वार्षिक बुलेटिन

२०८३

नेपाल सरकार

स्वास्थ्य तथा खाद्य स्वच्छता मन्त्रालय

औषधि व्यवस्था विभाग

बिजुलीबजार, काठमाडौं

सम्पादक मण्डल

१)	श्री शिवानी खड्गी	-	प्रधान सम्पादक
२)	श्री सचिता जोशी	-	सम्पादक
३)	श्री किरण सुन्दर बज्राचार्य	-	सम्पादक
४)	श्री उर्मिला अधिकारी	-	सम्पादक
५)	श्री पुष्पा खत्री	-	सम्पादक
६)	श्री डा. रुपेन्द्र पूरी	-	सम्पादक
७)	श्री बिनला जोशी	-	सम्पादक

नेपाल सरकार
स्वास्थ्य तथा खाद्य स्वच्छता मन्त्रालय
औषधि व्यवस्था विभाग

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बिजुलीबजार, काठमाण्डौ, नेपाल

मेरो भनाई

औषधि व्यवस्था विभागद्वारा प्रकाशित यस वार्षिक बुलेटिनमार्फत विभागका प्रमुख गतिविधि, उपलब्धि, नियामकीय पहल तथा औषधि क्षेत्रको समग्र प्रगति सम्बन्धी जानकारी सम्पूर्ण सरोकारवाला निकाय समक्ष प्रस्तुत गर्न पाउँदा अत्यन्त हर्षित छु ।

जनस्वास्थ्यको संरक्षणका लागि गुणस्तरीय, सुरक्षित, प्रभावकारी र सहज पहुँचयोग्य औषधिको सुनिश्चितता गर्नु विभागको प्रमुख जिम्मेवारी हो । यस उद्देश्यलाई आत्मसात् गर्दै विभागले औषधि दर्ता, गुणस्तर नियमन, बजार अनुगमन, निरीक्षण तथा नियामकीय प्रणालीलाई समयानुकूल सुदृढ बनाउँदै आएको छ ।

परिवर्तनशील विश्व औषधि क्षेत्रमा देखिएका नयाँ प्रविधि, चुनौती र अवसरलाई सम्बोधन गर्न नियामक निकाय, औषधि उद्योग, स्वास्थ्यकर्मी तथा सम्पूर्ण सरोकारवालाबीचको सहकार्य र प्रतिबद्धता अत्यन्त महत्वपूर्ण रहेको छ । समयसँगै औषधि क्षेत्रले नयाँ अवसरसँगै जटिल चुनौतीहरूको सामना गरिरहेको छ । विश्वव्यापी रूपमा बढ्दो प्रतिजैविक प्रतिरोध (Antimicrobial Resistance), औषधि आपूर्ति शृङ्खलाको विविधता, प्रविधिको दुरुपयोगमार्फत हुने अनाधिकृत औषधि कारोबार, औषधिको मूल्यमा देखिने अन्तर, सीमित स्वदेशी उत्पादन क्षमता तथा नेपालको भौगोलिक अवस्थाले औषधि नियमनलाई थप चुनौतीपूर्ण बनाएको छ । साथै, औषधि विज्ञानमा भइरहेका तीव्र विकास र नवीन प्रविधिको प्रयोगले नियामकीय प्रणालीलाई निरन्तर अद्यावधिक र सक्षम बनाउँदै लैजानुपर्ने आवश्यकता सिर्जना गरेको छ । सीमित जनशक्ति र स्रोतका बाबजुद विभागले जोखिममा आधारित नियमन, गुणस्तर सुनिश्चितता, बजार अनुगमन, औषधि सुरक्षा निगरानी, डिजिटल प्रणालीको विस्तार तथा अन्तर्राष्ट्रिय मापदण्डअनुकूल नियामकीय अभ्यासलाई प्राथमिकतामा राख्दै आएको छ ।यी प्रयासहरूले औषधिको गुणस्तरप्रति जनविश्वास अभिवृद्धि गर्न तथा समग्र जनस्वास्थ्य संरक्षणमा महत्वपूर्ण योगदान पुऱ्याएको विश्वास लिएको छु ।

परिवर्तनशील विश्व परिवेशमा नेपालको औषधि नियमन प्रणालीलाई अझ प्रभावकारी, आधुनिक र विश्वसनीय बनाउन सरकार, औषधि उद्योग, स्वास्थ्यकर्मी, विज्ञ, अनुसन्धानकर्ता तथा सम्पूर्ण सरोकारवालाबीच सहकार्य र समन्वय अपरिहार्य छ । आगामी दिनमा विज्ञान, प्रविधि र अन्तर्राष्ट्रिय उत्कृष्ट अभ्यासलाई आत्मसात् गर्दै सुरक्षित तथा गुणस्तरीय औषधिको पहुँच सुनिश्चित गर्ने दिशामा विभाग निरन्तर प्रतिबद्ध रहनेछ ।

औषधि व्यवस्था विभागद्वारा प्रकाशित यस वार्षिक बुलेटिनले विभागका गतिविधि, उपलब्धि,

नियामकीय पहल, औषधि क्षेत्रका समसामयिक विषय तथा भावी कार्यदिशालाई समेट्दै औषधि क्षेत्रका सरोकारवालाहरूका लागि ज्ञान र सूचनाको उपयोगी स्रोतका रूपमा योगदान गर्ने अपेक्षा लिएको छु ।यस वार्षिक बुलेटिनको प्रकाशनमा प्रत्यक्ष तथा अप्रत्यक्ष रूपमा योगदान पुऱ्याउनुहुने सम्पूर्ण महानुभावहरूमा हार्दिक धन्यवाद व्यक्त गर्दै, यसको सफल प्रकाशन तथा उपयोगिताको लागि शुभकामना व्यक्त गर्दछु ।

शिवानी खड्गी
नि. महानिर्देशक

विषयसूची

Antimicrobial resistance & Antimicrobial Use

Antimicrobial Use in Nepal : A Critical Whistleblower for the growing threat of Antimicrobial Resistance

Kiran Sunder Bajracharya
Senior Drug Administrator, DDA

Introduction

Antimicrobial resistance (AMR) is one of the most pressing global health threats. Updated Global Burden of Disease analyses estimate that bacterial AMR was associated with more than 4.7 million deaths worldwide in 2021 and project approximately 1.91 million deaths attributable to, and 8.22 associated with, AMR by 2050 if unchecked, with significant economic and health burdens in low- and middle-income countries like Nepal. In Nepal the burden is already severe. In 2019 an estimated 6,400 deaths were directly attributable to AMR and 23,200 deaths were associated with resistant infections, placing AMR among the top three causes of death in the country. National laboratory surveillance continues to document high rates of multi-drug resistance among priority pathogens (e.g., ~51 % of E. coli, ~56 % of Klebsiella spp., ~72 % of Acinetobacter spp.).

Because the relationship between antimicrobial consumption and the emergence and spread of resistance is well established, monitoring use itself functions as a practical early-warning system. Excess volume, predominance of broad-spectrum (Watch) agents, or rising Reserve use all signal mounting selection pressure long before clinical resistance rates become irreversible. The WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS-AMU) supplies the standardized metric—defined daily doses per 1,000 inhabitants per day (DID)—needed for temporal and cross-country comparison.

The WHO AWaRe classification further stratifies antibiotics by their resistance-selection potential: Access (narrower-spectrum, first-line), Watch (higher resistance risk), and Reserve (last-resort). The 2024 United Nations General Assembly political declaration and WHO targets call for at least 70 % of total antibiotic consumption to come from the Access group by 2030.

A practical way to understand the pressure driving resistance is to examine antimicrobial use itself, since the relationship between antimicrobial use and resistance is well documented. For this reason, antimicrobial use can be treated as a kind of whistle-blower: when use is excessive, poorly targeted, or dominated by higher-risk agents, it warns that resistance pressure is rising.

National Trends In Antimicrobial Consumption (2016-2024)

Nepal's antibiotic consumption has fluctuated considerably between 2016 and 2024. Total consumption increased steadily from approximately 40 DID in 2016 to 57 DID in 2019, reflecting growing antibiotic use in both community and healthcare settings. A sharp rise occurred during the COVID-19 pandemic, peaking at 79.53 DID in 2021, likely due to widespread empirical and often inappropriate prescribing of antibiotics for viral respiratory infections, concerns about secondary bacterial infections, and increased self-medication. Following the pandemic,

consumption declined substantially to 28–33 DID during 2022–2024, suggesting a return to more routine prescribing practices.

