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GOVERNMENT OF NEPAL
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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

Managing the COVID Crisis in Nepal

The Coronavirus Disease (COVID-19), which was first discovered in Wuhan, China in December 2019, caused crores of infections and incalculable damage mentally, physically and psychologically. Most of the countrie's administrations have been struggling to keep their health care system sustained from COVID-19 pandemic. . Meanwhile, most people are struggling to stay alive and keep their families safe and sane while maintaining their lives around the new normal of country-wide lockdowns and social distancing. Least developing countries including Nepal are having their hardest time to get sufficient essential, lifesaving medicines, including vaccines, Personal Protective Equipment and other protective measures. Clearly, this new virus has taken the world by storm, perplexing scientists, health care professionals, public health experts, pharmacists and leaders of every country.

In the COVID-19 pandemic, countries across the world went into lockdown, shutting down or reducing transport within and between them. This affected the manufacturing, supply and distribution of medicines, leading to constraints in the global medicines supply chain. There was also an increase in demand for some medicines used in patients with COVID-19. These included some live saving drugs, analgesics, antibiotics and steroids a as well as some medicines used off-label.

In response to this crisis, Nepal Government is working tirelessly and against the clock. The basic principles of management of any disease in modern medicine, namely therapy and prevention, are being implemented in the management of the COVID-19 crisis.

The Ministry of Health and Population (MOHP), in coordination with other related ministries of the Nepal Government, is tackling the current crisis. In

order to implement the decision of Health Emergency Operation Center (HEOC) for easy availability of medicines to be used in Covid-19 and to prevent shortage of emergency and life-saving medicines, Department of Drug Administration has facilitated the manufacturers and importers.

Under the umbrella ministry i.e. MoHP, the Department of Drug Administration (DDA) is also fulfilling its duties and responsibilities at this hour of need for the country. DDA is committed during these extraordinary times to provide support to manufacturers and to general public to help ensure the quality of medicines, hand sanitizers and personal protective equipment which are extensively used in the prevention, treatment in Covid-19 in order to promote public health. Based on WHO Guide to Local Production: WHO Recommended Hand rub Formulations, DDA published the "Instant Hand Sanitizer Standard, Alcohol Based, 2076" with an objective to define the requirements of the method of tests for alcohol based instant hand sanitizers and National Medicines Laboratory has developed the required provision for testing of hand sanitizer. Manufacturers are encouraged to produce hand sanitizer by using this documentary standard with the objective of fulfilling the need of crisis of hand sanitizer by enhancing availability all over the country.

The DDA also signed a tripartite agreement (initiated by the MoHP), along with MoHP and National Health and Research Council (NHRC) to conduct government sponsored clinical studies or clinical trials on potential treatment in COVID-19. Through this agreement, the COVID-19 patients are getting promising but yet to be registered medicines which are being administered under direct stringent monitoring by the specialized physicians. The data collected from the trials is being stored in the NHRC online database.

Anticipating the possibility of shortages of medicines, to prevent and mitigate supply disruption during the pandemic, DDA also prepared list emergency and lifesaving drugs that will be crucial in the critically ill patients of COVID-19 in coordination with health experts. An online form was generated to provide a platform to the importers/ manufacturers for stock update of the listed medicines. This would thus help to plan for unhindered

availability of the medicines in the country and also to cope with the demand for medicines. DDA also actively participated in formulating various National Standards for PPE in coordination with National Bureau of Standard and Meterology.

Clearly, these are very testing times in healthcare management. DDA must continue to play a vital role in the management of this crisis by strategic leadership and coordinated action with health experts and scientists to ensure the availability of essential medicines so that the country can get over the crisis as quickly as possible and return to normalcy.

Bharat Bhattarai
(Director General)

Chief Editor

WHO GMP र औषधि उत्पादन कुशल अभ्यास प्रमाणीकरणको सूची

सि.नं.	उद्योगको नाम र ठेगाना	WHO GMP Validity	औषधि उत्पादन कुशल अभ्यास Validity
1.	Asian Pharmaceuticals Pvt. Ltd., Bhairahawa	22/02/2022	2077/01/09
2.	CTL Pharmaceuticals Pvt. Ltd., Bhaktapur.	06/07/2021	2078/03/21
3.	Deurali-Janta Pharmaceuticals Pvt. Ltd., Kathmandu	10/02/2021	2077/10/27
4.	Everest Pharmaceuticals Pvt. Ltd., Bhaktapur	06/07/2021	2077/05/02
5.	Genetica Laboratories Pvt. Ltd., Bara	13/06/2020	2077/02/30
6.	Lomus Parenterals & Formulations Pvt. Ltd.. Janakpur	13/06/2020	2077/02/30
7.	Lomus Pharmaceuticals Pvt. Ltd., Kathmandu	16/10/2021	2078/06/29
8.	Magnus Pharmaceuticals Pvt. Ltd., Bara	12/11/2020	2077/07/26
9.	National Healthcare Pvt. Ltd., Bara	08/04/2021	2077/10/27
10.	Nepal Pharmaceuticals Lab. Pvt. Ltd., Bara	08/04/2021	2077/10/27
11.	Nova Genetica Pvt. Ltd., Dhading	22/02/2022	2078/11/10

12.	Ohm Pharmaceuticals Pvt. Ltd., Bhaktapur	10/02/2021	2077/10/27
13.	Panas Pharmaceuticals Pvt. Ltd., Nepalgunj	19/05/2020	2078/09/22
14.	Pharmaco Industries Pvt. Ltd.. Kathmandu	06/07/2021	2078/03/21
15.	Qmed Formulation Pvt. Ltd, Bhaktapur	12/11/2020	-
16.	Quest Pharmaceuticals Pvt. Ltd., Bara	08/04/2021	2077/02/30
17.	Samar Pharma Company Pvt. Ltd., Birgunj	12/11/2020	2077/07/26
18.	Sumy Pharmaceuticals Pvt. Ltd., Nawalparasi	13/06/2020	2077/02/30
19.	Time Pharmaceuticals Pvt. Ltd., Nawalparasi	22/04/2020	2077/10/27
20.	Vega pharmaceuticals Pvt. Ltd, Lalitpur	19/05/2020	2077/02/05
21.	Vijayadeep Laboratories Pvt. Ltd., Lalitpur	16/10/2021	2078/06/29
22.	Curex Pharmaceuticals Pvt. Ltd., Kavre.	07/06/2022	2079/02/25
23.	Amtech Med Pvt. Ltd., Biratnagar	07/06/2022	2078/03/21
24.	Biogain Remedies Pvt. Ltd., Rupendehi	07/06/2022	2079/02/25
25.	Alive Pharmaceuticals Pvt.	15/07/2022	2077/12/15

	Ltd., Biratnagar		
26.	Simca Laboratories Pvt. Ltd. , Bhaktapur	15/07/2022	2077/02/05
27.	Apex Pharmaceuticals Pvt. Ltd., Birgunj	23/01/2020	2077/07/26
28.	Maruti Pharma Pvt. Ltd., Bara	04/11/2022	2077/05/02
29.	Omnica Laboratories Pvt. Ltd., Bhaktapur	12/10/2019	2078/06/29
30.	Siddhartha Pharmaceuticals Pvt. Ltd., Bhairahawa	13/07/2018	2077/02/05
31.	Universal Formulations Pvt. Ltd. Bhairahawa	16/12/2014	2077/12/25
32.	Hester Biosciences Nepal Pvt. Ltd., Kabhre	20/01/2023	2079/10/07
33.	Bhaskar Herbaceuticals Pvt. Ltd., Parsa	21/02/2023	-

REGULATORY MATTERS

Rivaroxaban

Thromboprophylaxis not recommended in patients with TAVR

Ireland. The HPRA has announced that the SmPC for rivaroxaban (Xarelto®) has been updated to reflect that it should not be used for thromboprophylaxis in patients who have recently undergone transcatheter aortic valve replacement (TAVR) due to the risk of all-cause mortality, thromboembolic and bleeding events.

