
15.	Unique Phrmaceuticals Pvt. Ltd., Bara	1/6/2079	1/5/2081
16.	QbD Pharmaceuticals Pvt. Ltd., Kavre	1/6/2079	1/5/2081
17.	Universal Formulations Pvt.Ltd.	8/3/2078	8/2/2080
18.	Apex Pharmaceuticals Pvt.Ltd.	10/26/2078	10/25/2080
19.	Aadee Remedies Pvt.Ltd.	8/3/2078	8/2/2080
20.	Alliance Pharmaceuticals Pvt.Ltd,	9/27/2078	9/26/2080
21.	Live care Pharmaceuticals Pvt.Ltd,	10/26/2078	10/25/2080
22.	Vega Pharmaceuticals Pvt. Ltd.	6/6/2078	6/5/2080
23.	Time Pharmaceuticals P.Ltd., Nawalparasi	2/10/2079	2/9/2081
24.	Amtech Med Pvt. Ltd., Morang	2/10/2079	2/9/2081

List of Domestic Manufacturers awarded with WHO GMP in 2078/079			
S. No.	**Name of Manufacturer**	**Decision Date**	**Validity (D/M/Y)**
1.	Genetica Laboratories Pvt. Ltd., Bara	1/6/2079	18/04/2024
2.	Magnus Pharmaceuticals Pvt. Ltd., Bara	1/6/2079	18/04/2024
3.	National Healthcare Pvt. Ltd.	7/5/2078	21/10/2023
4.	Nepal Pharmaceuticals Lab. Pvt. Ltd.	10/26/2078	8/2/2024
5.	Nova Genetica Pvt. Ltd.	1/6/2079	18/04/2024
6.	Ohm Pharmaceuticals Laboratories Pvt. Ltd.	8/3/2078	18/11/2023
7.	Panas Pharmaceuticals Pvt. Ltd., Nepalgunj	5/24/2022	23/05/2024
8.	Quest Pharmaceuticals Pvt. Ltd.	6/6/2078	21/09/2023
9.	Samar Pharma Company Pvt. Ltd., Birgunj	10/26/2078	8/2/2024
10.	Vega pharmaceuticals Pvt. Ltd, Lalitpur	6/6/2078	21/09/2023
11.	Florid Laboratories Pvt. Ltd.	4/26/2078	15/07/2023
12.	Supreme Healthcare Pvt. Ltd.	4/6/2078	9/8/2023
13.	Siddhartha Pharmaceuticals Pvt. Ltd., Rupandehi	7/5/2078	21/10/2023
14.	Omnica Laboratories Pvt. Ltd., Bhaktapur	7/5/2078	21/10/2023
15.	Apple Pharmaceuticals Pvt. Ltd., Rupandehi	10/26/2078	8/2/2024
16.	Unique Phrmaceuticals Pvt. Ltd., Bara	1/6/2079	18/04/2024
17.	QbD Pharmaceuticals Pvt. Ltd., Kavre	1/6/2079	18/04/2024
18.	Grace Pharmaceuticals Pvt. Ltd., Rupandehi	7/28/2022	27/07/2024
19.	Grace Pharmaceuticals Pvt. Ltd.(Unit-2), Rupandehi	7/28/2022	27/07/2024
20.	Apex Pharmaceuticals Pvt. Ltd.	10/26/2078	8/2/2024