Table 1: Total antimicrobial use (DID) by Major class, Nepal, 2016-2024

Group	2016	2017	2018	2019	2020	2021	2022	2023	2024
Antibiotics	40.37	50.83	48.89	57.10	50.15	79.53	28.48	33.27	29.43
Antivirals	0.07	0.21	NR	0.29	0.27	0.31	0.66	0.18	0.22
Antifungals	0.24	0.18	0.17	3.59	3.00	2.79	1.99	1.50	2.42
Anti-TB	0.03	0.02	0.04	0.06	0.05	0.08	0.16	1.07	0.05
Antimalarials	NR	NR	NR	0.09	0.13	0.21	0.02	0.14	0.24

NR = not reported

AWaRe Classification: The Core Stewardship Signal

The distribution of use across AWaRe categories is the most policy-relevant indicator (Figure 1). Access antibiotics reached a maximum share of only 36.2 % in 2024—still less than half the WHO/UN 70 % target. Watch-group agents accounted for 47–74 % of total antibiotic DID in every year examined. Reserve use remained low in absolute terms but showed a modest upward trend after 2021. A non-negligible fraction of consumption was classified as "Not recommended" in several pandemic-adjacent years, reflecting continued circulation of fixed-dose combinations lacking a clear evidence base.

These national figures are corroborated by independent hospital point-prevalence surveys. A nationally representative multi-hospital study reported inpatient antibiotic consumption of 29.8 % Access, 70.1 % Watch and 0.1 % Reserve; ceftriaxone and piperacillin–tazobactam dominated the Watch category. Earlier Fleming Fund–supported PPS work likewise found average antibiotic prevalence of ~69 % of inpatients, with >50 % of prescribed agents belonging to the Watch group.

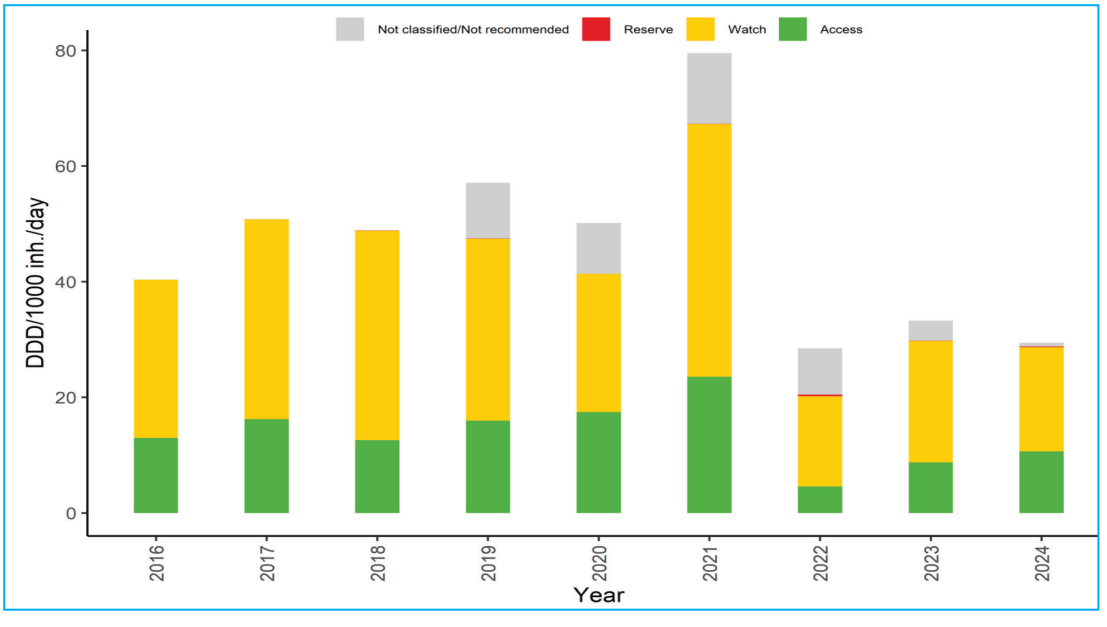


Figure 1: Use of antibiotics (DID) by AWaRe classification

Use by Antibiotic Subgroup (ATC Level 3/4) and DU75

Disaggregation to the ATC3/ATC4 level reveals the specific pharmacological drivers of resistance pressure:

- **Macrolides (J01FA):** Frequently 17–30 % of total use (e.g., 8.24 DID / ~28 % in 2024). High macrolide exposure selects for resistant Streptococcus pneumoniae and other respiratory pathogens.
- **Third-generation cephalosporins (J01DD):** Consistently 18–25 % share (5.53 DID in 2024). These agents are major drivers of extended-spectrum β-lactamase (ESBL)–producing Enterobacterales.
- **Fluoroquinolones (J01MA):** Historically dominant (up to ~29 % in 2016) but declining to ~9–10 % in recent years—a positive trend that should be protected.
- **Penicillins with β-lactamase inhibitors (J01CR) and nitroimidazoles (P01AB):** Substantial shares reflecting common treatment of respiratory and gastrointestinal infections.

Drug Utilization 75 % (DU75) analysis shows marked concentration: typically, only 5–9 substances account for three-quarters of oral antibiotic use. In recent years azithromycin and cefixime (both Watch) have ranked at the top. Parenteral DU75 is dominated by ceftriaxone, often exceeding 40 % of all parenteral antibiotic DID—mirroring the hospital PPS findings.

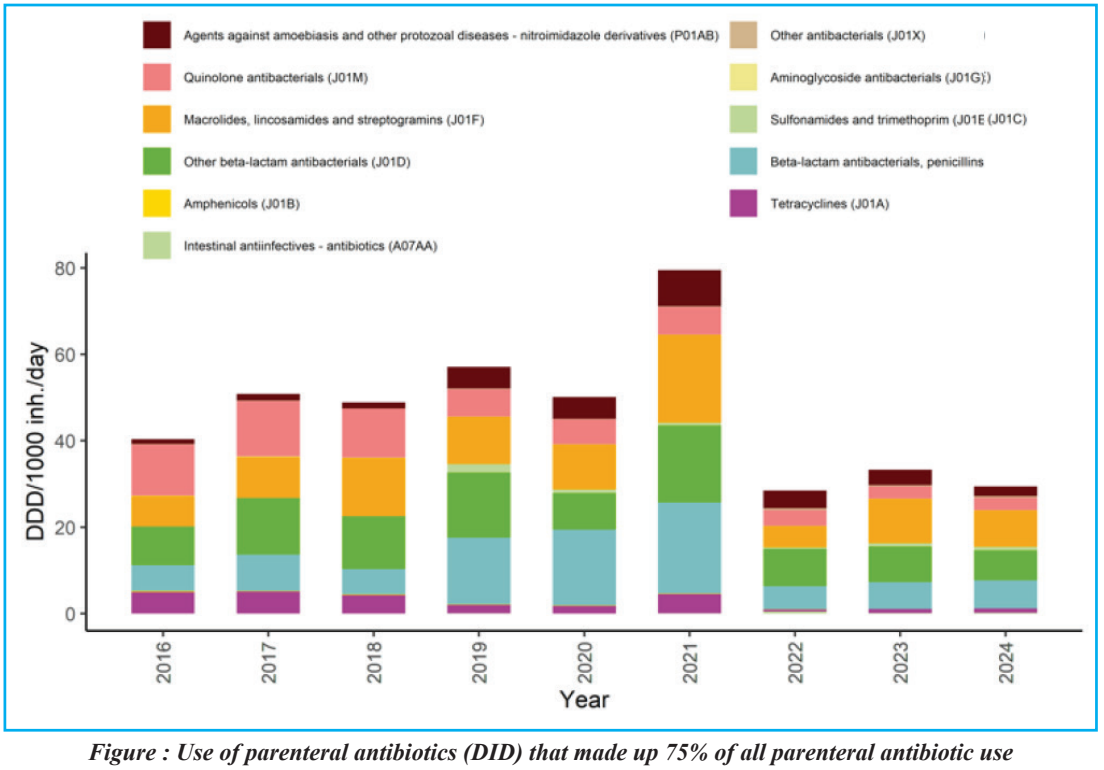
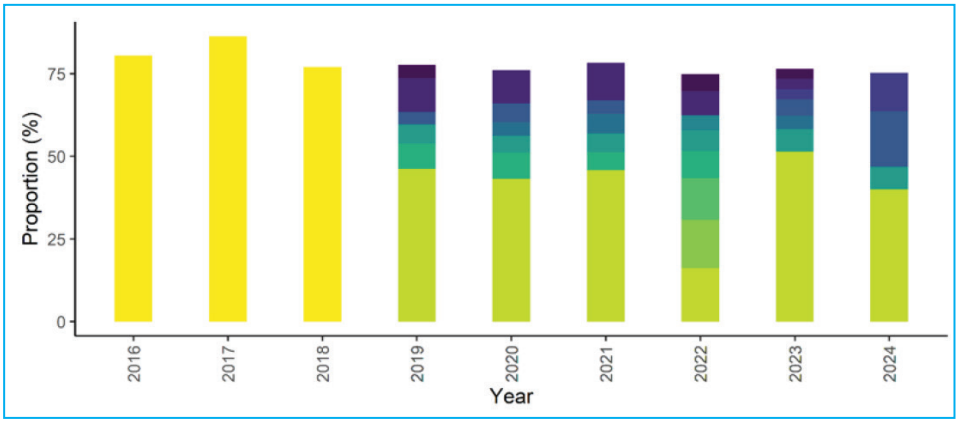