Rivaroxaban is an anticoagulation medicine and is indicated to treat and prevent blood clots.

The EMA's PRAC undertook a review of patients treated with rivaroxaban after TAVR. The committee considered the final results of a phase III clinical study (GALILEO), which identified an increase in all-cause mortality, thromboembolic and bleeding events in patients treated with rivaroxaban after TAVR, other randomized clinical trials and spontaneous reports.

The PRAC concluded that rivaroxaban should not be used for thromboprophylaxis in patients having recently undergone TAVR and recommended an update of SmPCs. It also determined that the benefit-risk balance for rivaroxaban for the approved indications remains positive.

Source: WHO Pharmaceuticals Newsletter No.3, 2020

Proton pump inhibitors (PPIs)

Risk of acute kidney injury

India. The NCC-PvPI has made a recommendation to CDSCO requesting that the PIL for proton pump inhibitors (PPIs) marketed in India should be revised to incorporate acute kidney injury as a clinically significant adverse drug reaction.

PPIs are used to treat gastric ulcers, duodenal ulcers, gastrooesophagal reflux disease and Zollinger Ellison syndrome. Between July 2011 and July 2019, the NCC-PvPI has received 23 ICSRs of PPI associated acute kidney injury. The cases were carefully reviewed by SRP at NCC-PvPI, IPC, and a strong causal relationship between PPIs and acute kidney injury was concluded.

Source: WHO Pharmaceuticals Newsletter No.6, 2019

In Nepal: Health care professionals are warned of the risk of acute kidney injury with use of Proton pump inhibitors.

Arsenic trioxide

Risk of Wernicke's encephalopathy

Japan. The MHLW and the PMDA have announced that the package insert for arsenic trioxide (Trisenox®) should be revised to include Wernicke's encephalopathy as an adverse drug reaction.

Arsenic trioxide is indicated for recurrent or refractory acute promyelocytic leukemia.

Although no cases involving Wernicke's encephalopathy have been reported so far in patients taking arsenic trioxide in Japan, the revision was based on cases overseas. It was determined appropriate as currently there is no evidence on ethnic differences in the safety profile of the drug between patients in Japanese and those overseas.

Source: WHO Pharmaceuticals Newsletter No.2, 2020

In Nepal: Health care professionals are warned of the risk of Wernicke's encephalopathy with use of arsenic trioxide.

Fluoroquinolones, quinolones (oral, injectable)

Risk of tendon disorders, peripheral neuropathy and psychiatric symptoms

Japan. The MHLW and the PMDA have announced that the package inserts for fluoroquinolones and quinolones should be revised to include tendon disorders, peripheral neuropathy and psychiatric symptoms as adverse drug reactions.

Fluoroquinolones and quinolones are antibacterials, indicated for conditions such as superficial skin infections, thermal burn, tonsillitis, acute bronchitis and pneumonia. Examples of fluoroquinolones include levofloxacin (Cravit®), moxifloxacin (Avelox®), ofloxacin (Tarivid®) and pipemidic acid (Dolcol®).

The MHLW/PMDA decision follows the European and US revisions to the package insert. It is thought that collagen tissue disorders and suppression of GABA nerves were potential mechanisms of onset of tendon disorders and psychiatric symptoms. These mechanisms and risks are common to all the antibacterials of this class.

Currently there is not enough information on the mechanism of action for peripheral neuropathy or epidemiological information to indicate that this event is a risk common to all fluoroquinolones and quinolones, but cases have been reported in Japan in patients treated fluoroquinolones such as evofloxacin.

MHLW and PMDA have concluded that revision of the package insert was necessary to include a precaution in all fluoroquinolone and quinolone antibacterials based on the results of the investigation.

Source: WHO Pharmaceuticals Newsletter No.6, 2019

SAFETY OF MEDICINES

Ondansetron

Risk of oral clefts

United Kingdom. The MHRA has announced that exposure to ondansetron (Zofran®) during the first trimester of pregnancy is suggested to be associated with a small increased risk of the baby having a cleft lip and/or cleft palate.

Ondansetron, a 5-HT3 receptor antagonist, is indicated for the management, prevention or treatment of nausea and vomiting.

Recent epidemiological studies reported a small increased risk of orofacial malformations in babies born to women who used ondansetron in early pregnancy. Key evidence was an observational study of 1.8 million pregnancies in the US. The data were recently reviewed within Europe and considered to be robust.

The decision to use ondansetron during pregnancy should be based on professional judgement, and in consultation with the woman who is informed of the potential benefits and risks of use, both to her and to her unborn baby.

Source: WHO Pharmaceuticals Newsletter No.2, 2020
In Nepal: Health care professionals are warned of the risk of oral clefts with use of Ondansetron.

Clozapine

Risk of serious bowel complications

USA. The FDA has strengthened the existing warning that constipation caused by clozapine (Clozaril®, Fazaclo ODT® and Versacloz®) can progress to serious bowel complications.

Clozapine is indicated for schizophrenia. Clozapine affects how the intestines function in the majority of patients.

The serious bowel complications can lead to hospitalization or even death if constipation is not diagnosed and treated quickly.

Patients should contact a health-care professional if they have symptoms that can be associated with serious bowel problems such as nausea, vomiting or stomach pain.

Health-care professionals should avoid co-prescribing clozapine with other

anticholinergic medicines that can cause gastrointestinal hypomotility; advise patients frequently of the significant risk of constipation and life threatening bowel issues and the need to stay hydrated to prevent constipation; and monitor patients for symptoms of potential complications associated with gastrointestinal hypomotility such as nausea, abdominal distension and vomiting.

Source: WHO Pharmaceuticals Newsletter No.2, 2020

In Nepal: Health care professionals are warned of the risk of serious bowel complications with use of Clozapine.

Nitrofurantoin

Risk of pulmonary and hepatic impairment and peripheral neuropathy

New Zealand. Medsafe has announced that the use of nitrofurantoin in patients with significant renal impairment can cause pulmonary or hepatic impairment or peripheral neuropathy.

Nitrofurantoin is a bactericidal antibiotic with activity exclusively in the urine. It is indicated for the treatment and prophylaxis of urinary tract infections. Significant renal impairment is a contraindication to nitrofurantoin.

