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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

18th International Conference of Drug Regulatory Authorities, 2018, Ireland

The International Conference of Drug Regulatory Authorities (ICDRA) established in 1980 is common platform of regulatory authorities from among WHO member states as well as international stakeholders aimed to harness collaboration, mutual understanding, reliance, research and development and promotion of good regulatory practices. The ICDRA conference provides a unique forum to guide regulatory authorities, WHO and international stakeholders in confronting the challenges and highlighting the opportunities of the regulatory arena.

The 18th International Conference of Drug Regulators (ICDRA) was held in Dublin Ireland from 3 to 7 September, 2018. The event was co-hosted by the Health Product Regulatory Authority of Ireland and the World Health Organization. More than 300 delegates from regulatory authorities of WHO Member States participated in the 18th ICDRA. The first two days, Pre ICDRA (3-4 September), was open for regulators and industry as well as other representatives across academia, government organizations etc. The second part of the week, ICDRA (5-7 September) was restricted to official regulators from WHO member states. Delegates from different countries participated in the event programs designed to evoke ideas and discussion on the current key priorities in the healthcare product regulatory environment. Focused discussions were held on quality issues, regulatory reform and strengthening regulatory systems, safety of medical products, substandard and falsified products, access, regulation of clinical trials, regulatory collaboration, harmonization, convergence and reliance, new technologies, regulation of herbal medicines. The theme of the conference was: Smart safety surveillance: a life-cycle approach to promoting safety of medical products.

The conference recommendations were presented by the moderators in the closing plenary session and were finalized following comments received from participants as well as non-participating authorities (as detailed in the upcoming pages). Several cross-cutting thematic areas covered during the conference deliberation are as follows:

Key Thematic area of discussion

- ❖ Promoting regulatory collaboration, convergence and harmonization;
- ❖ Advocating electronic CPP template with inclusion of current manufacturing situations;
- ❖ Supporting regulatory preparedness for public health emergencies and the feasibility of "conditional approvals" for public health emergencies;
- ❖ Expediting the finalization of GRP suite of guidance thereby enabling access to innovative medical products;
- ❖ Promoting alignment for eliminating unnecessary differences in national and regional CTD requirements;
- ❖ Strengthening the Global Benchmarking Tool for mature and innovative regulatory systems;
- ❖ Expanding scope of WHO PQP;
- ❖ Supporting trust building among regional regulatory networks;
- ❖ Continuing support to implement Global Action Plan (GAP) on AMR;
- ❖ Encouraging discussions on promoting local production;
- ❖ Strengthening hands on strategic and practical aspects of adaptation of procurement practices, supply systems and sustainable financing;
- ❖ Promoting supply chain integrity thereby implementing risk-based post market surveillance and also curbingthreat of SF medical products;
- ❖ Supporting regulatory authorities with a tool kit for smart safety surveillance strategy and risk-based prioritization;
- ❖ Improving access and identify risk and benefit of medical products throughout the product life cycle;
- ❖ Training and preparing policy makers for effective communication on risk and benefit of such medical products;
- ❖ Improving collaboration in areas of regulation of medical devices;
- ❖ Prioritizing risk based inspections;
- ❖ Facilitating exchange of safety information from clinical trials and include vulnerable population in WHO guidance, also collaborate through network such as AVAREF;

- ❖ Developing platform for reliance in PV programs;
- ❖ Developing national guidance and legislation on advanced therapies;
- ❖ Organizing programs to accelerate use and regulation of biosimilars and also creating public assessment reports;
- ❖ Supporting establishment of hemovigilance systems and support for global hemovigilance database systems.

Recommendations made by the conference are expected to help provide priority action points for both WHO and Member States so that they can be aligned with their ongoing activities. Implementation of these recommendations will no doubt improve the access to quality, efficacious, and safety medicines and medical products throughout the world thus creating an environment of harmony, reliance and convergence among drug regulatory authorities. Such efforts will definitely reduce regulatory costs, improve research and development to address suitable remedies for difficult to treat diseases and global problems in health. The intent of these recommendations can only be realized when there is wider stakeholders support and commitment to implement them.

Narayan Prasad Dhakal
Chief Editor

REGULATORY NEWS

Recommendations of the 18th International Conference of Drug Regulatory Authorities, 3-7 September, 2018, Dublin, Ireland

Introduction

The 18th International conference of drug regulators (ICDRA) was held in Dublin Ireland from 3 to 7 September 2018. The event was cohosted by the Health Product Regulatory Authority of Ireland and the World Health Organization. More than 300 delegates from regulatory authorities of WHO Member States participated in the 18th ICDRA. The discussions and deliberations were focused on several cross-cutting themes (total of 21 themes) which can be grouped and consolidated and include e.g. promoting regulatory collaboration, convergence and harmonization throughout the products life cycle; improving coordination, risk-based prioritization of investments, reliance, work- sharing and use of regional networks; promoting greater transparency, awareness and communication; enabling regulatory preparedness for public health emergencies; enabling access to innovative medical products; development of international standards; and provision of technical assistance to support implementation.
The recommendation reproduced here are as provided by the moderators in the closing plenary session and as finalized following comments received from participants as well as non-participating authorities.

Recommendations to WHO and Member states

Theme 1: **promoting regulatory collaboration, convergence and harmonization throughout the products life cycle**

To WHO:

1. Regulatory collaboration, convergence and harmonization activities should incorporate not only initial authorization but also life-cycle management and pharmacovigilance.
2. WHO should provide a toolbox with all the available options for regulatory collaboration, convergence and harmonization and increase awareness to facilitate selection of the appropriate mechanisms by member states.

To member states:

1. When sharing assessment or inspection reports, Member States should share unredacted reports, where possible, which is important to build trust and to optimize reliance on outcomes from other regulators.

Theme 2: **Certification of pharmaceutical products**

To WHO:

1. WHO should advocate for the use of an electronic CPP template by issuing and receiving authorities to expedite the process and mitigate against any further need for "legalization."
2. WHO should advocate for the CPP standard procedure specifying that value-added, unredacted documents either accompany the CPP or are provided upon request by any receiving agency.
3. The CPP template should be updated to reflect current manufacturing situations by including: (a) the sites of manufacture with addresses, and (b) are minder that the receiving country should check that the product being shipped to it is exactly the same as the product being certified by the issuing country.