Figure : Use of parenteral antibiotics (DID) that made up 75% of all parenteral antibiotic use



Regional and Global Comparisons

Nepal's consumption levels are comparable to or exceed those in several South Asian peers, underscoring a shared regional challenge.

South Asia Snapshot (approximate DDD/1000/day from GLASS and national reports):

- Bangladesh: 27–62 DDD (high variability, oral route dominant; increased during 2021–2022).
- Pakistan: Significant consumption with projections showing continued high use; notable fluoroquinolone and cephalosporin reliance.
- India: Among the highest global consumers (often >20–30 DDD nationally, with massive total volumes due to population size). High Watch group use.
- Nepal: Averages ~30–50+ DDD, with peaks higher than some neighbors but patterns (cephalosporins, macrolides) similar.

Global Context:

- Many high-income countries report <20 DDD/1000/day with stronger stewardship.
- South-East Asia Region often shows higher resistance burdens (e.g., ~31% resistance in key infections per recent GLASS).
- Nepal's data shows higher reliance on critical antibiotics compared to optimal AWaRe distributions recommended by WHO (Access >60%, Watch/Reserve minimized).

Nepal has made progress through GLASS participation, national AMR action plans, and the Department of Drug Administration's regulatory efforts. However, data gaps (e.g., private sector coverage) and enforcement challenges remain.

Policy Landscape and Progress

Nepal enrolled in GLASS-AMU in 2020 and has submitted national data, enabling the time series presented here.[13] The revised National Action Plan for AMR (endorsed by Cabinet in 2024) adopts a One Health framing and explicitly prioritizes stewardship, surveillance expansion, and regulatory enforcement.[3] Concrete regulatory steps already taken include

mandatory red-line labelling on antibiotic packaging and restrictions on the import and sale of agents absent from WHO-recommended lists.[3]

Data gaps persist—most notably incomplete private-sector coverage and limited linkage between AMU and AMR datasets—yet the existing GLASS-aligned series already provides a sufficiently clear whistleblower signal to guide immediate action.

Recommendations

1. **Institutionalize AWaRe-based stewardship.** Adopt national and hospital guidelines that preferentially recommend Access agents; audit compliance quarterly; set facility-level targets for Access share ≥60 % within three years.
2. **Reduce high-volume Watch agents.** Prioritize stewardship interventions on azithromycin, cefixime and ceftriaxone—the substances that dominate both national DID and hospital DU75 lists.
3. **Enforce prescription-only sales and curb self-medication.** Strengthen inspection of community pharmacies and public communication campaigns on the risks of incomplete courses and non-prescription use.
4. **Expand and integrate surveillance.** Extend GLASS-AMU coverage to the private sector and primary-care settings; link AMU metrics in near-real time with AMR laboratory data to enable feedback loops.
5. **Accelerate National Action Plan implementation.** Secure dedicated financing, establish provincial stewardship committees, and publish annual public dashboards of AWaRe shares and priority-agent consumption.
6. **Regional collaboration.** Share best practices and surveillance protocols with SAARC partners facing similar Watch-group dominance.

Conclusion

Nepal's GLASS-AMU data provide a robust, standardized "whistleblower" on antimicrobial use patterns that strongly predict future AMR burdens. While total consumption has moderated post-pandemic, the persistent dominance of Watch antibiotics and low Access share signal ongoing stewardship challenges. Urgent, evidence-based interventions—guided by these data—can help preserve antibiotic efficacy, reduce treatment failures, and mitigate the public health and economic consequences of AMR in Nepal.

पशु स्वास्थ्य क्षेत्रमा प्रतिजैविक औषधि उपभोग (Antimicrobial Consumption) र प्रतिजैविक प्रतिरोध (Antimicrobial Resistance: AMR): नेपालका सन्दर्भमा चुनौती, अवस्था र नीतिगत मार्गचित्र

रितेश रिमाल
केन्द्रीय अध्यक्ष
नेपाल पशुपंक्षी औषधि व्यवसायी संघ

सारांश (Abstract)

प्रतिजैविक औषधिहरू आधुनिक पशु स्वास्थ्य व्यवस्थापनको अभिन्न हिस्सा हुन् । पशुपंक्षी क्षेत्रमा संक्रमणजन्य रोगहरूको रोकथाम, उपचार तथा उत्पादन प्रणालीको स्थायित्व सुनिश्चित गर्न प्रतिजैविक औषधिको महत्वपूर्ण भूमिका रहेको छ । तथापि, पछिल्ला दशकहरूमा यी औषधिहरूको अत्यधिक, अव्यवस्थित तथा अविवेकी प्रयोगका कारण प्रतिजैविक प्रतिरोध (Antimicrobial Resistance: AMR) विश्वव्यापी जनस्वास्थ्य चुनौतीका रूपमा उदाएको छ । पशु स्वास्थ्य क्षेत्रमा प्रतिजैविक औषधि प्रयोगले प्रतिरोधी सूक्ष्मजीवको विकासलाई तीव्रता दिन सक्ने भएकाले यसले मानव स्वास्थ्य, खाद्य सुरक्षा, कृषि उत्पादन तथा वातावरणीय स्वास्थ्यमा समेत बहुआयामिक प्रभाव पार्ने गरेको छ ।

नेपालमा पशुपालन व्यवसायको व्यावसायिक विस्तारसँगै पशु स्वास्थ्य सेवामा औषधि प्रयोग बढ्दै गएको देखिन्छ । विशेषतः पोल्ट्री, डेरी, सुँगुर तथा मत्स्य क्षेत्रमा एन्टिबायोटिक प्रयोगको मात्रा वृद्धि भएको छ । यद्यपि, प्रतिजैविक औषधि उपभोगसम्बन्धी व्यवस्थित तथ्यांक, प्रभावकारी निगरानी प्रणाली तथा सुदृढ नियमनको अभावले AMR नियन्त्रण चुनौतीपूर्ण बन्दै गएको छ । यस लेखमा पशु स्वास्थ्य क्षेत्रमा प्रतिजैविक औषधिको उपभोगको अवस्था, AMR को विकास प्रक्रिया, नेपालमा विद्यमान चुनौतीहरू तथा सम्भावित नीतिगत समाधानका विषयमा विश्लेषण गरिएको छ ।

मुख्य शब्द : प्रतिजैविक प्रतिरोध (AMR), प्रतिजैविक औषधि, पशु स्वास्थ्य, एक स्वास्थ्य, जैविक सुरक्षा, निगरानी प्रणाली, नेपाल ।

१. परिचय

प्रतिजैविक औषधिहरूले आधुनिक पशु चिकित्सा विज्ञानमा क्रान्तिकारी परिवर्तन ल्याएका छन् । ब्याक्टेरियल संक्रमणहरूको उपचार, रोग नियन्त्रण तथा पशु उत्पादन प्रणालीको प्रभावकारिता वृद्धि गर्न यिनको महत्वपूर्ण भूमिका रहेको छ । पशुपालन व्यवसायको व्यवसायीकरणसँगै पशु स्वास्थ्यमा संक्रमणजन्य रोगहरूको नियन्त्रण अपरिहार्य बन्दै गएको छ, जसका कारण एन्टिबायोटिक लगायतका प्रतिजैविक औषधिको प्रयोग विश्वव्यापी रूपमा बढेको छ ।