Adequate glomerular filtration and renal tubular secretion is needed to achieve an effective therapeutic concentration in the urine. While therapeutic doses of nitrofurantoin are rapidly excreted into the urine in patients with normal renal function, in patients with impaired renal function the plasma concentration increases and there is a higher risk of nitrofurantoin toxicity.

The Medicines Adverse Reactions Committee reviewed the evidence for safe use of nitrofurantoin in patients with a greater degree of renal impairment. During the 10- year period to 2019, the Centre for Adverse Reactions Monitoring (CARM) received 150 adverse reaction reports in which nitrofurantoin was a suspect medicine. Of the reports, 46 were on interstitial lung disease, 17 were on hepatic reactions including hepatic cirrhosis and pneumonitis and 3 were on peripheral neuropathy.

Source: WHO Pharmaceuticals Newsletter No.2, 2020

In Nepal: Health care professionals are warned of the risk of pulmonary and hepatic impairment and peripheral neuropathy with use of Nitrofurantoin.

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.

Agomelatine and Increased Blood Pressure

Dr. Tamás Paál, Hungary

Summary

Agomelatine is a non-selective melatonin receptor MT1 and MT2 agonist plus a neutral serotonergic 5- HT2C antagonist indicated for the treatment of major depressive episodes. Of the 24 reports from eight countries on increased blood pressure and agomelatine in the WHO global database of individual case safety reports (VigiBase), twelve were eligible for assessment. Of these, six revealed a consistent pattern of a short time to onset and nine reported recovery on dechallenge, with a positive rechallenge in two of them. Although data on the mechanism of action of agomelatine, as well as a former signal, suggest a mild hypo- rather than hypertensive action, it is also true that melatonin, which is structurally closely related to agomelatine, has hypertension as a labelled adverse effect. Thus, despite the presence of additional risk factors for hypertension in a considerable proportion of these cases, a contributory role of agomelatine to the events cannot be excluded.

Introduction

Agomelatine has been authorised in the European Union and other countries for the treatment of major depressive episodes. It has not been authorised in the USA. Agomelatine is a potent, non-selective melatonin receptor MT1 and MT2 agonist plus a neutral serotonergic 5-HT2C antagonist. Synergy between the two types of receptors has been hypothesized as accounting for its mode of action. Inhibition of the 5-HT2C receptor is held responsible for the direct antidepressant effect. Unlike other antidepressants that often trigger sleep disorders the advantage of agomelatine is that it has a beneficial effect on sleep.[1-3]

Agomelatine is indicated for adults (over 18 years) because of the lack of data in paediatric populations. The recommended dose is 25 to 50 mg daily taken orally

at bedtime. Its safety profile requires regular monitoring of liver function in all patients before and during treatment. Agomelatine is metabolised mainly by CYP1A2 (90%) and CYP2C9/19 (10%). Consequently, drugs that interact with these isoenzymes may interact with agomelatine.[4]

Normal blood pressure (BP) varies with age and is influenced by various factors such as cardiac output, vascular resistance and venous return and pressure; any change in these variables can lead to fluctuations in BP. Thus, there is no absolute threshold to define "normal BP". In general, patients are taught that 120/80 (systolic/diastolic in mmHg) is taken as "normal", 130/85 as "high normal", then higher values as different stages of hypertension. However, these values vary with age (e.g. the normal values are 117/77 and 134/87 mmHg between 14 to 19, and 60 to 64 years, respectively).[5]

Twenty-four reports have been observed in the WHO global database of individual case safety reports (ICSRs), VigiBase, for blood pressure increased (BPI) under agomelatine treatment.

Reports in VigiBase

On 14 April 2019, 24 reports were retrieved from VigiBase for BPI following agomelatine administration (Table 1). The adverse events occurred between December 2012 and November 2017. The ICSRs originated from eight countries: Germany (15 cases), Austria (2), Switzerland (2), and Australia, the Czech Republic, Portugal, South Africa, and Turkey (one each). They were spontaneous reports except cases 2 and 21 which came from clinical studies. The reporters were physicians with the exception of cases 1 and 16 (non-health-care professionals), 12 (pharmacist), as well as 10 and 20 (other health-care professionals), while in case 11 the reporter was unknown. In cases 3, 7 and 14 the outcome was not reported, otherwise, except in cases 11 and 16, the patients recovered. In the reports agomelatine was the only suspected drug, except case 9 where all those administered except esomeprazole were reported as suspected. In 14 cases where the increased blood pressure values were also reported, they varied considerably.

The cases in Table 1 were analysed first to exclude those where the concomitant medication could cause BPI/hypertension. The European product information of the concomitant drugs (European Medicines Agency webpage or the MRI product index) revealed that, in addition to typical antidepressants (trazodone, paroxetine, venlafaxine, sertraline and clomipramine), pregabalin (used, among

others, in cases of generalised anxiety) and ezetimibe (primary hypercholesterinaemia) have hypertension labelled as an adverse effect. Thus, cases 3, 4, 9 and 13 were not used for the initial review. (In cases 8, 21 and 23, paroxetine or clomipramine were indicated as concomitant drugs, however, their administration was discontinued before agomelatine was started, and the BPI occurred days later, so these cases were included.)

During the next "filtering", the following cases were excluded: cases 2, 5 and 8 (one and a half months, two years and nine months agomelatine treatment before the onset of BPI, respectively), case 7 (poor reporting), case 10 (according to its narrative, the agomelatine treatment was maintained, but the patient's BP improved), case 14 (onset of BPI reported on the day of the agomelatine administration, then the treatment was continued with no further data), case 15 (it was a suicide attempt, taking among others, 1050 mg agomelatine with no BPI first then 150/90 mmHg value later, but the patient had a mild hypertension), and case 22 as the patient had an underlying hypertension and, according to the narrative, a reduction of the antihypertensive treatment was made at the time of agomelatine initiation.

Thus, only 12 ICSRs (cases 1, 6, 11, 12, 16-21, 23 and 24) remained for detailed analysis. Well-controlled arterial hypertension/hypertension as one of the patients' underlying diseases was reported in cases 17-20 and 24. The reported time to onset of the increased blood pressure was a few hours in case 17, three days in case 23, about seven days in cases 12 and 21, while general statements (such as "after introduction" or "initiation", "since she took it") indicated that the time to onset seemed to be short (in cases 1, 16, 20, 24). In case 18 the BPI happened "after the dose was increased from 25 mg to 50 mg". In nine cases (1, 6, 12, 17, 19, 20, 21, 23 and 24) positive dechallenge (plus in case 18 reaction abated for dose reduction) while in two cases (1, 12) positive rechallenge were reported. It should also be stressed that labelled adverse effects of agomelatine (e.g. migraine, nausea, sweats, anxiety, restlessness, insomnia, dizziness and blurred vision), if they occurred in the analysed cases, also abated at the same time as BPI did (cases 19-21 in Table 1). In case 12 increased heart rate abated together with BPI while the outcome of other events labelled for agomelatine (tiredness, somnolence and headache) was not reported.

It should be noted that 17 reports for hypertension following agomelatine administration were also found in VigiBase (13 October 2019). In six of them no concomitant medication was reported and in six other cases, although there was concomitant medication, agomelatine was reported as the only suspect drug.