७. आ.व. २०७८/७९ मा विभागमा सूचीकारण भएका विदेशी औषधि उत्पादकहरुको सूची

S.N.	Name of Company	Factory/Site Address	Date of approval	Importers Name & Address
1	Demo S.A Pharmaceuticals Industry	Attiki, Greece	2078/ 04/03	Human lifescience Pvt. Ltd., lalitpur
2	Lupin Limited	Pune 412125 Maharashtra India	2078/ 04/11	Pharmachem Private limited, Birgunj
3	Ever Neuro Pharma	Str 15, 07745 Jena Germany	2078/ 04/10	Gunjeshwari pharma, Birgunj
4	Zambon Switzerland ltd	Ch-6814 Cadempino Switzerland	2078/ 04/11	Shree om Brothers pvt.ltd., Ktm.
5	Terumo Yamaguchi and d corporation	Yamaguchi 754-0894, Japan	2078/ 04/22	Pharmachem private limited, Birgunj
6	Gan and Lee Pharmaceuticals	Beijing 101109, china	2078/ 04/21	Pharmachem private limited, Birgunj
7	Sanquin plasma products B.V.	Amsterdam the Netherlands	2078/ 04/02	Human life science pvt ltd, Lalitpur
8	Man kind Pharma ltd unit III	Sirmour-173025, India	2078/ 05/20	Vriddhi International P.ltd
9	Pt Tunggal Idaman Abdi	Jakarta Timur Indonesia	2078/ 05/20	Medi sky concern Pvt. Ltd.
10	Central veterinary Medicine Jsc -no-5	Vietnam	2078/ 05/22	Big B Vet Trading
11	Alcon Research LLC	6201 South Freeway Forth worth Tx 76134, USA	2078/ 05/30	Agile medisales, lalitpur
12	ACS Dobfar S.P.A	Tordino 64100 Teramo Italy	2078/ 06/06	Human life science Pvt. Ltd.

S.N.	Name of Company	Factory/Site Address	Date of approval	Importers Name & Address
13	Biocare Manufacturing Sdn Bhd	Seri iskandar, Perak, Malaysia	2078/ 07/02	Gama Trade Concern Nepal Pvt. Ltd
14	Caplin Steriles limited	Survey no. 895 & 897, thiruvallur (district), gummidipoondi, tamil nadu 601201, India	2078/ 07/10	Human life science pvt.ltd., lalitpur
15	Kendrion S.P.S., Italy	S.P.A., S.S. 7, bis km 19.5, 80029-sant antimo (naples), Italy	2078/ 08/02	R.S. Pharmaceuticals Enterprises, Ktm.
16	Serum Institute of India Pvt. Ltd.	Sippl,S.No.105-110, Manjari BK,Pune 412 307,Maharashtra, India	2078/ 08/20	Shree om Brothers Pvt. Ltd., Ktm
17	Marksons Pharma Ltd.	Plot no. l-82, l-83, verna Industrial estate, Verna Goa-403 722 Maharashtra, India	2078/ 09/13	Yamuna pharma pvt.ltd
18	Dragenopharm Apothekar Puschi GmbH	Gollstrabe 184529, Tittmoning, Germany	2078/ 08/20	Synergy Overseas Private Limited
19	Ximen Innovax Biotech Co. Ltd.,	No.52, shanbianhong east road, haicang district, xiamen, fujian, China	2078/ 10/23	Nanda Chem Drug Distributors Pvt. Ltd.
20	Eugia Pharma Specialities Ltd.,	Unit-2, a-1128, RIICO Industrial area phase-III, Alwar bhiwadi, Rajasthan 301019, India	2078/ 10/18	Human Life Science Pvt.Ltd.
21	Brooks Steriscience Limited,	Unit II, village manglej, Nareshwar road, off NH8 Vadodara-391210, Gujarat, India	2078/ 09/07	Blue Sky Healthcare Pvt. Ltd.
22	Cipla limited	Plot no. l-139 to l-146, verna industrial estate, Verna Goa India	2078/ 12/29	Instyle trading concern.,