Theme 3: **regulatory preparedness for public health emergencies**

To WHO

1. WHO should facilitate communication between stakeholders (manufacturers of IVDs, vaccines and therapeutics) and regulators on needs for products, development work and risk assessment work. This should be facilitated by WHO setting up a pre-Emergency Use Listing scheme.
2. WHO should encourage the use of regulatory networks such as ICMRA in the case of public health emergencies and should support effective transition from emergency use to in-country approval.

To member states

1. Member States should consider the feasibility of "conditional approvals" for PHE products with strengthened pharmacovigilance and long-term monitoring after outbreaks.

Theme 4: **Enabling access to innovative medical products**

To WHO:

1. WHO is asked to rapidly finalize the good regulatory practice suite of guidance, with a particular focus on developing practical advice options, and best practices to promote regulatory collaboration and reliance for the whole lifecycle management of medical products, both for individual National Regulatory Authorities and for regional networks.
2. WHO is asked to use its position in the various international regulatory harmonization forums to help promote alignment of regulatory application dossier formats, including elimination of unnecessary differences in the national and regional CTD requirements.

To member states

1. While fully recognizing that there are different languages and different regulatory systems, Member States are urged to review their current application dossier formats to ensure that all requirements are scientifically justified and better aligned with internationally agreed harmonized standards.

Theme 5: **Benchmarking of Regulatory Systems: towards mature regulatory systems**

To WHO

1. Continue support for regulatory systems strengthening to Member States utilizing the Global Benchmarking Tool which has proven to be effective in promoting one global standard for regulatory systems.
2. Support regulatory systems strengthening to Member States at different maturity levels in a strategic manner.
3. Further develop the process for designating WHO Listed Authorities with input from Member States.
4. Further clarify the role of WHO Listed Authorities at Maturity Level 3 or Maturity Level 4 and describe how this information can be utilized by Member States to support and advance their regulatory work.

To member states

1. Invest resources to strengthen regulatory systems utilizing the Global Benchmarking Tool and work towards attaining at least Maturity Level 3 while implementing principle of continuous improvement for all maturity levels.
2. Explore approaches to utilize concept of reliance and collaborative decision-making to increase timely access to safe and effective medical products.

Theme 6: **Future direction of WHO Prequalification (PQT)**

To WHO

1. Recognizing PQP's demonstrated effective contribution to UHC by facilitating access to quality assured medical products, WHO should expand the scope of products eligible for PQ assessment and diversify the pathways to PQ product listing to include increased reliance on WLAs and on quality assured assessments by regulatory networks.

To member States

1. Member states should where possible take advantage of opportunities offered by WHO through its Prequalification Programme by signing up and using the collaborative registration procedures and utilizing the practical training and capacity building opportunities offered through PQT.

Theme 7: **Regional regulatory networks: progress and challenges**

To WHO

1. Support trust building by providing or using existing platforms for exchange of information to avoid having to rebuild a system for each regional network/collaborative initiative.

To member State

1. National Regulatory Authorities/regional networks should engage with stakeholders to ensure that the added value and strength of the network is presented and understood, and to build confidence among all National Regulatory Authorities.

Theme 8: **Regulators role in containing antimicrobial**

To who

1. Continue to support member states to implement Global Action Plan (GAP) in particular, improve awareness and understanding of AMR and monitor/support countries in implementing national action plans.

To member states

1. Regulators should consider ways that will facilitate the development of new antibiotics and diagnostic tools such as harmonized technical standards, scientific advice accelerated pathways and incentivized research.
2. Member States/regulators should promote the implementation of national action plans including awareness and understanding of AMR, surveillance of AMR and the rational use and prescribing of medicines.

Theme 9: **Local production**

To WHO

1. Maintain local production as a discussion topic for further ICDRAs.

To member states

1. Members States are encouraged to promote communication and transparency between regulators and the industry to overcome the challenges in local production of medical products in assuring quality, efficacy and safety.

Theme 10: **Changing procurement models (in countries transitioning from support provided by Global Health Programmes)**

To who

1. WHO should develop options on how to provide advice and support in terms of strategic and practical aspects of adaptation of procurement practices.

2. WHO should continue to encourage/advocate procurement agencies and donors to adhere to national regulatory requirements.

To member states

1. Member States should raise awareness on selection, prices, supply systems, sustainable financing and regulatory systems.
2. Member States should encourage all stakeholders to be involved and coordinated on national level, from industry and donors to regulators in the process of procurement.
3. Member States should put the focus on quality-assured essential medicines and simplify the pathways for getting them to the patients.

Theme 11: **Promoting medical products safely: supply chain integrity**

To WHO

1. WHO should support Member States with guidelines on implementation on risk-based post market surveillance.
2. WHO should support the Member States to build the capacity to implement the risk-based post market surveillance.

To member states

1. Member States should plan and implement risk-based post market surveillance programmes.
2. Member States should put in place a system for effective response in surveillance to address serious public health threats related to Substandard and Falsified (SF) medical products.

Theme 12: **Smart safety surveillance – a shared responsibility**

To who

1. WHO should develop guidance and a toolkit to support Member States in the implementation of the Smart Safety Surveillance strategy, one that embraces a risk-based prioritization of investments, work-sharing, joint activities and reliance for maximum return on investment for all medical products.

To member states

1. Member States should further explore the concept with a view towards WHO Smart Safety Surveillance strategy.

Theme 13: **WHO Strategic approaches to improving access to safe medical products**

To WHO

1. WHO RHT strategy should ensure a comprehensive approach to improve patient access for all medical products, including for blood and blood components.

2. WHO Coalition of Interested Partners model should be used as a collaborative platform to advance "Smart" approaches, reliance and work-sharing among stakeholders for effective regulation.

To member states

1. Member States should work with harmonized systems, across product streams, supply chains and public health programmes, to ensure data are shared with the regulator, to inform policies, and for quality of care.

Theme 14: **Safety of medical products throughout the product life cycle**

To WHO

1. Support countries to proactively assess risks and benefits of medical products throughout the product life cycle.
2. Develop guidance and document best practice for effective communication on risk and benefit of all medical products (including vaccines).

To member states

1. Train and prepare all policy makers and other stakeholders on effective communication of both benefits and risks of medical products, including vaccines, based on robust scientific data.
2. Accumulate evidence and build evolving risk management plans from early stages of medical product development.

Theme 15: **Collaboration in the area of regulation of medical devices (including IVDs)**

To member states

1. Reliance mechanisms should be developed and integrated in the medical devices regulations to avoid duplication of work.
2. Regulatory capacity for medical devices should be established in Africa to convert the Pan-African Harmonization Working Party into a continental expert working group, under the AMRH initiative, building on existing regulatory models and available guidance.
3. More efforts should be invested in medical devices post-market surveillance as a critical element of regulations.