(Only two of these latter six cases also reported concomitant medications which have hypertension as a labelled ADR, i.e. allopurinol and sertraline.) In four cases positive dechallenge also occurred. The time to onset, when it could be identified from the reports, varied from "same day" (three cases) to two days (two cases), and around two weeks (two cases) up to one month or longer (seven cases). Labelled adverse effects of agomelatine occurred and abated together with the hypertension in ten cases. Although these "agomelatine and hypertension" reports were not combined with the "agomelatine and BPI" ones, they seem to be in line with the latter and strengthen the results of this analysis.

Literature and labelling

Hypertension/BPI is not listed in the European Summary of Product Characteristics of agomelatine. Furthermore, it states that "agomelatine had neutral effect on heart rate and blood pressure in clinical trials".[4] (There were clinical trials where hypertension was reported in the agomelatine arm. Its frequency was found to be 1.2%[7] but because of the limited number of the subjects involved and the lack of a placebo arm in this trial, the causality could not be established.)

It is also well-known that people suffering from depression are more likely than the others to develop hypertension.[8]

Experiments have suggested that agomelatine prevents rather than causes hypertension.[9]

Moreover, in 2014, the Uppsala Monitoring Centre published a signal on hypotension occurring under agomelatine treatment. In response to the signal the marketing authorisation holder accepted that 5- HT2C/5-HT2B antagonists could induce an antihypertensive effect in animals and/or humans with hypertension, while it did not endorse it as a clinically relevant safety concern.[10]

Melatonin, structurally closely related to agomelatine but binding to the MT receptors exclusively is used for sleep disorders such as short-term primary insomnia or to decrease jet-lag.[11] It is interesting that clinical studies revealed that its use at night an hour before sleep appeared to lower BP. (There is some debate about its mechanism: is it based on serotonin antagonism by melatonin or is it because the subjects had fuller, better quality sleep?)[11, 12] On the other hand, melatonin has hypertension as a labelled adverse effect[13, 14] with a frequency of "uncommon" (that means 0.1 to 1.0%).[13]

It is also well-known that some medicines that usually lower blood pressure may paradoxically increase blood pressure.[14] There are drugs (such as pregabalin, indicated, among others, to generalised anxiety disorders) that have labelled adverse reactions both hypo- and hypertension with the same frequency.[15]

Discussion and conclusion

Based on the overall reporting of adverse reactions for agomelatine and of the adverse reaction BPI in VigiBase as a whole, the expected value for the number of reports of the combination is 16 and the IC025 is negative (as of 27 June 2019). However, agomelatine is not used in the USA where BPI is more commonly reported overall, and in a disproportionality analysis adjusted for region of origin, the expected value is around 10, rendering a stronger statistical association which would be highlighted as disproportionally reported by IC analysis. This means that if its calculation is restricted to the rest of the world (non-US reports), the IC025 is positive. Moreover, taking the high number of positive dechallenges in the analysed ICSRs into account (where labelled adverse effects of agomelatine abated together with the BPI) and the positive (in one case double) rechallenges, they strongly suggest a positive causal relationship.

The BPI action of agomelatine might be dose-dependent (it occurred only at higher doses in one case and the patient who experienced repeated rechallenges was a slow CYP metaboliser). Moreover, the fact that the individual variability of the absolute bioavailability of agomelatine is substantial[4] might explain its rare and sporadic occurrence.

Considering also the mild hypotensive action of agomelatine and the preceding signal on agomelatine – hypotension,[10] where the number of positive dechallenges were also high with one positive rechallenge, the former statement may be extended to agomelatine – change in BP (both hypo- and hypertension). The paradoxical action of certain antihypertensives causing BPI may be explained by an impaired BP regulation system that "over-reacts" to the stimulus. Indeed, five patients of the analysed 12 ICSRs (in cases 17-20 and 24) had reported "well-controlled" hypertension (i.e. an underlying disease where the BP regulation was impaired).

The marketing authorisation holder's statements in certain ICSR narratives that the cases do not trigger any changes in the core data sheet are fully agreed upon, the reaction is far from being proven and can be extremely rare. However, a

signal only means information on a possible causal relationship between an adverse event and a drug. Considering the above-mentioned aspects, in conclusion, agomelatine and BPI (perhaps also more widely: agomelatine and change in BP) is considered a signal.

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Source: WHO Pharmaceuticals Newsletter No.2, 2020

फार्मेसी निलम्बनको विवरण

सि.न.	फार्मेसी	निलम्बन अवधि	कारण
१.	स्पर्श फार्मेसी	१५ दिन	Pregastar-75 (10 cap), Spaspain (10 tab) बिना Prescription बिक्रि वितरण गरेको ।
२.	नेचुरल मेडिकल हल	१५ दिन	Revlin-75 (10 cap), Spaspain (10 tab) बिना Prescription बिक्रि वितरण गरेको ।
३.	जिना मेडिकल हल	१५ दिन	Pregout Kit 5 tabs संचय गरेको, TT 20 Amps Freeze मा नराखेको, Clonaz 0.25 mg 14 tabs को खरिद बिल पेस नगरेको,Trama 20 Caps संचय गरेको
४.	देभिजफल मेडिकल हल	१५ दिन	Tramadol 150 capsules बिक्रि वितरणको लागि संचय गरेको ।
५.	पशुपति मेडिकल	२१ दिन	ब्यबसायी अनुपस्थित, लागु तथा मनोदिपक औषधिहरुको रेकर्ड दुरुस्त नभएको,म्याद समाप्त भएका औसधी संचय गरेको ।
६.	सुमार्ग फार्मेसी	७ दिन	दर्ता नभएको D'clin संचय गरेको ।
७.	ज्वलन्त फर्मा	१०दिन	Nimodip 91 tabs, Nemadol Inj 40 amps बिक्रि वितरणको लागि संचय गरेको ।
८.	Kantipur Hospital Pvt Ltd Pharmacy Unit	सिलबन्दी गरिएको	पसल दर्ता नगरी संचालन गरेको ।
९.	अतिथी फार्मेसी	७ दिन	Repegra 100 को 105 tabs, Nefrosave 135 tabs संचालन गरेको ।
१०.	कुवापानि मेडिसिन सप्लायर्स	६ महिना	Tramadol 300 capsules,Zenegra 100 को 156 tabs, Zenegra Red 100 को 32 tabs संचय गरेको ।