यद्यपि, यस्ता औषधिहरूको अनियन्त्रित, अत्यधिक वा अनुचित प्रयोगले गम्भीर स्वास्थ्य जोखिम निम्त्याइरहेको छ । विशेषतः प्रतिजैविक प्रतिरोध (AMR) अहिले विश्व स्वास्थ्य क्षेत्रकै प्रमुख चुनौतीमध्ये एकको रूपमा स्थापित भएको छ । AMR भन्नाले सूक्ष्मजीवहरूले प्रयोग भइरहेका

औषधिप्रति प्रतिरोध क्षमता विकास गर्ने प्रक्रिया बुझिन्छ, जसका कारण पहिलेदेखि प्रभावकारी रहेका औषधिहरू क्रमशः निष्प्रभावी बन्दै जान्छन् ।

विश्व स्वास्थ्य समुदायले AMR लाई शान्त महामारी "silent pandemic" को संज्ञा दिँदै यसलाई नियन्त्रण नगरे भविष्यमा सामान्य संक्रमणहरू समेत उपचार गर्न कठिन हुने चेतावनी दिँदै आएको छ । पशु स्वास्थ्य क्षेत्रमा यसको प्रभाव अझ संवेदनशील छ, किनकि पशुजन्य खाद्य पदार्थ, वातावरण तथा प्रत्यक्ष सम्पर्कमार्फत AMR मानव स्वास्थ्यमा समेत सर्न सक्ने सम्भावना रहन्छ ।

२. पशु स्वास्थ्य क्षेत्रमा प्रतिजैविक उपभोगको अवस्था

पशुपंक्षी उत्पादन प्रणालीमा प्रतिजैविक औषधिको प्रयोग मुख्यतः उपचारात्मक (Therapeutic), रोग निवारक (Prophylactic) तथा कतिपय अवस्थामा समूहगत रोग नियन्त्रण (Metaphylactic) प्रयोजनका लागि गरिन्छ । विगतमा केही मुलुकहरूमा उत्पादन वृद्धि (Growth Promotion) का लागि समेत एन्टिबायोटिक प्रयोग हुने गरेको भए तापनि हाल विश्वव्यापी रूपमा यसको प्रयोग नियन्त्रणतर्फ उन्मुख रहेको छ ।

नेपालको सन्दर्भमा पशुपालन व्यवसायको तीव्र व्यावसायिक विस्तारसँगै पशु स्वास्थ्य सेवामा औषधिको प्रयोग उल्लेखनीय रूपमा बढेको देखिन्छ । विशेषतः निम्न क्षेत्रमा प्रतिजैविक उपभोग बढी हुने गरेको पाइन्छः

- व्यावसायिक पोल्ट्री (Broiler, Layer, GP तथा Parent Stock) फार्म
- डेरी पशुपालन (गाई तथा भैंसी)
- सुँगुर तथा बाख्रा पालन
- मत्स्यपालन (Aquaculture)

पशु स्वास्थ्य क्षेत्रमा प्रचलित प्रमुख प्रतिजैविक समूहहरूमा Tetracyclines, Penicillin, Sulfonamide, Fluoroquinolone, Macrolide तथा Aminoglycoside समावेश छन् । यद्यपि, औषधिको वैज्ञानिक उपयोग, परीक्षण-आधारित उपचार तथा चिकित्सकीय परामर्शको अभ्यास अझै पूर्ण रूपमा संस्थागत भइसकेको छैन ।

कतिपय अवस्थामा किसान वा फार्म सञ्चालकहरूले लक्षणका आधारमा स्वनिर्णयबाट औषधि प्रयोग गर्ने प्रवृत्ति देखिन्छ, जसले औषधिको विवेकपूर्ण प्रयोग (Rational Use of Antimicrobials) मा चुनौती सिर्जना गरेको छ ।

३. प्रतिजैविक औषधि उपभोग वृद्धि हुनुका प्रमुख कारणहरू

३.१ व्यवसायिक पशुपालनको तीव्र विस्तार

नेपालमा मासु, दूध तथा अण्डाको बढ्दो मागसँगै पशुपालन व्यवसाय व्यवसायिक बन्दै गएको छ । उच्च उत्पादन कायम राख्न रोग नियन्त्रणमा तत्काल प्रभाव पार्ने औषधिहरूको प्रयोग बढ्नु स्वाभाविक देखिन्छ ।

३.२ जैविक सुरक्षा (Biosecurity) को कमजोर अवस्था

फार्म स्तरमा पर्याप्त जैविक सुरक्षा उपायहरू (Biosecurity Measures) को अभावले संक्रमण जोखिम बढाउने भएकाले रोग नियन्त्रणका लागि एन्टिबायोटिकमा निर्भरता बढेको देखिन्छ ।

३.३ परीक्षणविना औषधि प्रयोग

रोगको कारण पहिचान वा प्रयोगशाला परीक्षण नगरी अनुमानका आधारमा औषधि प्रयोग गर्ने प्रवृत्तिले अनावश्यक औषधि प्रयोग बढाएको छ ।

३.४ निवारक प्रयोग (Prophylactic Use)

केही अवस्थामा सम्भावित रोगको जोखिम कम गर्न अग्रिम रूपमा एन्टिबायोटिक प्रयोग गरिन्छ, जसले दीर्घकालीन रूपमा प्रतिरोध विकासलाई बढावा दिन सक्छ ।

३.५ आर्थिक दबाब र उत्पादन जोखिम

रोगका कारण उत्पादन घट्दा व्यवसायिक घाटा हुने भएकाले धेरै फार्म सञ्चालकहरूले जोखिम न्यूनीकरणका लागि अत्यधिक औषधि प्रयोग गर्ने गरेको पाइन्छ ।

४. प्रतिजैविक प्रतिरोध (AMR) को विकास प्रक्रिया

AMR प्राकृतिक जैविक प्रक्रिया भए तापनि मानव तथा पशु क्षेत्रमा प्रतिजैविक को अत्यधिक प्रयोगले यसको गति तीव्र बनाएको छ ।

जब कुनै पशुमा बारम्बार एउटै वा समान प्रकृतिका औषधिहरू प्रयोग गरिन्छ, संवेदनशील ब्याक्टेरिया नष्ट हुन्छन् भने केही प्रतिरोधी ब्याक्टेरिया जीवित रहन्छन् । समयसँगै यिनले आनुवंशिक परिवर्तन (Mutation) वा जीन आदानप्रदान (Gene Transfer) मार्फत प्रतिरोध क्षमता विकास गर्छन् । फलस्वरूप सामान्य संक्रमणहरूमा समेत उपचार कठिन बन्दै जान्छ ।

यस प्रक्रियाबाट बहुऔषधि प्रतिरोधी सूक्ष्मजीव (Multi–drug Resistant Organisms) तथा "Superbugs" को विकास हुन सक्छ, जसले उपलब्ध धेरै औषधिलाई निष्प्रभावी बनाउने जोखिम उत्पन्न गर्दछ ।

५. पशु स्वास्थ्य क्षेत्रमा AMR का प्रभावहरू

५.१ पशु स्वास्थ्यमा प्रभाव

AMR का कारण रोग उपचार जटिल बन्नुका साथै उपचार अवधि लम्बिन सक्छ । यसले पशु मृत्यु दर वृद्धि, उत्पादन क्षमता कमी तथा स्वास्थ्य व्यवस्थापन खर्च बढाउन सक्छ ।

५.२ आर्थिक प्रभाव

प्रतिरोधी संक्रमण नियन्त्रण गर्न महँगा औषधिको आवश्यकता पर्न सक्छ, जसले उत्पादन लागत बढाउँछ । साथै, अन्तर्राष्ट्रिय बजारमा खाद्य सुरक्षासम्बन्धी मापदण्ड कडा बन्दै जाँदा निर्यात क्षमतामा समेत नकारात्मक प्रभाव पर्न सक्छ ।

५.३ मानव स्वास्थ्यमा जोखिमः वन हेल्थ (One Health) दृष्टिकोण

AMR पशु क्षेत्रमा मात्र सीमित समस्या होइन । पशुमा विकसित प्रतिरोधी सूक्ष्मजीवहरू प्रत्यक्ष सम्पर्क, दूषित वातावरण वा पशुजन्य खाद्य पदार्थ (मासु, दूध, अण्डा) मार्फत मानवमा सर्न सक्ने जोखिम रहन्छ ।

यसैले AMR नियन्त्रणका लागि मानव स्वास्थ्य, पशु स्वास्थ्य तथा वातावरणीय स्वास्थ्यबीचको अन्तरसम्बन्धलाई स्वीकार गर्ने "One Health" अवधारणा अत्यन्त महत्वपूर्ण मानिन्छ ।