Theme 16: **Risk based inspections**

To WHO

1. In support of transparency, companies should consent to the sharing of full information amongst regulators and procurement agencies on inspections.

To member states

1. NRAs should embed the use of reliance procedures in their regulatory decision processes relating to inspections.
2. NRAs should monitor foreign inspections and support desk-top assessments with defined conditions

Theme 17: **Regulation of clinical trials: focus on patient safety**

To WHO

1. Facilitate exchange of safety information from clinical trials and other related activities at local, regional, and global level.

To member states

1. Implement any existing WHO guidance for inclusion of vulnerable populations, children, pregnant women and women of child bearing age in clinical trials to gain knowledge of safety in these populations in a controlled setting. This will facilitate access, if benefit/risk is favorable, in these populations to important medical products.
2. Utilize opportunities for collaboration through networks such as AVAREF to assess clinical trial applications and develop processes for monitoring and follow up on safety data.

Theme 18: **Harmonization, work-sharing and reliance in pharmacovigilance**

To WHO

1. WHO should coordinate Member States efforts to develop a platform for sharing best practice and emerging data in pharmacovigilance.

Theme 19: **Regulation of advanced therapies**

To WHO

1. WHO to develop with Member States a "current state of the art" document capturing areas where agreement among experienced regulatory authorities exists, noting where harmonization has yet to be achieved, and documenting existing areas of uncertainty; areas covered could include definitions, quality attributes, standards, and clinical development pathways.

To member states

1. Member States are encouraged to develop national guidance and legislation on advanced therapies.

Theme 20: **Regulation of biosimilars**

To WHO

1. WHO should keep organizing implementation workshops to accelerate use by Member States of the WHO guidelines on biosimilars, focusing more on analytical comparability than on comparability in clinical data, and emphasizing the importance of regulatory oversight throughout the entire life cycle of biosimilars.

To Member states

1. Member States are encouraged to collaborate, to use existing resources in more efficient manner and to improve transparency by making Public Assessment Reports (PARs) detailed enough, particularly on comparability, and publishing PAR for both approved and rejected biotherapeutics.
2. Member States should, in accordance with their respective mandates, define prerequisites for interchangeability and substitutability of biosimilars, which is a national responsibility.

Theme 21: **Safety of blood and blood products**

To WHO

1. WHO should support the establishment of national hemovigilance systems in Member States through the facilitation of education and training opportunities at the regional level.
2. WHO should take steps to ensure standardization, harmonized terminology and common good practices for national, regional and global hemovigilance database systems.

To member states

1. Member States should take steps to establish or strengthen their national hemovigilance system in accordance with the 2016 WHO guide.
2. Member States should engage in self-assessments and external assessments of their national hemovigilance systems using the WHO Global Benchmarking Tool, integrating the WHO Assessment Criteria for National Blood Regulatory Systems.

IMPORTANT INFORMATION

Sodium-glucose cotransporter-2 (SGLT2) inhibitors
Risk of serious infection of the genital area
The US FDA (United States Food and Drug Administration) has recommended that the prescribing information and patient medication guides for all sodium-glucose cotransporter-2 (SGLT2) inhibitors should include a new warning about the risk of a rare but serious infection of the genital area. SGLT2 inhibitors include canagliflozin, dapagliflozin, empagliflozin and ertugliflozin, and are indicated to treat type2 diabetes. Cases of the infection of the genital area have been reported.

Source: WHO Pharmaceuticals Newsletter No.5, 2018
In Nepal: Health care professionals and patients are warned of the risk of serious infection of the genital area with the use of SGLT2 inhibitors.

Valproate
Risk of teratogenicity
The HSA (Health Sciences Authority) has placed several local risk mitigation measures to manage the teratogenic risks of valproate (Epilim®). Valproate is indicated for the treatment of various types of epileptic seizures, such as generalised and partial seizures. Valproate is a known teratogen that has been associated with congenital malformations and developmental disorders in children born to women taking the medicine during pregnancy. The measures include: strengthening warnings of the risk of teratogenicity and precautions against its use during pregnancy in the Singapore package inserts for valproate. This decision follows the EMA's recommendation to introduce new measures. HSA has not received any local cases of adverse events associated with the exposure of valproate during pregnancy.

Source: WHO Pharmaceuticals Newsletter No.5, 2018
In Nepal: Health care professionals are warned of the risk of teratogenicity with the use of valproate.

Febuxostat
Interaction with azathioprine or mercaptopurine
Medsafe has issued a warning about the interaction between febuxostat (Adenuric®) and azathioprine or mercaptopurine. When used in combination, febuxostat could potentially increase blood levels of mercaptopurine. Febuxostat is used for the treatment of chronic hyperuricaemia in patients with gout. Febuxostat is not recommended in patients concomitantly treated with azathioprine or mercaptopurine. Azathioprine is first metabolized to 6- mercaptopurine, which in turn is converted to inactive products by xanthine oxidase. Inhibition of

xanthine oxidase by febuxostat may cause increased plasma concentrations of mercaptopurine, leading to toxicity. As on 30 June 2018 there have been no reports of this interaction in New Zealand.

Source: WHO Pharmaceuticals Newsletter No.5, 2018
In Nepal: Health care professionals are warned of the risk of toxicity due to the interaction with azathioprine or mercaptopurine with the use of febuxostat.

Rotavirus vaccines
Potential risk of intussusceptions
Medsafe has announced that 11 cases of intussusception associated with rotavirus vaccines (RotaTeq® and Rotarix®) were reported. Rotavirus vaccine is an oral vaccine used against rotavirus infection. Intussusception is the most common abdominal emergency in young children. About 1-6 in 100,000 children may experience intussusception due to vaccination with rotavirus vaccine. In Ten of the 11 cases, patients recovered (the outcome was unknown in one case). The time between vaccination and onset of the reaction ranged from four days to two months. The benefits of rotavirus vaccination continue to outweigh the risks of harm. Parents and guardians should be advised to seek prompt medical assistance if any of the symptoms of intussusception occur.

Source: WHO Pharmaceuticals Newsletter No.5, 2018
In Nepal: Health care professionals and parents are warned of the risk of intussusceptions with the use of rotavirus vaccines.