११.	राय मेडिकल हल, मिक्लाजुङ गा.पा.	३० दिन	विना दर्ताको औषधि संचय गरेको र औषधिको स्ट्रिप खोलि ट्यावलेट बट्टामा राखेको
१२.	हाम्रो फ्रन्डसिप फार्मेसी विराटनगर	५ महिना	औषधिको अनुचित प्रयोग र दुरुपयोग
१३.	सिध्दि मेडिकल हल शम्भुनाथ -०३ सप्तरी	३५ दिन	विना दर्ताको औषधि संचय गरेको
१४.	महाविर मेडिकल हल धरान-१८ सुनसरी	७ दिन	विना दर्ताको औषधि संचय गरेको
१५.	प्रतियुष मेडिसिन डिस्ट्रिब्युटर्स गोलबजार -०४ सिराहा	१५ दिन	व्यवसायी अनुपस्थित
१६.	सुनिधि फार्मेसी विराटनगर -०६ मोरंग	१५ दिन	विना दर्ताको औषधि संचय गरेको
१७.	इसान्त फार्मेसी रंगेली , मोरंग	३५ दिन	विना दर्ताको औषधि संचय गरेको
१८.	सिमाना फार्मेसी वितर्तामोड झापा	१५ दिन	मुल्य वृदिको उजुरी, अनुसन्धानमा ठोस प्रमाण नजुटेको
१९.	वि केयर फार्मेसी , विराटनगर मोरंग	१५ दिन	विना दर्ताको औषधि संचय गरेको
२०.	सविन फार्मेसी विराटनगर -०४ मोरंग	२१ दिन	विना दर्ताको औषधि संचय गरेको, व्यवसायी अनुपस्थित
२१.	श्री एहसान आयुर्वेदिक मेडिकल विष्णुपुर सिराहा	१५ दिन	विना दर्ताको औषधि संचय गरेको

२२.	रोकाया टर्इन्स फार्मेसी जाजरकोट	१५ दिन	नेपालमा दर्ता नभएको औषधि संचय
२३.	डेभिड मेडिकल स्टोर, जाजरकोट	१० दिन	नेपालमा दर्ता नभएको औषधि संचय
२४.	रारा मेडिकल हल, बाँके	२१ दिन	सहायक फर्मासिष्ट अन'पस्थित र नेपालमा दर्ता नभएको औषधि संचय
२५.	ओझा मेडिकल अल, डोटी	३० दिन	नेपालमा दर्ता नभएको औषधि संचय
२६.	चितवन ऐग्रो भेट सेन्टर, बाँके	१० दिन	नेपालमा दर्ता नभएको औषधि संचय
२७.	शुक्लाफाटा फार्मेसी, कञ्चनपुर	१५ दिन	व्यवसायी अनुपस्थित र नेपालमा दर्ता नभएको औषधि संचय
२८.	ठकुल्ला फार्मेसी, कञ्चनपुर	१० दिन	नेपालमा दर्ता नभएको औषधि संचय
२९.	प्रिती फार्मेसी, कञ्चनपुर	२१ दिन	सहायक फर्मासिष्ट अन'पस्थित र नेपालमा दर्ता नभएको औषधि संचय

REGULATORY NOTICES

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७७/०४/१८

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको नमुना परिक्षण गर्दा तपसिल बमोजिमका उत्पादकबाट उत्पादित तपसिलको ब्याच न. का औषधि न्यून गुणस्तर भएको पाइएकोले सो औषधि औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरि बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सो को विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योगको अधिकारिक आयातकर्ता तथा तिनका अधिकारिक 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.	BEN-A (Albendazole Tablet USP)	T0598059	Aug.2018/ Aug.2021	Not comply w.r.t. Dissolution	ACME Laboratories, Dhaka, Bangladesh

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०७७/०५/०४

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको 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 सो को विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योगको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त औषधि सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

सि.न.	औषधिको नाम	ब्याच.न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	Routin 10 (Rosuvastatin Tablets IP)	ROT 06	Dec.2018/ Nov. 2020	Not comply w.r.t. Assay and Dissolution	CTL Pharmaceuticals Pvt.Ltd., Bhaktapur, Nepal

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति: २०७७/०५/१८

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको नमुना परिक्षण गर्दा तपसिल अनुसारका उत्पादकबाट उत्पादित तपसिलका ब्याच न. का औषधिहरु न्यून गुणस्तर भएको पाइएकाले ती औषधिहरु औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरी बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सो को विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योगलाई जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै ती औषधिहरु सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपसिल

सि. न.	औषधिको नाम	ब्याच. न.	Mfg. Date /Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	Eloz-100 (Itraconazole Capsules)	058025	Apr. 2019/ Mar. 2021	Does not comply w.r.t. Dissolution test	Maruti Pharma Pvt Ltd, Bara, Nepal
2.	Eloz-200 (Itraconazole Capsules)	ELC-18009	Nov. 2018/ Oct. 2020	Does not comply w.r.t. Dissolution test	Maruti Pharma Pvt Ltd, Bara, Nepal

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था बिभाग

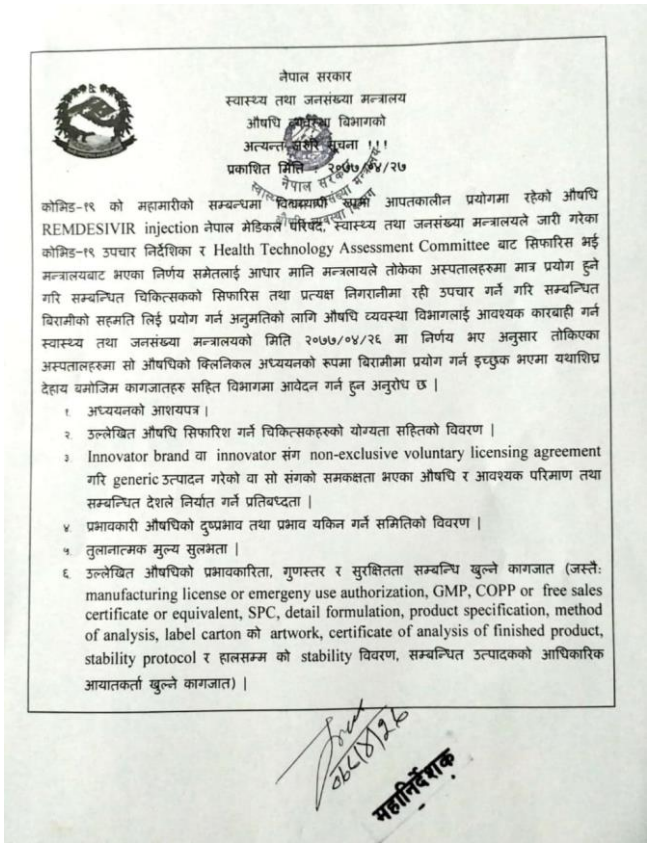
औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरूरी सूचना

सूचना प्रकाशन मिति २०७७/०५/१३

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको 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 आयातकर्ता तथा प्रतिनिधिहरुलाई जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त औषधि सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ।

तपशिलः

सि.नं.	औषधिको नाम	ब्याच. नं.	Mfg./Exp.Date	कारण	उत्पादकको नाम र ठेगाना
१.	Alcox 250 mg Capsule (Clocacillin Sodium USP)	BC1048	Oct.2018/Sep. 2020	Does not comply as per USP 2018 w.r.t. Assay	Leben Laboratories Pvt Ltd, India



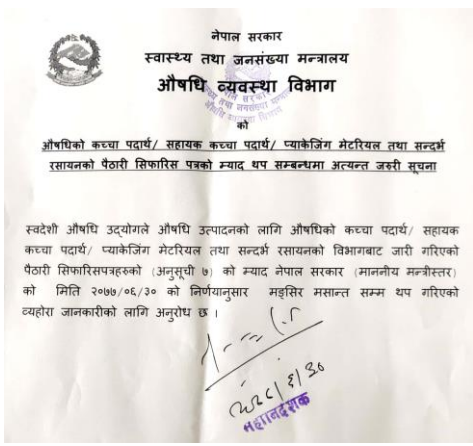
नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभागको
अत्यन्त जरुरी सूचना !!!
प्रकाशित मिति : २०७७/०४/२७