६. नेपालमा AMR सम्बन्धी अवस्था र चुनौतीहरू

नेपालले पछिल्ला वर्षहरूमा AMR नियन्त्रणका लागि नीतिगत पहलहरू सुरु गरेको छ । राष्ट्रिय कार्ययोजना तथा वन हेल्थ अवधारणामार्फत बहु-क्षेत्रीय सहकार्यलाई प्राथमिकता दिइएको छ । तथापि, पशु स्वास्थ्य क्षेत्रमा अझै केही महत्वपूर्ण चुनौतीहरू विद्यमान छन्-

- प्रतिजैविक उपभोगसम्बन्धी व्यवस्थित तथ्यांकको अभाव
- AMR निगरानी (Surveillance) प्रणाली सीमित हुनु
- प्रयोगशाला परीक्षण सेवाको अपर्याप्त पहुँच
- फार्म स्तरमा कमजोर अनुगमन प्रणाली
- औषधि प्रयोगसम्बन्धी जनचेतनाको कमी
- अनौपचारिक बजारमार्फत औषधि उपलब्धता

विशेषतः नेपालमा पोल्ट्री क्षेत्रलाई उच्च जोखिमयुक्त क्षेत्रको रूपमा हेरिने गरिएको छ, किनकि यहाँ संक्रमणजन्य रोगको जोखिम उच्च रहने तथा औषधि प्रयोगको मात्रा तुलनात्मक रूपमा बढी हुने गर्दछ ।

७. प्रतिजैविक उपभोग (AMC) निगरानीको आवश्यकता

प्रतिजैविक उपभोग (Antimicrobial Consumption: AMC) निगरानी भन्नाले कुन प्रकारका औषधिहरू कति मात्रामा, कहाँ र कसरी प्रयोग भइरहेका छन् भन्ने तथ्यांक संकलन तथा विश्लेषण गर्ने प्रणालीलाई बुझिन्छ ।

AMC निगरानीका प्रमुख उद्देश्यहरू निम्न छन्-

- औषधि प्रयोगको वास्तविक अवस्था पहिचान
- जोखिमयुक्त क्षेत्रहरूको पहिचान
- अनावश्यक वा अनुचित प्रयोग नियन्त्रण
- नीतिगत निर्णयमा सहयोग
- AMR रोकथाम रणनीति विकास

नेपालमा AMC प्रणाली अझै प्रारम्भिक चरणमा रहेकाले राष्ट्रिय स्तरको डिजिटल डेटा प्रणाली तथा नियमित प्रतिवेदन प्रणाली विकास गर्नु आवश्यक देखिन्छ ।

८. एन्टिबायोटिकको अविवेकी प्रयोगका चुनौतीहरू

पशु क्षेत्रमा एन्टिबायोटिकको अविवेकी प्रयोगले प्रतिरोध विकासलाई तीव्रता दिने गरेको छ । विशेषत: निम्न अभ्यासहरू जोखिमपूर्ण मानिन्छन्-

- किसानद्वारा स्वनिर्णयमा औषधि प्रयोग (Self–medication)
- निर्धारित मात्रा भन्दा कम वा बढी प्रयोग (Under/Over-dosing)
- औषधिको उपचार अवधि पूरा नगर्नु
- Withdrawal Period पालना नगर्नु
- विभिन्न औषधिको अनियन्त्रित मिश्रण (Mix Formulations)

यी अभ्यासहरूले औषधिको प्रभावकारिता घटाउनुका साथै खाद्य सुरक्षामा समेत चुनौती सिर्जना गर्न सक्छन् ।

९. समाधान तथा नीतिगत रणनीतिहरू

९.१ नियमन तथा नीतिगत सुधार

पशु क्षेत्रमा एन्टिबायोटिकको विवेकपूर्ण प्रयोग सुनिश्चित गर्न Prescription-only Policy लाई प्रभावकारी रूपमा कार्यान्वयन गर्नु आवश्यक छ । पशु चिकित्सकको सिफारिसबिना औषधि प्रयोग तथा बिक्री नियन्त्रणतर्फ विशेष ध्यान दिनुपर्छ ।

९.२ AMC तथा AMR Surveillance सुदृढीकरण

राष्ट्रिय स्तरको डेटा प्रणाली स्थापना, प्रयोगशाला सञ्जाल विस्तार तथा नियमित निगरानी संयन्त्र विकासमार्फत AMR नियन्त्रणलाई सुदृढ गर्न सकिन्छ ।

९.३ जैविक सुरक्षा सुधार

फार्म स्तरमा स्वच्छता, Quarantine प्रणाली, Vaccination कार्यक्रम तथा संक्रमण नियन्त्रण उपायहरू सुदृढ गर्न सके एन्टिबायोटिक निर्भरता उल्लेखनीय रूपमा घटाउन सकिन्छ ।

९.४ क्षमता अभिवृद्धि र जनचेतना

किसान, पशु प्राविधिक, औषधि व्यवसायी तथा पशु चिकित्सकहरूको नियमित तालिम तथा सचेतना कार्यक्रम आवश्यक छ । जिम्मेवार औषधि प्रयोगसम्बन्धी सन्देश प्रभावकारी रूपमा प्रवाह गर्नुपर्ने देखिन्छ ।

९.५ वैकल्पिक उपायहरूको प्रवर्द्धन

एन्टिबायोटिकको विकल्पका रूपमा Immunomodulators, Essential Oils, Probiotics, Prebiotics तथा Herbal Feed Additives जस्ता उपायहरूको प्रयोगलाई प्रोत्साहन गर्न सकिन्छ ।

१०. एक स्वास्थ्य अवधारणाको (One Health Approach) अपरिहार्यता

AMR नियन्त्रणका लागि एकल क्षेत्रीय प्रयास पर्याप्त हुँदैन । मानव, पशु तथा वातावरणीय स्वास्थ्य एकअर्कासँग गहिरो रूपमा जोडिएका भएकाले बहु-क्षेत्रीय समन्वय आवश्यक हुन्छ ।

एक स्वास्थ्य दृष्टिकोण अन्तर्गत:

- चिकित्सक
- पशु चिकित्सक
- वातावरण विज्ञ
- अनुसन्धान संस्था
- नीति निर्माता
- औषधि नियामक निकाय

बीचको सहकार्य अपरिहार्य हुन्छ । नेपालजस्तो कृषि-आधारित अर्थतन्त्रमा यस अवधारणालाई संस्थागत रूपमा सुदृढ गर्नु समयको आवश्यकता हो ।

११. निष्कर्ष

प्रतिजैविक औषधिहरू पशु स्वास्थ्य तथा पशुपंक्षी उत्पादन प्रणालीका लागि अत्यन्त महत्वपूर्ण साधन हुन् । तथापि, यिनको अनियन्त्रित तथा अविवेकी प्रयोगले प्रतिजैविक प्रतिरोधको गम्भीर संकट निम्त्याइरहेको छ । नेपालमा पशुपालन व्यवसायको तीव्र व्यवसायीकरणसँगै AMR जोखिम अझ बढ्दो अवस्थामा रहेको देखिन्छ ।

यदि समयमै प्रतिजैविक औषधि उपभोग निगरानी, AMR Surveillance, फार्म स्तरको जैविक सुरक्षा, चिकित्सकीय सुपरिवेक्षण तथा जनचेतना कार्यक्रमलाई प्राथमिकतामा राखिएन भने भविष्यमा सामान्य संक्रमणहरूको उपचार समेत चुनौतीपूर्ण बन्न सक्छ ।

यसकारण, औषधि व्यवस्था विभाग, पशु सेवा निकाय, पशु चिकित्सक, औषधि व्यवसायी, किसान तथा नीति निर्माताहरूबीच समन्वित प्रयासमार्फत "Responsible and Rational Use of Antimicrobials" लाई संस्थागत गर्न आवश्यक छ । यही प्रयासले मात्र पशु स्वास्थ्य, जनस्वास्थ्य तथा खाद्य सुरक्षाको दिगो संरक्षण सम्भव हुनेछ ।

सिफारिसहरू (Recommendations)