Ketoconazole
Risk of severe liver injury and adrenal gland problems
The Food and Drugs Authority in Ghana has suspended the registration, importation and manufacturing of oral ketoconazole products due to the risk of severe liver injury, adrenal gland problems and harmful drug interactions. Ketoconazole is a synthetic antifungal agent available as a preparation for oral administration and as a cream or shampoo for topical application. Risk minimization measures recommended by the Technical Advisory Committee on Safety of Medicines (TAC-SM) in 2013 were not effective in preventing the risk of liver related adverse drug reactions associated with the use of oral ketoconazole. The use of less harmful alternatives to oral ketoconazole (itraconazole, terbinafine and fluconazole) should be used in place of oral ketoconazole.

Source: WHO Pharmaceuticals Newsletter No.6, 2018
In Nepal: Health care professionals are warned of the risk of severe liver injury and adrenal gland problems with the use of oral ketokonazole.

Lamotrigine
Risk of haemophagocytic syndrome
MHLW (Ministry of Health, Labor, and Welfare) and PMDA (Pharmaceuticals and Medical Devices Agency) have announced that the package insert for lamotrigine (Lamictal®) should be revised to include haemophagocytic syndrome as an adverse reaction. Lamotrigine is indicated for several types of seizures in epileptic patients. Cases of haemophagocytic syndrome have been reported in patients treated with lamotrigine in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation using currently available information.

Source: WHO Pharmaceuticals Newsletter No.6, 2018
In Nepal: Health care professionals are warned of the risk of haemophagocytic syndrome with the use of lamotrigine.

Atorvastatin and antivirals: interaction
Increase in atorvastatin plasma levels
The Egyptian Pharmaceutical Vigilance Center (EPVC) has announced that the product information for atorvastatin will be updated to include a warning about the potential increase in atorvastatin levels when coadministered with elbasvir/grazoprevir and glecaprevir/pibrentasvir. The combined use of glecaprevir/pibrentasvir with atorvastatin is now contraindicated. Atorvastatin is a synthetic lipidlowering agent indicated for the prevention of cardiovascular diseases and hypercholesterolaemia. Elbasvir/grazoprevir and glecaprevir/pibrentasvir preparations are indicated for the treatment of hepatitis C (HCV). Risk of myopathy may be increased with the concomitant use of atorvastatin and antivirals for treatment of HCV.

Source: WHO Pharmaceuticals Newsletter No.1, 2019
In Nepal: Health care professionals are informed of the risk of increasing atorvastatin plasma levels with concomitant use of antivirals.

Direct-acting antivirals for chronic hepatitis C
Risk of hypoglycaemia in patients with diabetes
The Medicines and Healthcare Products Regulatory Agency (MHRA) is updating the Summary of Product Characteristics and Patient Information Leaflets for direct acting antivirals (e.g. daclatasvir (Daklinza®), sofosbuvir/velpatasvir (Epclusa®) and ledipasvir/sofosbuvir (Harvoni®)), to include safety advice to minimise the risk of hypoglycaemia in patients taking medicines for diabetes. Studies show that some diabetic patients, initiating direct-acting antiviral therapy for chronic hepatitis C infection, have experienced hypoglycaemia. This was confirmed in an EU review. Glucose levels should be monitored closely in patients with diabetes

during directacting antiviral therapy for hepatitis C and medicines should be modified when necessary.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of developinghypoglycaemia in patients with diabetes with the use of direct-acting antivirals for chronic hepatitis C.

Fluoroquinolone antibiotics

1. Risk of tendon damage and neuropathies

The Health Products Regulatory Authority (HPRA) has updated the Summary of Product Characteristics (SmPC) and Package Leaflets (PL) for all fluoroquinolone antibiotics to include tendonitis, tendon rupture, neuropsychiatric effects and neuropathies associated with paraesthesia as adverse reactions. The update followed conclusions from a recent review by EMA's Pharmacovigilance Risk Assessment Committee (PRAC)'s. Fluoroquinolonesare a class of broad spectrum antibiotics and include ciprofloxacin, levofloxacin, ofloxacin and moxifloxacin. The PRAC recommended that fluoroquinolone antibiotic use should be further restricted, and the information provided to patients on potential adverse reactions should be expanded to emphasize the possibility of persisting effects.

2. Risk of aortic aneurysm and aortic dissection

The MHLW and the PMDA have announced that the package inserts for fluoroquinolones (e.g. moxifloxacin (Avelox®), levofloxacin (Cravit®), ofloxacin (Tarivid®)) should be revised to include aortic aneurysm and aortic dissection as adverse drug reactions. Results of several epidemiological studies and a non-clinical study have suggested an association between fluoroquinolone use and development of aortic aneurysm or aortic dissection. Although no cases involving aortic aneurysm or aortic dissection have been reported in Japan during the previous three fiscal years, MHLW/PMDA concluded that revision of the package inserts was necessary based on the opinions of the expert advisors. Patients should be carefully monitored and instructed to seek medical attention immediately if they experience symptoms such as pain in the abdomen, chest or back. Imaging assessment should be considered if necessary, for patients at risk.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of tendon damage and neuropathies and of aortic aneurysm and aortic dissection with the use of fluoroquinolone antibiotics.

Hydrochlorothiazide

Risk of non-melanoma skin cancer

The EPVC has announced that the Summary of Product Characteristics and Package Leaflet for hydrochlorothiazide will be updated to include the risk of non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma) as an adverse reaction. Hydrochlorothiazide is widely used to treat hypertension, cardiac, hepatic and nephrogenicoedema or chronic heart insufficiency. Pharmacoepidemiological studies have shown an increased risk of nonmelanoma skin cancer with exposure to increasing cumulative doses of hydrochlorothiazide. Patients taking hydrochlorothiazide should be informed of the risk and advised to regularly check their skin. Also, patients should be advised to limit exposure to sunlight and UV rays, and suspicious skin lesions should be examined, potentially by performing histological examinations of biopsies.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of development of non-melanoma skin cancer with the use of hydrochlorothiazide.

Azithromycin

Risk of haematological relapses

The HSA has announced that a clinical trial, investigating effectiveness of long-term azithromycin to prevent bronchiolitis obliterans syndrome (BOS) in certain haematological patients, was terminated prematurely because of an increase in the rate of haematological malignancy relapses and mortality in patients that had a haematopoietic stem cell transplantation (HSCT). Azithromycin is a macrolide antibiotic. It is not approved for the prophylaxis of BOS in HSCT patients. There are 15 generic azithromycincontaining products registered in Singapore. The aim of the clinical trial was to investigate if early administration of azithromycin could improve airflow declinefree survival two years after allogeneic HSCT. The trial investigators concluded that early administration of azithromycin for prophylaxis of BOS in HSCT patients resulted in worse airflow decline-free-survival than did placebo. However, the findings were limited by the early termination of the trial and further investigation was required.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of haematological relapses with the use of azithromycin.