कोभिड-१९ को महामारीको सम्बन्धमा विशेषगरी यसमा आपतकालीन प्रयोगमा रहेको औषधि REMDESIVIR injection नेपाल मेडिकल परिषद्, स्वास्थ्य तथा जनसंख्या मन्त्रालयले जारी गरेका कोभिड-१९ उपचार निर्देशिका र Health Technology Assessment Committee बाट सिफारिस भई मन्त्रालयबाट भएका निर्णय समेतलाई आधार मानि मन्त्रालयले तोकेका अस्पतालहरुमा मात्र प्रयोग हुने गरि सम्बन्धित चिकित्सकको सिफारिस तथा प्रत्यक्ष निगरानीमा रही उपचार गर्ने गरि सम्बन्धित बिरामीको सहमति लिई प्रयोग गर्न अनुमतिको लागि औषधि व्यवस्था विभागलाई आवश्यक कारबाही गर्न स्वास्थ्य तथा जनसंख्या मन्त्रालयको मिति २०७७/०४/२६ मा निर्णय भए अनुसार तोकिएका अस्पतालहरुमा सो औषधिको क्लिनिकल अध्ययनको रुपमा बिरामीमा प्रयोग गर्न इच्छुक भएमा यथाशिघ्र देहाय बमोजिम कागजातहरु सहित विभागमा आवेदन गर्न हुन अनुरोध छ ।

१. अध्ययनको आशयपत्र ।
२. उल्लेखित औषधि सिफारिश गर्ने चिकित्सकहरुको योग्यता सहितको विवरण ।
३. Innovator brand वा innovator संग non-exclusive voluntary licensing agreement गरि generic उत्पादन गरेको वा सो संगको समकक्षता भएका औषधि र आवश्यक परिमाण तथा सम्बन्धित देशले निर्यात गर्ने प्रतिबध्दता ।
४. प्रभावकारी औषधिको दुष्प्रभाव तथा प्रभाव यकिन गर्ने समितिको विवरण ।
५. तुलानात्मक मुल्य सुलभता ।
६. उल्लेखित औषधिको प्रभावकारिता, गुणस्तर र सुरक्षितता सम्बन्धि खुल्ने कागजात (जस्तैः manufacturing license or emergeny use authorization, GMP, COPP or free sales certificate or equivalent, SPC, detail formulation, product specification, method of analysis, label carton को artwork, certificate of analysis of finished product, stability protocol र हालसम्म को stability विवरण, सम्बन्धित उत्पादकको आधिकारिक आयातकर्ता खुल्ने कागजात) ।

२८।८।२०

महानिर्देशक



नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

को

औषधिको कच्चा पदार्थ/ सहायक कच्चा पदार्थ/ प्याकेजिंग मेटरियल तथा सन्दर्भ रसायनको पैठारी सिफारिस पत्रको म्याद थप सम्बन्धमा अत्यन्त जरुरी सूचना

स्वदेशी औषधि उद्योगले औषधि उत्पादनको लागि औषधिको कच्चा पदार्थ/ सहायक कच्चा पदार्थ/ प्याकेजिंग मेटरियल तथा सन्दर्भ रसायनको विभागबाट जारी गरिएको पैठारी सिफारिसपत्रहरुको (अनुसूची ७) को म्याद नेपाल सरकार (माननीय मन्त्रीस्तर) को मिति २०७७/०६/३० को निर्णयानुसार मङ्सिर मसान्त सम्म थप गरिएको व्यहोरा जानकारीको लागि अनुरोध छ ।

२८।९।३०

महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

मिथानोल (Methanol) को प्रयोग सम्बन्धि

अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७७/०५/३१

यस विभागले बजारमा बिक्रिवितरणमा रहेका ह्यान्ड स्यानीटाईजर (Hand Sanitizer) हरुको नमूना संकलन गरी श्री राष्ट्रिय औषधि प्रयोगशालामा परिक्षण गर्दा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धि स्तर २०७६" विपरित विषाक्त रसायन मिथानोल समावेश भएको पाईएकोले त्यस्ता ह्यान्ड स्यानीटाईजर प्रयोग नगर्न/नगराउन सबै सरोकारवालाहरुको जानकारीका लागि मिति २०७७/०५/२७ कान्तिपुर राष्ट्रिय दैनिक र विभागको website: www.dda.gov.np मा सूचना प्रकाशन गरिएको थियो।

उक्त मिथानोल रसायन मानिसमा स्वासप्रस्वाश, मुख, छाला र आँखाको माध्यमबाट शरीरमा प्रवेश गरि नकारात्मक असरहरु जस्तै खोकी लाग्ने, टाउको दुख्ने, रिंगटा लाग्ने, वाकवाकी भई वान्ता हुने, कमजोरी हुने, स्वास फेर्न अप्ठ्यारो हुने, छाला सुख्खा तथा रातो हुने, दृष्टि धुमिल भई दृष्टि गुम्न सक्ने र मानिसको ज्यान समेत जान सक्ने हुनाले सो को प्रयोग मानिसमा गर्नु हुदैन।

सामान्यतया मिथानोलको प्रयोग प्रयोगशालाहरुमा विभिन्न परिक्षण/विश्लेषण तथा अनुसन्धान कार्यका लागि प्रयोग हुन्छ। मिथानोल मिसावट गरि रक्सीजन्य पेय पदार्थ (Alcohol)को सेवनले गर्दा विभिन्न देशहरुमा मानिसको ज्यान समेत गएको उदाहरणहरु पाइन्छ। हाल नेपालमा मिथानोल समावेश भएको ह्यान्ड स्यानीटाईजरहरु बजारमा बिक्रिवितरणमा रहेको देखिएकाले विभागले सम्बन्धित निकायहरुसंग समन्वय गरी कारवाही गरिरहेको व्यहोरा जानकारी गराउदै मिथानोल मिश्रित ह्यान्ड स्यानीटाईजरको प्रयोग नगर्न/नगराउनु हुन सम्बन्धित सबै सरोकारवालाहरुको जानकारीका लागि पुनःअनुरोध छ। साथै सो रसायनसंग सम्पर्क भएमा वा प्रभावित भएमा सफा पानीले राम्रोसंग पखाल्नु पर्दछ र माथि उल्लेखित नकरात्मक असरहरु देखा परेमा नजिकैको अस्पताल/ स्वास्थ्य संस्थाहरुमा सम्पर्क राख्नुहुन अनुरोध छ।

थप जानकारीका लागि :

१. International Chemical Safety Card(ICSC): 0057 Methanol published by International Labor Organization and World Health Organization on May, 2018.

२. Material safety datasheet of Methanol published by The National Institute for Occupational Safety and Health (NIOSH), Centre for Disease Control and Prevention (CDC), last reviewed on May 12, 2011.