१. पशु क्षेत्रमा Veterinary Antimicrobial Use Guideline कडाइका साथ लागू गर्ने ।
२. राष्ट्रिय स्तरमा AMC तथा AMR Surveillance Network विस्तार गर्ने ।
३. फार्म स्तरमा अनिवार्य Veterinary Supervision लागू गर्ने ।
४. औषधि बिक्री तथा अनुगमन प्रणाली डिजिटलाइज गर्ने ।
५. एक स्वास्थ्यमा आधारित राष्ट्रिय रणनीति प्रभावकारी रूपमा कार्यान्वयन गर्ने ।
६. Biosecurity तथा Vaccination कार्यक्रम विस्तार गरी एन्टिबायोटिक निर्भरता घटाउने ।
७. वैकल्पिक उपायहरूको अनुसन्धान तथा प्रयोगलाई प्रोत्साहन गर्ने ।

नेपालमा प्रतिजैविक औषधिको उत्पादन, आयात, वितरण, खपत तथा प्रतिरोधः वर्तमान अवस्था र चुनौती

पवन आचार्य
अध्यक्ष
नेपाल औषधि आयातकर्ता संघ (MIAN)

प्रतिजैविक औषधिको विकास आधुनिक चिकित्सा विज्ञानको सबैभन्दा महत्वपूर्ण उपलब्धिमध्ये एक हो । कुनै समय सामान्य संक्रमणका कारण मृत्यु हुने अवस्था रहेको मानव समाज आज प्रतिजैविक औषधिकै कारण सुरक्षित जीवनतर्फ अघि बढ्न सफल भएको छ । निमोनिया, टाइफाइड, क्षयरोग, सेप्सिस, शल्यक्रियापछिका संक्रमण तथा अन्य धेरै संक्रामक रोगहरूको प्रभावकारी उपचार प्रतिजैविक औषधिको उपलब्धताले सम्भव बनाएको हो ।

पछिल्ला केहि वर्षहरूमा प्रतिजैविक औषधिको अत्याधिक तथा अनुचित प्रयोगका कारण विश्वव्यापी रूपमा प्रतिजैविक प्रतिरोध (Antimicrobial Resistance, AMR) तीव्र रूपमा बढिरहेको छ । विश्व स्वास्थ्य संगठन (WHO) ले प्रतिजैविक प्रतिरोधलाई मानव स्वास्थ्यका लागि सबैभन्दा ठूलो सार्वजनिक स्वास्थ्य चुनौतीमध्ये एकको रूपमा पहिचान गरेको छ । नेपाल पनि यस समस्याबाट अछुतो रहेको छैन । नेपालको स्वास्थ्य क्षेत्रमा प्रतिजैविक औषधिको प्रयोग उल्लेखनीय रूपमा बढिरहेको छ । निजी स्वास्थ्य सेवा विस्तार, समुदायस्तरमा औषधिको सहज उपलब्धता, आफैं औषधि सेवन गर्ने बानी (self-medication) चिकित्सकको सल्लाहबिना औषधि सेवन तथा broad-spectrum antibiotics को बढ्दो प्रयोगले प्रतिजैविक औषधिको उपभोग (Antimicrobial Consumption, AMC) वृद्धि भइरहेको छ । यससँगै Resistant Microorganisms को वृद्धिले भविष्यको उपचार प्रणालीलाई जटिल बनाउने संकेत देखिएको छ । यस्तो अवस्थामा प्रतिजैविक औषधिको आयात, उत्पादन, सिफारिस, गुणस्तर नियन्त्रण तथा विक्री-वितरण प्रणालीलाई थप व्यवस्थित र वैज्ञानिक बनाउनु अत्यन्त आवश्यक भइसकेको छ । यस कार्यमा औषधि व्यवस्था विभाग (DDA), स्वास्थ्यकर्मी, औषधि आयातकर्ता, औषधि उद्योग, वितरक तथा सम्पूर्ण सरोकारवालाहरूको साझा भूमिका रहन्छ ।

प्रतिजैविक औषधि सम्बन्धि वर्तमान अवस्था

नेपाल जस्तो विकासोन्मुख मुलुकमा संक्रामक रोगहरू अझै पनि मुख्य स्वास्थ्य समस्याका रूपमा रहेका छन् । स्वास्थ्य शिक्षा, व्यक्तिगत सरसफाई, शहरीकरण, जनसंख्या वृद्धि, वातावरणीय प्रदूषण, स्वास्थ्य सेवामा असमान पहुँच, तथा संक्रमणजन्य रोगहरूको वृद्धिका कारण प्रतिजैविक औषधिको आवश्यकता र माग दिन प्रतिदिन बढिरहेको छ । विशेषगरी विभिन्न रोगहरु, महामारी तथा सरुवा रोगहरु तथा अस्पतालजन्य संक्रमणहरूको उपचारमा प्रतिजैविक औषधिको प्रयोग व्यापक रूपमा भइरहेको छ । कोविड-१९ महामारीमा नेपालमा प्रतिजैविक औषधिको प्रयोग उच्च रहेको देखिएको थियो । भाईरल संक्रमण लगायतका संक्रमण रोकथामका नाममा समेत प्रतिजैविक औषधिको प्रयोग गर्ने अभ्यासले

प्रतिजैविक औषधिको उपभोग (AMC) वृद्धि गर्न योगदान पुऱ्याएको छ । नेपालमा प्रयोग हुने प्रतिजैविक औषधिहरु विदेशी औषधिहरु आयात तथा स्वदेशी औषधिहरु उद्योगहरूको उत्पादन मार्फत उपलब्ध हुने गरेका छन् । ति मध्ये नयाँ, सुइजन्य तथा आरक्षित वर्गका एन्टिबायोटिक (Reserve Category Antibiotic) का औषधिहरूका लागि नेपाल अझै आयातमा निर्भर रहेको छ ।

प्रतिजैविक औषधिको उत्पादन तथा आयातको बिधि

नेपालमा प्रतिजैविक औषधिको आयात, उत्पादन तथा वितरणसम्बन्धी कार्य औषधि व्यवस्था विभागले नियमन गर्दछ । औषधि ऐन, २०३५, औषधि दर्ता नियमावली, २०३८, औषधि दर्ता कार्यविधि २०७२, राष्ट्रिय औषधि नीति कानूनी आधारका रूपमा रहेका छन् । यी कानून तथा नीतिहरूको मुख्य उद्देश्य गुणयुक्त, असर्युक्त र जनसुरक्षित औषधिहरुको समुचित प्रयोग सुनिश्चित गर्नुका साथै प्रतिजैविक प्रतिरोध (AMR) नियन्त्रण गर्नु हो ।

नेपालमा प्रतिजैविक लगायतका अन्य औषधि उत्पादन गर्न चाहनेले औषधि उद्योग दर्ता गरी औषधि व्यवस्था विभागबाट उत्पादन अनुमति लिनुपर्छ । उत्पादन गर्न लागिएको प्रत्येक औषधिको छुट्टाछुट्टै दर्ता आवश्यक हुन्छ । विभागले औषधि उद्योगको भौतिक संरचना, जनशक्ति, उपकरण तथा गुणस्तर प्रणालीको निरीक्षण गरी औषधि उत्पादन स्वीकृति प्रदान गर्दछ ।यसका साथै औषधिको उत्पादन सुविधा, रासायनिक संरचना, डोसेज फर्म, कच्चा पदार्थको स्रोत, उत्पादन प्रक्रिया, गुणस्तर परीक्षण प्रतिवेदन, स्थायित्व परीक्षण (stability test), प्याकेजिङ तथा लेबलिङसम्बन्धी सम्पूर्ण विवरण पेश गर्नुपर्छ । औषधि उत्पादन गर्ने उद्योगले Good Manufacturing Practice -GMP) मापदण्ड पालना गर्न अनिवार्य गरिएको छ ।

प्रतिजैविक लगायतका अन्य औषधिको आयातका लागि विदेशी उत्पादक कम्पनीका नेपालस्थित आधिकारिक आयातकर्ताले विभागबाट औषधि दर्ता तथा आयात अनुमति लिनुपर्छ । आयात प्रक्रियामा विदेशी उत्पादकको भौतिक निरीक्षण गरि औषधि उद्योगको भौतिक संरचना, जनशक्ति, उपकरण तथा गुणस्तर प्रणालीको सुनिस्चितता गरि मात्र विभागमा उत्पादक दर्ता पश्चात प्रत्येक औषधिको उत्पादन गर्ने देशमा दर्ता रहेको अद्यावधिक उत्पादन प्रमाणपत्र, WHO–GMP प्रमाणपत्र, गुणस्तर परीक्षण प्रतिवेदन, स्थायित्व परीक्षण (stability test), मूल्य, Certificate of Pharmaceutical Product (CoPP) लगायतका आवश्यक कागजात र विवरणहरु पेश गर्नुपर्छ । विभागले आवश्यक देखेमा नमुना परीक्षण गरी तोकिएको शुल्क लिई बजारमा बिक्री वितरणको अनुमति दिन्छ । यस प्रक्रियाले न्यून गुणस्तर भएका वा नक्कली औषधिको आयात तथा बिक्रि वितरण गर्ने अवस्था रहदैन ।