S.N.	Name of Company	Factory/Site Address	Date of approval	Importers Name & Address
23	Cipla limited	plot no. a-2,a-33,a-42 and a-37/2/2, Patalganga Industrial area, raigad, Maharashtra 410220	2078/ 12/22	Instyle trading concern.,
24	Meda manufacturing,	Avenue jf kennedy, Merignac 33700, France	2078/ 12/29	Pharmachem Pvt. Ltd., Birgunj
25	Abb vie inc.	1401, sherdan road, north chcago, il 60064	2079/ 02/11	
26	Mylan laboratories SAS	Route de belleville, lieu-dit maillard, chatillon sur chalaronne 01400,France	2079/ 02/17	
27	ACS Dobfar S.P.A.,	via alessandra fleming 2-37135, verona (vr), Italy	2079/ 03/13	Shree Om Brother Pvt.ltd., Ktm

८. आ.व. २०७८/७९ मा विभागबाट पैठारीका लागि अनुमति प्रदान भएका **Hand Sanitizer** को सूची

S. N	उत्पादकको नाम/ ठेगाना	SANITIZER को नाम/ बनावट	आधिकारिक पैठारीकर्ता
1	Rl Corp, Gujarat, India	1. Sanitive instant hand rub sanitizer, 2 liter 2. Sanitive instant hand rub sanitizer,5 liter	Matrix pvt. ltd., lalitpur
2	RL Corp, Gujarat, India	1. Pamacare instant rub sanitizer, 5 liter	SB Trade international, ktm
3	Research Medicine Pvt. ltd., India	Brackish hand sanitizer 500 ml	Nepal marketing solution ktm.
4	Multani Pharmaceuticals ltd. Haridwar	1. Kuka hand sanitizer (neem and lemon), 100 ml 2. Kuka hand sanitizer (neem and lemon), 200 ml 3. Kuka hand sanitizer (neem and lemon), 5 liter	Dipali pharmaceticals
5	Nagindas Hiralal Bhayani, Gujarat,India (Mfg.for: Schulke India pvt.ltd. New Delhi)	1. Microshield handrub 100 ml 2. Microshield handrub 500 ml (pink colored) 3. Desderman hand sanitizer 500 ml	Moon light traders, Kathmandu
6	Hind Pharma Bhopal 462022, India	1. Sterinol instant hand sanitizer 100 ml liq. 2. Sterinol instant hand sanitizer 500 ml 3. Guard h. instant hand sanitizer 90 ml 4. Guard h. instant hand sanitizer 90ml	Saral Exim Pvt. ltd. Ktm
7	Vapi Organic Chemicals Pvt. ltd. Gujarat, India (Mktd by: Diversey India Hygiene Pvt. ltd.)	Soft care (e) spray hand sanitizer, 5 liter	Web Trading concern pvt. ltd. kathmandu
8	Rl Corp Gujarat, India	Pamacare instant handrub sanitizer 130 ml, 250 ml	SB Trade, Ktm

S. N	उत्पादकको नाम/ ठेगाना	SANITIZER को नाम/ बनावट	आधिकारिक पैठारीकर्ता
9	Natural Fragranles llc UAE	1. smart ipa 70 %, 250 ml 2. smart instant hand sanitixer spray 20 ml 3. smart instant hand sanitizer spray 125 ml 4. smart instant hand sanitixer spray 100 ml 5. smart instant hand sanitizer spray 250 ml 6. smart instant hand sanitixer spray 150 ml 7. smart hand sanitizer spray,100 ml smart instant hand sanitizer gel, 65 ml 8. smart inst. hand sanitizer gel,250 ml 9. smart i.hs. spray,300 ml smart i.h.s gel 500 ml 10. smart i.h.s spray, 45 ml	Nawa durga trading concern, ktm.
10	VVF India ltd. Daman (Mktd by: Reckkit Benekiser India Pvt. Ltd.	Dettol instant hand sanitizer gel ,25ml	Kathmandu marketing & Trading house pvt. ltd.
11	Comex Herbal Product India	Comex hand sanitizer 100 ml, 500ml, 5 liter	Sagarmatha Surgical House, Ktm