३. Information note on Methanol poisoning outbreaks published by World Health Organization on July, 2014.

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषध व्यवस्था विभाग

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७७।०६।०१

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरूको नमुना परीक्षण गर्दा तपसिल बमोजिमको उत्पादकबाट उत्पादित तपसिलको ब्याच न. को औषधि न्यून गुणस्तर भएको पाइएकोले सो औषधि औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्री वितरण रोक्का गरी बजारबाट तुरून्त फिर्ता (Recall) गर्न र सो को विवरण यस विभागमा पेस गर्न सम्बन्धित आयातकर्ता तथा प्रतिनिधिहरूलाई जानकारीका लागि यो सूचना प्रकाशित गरिएको छ। साथै उक्त औषधि सिफारिस, बिक्री 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.	Aciloc (Ranitidine Injection IP 25mg/ml)	19075	Nov.2019/ Oct. 2022	Does not comply as per IP 2018 w.r.t. Sterility Test	Cadila Pharmaceuticals, India

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Instant Hand Sanitizer फिर्ता (RECALL) सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७७/०६/१४

यस विभागले बजारमा बिक्रि-वितरणमा रहेका तपसिल अनुसारका ह्यान्ड स्यानीटाईजर (Hand Sanitizer) हरुको नमूना संकलन गरी श्री राष्ट्रिय औषधि प्रयोगशालामा परीक्षण गर्दा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धी स्तर २०७६" अनुसार नमूना परीक्षण गर्दा तपसिल अनुसारका उत्पादकहरुबाट उत्पादित तपसिलका ब्याच न. का Instant Hand Sanitizer हरु न्यून गुणस्तर भएको पाइएकाले ती Instant Hand Sanitizer हरु को बिक्रि-वितरण रोक्का गरी बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योगहरुलाई जानकारीको लागि यो सूचना प्रकाशित गरिएको छ । साथै ती Instant Hand Sanitizer हरु सिफारिस, बिक्रि वितरण तथा प्रयोग नगर्न र नगराउनु हुन समेत सम्बन्धित सबैलाई अनुरोध छ ।

तपसिल

सि.न.	उत्पादनको नाम	ब्याच. न.	Mfg. Date	Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	Safe Hands 200 ml	GSH-001	Apr. 2020	Mar. 2021	Does not comply with Assay of Ethyl Alcohol	Prime Pharmaceuticals Pvt Ltd, Birgunj
2.	Hand Rub Instant Hand Sanitizer, 1 Ltr.	B.N.001	Jun.2020	12 months from the date of Mfg	Does not comply with Assay of Ethyl Alcohol	Himalayan Sherpa Herbs Pvt. Ltd., Kathmandu, Nepal

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औषधि फिर्ता (Recall) गर्नेसम्बन्धी अत्यन्त जरूरी सूचना

प्रकाशित मितिः २०७७/०७/०५

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

तपसिल

सि.नं.	औषधिको नाम	ब्याच नं.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना
1.	Trace-100 (Itraconazole Capsules)	ICC-10	Mar.2019/ Feb. 2021	Does not comply as per BP 2019 w.r.t. Dissolution Test	Nova Genetica Pvt. Ltd. Dhading, Nepal

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विषाक्त रसायन Methanol मिश्रित ह्यान्ड स्यानीटाईजर (Hand Sanitizer) सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मिति : २०७७/०६/१२

यस विभागले बजारमा बिक्रिवितरणमा रहेका तपसिल अनुसारका ह्यान्ड स्यानीटाईजर (Hand Sanitizer) हरुको नमूना संकलन गरी श्री राष्ट्रिय औषधि प्रयोगशालामा परीक्षण गर्दा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धी स्तर २०७६" विपरित विषाक्त रसायन (Methanol) समावेश भएको तथा मापदण्ड विपरितका समिश्रण पाईएकोले मानव स्वास्थ्यमा गम्भीर नकरात्मक असर पार्ने हुँदा सर्वसाधारणहरुले प्रयोग नगर्न/नगराउनुहुन र साथै त्यस्ता स्यानीटाईजरहरुको उत्पादन तथा बिक्रि वितरण अभिलम्ब रोक्का राख्न सम्पूर्ण सरोकारवालाहरुलाई सूचित गरिन्छ ।

तपशिलः

S. No.	Name of the product	Mfg. Date	उत्पादक/Repack गर्नेको नाम र ठेगाना	कारण
1.	Herbaltree Hand Rub 500 ml (B.N.273)	Aug-2020	Shivika Cosmeceuticals India Pvt Ltd, Pantnagar, Uttarakhand, India	Contains Methanol (62% v/v)
2.	KUM Hand Sanitizer 5 Lit. (B.N.03)	Mar-2020	Repacked By: R. Chemical & Packaging Industries, Parsa, Nepal	Contains Isoporpyl Alcohol (25 % v/v)
3.	Clean Hand Sanitizer 5 Lit (B.N.03)	Mar-2020	Repacked By: R. Chemical & Packaging Industries, Parsa, Nepal	Contains Methanol (8% v/v), Ethanol
4.	KUMKUM Instant Hand Sanitizer Gel 500 ml (B.N.01)	July-2020	Kumkum Herbal Industries Pvt. Ltd., Banepa, Neapl	Contains Methanol (52% v/v)
5.	Instant Hand Sanitizer Gel 5 Lit (B.N.01)	Aug-2020	Kumkum Herbal Industries Pvt. Ltd., Banepa, Nepal	Contains Methanol (72% v/v)
6.	Instant Hand Sanitizer Original, 1 Ltr. (B.N. OA-08)	Jun-2020	Om Arogya Healthcare Pvt. Ltd., Mahalaxmi-4, Imadol, Lalitpur, Nepal	Contains Methanol (75 % v/v)
7.	Sadhana Instant Hand Sanitizer, 5 Ltr. (B.N. 05)	Aug-2020	Sadhana Suppliers, Kathmandu, Nepal	Contains Methanol (41 % v/v),
8.	Drone Hand Sanitizer, 500 ml (B.N. 05) Yellow Colour	Sep-2020	Kalika Soap and Chemicals Pvt. Ltd., Kathmandu, Nepal	Contains Methanol (32 % v/v), Ethanol (9% v/v), Isopropyl Alcohol (31 % v/v), pH: 9.51
9.	Drone Hand Sanitizer, 500 ml (B.N. 05) Colourless	Sep-2020	Kalika Soap and Chemicals Pvt. Ltd., Kathmandu, Nepal	Contains Methanol (33 % v/v), Ethanol (10% v/v), Isopropyl Alcohol (32 % v/v), pH: 9.45

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विषाक्त रसायन Methanol मिश्रित ह्यान्ड स्यानीटाईजर (Hand Sanitizer) सम्बन्धी अत्यन्त जरूरी सूचना

प्रकाशित मिति : २०७७/०६/२४

यस विभागले बजारमा बिक्रि वितरणमा रहेका तपसिल अनुसारका ह्यान्ड स्यानीटाईजर (Hand Sanitizer) को नमूना संकलन गरी श्री राष्ट्रिय औषधि प्रयोगशालामा परीक्षण गर्दा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धी स्तर २०७६" विपरित विषाक्त रसायन (Methanol) समावेश भएको तथा मापदण्ड विपरितका समिश्रण पाईएकोले मानव स्वास्थ्यमा गम्भीर नकरात्मक असर पार्ने हुँदा सर्वसाधारणहरुले प्रयोग नगर्न/नगराउनुहुन र साथै त्यस्ता स्यानीटाईजरहरुको उत्पादन तथा बिक्रि वितरण अभिलम्ब रोक्का राख्न सम्पूर्ण सरोकारवालाहरुलाई सूचित गरिन्छ ।