Beta-blocker, statins, selective serotonin re-uptake inhibitors and varenicline

Risk of parasomnias

Medsafe has announced that beta-blockers, statins, selective serotonin reuptake inhibitors (SSRIs) and nicotine replacement therapies may cause various parasomnias. Parasomnia is an umbrella term for complex movements or

behaviours during sleep, including abnormal dreaming, nightmares (paroniria) and sleepwalking (somnambulism). The Centre for Adverse Reactions Monitoring (CARM) received over 70 reports of various parasomnias over the past five years. The most frequently reported terms are abnormal dreams, paroniria and sleep disorder. Commonly reported medicines include statins, varenicline and montelukast.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of parasomnias with the use of beta-blockers, statins, selective serotonin re-uptake inhibitors and varenicline.

Erythropoietin

Risk of pure red cell aplasia

Medsafe has announced that pure red cell aplasia (PRCA) may occur after treatment with erythropoietin (Eprex®) in patients with chronic kidney disease. Erythropoietin is an erythropoiesis-stimulating agent used to treat or prevent anaemia of varying origins. The CARM received 11 case reports of PRCA after treatment with erythropoietin. If PRCA is diagnosed, erythropoietin treatment must be discontinued immediately, and testing for erythropoietin antibodies should be considered. If antibodies to erythropoietin are detected, patients should not be switched to another erythropoiesisstimulating agent because antierythropoietin antibodies crossreact with other erythropoiesisstimulating agents.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the development of pure red cell aplasia with the use of erythropoetinin patients with chronic kidney disease.

Sulfamethoxazole

Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): insufficient evidence

Health Canada has announced that its review concluded that there is not enough evidence at this time to establish a link between the risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), and the use of sulfamethoxazole containing products. Sulfamethoxazole is used to treat a wide range of infections caused by bacteria. Health Canada's review was triggered by a signal from the WHO global database for reports of adverse reactions which suggested DRESS was being reported at a higher rate than expected for sulfonamides. Health Canada received four unique Canadian reports of DRESS that could be related to sulfamethoxazole use, and found a possible link between DRESS and sulfamethoxazole in two reports. Also, the review looked at five international reports of DRESS and two of them showed a possible link between DRESS and sulfamethoxazole use. However, after looking at all the available evidence, Health

Canada concluded that there is not enough evidence at this time to establish a link between the risk of DRESS and the use of sulfamethoxazole containing products, and that the safety information of the products is appropriate at this time.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) with use of sulfamethoxazole.

Tapentadol

Risk of seizures and serotonin syndrome when co-administered with other medicines

The MHRA has announced that tapentadol (Palexia®) may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants such as serotonin reuptake inhibitors (SSRIs), serotoninnoradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants and antipsychotics. Tapentadol is an opioid analgesic indicated for the relief of acute, moderate to severe pain that can only be adequately managed with opioid analgesics in adults and children aged two years and older. The risk of seizures is a recognized adverse drug reaction for all opioid medicines, but a recent review for tapentadol in the EU identified the need for strengthened advice about the risk of seizures. Approximately half of the identified spontaneous reports of seizures reflected coadministration of tapentadol with at least one other drug known to lower seizure threshold. Also, MHRA is aware of reports of serotonin syndrome identified when tapentadol is co-administered with SSRIs, SNRIs, tricyclic antidepressants and antipsychotics. Withdrawal of the serotoninergic medicine, together with supportive symptomatic care, usually brings about a rapid improvement. The continued use of tapentadol must be evaluated on an ongoing basis.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

In Nepal: Health care professionals are warned of the risk of seizures and serotonin syndrome with use of tapentadol in patients taking relevant medicines to lower seizure threshold, antidepressants, antipsychotics etc.

SIGNAL

Methotrexate – Incorrect drug administration rate
Marian Attalla, Uppsala Monitoring Centre

Methotrexate is a folic acid antagonist used in the treatment of rheumatoid arthritis and severe psoriasis when the patient has been unresponsive to other, conventional therapies. It is also used to induce regression in neoplastic conditions such as acute leukaemia, non-Hodgkin's lymphoma, soft-tissue and osteogenic sarcomas, and solid tumours such as breast, lung, head and neck, bladder, cervix, ovaries, and testicles carcinoma. In the treatment of rheumatoid arthritis and psoriasis, methotrexate is given as a weekly dose. This dose can be divided into three doses to be taken within 24 hours, at 12-hour intervals (applicable for the tablet formulation). In cancer treatment, single doses of methotrexate are given on not more than five consecutive days, followed by a rest period of at least two weeks between treatments.

In VigiBase, there are 24 cases reporting incorrect drug administration rate for methotrexate between 2009 and January 2018. Thirteen cases are from France, three from Bulgaria, three from USA, and one each from Denmark, Germany, Spain, Switzerland and UK. The patient age ranged from 3 to 92 years, with a median age of 63 years, based on the 21 reports where age was provided. Men accounted for 15 and women for 9 reports. The indications for treatment were reported as psoriasis in three cases, rheumatoid arthritis in three cases, various cancers in three cases (acute lymphocytic leukaemia, B cell lymphoma, cerebral lymphoma), bullous pemphigoid in one case and asthma in another case. In the remaining 13 cases, the indication was unspecified. Methotrexate was administered intravenously in five cases and orally in 19 cases.

In the cases where oral methotrexate was prescribed, the patients had taken it daily instead of weekly. In one case, a prescription error was reported. However, in most cases it appears that the patient did not understand that methotrexate was to be taken weekly and not daily. In addition to errors in administration, other reactions were reported. The five most reported reactions included mouth ulceration (4), thrombocytopenia (4), gastritis (4), pancytopenia (3) and pharyngitis (3). The outcome was recovered in 15 cases, not recovered in one case and unknown in another case. In the remaining two cases, the patient died.

Both the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) state that methotrexate is to be taken weekly. However, these reports show that the patient took it daily instead, with significant adverse effects. The dosing instructions can be particularly confusing in the cases where the weekly dose is divided into three doses to be taken within 24 hours, with a 12-hour gap between each dose. Based on the reports in VigiBase, it appears that clearer instructions both in the SPC and by the prescriber are necessary, and that health care professionals should verify that the patient has understood how the medication needs to be taken.