औषधि व्यवस्था विभागको भूमिका

औषधि व्यवस्था विभागको प्रभावकारी नियमनका कारण नेपालमा गुणस्तरीय औषधिको पहुँच विस्तारमा महत्वपूर्ण योगदान पुगेको छ । विभागले औषधिको दर्ता प्रक्रिया वैज्ञानिक मूल्यांकनका आधारमा गर्ने गर्दछ । विभागले औषधि ऐन, २०३५, औषधि दर्ता नियमावली, २०३८, औषधि दर्ता कार्यविधि २०७२ तथा राष्ट्रिय औषधि नीतिको अधिनमा रही औषधि आयातकर्ता, औषधि उत्पादक, औषधिका थोक विक्रेता, खुद्रा फार्मेसी तथा अस्पताल फार्मेसी दर्ता गरि तिनको निरीक्षण/अनुगमनका साथै बिभाग अन्तर्गतको राष्ट्रिय

औषधि प्रयोगशालाले औषधिको गुणस्तर परिक्षण गर्ने कार्य गर्दछ । यसको मुख्य उद्देश्य नागरिकलाई जनसुरक्षित, गुणयुक्त र असरयुक्त औषधिको उपलब्धता सुनिश्चित गर्नु हो ।

गुणस्तर नियन्त्रण र Post–marketing Surveillance

विभागले Post-Marketing Surveillance (PMS) सम्बन्धि कार्यविधि तयार गरि प्रत्येक वर्ष औषधिको गुणस्तर निगरानीका लागि Post Marketing Surveillance (PMS) कार्यक्रम सञ्चालन गरेको छ । यस अन्तर्गत बजारमा बिक्री-वितरण भइरहेका औषधिको नमुना संकलन गरी राष्ट्रिय औषधि प्रयोगशालामा परीक्षण गरिन्छ । गुणस्तरहीन, नक्कली वा मापदण्डविपरीतका औषधि भेटिएमा बिक्री रोक्का, फिर्ता (recall) तथा अन्य कानूनी कारबाही गरिन्छ । विभागले प्रत्येक आ.व. मा सो सम्बन्धि प्रतिबेदन सार्वजनिक गर्ने गरेकाले बजारमा गुणयुक्त, असरयुक्त र जनसुरक्षित औषधिको उपलब्धता सुनिस्चित गरेको छ ।

प्रतिजैविक औषधिको वितरण प्रणाली

स्वदेशी औषधि उत्पादकले आफ्नो उत्पादन तोकिएका थोक औषधि बिक्रेता मार्फत र औषधि आयातको हकमा अधिकारिक आयातकर्ताले औषधिका थोक बिक्रेता मार्फत खुद्रा फार्मेसी, अस्पताल फार्मेसीलाई बिक्री-वितरण गरिन्छ । खुद्रा फार्मेसी, अस्पताल फार्मेसी तथा स्वास्थ्य संस्थामार्फत बिरामीसम्म औषधि पुग्छ । यस सम्पूर्ण प्रणालीको नियमन तथा निरिक्षण/अनुगमन औषधि व्यवस्था विभागले गरि ऐन, नियम तथा कार्यविधि र संहिताको पूर्ण पालनाको सुनिश्चितता गर्दछ ।

व्यवहारिक रूपमा नेपालमा प्राय: प्रतिजैविक औषधि समूह "ख" अन्तर्गत डाक्टरको सिफारिसमा बिक्री-वितरण गर्नुपर्ने श्रेणीमा पर्दछन । समूह "क" र "ख" का औषधिहरु चिकित्सकको प्रेस्क्रिप्सन बिना बिक्री-वितरण र प्रयोग गर्न नपाइने व्यवस्था छ । अस्पतालमा सामान्यत: चिकित्सकको सिफारिस अनुसार फार्मेसीबाट औषधि वितरण हुन्छ र केही हदसम्म यो प्रणाली व्यवस्थित देखिन्छ । तर सामुदायिक तथा खुद्रा फार्मेसीमा भने यो नियम पूर्ण रूपमा पालना भएको छैन । धेरै ठाउँमा बिरामीहरूले चिकित्सकलाई नदेखाई सिधै फार्मेसीबाट प्रतिजैविक औषधि खरिद गर्ने गरेको पाईन्छ ।व्यवहारमा सामान्य ज्वरो, रुघाखोकी, घाँटी दुख्ने वा पखाला जस्ता सामान्य लक्षणमा पनि मानिसहरूले तुरुन्त प्रतिजैविक औषधिको प्रयोग गर्ने बानी छ । फार्मेसी सञ्चालकले समेत बिरामीको दबाब वा व्यापारिक कारणले बिना प्रेस्क्रिप्सन औषधि दिने गरेको देखिन्छ । यस प्रकारको आफैं औषधि प्रयोग गर्ने बानी (Self-Medication) र अनुचित प्रयोग (Irrational Use) ले अनावश्यक प्रयोग बढिरहेको र दीर्घकालमा प्रतिजैविक प्रतिरोध (AMR) जस्ता गम्भीर समस्यालाई बढावा दिएको देखिन्छ ।

प्रतिजैविक औषधिको उपभोग (AMC) र प्रतिजैविक प्रतिरोध (AMR) को वर्तमान अवस्था

प्रतिजैविक औषधिको उपभोग (AMC) भन्नाले निश्चित समय र निश्चित जनसंख्यामा कति मात्रामा प्रतिजैविक औषधि प्रयोग भयो भन्ने मापनलाई जनाउँछ । AMC को सही निगरानी गर्नु प्रतिजैविक प्रतिरोध (AMR) नियन्त्रणको अत्यन्त महत्वपूर्ण आधार हो, किनकि औषधिको अनावश्यक वा अत्यधिक प्रयोगले

सूक्ष्मजीवहरूमा प्रतिरोध क्षमताको विकास गराउँछ । नेपालमा पछिल्ला वर्षहरूमा प्रतिजैविक औषधिको को प्रयोग उल्लेखनीय रूपमा बढेको देखिन्छ । विशेषगरी Meropenem, Vancomycin, Clindamycin, Azithromycin, Cefixime, Ceftriaxone, Ciprofloxacin, Amoxicillin-clavulanic acid जस्ता औषधिहरू धेरै प्रयोग भइरहेका छन् । यीमध्ये धेरै प्रतिजैविक औषधि WHO को Watch category मा पर्छन्, जसको अर्थ यी औषधि प्रभावकारी भए पनि अनियन्त्रित प्रयोग भएमा प्रतिरोध (Resistance) विकासको जोखिम धेरै हुन्छ । कोविड-१९ महामारीका समयमा त भाइरल संक्रमण भएकै अवस्थामा पनि प्रतिजैविक औषधिको को अत्याधिक प्रयोग भएकाले प्रतिजैविक औषधिको उपभोग बढ्न गै प्रतिजैविक प्रतिरोध (AMR) सम्बन्धि समस्या बढ्न गएको थियो ।

प्रतिजैविक प्रतिरोध (AMR) भनेको Bacteria, Virus, Fungi वा Parasites ले औषधिको प्रभावलाई जित्ने वा प्रतिरोध गर्ने क्षमता विकास गर्नु हो । यसले गर्दा पहिले सजिलै निको हुने संक्रमणहरू उपचार गर्दा समेत निको नहुने वा उपचार अवधि लामो हुने हुन्छ र कहिलेकाहीँ मृत्युको जोखिम समेत हुन्छ । हालका दिनमा बिरामीहरुको प्रयोगशाला परिक्षण प्रतिवेदनहरुमा Multidrug-resistant बढ्दै गएको देखिएकोले यो समस्या गम्भीर बन्दै गैरहेको छ ।

प्रतिजैविक प्रतिरोध (AMR) का प्रमुख कारणहरू:

१. **प्रतिजैविक औषधिको अत्याधिक प्रयोग**

सामान्य ज्वरो, रुघाखोकी, घाँटी दुख्ने जस्ता हल्का संक्रमणमा पनि आवश्यक नभई प्रतिजैविक औषधिको प्रयोग गर्ने अभ्यास व्यापक छ । यसले सूक्ष्मजीवहरूमा औषधिप्रति प्रतिरोध विकास गराउँछ ।