तपशिल:

S.No.	Name of the product	Mfg. Date/Exp Date	उत्पादक/Repack गर्नेको नाम र ठेगाना	कारण
1.	Aerosoft Instant Hand Sanitizer, 5 Lts (B.N. S15L202008)	Aug-2020/Aug-2022	Susankya Industries Pvt Ltd., Kathmandu	Contains Methanol (47 % v/v)

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औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरूरी सूचना

प्रकाशित मितिः २०७७/०६/२४

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको नमुना परीक्षण गर्दा तपसिल बमोजिमको उत्पादकबाट उत्पादित तपसिलका ब्याच नं. का औषधि स्थल 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 उद्योगको 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.नं.	औषधिको नाम	ब्याच. न.	Mfg./Exp.Date	कारण	उत्पादकको नाम र ठेगाना
1.	Alexofen-120 (Fexofenadine Hydrochloride Tablets USP)	ALE 33	Dec.2019/ Nov. 2021	Not comply w.r.t. Dissolution test	CTL Pharmaceuticals Pvt. Ltd., Bhaktapur

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औषधि व्यवस्था विभागको

विषाक्त रसायन Methanol मिश्रित ह्यान्ड स्यानिटाईजर (Hand Sanitizer) सम्बन्धी

अत्यन्त जरूरी सूचना

प्रकाशित मिति : २०७७/०५/२७

यस विभागले बजारमा बिक्री वितरणमा रहेका तपसिल अनुसारका ह्यान्ड स्यानीटाइजर (Hand Sanitizer) हरूको नमूना संकलन गरी श्री राष्ट्रिय औषधि प्रयोगशालामा परीक्षण गर्दा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धी स्तर २०७६" विपरित विषाक्त रसायन (Methanol) समावेश भएको पाइएकोले मानव स्वास्थ्यमा गम्भीर नकारात्मक असर पार्ने हुँदा सर्वसाधारणहरूले प्रयोग नगर्न/नगराउनु हुन र साथै त्यस्ता स्यानिटाईजरहरूको उत्पादन तथा बिक्री वितरण अबिलम्ब रोक्का राखन सम्पूर्ण सरोकारवालाहरूलाई सूचित गरिन्छ ।

तपसिल

S.N.	Name of the product	Manufacturer's Name	Address
1.	Instant Hand Sanitizer	Nepal Kayakalpa Udhyog	Bhaktapur
2.	Instant Hand Sanitizer Original	Hygiene Soap and Chemical Pvt. Ltd.	Kathmandu
3.	Advanced Hand Sanitizer	Adhar Chemicals and Food Industry Pvt. Ltd.	Kathmandu
4.	Instant Hand Sanitizer Refreshing Gel	Search Chem Cum Herbal Products	Kathmandu
5.	Suryamukhi Hand Sanitizer	Suryamukhi Herbal Products	Kathmandu

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

विषाक्त रसायन Methanol मिश्रित र न्युन गुणस्तरको ह्यान्ड स्यानीटाईजर (Hand Sanitizer) सम्बन्धि अत्यन्त जरूरी सूचना

प्रकाशित मिति : २०७७/०५/३१

यस विभागले बजारमा बिक्रि वितरणमा रहेका तपसिल अनुसारका ह्यान्ड स्यानीटाईजर (Hand Sanitizer) हरुको नमूना संकलन गरी श्री राष्ट्रिय औषधि प्रयोगशालामा परिक्षण गर्दा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धि स्तर २०७६" बिपरित विषाक्त रसायन (Methanol) समावेश भएको (सि.नं. २ र ४) र न्युन गुणस्तरको (सि.नं. १ र ३) पाईएकोले सो प्रयोग गर्दा मानव स्वास्थ्यमा गम्भीर नकारात्मक असर पर्ने हुँदा सर्वसाधारणहरुले प्रयोग नगर्न/नगराउनुहुन र साथै त्यस्ता स्यानीटाईजरहरुको उत्पादन तथा बिक्रि वितरण अबिलम्ब रोक्का राखी सम्बन्धित आपुर्तिकर्ता/उत्पादकलाई फिर्ता गर्न सम्पूर्ण सरोकारवालाहरुलाई सुचित गरिन्छ ।

तपशिल:

सि.नं.	उत्पादनको नाम	उत्पादकको नाम र ठेगाना	कारण
१.	Opekal Non-washing Antibacterial Solution 120 ml	Guangzhou Obopekal Fine Chemical Co. Ltd., Guangzhou, China	Contains Ethanol (68 % v/v)
२.	Sasa Instant Hand Sanitizer 50 ml	Sampada Healthcare Pvt. Ltd., Imadol, Lalitpur	Contains Ethanol (13.78 % v/v), Methanol (39.34 % v/v)
३.	Pamacare Instant Hand Sanitizer 60 ml	RL Corp India. Valsad, Gujrat, India	Contains Ethanol (66 % v/v)
४.	Unicare Instant Hand Sanitizer 65 ml	Shreenath Herbal & Cosmetic Industry (P) Ltd., Kathmandu	Contains Methanol (55 % v/v)

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

औषधि प्रयोग गर्दा ध्यान दिनुपर्ने कुराहरू:

- मान्यता प्राप्त स्वास्थ्यकर्मीको पूर्जामा मात्र औषधि प्रयोग गर्ने ।
- औषधिको प्रयोग सम्बन्धि पूर्ण जानकारी लिने ।
- औषधिको सेवन तोकिएको समयमा, तोकिए बमोजिमको फरकमा, तोकिएको समयसम्म प्रयोग गर्ने ।
- औषधि बालबच्चाको पहुँचबाट टाढा राख्ने ।
- यदि कुनै औषधि सेवन गर्न भूलेमा सम्झने बित्तिक्कै सेवन गर्ने तर अर्को मात्रा सेवन गर्ने समय नजिक भएमा सेवन नगरी अर्को मात्रा सेवन गर्ने ।
- आफू गर्भवती भएमा सो बारे स्वास्थ्यकर्मीलाई जानकारी दिने ।
- औषधि प्रयोग गर्दा जिउ चिलाएमा, छालामा डाबरहरु आएका, स्वास फेर्न गाह्रो भएमा वा यस्तै अन्य लक्षण देखा परेमा तुरुन्त औषधि प्रयोग गर्न छाडी स्वास्थ्यकर्मीलाई सम्पर्क राख्ने ।

एण्टिबायोटिक औषधि प्रयोग गर्दा मान्यता प्राप्त स्वास्थ्यकर्मीको सल्लाहमा तोकिएको अवधि र समयभित्र प्रयोग गरौं र गराऔं ।

औषधि सम्बन्धि थप जानकरीका लागि तल उल्लेखित ठेगानामा सम्पर्क राख्नुहोला ।

औषधि व्यवस्था विभाग

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