Source: WHO Pharmaceuticals Newsletter No.1, 2019

LIST OF PENALIZED PHARMACIES IN SECOND QUARTER 2075/76

औषधी व्यवस्था बिभाग, बिजुलीबजार

निलम्बन गरिएका औषधी पसलहरूको सूचि

क्र.स.	पसलको नाम	ठेगाना	कारबाही	निलम्बन अवधि
१	अक्षता फार्मेसी	टोखा न.पा. ०६	निलम्बन	२१ दिन
२	डायमण्ड पोलिक्लिनिक प्रा. लि. (फा.यु.)	का.म.न.पा. ०६	निलम्बन	१५ दिन
३	मनिष मेडिकल हल	टोखा न.पा. ११	निलम्बन	०७ दिन
४	निवारण पोलिक्लिनिक प्रा. लि. (फा.यु.)	ठिमी न.पा.-३, भक्तपुर	निलम्बन	१५ दिन

वन्द गरिएका औषधी पसलहरूको सूचि

१	अमन मेडिकल हल	टोखा न.पा. ०३	पसल बन्द गराईएको
२	जस्मिन क्लिनिक	का.म.न.पा. ०९९	पसल बन्द गराईएको

औषधी व्यवस्था बिभाग, शाखा कार्यालय, नेपालगंज

निलम्बन गरिएका औषधी पसलहरूको सुची

क्र.स.	फार्मेसी को नाम	ठेगाना	धनि/व्यबसायी को नाम	निलम्बन अवधी
१	जे बि फार्मेसी	कैलाली	नयन बहादुर ठकुल्ला	६० दिन
२	बबई पोलीक्लिनिक प्रा ली, फार्मा डिभिजन	धधबार-०३,बर्दिया	सन्तोष खनाल(ब्यबसायी) बबई पोलीक्लिनिक प्रा.लि (धनि)	३० दिन
३	सुजल फार्मेसी	दशेरा ग बि स-९, जाजर कोट,		३० दिन
४	रबिन मेडिकल हल	खलंगा-६, जाजरकोट	बेद बहादुर सिंह (ब्यबसायी) रत्न बहादुर घर्ति (धनि)	१५ दिन

सचेत गरिएका औषधी पसलहरूको सुची

क्र.स.	फार्मेसी को नाम	ठेगाना	धनि/ब्यबसायी को नाम
१.	सी ति फार्मेसी	बाँके	बिर केसी
२.	साझा स्वास्थ्य सेवा संस्था	बाँके	हरि लाल चौधरी
३.	सादा औषधी पसल	नेपालगंज-१३ बाँके	सन्तोष बि.क. (धनि) नबिन सुनार (ब्यबसायी)
४.	बिबेक मेडिकल हल	बि.न.पा -६, सुर्खेत	रुकुम बहादुर बि.क.(धनि) नबिन सुनार(ब्यबसायी)
५.	भेरी मेडिकल हल	छिन्चू-७, सुर्खेत	शोभा रेग्मी (धनि) प्रेमराज रेग्मी (ब्यबसायी)
६.	बोहोरा फार्मेसी	बि.न.पा-१, सुर्खेत	कस्मेर बहादुर थापा (ब्यबसायी) बिनोद बहादुर बोहरा (धनि)
७.	ओसियन फार्मेसी	बि.न.पा-६, सुर्खेत	रेशम लाल गौतम
८.	गणेश मेडिकल हल	छिन्चू -७, सुर्खेत	मन बहादुर शाही
९.	भृकुटी मेडिकल हल	बि.न.पा -६, सुर्खेत	हरि प्रसाद शर्मा (ब्यबसायी) निरक गुरुङ (धनि)
१०.	आरुषी फार्मेसी एंड मेडिकल हल	सुर्खेत	मनराज अधिकारी
११.	जन सेवा मेडिकल हल	सल्यान	भिम बहादुर सेन
१२.	ग्लोबल मेडिकल हल	मधुबन न पा १,बर्दिया	राम सिंह चुनारा
१३.	आशा क्लिनिक	राजापुर, बर्दिया	आशा खड्का
१४.	तिलगंगा पोलि क्लिनिक प्रा लि	राजापुर-१०, बर्दिया	रमेश चौधरी (ब्यबसायी)
१५.	श्रीजना फार्मेसी	घोराही न.पा्-११, दाङ	सुर्यमणि न्यौपाने
१६.	जनसेवा आयुर्बेद मेडिकल हल	तु न पा-५, दाङ	युबराज चौधरी
१८.	बिबन अनमोल फार्मेसी	रोल्पा-४	अनिल चौधरी

मुद्दा दर्ता गरिएको औषधी पसलहरूको सुची

क्र.स.	फार्मेसी को नामर ठेगाना	प्रतिवादी	अभियोग	मुद्दा दर्ता भएको मिति र स्थान
१.	- Veterinary को किर्ते कागजका लागि मुद्दा पठाएको	-	किर्ते कागज सम्बन्धि अनुसन्धानका लागि मुद्दामा सिफारिश गरिएको	-
२.	- Veterinary को किर्ते कागजका लागि मुद्दा पठाएको	-	किर्ते कागज सम्बन्धि अनुसन्धानका लागि मुद्दामा सिफारिश गरिएको f	-

औषधि व्यवस्था बिभाग, शाखा कार्यालय, बिराटनगर

निलम्बन भएका औषधि पसलहरूको सूची:

सि.न.	औषधिपसलको नाम	ठेगाना	धनी/व्यवसायीको नाम	निलम्बन अवधि
१	देबी माँ पाथिभरा फर्मा	बिराटनगर, मोरंग	देबी प्रसाद दुलाल/महेन्द्र खनाल	३५ दिन
२	जनक मेडिकल हल	धरान-४, सुनसरी	सुमन ढकाल/जनक प्रसाद श्रेष्ठ	७ दिन
३	सुमन फार्मेसी	धरान-४, सुनसरी	बिनयकुमार गुरुङ	७ दिन
४	स्काई मेडिको	दमक न.पा.-५, झापा	तोयानाथ सापकोटा	३५ दिन
५	राशिका फार्मेसी	दमक ११, झापा	यादब प्रसाद कोइराला/सोनाश्रेष्ठ	२१ दिन
६	आस्थामणि फार्मेसी	टंकीसिनवारी, बिराटनगर	प्रकास नारायण चौधरी	३ दिन
७	अनवर मेडिको सिराहा-१७, सिराहा	सिराहा-१७, सिराहा	मो.जुहेर अनवर	१५ दिन
८	सिम्पी फार्मेसी धरान सुनसरी	धरान १८ सुनसरी	सिम्पी कुमारी पोदार	७ दिन
९	श्री पंचवटी मेडिकल हल, मोरंग	बिराटनगर १६, मोरंग	प्रकाश कुमार साह, बिराटनगर	७ दिन