9. REGULATORY NOTICES

स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था बिभाग

प्रकाशित मितिः२०७९/०३/२३

औषधि व्यवस्था विभागको
अत्यन्त जरूरी सूचना

यस विभागमा दर्ता रहेका कतिपय Pharmaceuticals Dosage Form जस्तै ट्याब्लेट (Tablet), क्याप्सुल (Capsule) तथा झोल (Liquid) लगायतका औषधि र त्यसका समिश्रणहरु बजारमा खाद्यसमपूरक सामाग्रीहरुको रुपमा अत्यधिक मात्रामा पैठारी गरी संचय, बिक्रि वितरण र प्रयोग भईरहेको सम्वन्धमा यस विभागको गम्भीर ध्यानाकर्षण भएको छ।

औषधि ऐन, २०३५ को औषधिको परिभाषा अन्तर्गत कुनै पनि औषधीय तत्व समावेश भएका औषधीय बनावटका सबै बस्तुहरु औषधि अन्तर्गत पर्दछन् र यस्ता बस्तुहरुको उत्पादन, आयात तथा बिक्रि वितरण औषधि ऐन बमोजिम नियमन हुने प्रावधान रहेको विदितै छ। हाल बजारमा उपलब्ध कतिपय भिटामिन तथा लवणका सार तत्व भएका भनिएका वस्तु/औषधि स्वास्थ्यका दृष्टिले अनावश्यक र उपयोगिता नहुने भएका कारण औषधि ऐन,२०३५को दफा २५ को प्रावधान अनुसार २०४९ सालमा नै नेपाल राजपत्रमा सूचना प्रकाशित गरि प्रतिवन्ध गरिएको छ।

यसै बीच Zee laboratories, India बाट उत्पादित Biodee Drops [Vitamin D3 (Cholecalciferol)] बच्चाहरुमा प्रयोगगर्दा विभिन्न नकारात्मक असर/दुष्प्रभाव (Adverse Effect) देखिएको जानकारी अस्पताल लगायत विभिन्न संचार माध्यमबाट प्राप्त भएको तथा सो उत्पादन यस विभागमा समेत दर्ता नरहेको देखिएकाले सो Biodee Drops बिक्रि वितरण तथा प्रयोग नगर्न नगराउन हुन अनुरोध गरिन्छ।

औषधि ऐन,२०३५ बमोजिम यस विभागबाट अनुमति नभएका वस्तु औषधिका रुपमा मान्न नसकिने तथा सोको गुणस्तर तथा सुरक्षितता र प्रभावकारिता बारेमा समेत यकिन नहुने हुदाँ त्यस्ता बस्तुहरुको पैठारी तथा बिक्रि वितरण नगर्न नगराउन र औषधिको रुपमा प्रयोग नगर्न सम्वन्धित सबैमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

३/१२

महानिर्देशक

सूचना

प्रतिजैविक (ANTIBIOTICS) औषधिहरुको खपत विवरण तथा PMS सम्बन्धी सम्पुर्ण उत्पादकहरुलाई तालिमको सुचना

यस विभागमा हालसम्म दर्ता भएका प्रतिजैविक (ANTIBIOTICS) औषधिहरुको प्रयोगको खपत विवरण श्री विश्व स्वास्थ्य संगठन (WHO) लाई वार्षिक रुपमा अनिवार्य पेश गर्नु पर्ने भएकाले सो सम्बन्धि आवश्यक जानकारीको लागि तथा NARCOTIC AND PSYCHOTROPICS SUBSTANCES लगायतका अन्य अत्यावश्यक औषधिहरुको बिवरण PMS SOFTWARE मा प्रविष्ट समेत गर्ने सम्बन्धमा तालिम दिईने भएकोले सम्पूर्ण उत्पादकका एक जना आधिकारिक ONLINE सम्बन्धि कार्य गर्ने प्राविधिक व्यक्तिहरुलाई देहायको मिति, समय र स्थानमा अनिवार्य सहभागी हुनुहुन यसै सूचना मार्फत सुचित गरिन्छ।