औषधि व्यवस्था बिभाग, शाखा कार्यालय, बीरगंज

सचेत गरिएको औषधी पसलहरूको सुची

सि.नं.	पसलको नाम	व्यवसायीको नाम	धनीको नाम	पसलको ठेगाना
०१	शिवशक्ती मेडीकल हल	शिव शंकर सहनी	शिव शंकर सहनी	महोत्तरी
०२	उपेन्द्र मेडीकल हल	उपेन्द्र साह	उपेन्द्र साह	महोत्तरी
०३	गैर आयुर्वेदिक औषधि पसल	दिवेन्द्र कुमार झा	दिवेन्द्र कुमार झा	सर्लाही
०४	न्यु ओम आयुर्वेद फर्मा	राज किशोर महतो	राज किशोर महतो	महोत्तरी
०५	शर्मा भेट फर्मा	गोपाल कुमार शर्मा	गोपाल कुमार शर्मा	महोत्तरी
०६	श्री प्रकाश मेडीकल हल	राम प्रसाद जालान	राम प्रसाद जालान	महोत्तरी

०७	सिहजी मेडीकल हल	लक्ष्मेश्वर प्रसाद सिंह	लक्ष्मेश्वर प्रसाद सिंह	महोत्तरी
०८	आरोग्य मेडीकल हल	उमा शंकर प्रसाद साह	उमा शंकर प्रसाद साह	महोत्तरी
०९	ठाकुर मेडीकल हल	रामपृत ठाकुर	रामपृत ठाकुर	महोत्तरी
१०	पप्पु मेडीक हल	विन्देश्वर मिश्र	विन्देश्वर मिश्र	महोत्तरी
११	श्री शंकर मेडीकल हल	राम दास ठाकुर	राम दास ठाकुर	महोत्तरी
१२	श्री मेडीकल हल	राम पुकार पंडित	राम पुकार पंडित	सर्लाही
१३	धिरज मेडीकल हल	राम आशीष प्रसाद	राम आशीष प्रसाद	सर्लाही
१४	कमलामाई भेट सप्लार्यस	ओम प्रकाश श्रेष्ठ	ओम प्रकाश श्रेष्ठ	सिन्धुली
१५	अंजनी मेडीकल हल	बसन्त कुमार झा	बसन्त कुमार झा	महोत्तरी
१६	आर.के. एस. आयुर्वेद मेडीकल हल	राज किसोर साह	राज किसोर साह	सर्लाही
१७	पार्वती मेडीकल हल	विजय कुमार चौधरी	विजय कुमार चौधरी	सिन्धुली
१८	मरिण ठाकुर औषधि पसल	केशव प्रसाद देवकोटा	केशव प्रसाद देवकोटा	सिन्धुली
१९	ऋतु मेडीकल हल	राम विनय यादव	राम विनय यादव	धनुषा
२०	पुरुषोत्तम मेडीकल हल	नविन चौधरी	नविन चौधरी	रौतहट
२१	संझा मेडीकल हल	संजिव झा	संजिव झा	धनुषा
२२	साझा स्वास्थ्य सेवा	युवराज दुलाल	साझा स्वास्थ्य सेवा	धनुषा
२३	समरक्ष क्लिनिक मेडीकल हल	पप्पु यादव	पप्पु यादव	धनुषा
२४	न्यु सुनिल मेडीकल हल	सुजित कुमार भगत	सुजित कुमार भगत	धनुषा
२५	आयु आयुर्वेदिक मेडीकल हल	राम विनय मंडल	राम विनय मंडल	धनुषा
२६	किरण मेडीकल हल	प्रमोद लाल कर्ण	प्रमोद लाल कर्ण	धनुषा
२७	अमृत आयुवेद	विवेकानन्द सिंह	विवेकानन्द सिंह	धनुषा
२८	बारा ड्रग डिष्ट्रब्युटर्स	राम चन्द्र प्रसाद चौधरी	बारा ड्रग डिष्ट्रब्युटर्स	बारा
२९	राजदीप फार्मेसी	राजीव कुमार साह	राजीव कुमार साह	बारा
३०	जन्नत मेडीकल हल	सदाम हुसैन	सदाम हुसैन	पर्सा
३१	जिवन दिप मेडीकल हल	नागेन्द्र महतो	नागेन्द्र महतो	बारा
३२	सरस्वती मेडीसिन सेन्टर	उपेन्द्र राम	उपेन्द्र राम	बारा
३३	राजा मेडीकल हल	अच्छेलाल प्रसाद कोईरी	अच्छेलाल प्रसाद कोईरी	पर्सा
३४	श्री भवानी होस्पीटल एण्ड रिसर्च सेन्टर	रोहित कुमार मिश्र	श्री भवानी होस्पीटल एण्ड रिसर्च सेन्टर	पर्सा
३५	मेडी सेल्स फर्मा	जगरनाथ ओझा	जगरनाथ ओझा	चितवन
३६	ग्रिन तारा फार्मेसी	केशव प्रसाद साह	केशव प्रसाद साह	चितवन
३७	लाईफ मेडीसिन डिष्ट्रीब्युटर्स	राजु भण्डारी	अर्जुन आचार्य	चितवन

३८	नवोदित मेडीकल हल	हिम प्रसाद लामिछाने	नम्रता कुमारी न्यौपाने	चितवन
३९	हजुरको गगन मेडीकल हल	सविन कोईराला	सविन कोईराला	मकवानपुर
४०	एल.एस. फार्मेसी	पसिम लामा	पसिम लामा	मकवानपुर

बन्द गराईएको औषधी पसलहरूको सूची :