नोटः यस तालिम (TRAINING) मा सहभागी हुने सदस्यले मिति २०७९/०२/२६ बिहिवार सम्ममा विभागको योजना समन्वय तथा व्यवस्थापन महाशाखामा अनिवार्य रुपमा उत्पादकको आधिकारिक व्यक्ति पत्र सहित सम्पर्क गर्नु हुन समेत जानकारी गराईन्छ।

स्थानः औषधि व्यवस्था विभागको सभा कक्ष

मितिः २०७९/०२/२७ गते शुक्रवार (सम्पुर्ण उत्पादकका आधिकारिक प्रतिनिधिहरुका लागि)

समयः दिनको ११ बजे देखि २ बजे सम्म

महानिर्देशक

बोधार्थ

१ उद्योग शाखा

२ Association of Pharmaceutical Producers of Nepal (APPON)

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति: २०७८/११/२६

PMS Software user ID सम्बन्धी सूचना

यस विभागबाट उत्पादक तथा आयातकर्ताहरुबाट Hard Copy मा Narcotic, Psychotropic औषधिहरुको खपत विवरण अध्यावधिक गरि आएकामा हाल सो लाई सहजताका लागि Narcotic, Psychotropic सहित Antimicrobials पनि PMS Software मार्फत प्रविष्ट गर्नका लागि सबै औषधि उत्पादक तथा आयातकर्ताहरुलाई user ID आवश्यक हुने हुदाँ सो को लागि तपसिल बमोजिम दिईएको Google form Link/QR code भरी यथासिंघ्र विभागमा बुझाउनहुन अनुरोध छ ।

तपशिलः

Google form link: https://bit.ly/35BAxZF

९१/२३

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

नयाँ औषधि (New Molecule) का सम्बन्धमा ।

औषधि सल्लाहकार समितिको मिति २०७८/०९/१९ गते बसेको ५२ औ बैठकको निर्णयानुसार निम्न उल्लेखित नयाँ औषधि (New Molecule) हरु प्रकृया पुरा गरि दर्ता गर्न औषधि व्यवस्था विभागलाई परामर्श दिने निर्णय भएको हुँदा औषधिको विशेष सिफारिस सम्बन्धि (पहिलो संशोधन) कार्यविधि, २०७७ को दफा ११ को प्रयोजनको लागि सम्बन्धित सबैको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ ।

तपशिल:

S.N.	Generic Name
1.	Tenecteplase Powder for Injection
2.	Sofosbuvir & Daclatasvir tablet
3.	Umeclidinium Bromide 62.5 mcg Inhalational Powder
4.	Sofosbivir 400mg and Velpatasvir 100 mg tablet
5.	Nintedanib 100mg soft gelatin capsule
6.	Acetylcysteine 150 mg and Taurine 500 mg tablet
7.	Ranolazine 375mg tablet
8.	Ranibizumab 2.3 mg 10mg/ml Injection & 10 mg/ml Injection
9.	Dasatinib-100 tablet
10.	Ramucirumab 10 mg/ml Injection
11.	Carfilzomib 60mg/Vial, for injection
12.	Apremilast 10mg, 20 mg,30 mg
13.	Caspofungin Acetate eq. to Caspofungin 50 mg&70 n Injection
14.	Memantine and Donepezil tablet (5 & 10)
15.	Aminoethylsulfonic Acid 130mg, Acid 130mg, E- Aminocaproic Acid 130 mg, Chlorpheniramine Maleate 1.3 mg. Potassium Asparate 26 mg Eye Drops

२०८१।१।१२

महानिर्देशक

१

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७८/११/०२

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

तपसिल:

सि.न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	Microcef 200 DT (Cefpodoxime Proxetil)	MCTB0202	May-2020/ Apr-2022	Does not comply as per CEFO 075/076/AP048 with respect to dissolution test.	Micro Lab Limited, India
2.	Myvit-C (Vitamin C Chewable tablet IP)	TMS-044	May-2021/ Apr-2023	Does not comply with product specification of the company with respect to color of the tablets.	Curex Pharmaceuicals Pvt. Ltd., Janagaal, Kavre, Nepal
3.	Myvit-C (Vitamin C Chewable tablet IP)	TMS-045	May-2021/ Apr-2023	Does not comply with product specification of the company with respect to color of the tablets.	Curex Pharmaceuicals Pvt. Ltd., Janagaal, Kavre, Nepal

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/१०/०६

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

तपसिल:

सि.न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	NS 500ml (Sodium Chloride Injection IP (0.9%w/v))	1E11379	May-2021/ Apr-2024	Does not comply as per IP 2018 with respect to sterility test.	Aculife Healthcare Pvt. Ltd., Sachana, Gujurat 382150, India
2.	RL 500ml (Ringer Lactate Solution for Injection)	1E11351	May-2021/ Apr-2024	Does not comply as per IP 2018 with respect to sterility test.	Aculife Healthcare Pvt. Ltd., Sachana, Gujurat 382150, India
3.	5D 500ml (Dextrose Injection IP)	AE10816	May-2021/ Apr-2024	Does not comply as per IP 2018 with respect to sterility test.	Axa Parenterals Ltd, Plot No 936, 937, 939, Krishnapur, Jamalpur, Roorkee, 247667, Uttarakhand, India

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स्वास्थ्य तथा जनसंख्या मन्त्रालय
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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
महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/१०/०६

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

तपसिल:

सि.न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	NS 500ml (Sodium Chloride Injection IP (0.9%w/v))	1E11379	May-2021/ Apr-2024	Does not comply as per IP 2018 with respect to sterility test.	Aculife Healthcare Pvt. Ltd., Sachana, Gujurat 382150, India
2.	RL 500ml (Ringer Lactate Solution for Injection)	1E11351	May-2021/ Apr-2024	Does not comply as per IP 2018 with respect to sterility test.	Aculife Healthcare Pvt. Ltd., Sachana, Gujurat 382150, India
3.	5D 500ml (Dextrose Injection IP)	AE10816	May-2021/ Apr-2024	Does not comply as per IP 2018 with respect to sterility test.	Axa Parenterals Ltd, Plot No 936, 937, 939, Krishnapur, Jamalpur, Roorkee, 247667, Uttarakhand, India

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/०९/०६

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

तपसिल

सि.न.	औषधिको	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	TRIMOX-250 (Amoxycillin Trihydrate Capsules IP)	D20E010X	May-2020/ Apr-2022	Does not comply with IP 2018 with respect to Weight Variation.	Mapra Laboratories Pvt. Ltd., Daman, Mumbai, India

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औषधि व्यवस्था बिभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/०९/२७

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

तपसिलः

सि.न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	d-pill (Levonorgestrel Tablets IP 1.5mg)	HT20001	July-2020/ June-2022	Does not comply with IP 2018 with respect to Assay.	COOPER PHARMA LIMITED, Dehradhun 248197, Uttarakhand, India

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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/०८/०६

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

तपसिलः

सि. न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	CEPOBACT Dry Syrup (Cefpodoxime Proxetil for Oral Suspension USP)	CBD 24	08-2020/ 01-2022	Does not comply with USP 2018 with respect to Assay test.	Chemidrug Industries Pvt. Ltd., Thankot, Kathmandu, Nepal

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औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७८/०७/०६

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

तपसिल:

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

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था बिभाग

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७८/०६/१३

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

तपसिलः

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

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था 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 व्यवसायीको मान्यता प्रमाणपत्र हेर्ने गर्नुहोस ;
- औषधी खरिद गर्दा अनिवार्य बिल लिने बानी गर्नुहोस ।

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

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