सि.नं.	पसलको नाम	व्यवसायीको नाम	धनीको नाम	पसलको ठेगाना
१	विकास मेडीकल हल	विकास कुमार साह	विकास कुमार साह	महोत्तरी
२	राजन मेडीकल हल	कमलेश मुखिया	कमलेश मुखिया	महोत्तरी
३	वि. एस हेल्थ क्लिनीक	विनोद कुमार साह	विनोद कुमार साह	महोत्तरी
४	शान्ती कम्युनिटी	मनोज अधिकारी	मनोज अधिकारी	महोत्तरी
५	ठाकुर पशु उपचार केन्द्र	दिपेन्द्र कुमार ठाकुर	दिपेन्द्र कुमार ठाकुर	महोत्तरी
६	हाम्रो स्वास्थ्य क्लिनीक	प्रज्जवल आले मगर	प्रज्जवल आले मगर	सर्लाही
७	नाम नखुलेको	मनोज कुमार साह	मनोज कुमार साह	सर्लाही
८	एडभान्स क्लिनीक मेडीकल हल	गजेन्द्र चौधरी	गजेन्द्र चौधरी	रौतहट
९	नाम नखुलेको	रमेश साह	रमेश साह	रौतहट
१०	ओम शान्ति पोली क्लिनीक	रमन सिंह	रमन सिंह	धनुषा
११	निम्स अस्पताल फार्मेसी	महमद आलम अंसारी	महमद आलम अंसारी	बारा
१२	नाम नभएको पसल	लाल बाबु पटेल	लाल बाबु पटेल	पर्सा
१३	गौर अस्पताल फार्मेसी	धिरेन्द्र कुमार गुप्ता	गौर अस्पताल फार्मेसी	रौतहट
१४	नम नभएको पसल	राजु कुमार साह	राजु कुमार साह	रौतहट

मुद्दा दर्ता गरिएको औषधी पसल:

सि.नं.	व्यक्तिको नाम/ठेगाना	प्रतिवादी	अभियोग	मुद्दा दर्ता भएको मिति र स्थान
१	राजेश कुमार महतो / भारतको सितामढी जिल्ला सोनवर्षा ०१	राजेश कुमार महतो	विना दर्ता एवम् प्रतिबन्धित औषधि Spasmo proxyvon Plus (Dicyclomin 10 mg + Paracetamol 325 mg + Tramadol 50 mg) आयात गरेको	२०७५।११।१९ गते सर्लाही जिल्ला अदालत

REGULATORY NOTICES

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स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

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

तपसिल

सि.न.	औषधिको नाम	ब्याच. न	Mfg/ Expiry date	कारण	उत्पादकको नाम र ठेगाना
१.	Fexolar 180	FE-35	Apr 2018/ Mar 2020	Non-compliance w.r.t. dissolution test	Everest Pharmaceuticals Pvt. Ltd, Bhaktapur

मितिः २०७५/०१/०६ गते (January 20, 2019) गतेको गोरखापत्र राष्ट्रिय दैनिकमा प्रकाशित सूचना

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औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

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

सि.न.	औषधिको नाम	ब्याच. न	Mfg/ Expiry date	कारण	उत्पादकको नाम र ठेगाना
१.	MUPIR Ointment	MP01	Nov 2017/ Oct 2019	Non-compliance w.r.t. USP	AryaPharmalab Pvt. Ltd., Chhatapipara, Bara, Nepal.

मितिः २०७५/१०/१७ गते (January 31, 2019) गतेको गोरखापत्र राष्ट्रिय दैनिकमा प्रकाशित सूचना

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था बिभागको

औषधि फिर्ता (RECALL) गर्ने सम्बन्धि अत्यन्त जरुरी सूचना

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

तपसिल

सि.न.	औषधिको नाम	ब्याच. न	Mfg/ Expiry date	कारण	उत्पादकको नाम र ठेगाना
१	Polxin-NZ 15 gm (Neomycin and Polymyxin B Sulfates and Bacitracin Zinc USP)	PN02	Oct 2017/ Sep 2019	Non-compliance w.r.t. Assay	AryaPharmalab Pvt. Ltd., Chhatapipara, Bara, Nepal.
२	Polxin-NZ 15 gm (Neomycin and Polymyxin B Sulfates and Bacitracin Zinc USP)	PN03	Nov 2017/ Oct 2019		
३	Ringer Lactate Solution for Injection IP	CSL 7126	May 2017/ Apr 2019	Non-compliance w.r.t. sterility test	Eurolife Healthcare Pvt. Ltd., Uttarakhand, India

मितिः २०७५/११/१७ गते (March 1, 2019) गतेको गोरखापत्र राष्ट्रिय दैनिकमा प्रकाशित सूचना

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

औषधिको आम उपभोक्तालाई जानकारी

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

स्वस्थ्थकर्मी, औषधि सिफारिसकर्ता, औषधि उत्पादक, पैठारि कर्ता तथा व्यबशायीलाई जानकारी

- बिभागमा दर्ता नभएका औषधिको बिक्रि वितरण नगर्ने तथा बिल बिजक बिना कुनैपनि औषधिको खरिद बिक्रि नगरौ ;
- चिकित्सकहरुले वा स्वास्थ्यकर्मीहरुले ब्यबसायिक मर्यादा र आचरणमा बसी औषधिको सिफारिश गर्ने गरौ र कुनै औषधि कम्पनिबाट कुनै लाभ वा अवसरको संभौता गर्नु भएको छ भने पारदर्शी गर्ने गरौ;
- मूल्य नभएको तथा बिभागबाट मूल्य स्वीकृत नभएको औषधि को बिक्रि बितरण गर्ने नगरौ;
- उधोग तथा औषधि वितरकले दिने मभर्बा दयलगक पारदर्शी गर्ने गरौ र यसबाट उपभोक्तालाई लाभान्वित गरौ;
- Physician sample को दुरुपयोग नगरौं;
- औषधिको स्तर खुलाई मात्र औषधिको उत्पादन र बिक्रि वितरण गर्ने गरौ;
- लागु तथा मनोदिपक र एन्टिबायोटिक औषधिहरुको समुचित प्रयोग गर्ने बनि बसालौ र अरुलाई पनि सिकाउ;
- औषधि दर्ता भएनभएको जानकारी यस विभागबाट जानकारी लिऔ;
- थोक बिक्रेताले खुद्रा बिक्रेतालाई कारोबार गर्दा आधिकारिक बिल तथा अधावादिक दर्ता रहेको औषधि पसलमा मात्र गर्ने र
- लागु तथा मनोदिपक औषधिहरु को 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 प्रयाग 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 तुरन्त औषधि प्रयोग गर्न छाडी स्वास्थ्यकर्मीलाई सम्पर्क राख्ने ।

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

औषधि सम्बन्धि थप जानकारीका लागि तल उल्लेखित ठेगानामा सम्पर्क राख्नुहोला ।

औषधि व्यवस्था विभाग

मदनभण्डारी पथ-४, बिजुलीबजार, काठमाडौं

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