२. **आफैं औषधि प्रयोग गर्ने बानी (Self–medication)**

चिकित्सकको सल्लाह वा सिफारिस बिना फार्मेसीबाट आफै औषधि किनेर खानाले गलत औषधि वा गलत डोज प्रयोग हुँदा प्रतिरोध बढ्छ ।

३. **औषधि पूरा नखाने बानी (Incomplete dosage)**

रोगका लक्षण कम भएपछि औषधि बीचमै सेवन गर्न बन्द गर्नाले सबै जीवाणु नष्ट हुँदैनन् । बाँकी रहेका जीवाणुहरू बलिया भएर उक्त औषधिप्रति प्रतिरोध (Resistant) विकाश गर्छन ।

४. **Broad–spectrum antibiotics को अत्यधिक प्रयोग**

सामान्य संक्रमणमा पनि आवश्यकभन्दा शक्तिशाली broad-spectrum antibiotics प्रयोग गर्दा समेत प्रतिजैविक औषधिको प्रतिरोध बढ्न जान्छ ।

५. **Hospital-Acquired Infections (HAIs)**

अस्पताल तथा स्वास्थ्य संस्थामा उपकरणहरूको sterilization तथा संक्रमण नियन्त्रण प्रभावकारी नभएको अवस्थामा बिरामीहरूमा अस्पतालबाटै नयाँ संक्रमण सर्ने वा फैलिने हुँदा प्रतिजैविक औषधिको प्रतिरोध बढ्न सक्छ ।

६. **पशुपन्छी क्षेत्रमा प्रतिजैविक औषधिको अनियन्त्रित प्रयोगः**

नेपालमा पशुपालन क्षेत्रमा प्रतिजैविक औषधिको प्रयोग भेटेरिनरी चिकित्सक तथा बिशेषज्ञको परामर्श बिना नै गर्ने गरिएको छ जस्तै : कुखुरा र अन्य पशुमा छिटो तौल बढाउन, रोग लाग्नुभन्दा अगाडि नै रोगको रोकथाम आदिका लागि अनावश्यक प्रयोगबाट मासु तथा पशुजन्य पदार्थको सेवन मार्फत मानिसमा समेत प्रतिरोध विकाश हुन सक्छ ।

प्रतिजैविक प्रतिरोध (AMR) का असरहरू

प्रतिजैविक प्रतिरोध (AMR) बढ्दै गएमा भविष्यमा सामान्य संक्रमणहरूको उपचार समेत कठिन वा कहिलेकाहीँ असम्भव हुन सक्छ । यसको प्रत्यक्ष असर देशकै स्वास्थ्य प्रणाली र बिरामी दुवैमा गम्भीर रूपमा देखिन्छ । उपचारका लागि थप महँगा औषधि, लामो उपचार अवधि र बारम्बार परीक्षण आवश्यक पर्ने भएकाले उपचार खर्च उल्लेखनीय रूपमा वृद्धि हुन्छ । साथै, सामान्यतया छिटो निको हुने संक्रमणहरू पनि प्रतिरोध हुँदा बिरामीहरूलाई अस्पतालमा लामो समय बस्नुपर्ने अवस्था आउँछ, जसले आर्थिक र मानसिक बोझ बढाउँछ । उपयुक्त औषधिले काम नगर्दा संक्रमण नियन्त्रण कठिन हुने भएकाले मृत्यु दर पनि बढ्ने जोखिम उच्च रहन्छ । यस्तो अवस्थामा पहिले प्रयोग हुने सामान्य प्रतिजैविक औषधि प्रभावहीन भएपछि आरक्षित वर्गका एन्टिबायोटिक (Reserve Category Antibiotic) मा निर्भरता बढ्छ, जुन सीमित र साइड इफेक्ट बढी हुने औषधि हुन् । यसले विशेषगरी शल्यक्रिया, ICU उपचार, क्यान्सर उपचार तथा अन्य critical care सेवाहरूलाई अझ जटिल र जोखिमपूर्ण बनाउँछ, किनकि यस्ता सेवामा संक्रमण नियन्त्रण अत्यन्त महत्वपूर्ण हुन्छ । यदि प्रतिजैविक प्रतिरोध (AMR) नियन्त्रण प्रभावकारी रूपमा गर्न सकिएन भने भविष्यमा धेरै प्रतिजैविक औषधि क्रमशः प्रभावहीन बन्ने र आधुनिक चिकित्सा प्रणालीमा नै ठूलो चुनौतीमा आउन सक्ने जोखिम रहन्छ ।

औषधि आयातकर्ता क्षेत्रको जिम्मेवारी

नेपालमा नेपाल औषधि आयातकर्ता संघ (Medicine Importers Association of Nepal, MIAN) ले प्रतिजैविक लगायतका सम्पूर्ण गुणयुक्त, असरयुक्त, जनसुरक्षित तथा वैज्ञानिक रूपमा प्रमाणित औषधिहरुको आपूर्ति र वितरण सुनिश्चित गर्न महत्वपूर्ण भूमिका खेल्दै आएको छ । प्रतिजैविक औषधि लगायतका औषधिहरुको उपलब्धताका साथै प्रतिजैविक औषधिको उपभोग (AMC) र प्रतिजैविक प्रतिरोध (AMR) सँग समेत जोडिएको हुनाले MIAN सार्वजनिक स्वास्थ्य प्रणालीको एक जिम्मेवार साझेदारका रूपमा रहेको छ । MIAN को मुख्य भूमिकामध्ये औषधि व्यवस्था विभागले तोकेका मापदण्ड पुरा गरि गुणयुक्त, असरयुक्त, जनसुरक्षित तथा वैज्ञानिक रूपमा प्रमाणित औषधिहरुको आपूर्ति र वितरण सुनिश्चित गर्नु हो । यसले गुणस्तरहीन तथा नक्कली औषधिको आयात तथा वितरणको जोखिम घटाएर प्रतिजैविक औषधिको उपभोग (AMC) को अनियन्त्रित वृद्धि, सही वितरण प्रणालीको विकाशका साथै औषधिको तोकिएका गुणस्तर कायम रहने गरि उपभोक्तासम्म पुग्ने सुनिश्चितता गर्ने गरेको छ ।

औषधि व्यवस्था विभाग (DDA) सँग MIAN ले सहकार्य गर्दै तोकिएका प्रावधान पुरा गरि औषधि उद्योग तथा औषधि दर्ता प्रक्रिया, आयात अनुमति, प्रमाणपत्र तथा सिफारिसपत्रको नवीकरण, ऐन, नियम तथा संहिताको पूर्ण पालना तथा एयकत Marketing Surveillance (PMS) मा सक्रिय सहयोग पुऱ्याईरहेको

छ । बजारमा गुणस्तरीय प्रतिजैविक औषधिको उपलब्ध गराउने, अवैध, नक्कली तथा गुणस्तरहीन औषधिको आयात निषेध गर्ने तथा औषधि फिर्ता (Recall) प्रक्रियामा सहयोग गर्ने कार्यमा समेत सहयोग गरिरहेको छ । यसका साथै देशकै स्वास्थ्य प्रणाली (Healthcare System) का अन्य सरोकारवालाहरुसँग समेत समन्वय र सहकार्य गरिरहेको छ । चिकित्सक, फर्मासिस्ट, नर्स तथा अन्य स्वास्थ्यकर्मीसंग सहकार्य गर्दै प्रतिजैविक औषधिको प्रयोगलाई जिम्मेवार बनाउन कार्य गरिरहेको छ । साथै चिकित्सक, फर्मासिस्ट, नर्स तथा अन्य स्वास्थ्यकर्मीले संचालन गर्ने प्रतिजैविक औषधिको उपभोग (AMC) तथा प्रतिजैविक प्रतिरोध (AMR) सम्बन्धि वैज्ञानिक कार्यशाला, गोष्ठी तथा जनचेतनाका कार्यक्रमहरुमा आफै वा आफ्ना सदस्यहरु मार्फत सहकार्य गर्दै आईरहेको छ । यसरि औषधि व्यवस्था विभागले तोकेका मापदण्ड पुरा गरि गुणयुक्त, असरयुक्त, जनसुरक्षित तथा वैज्ञानिक रूपमा प्रमाणित प्रतिजैविक औषधिहरुको आपूर्ति र वितरण, प्रतिजैविक औषधिको समुचित प्रयोग सुनिश्चित गर्दै प्रतिजैविक औषधिको उपभोग (AMC) नियन्त्रण तथा प्रतिजैविक प्रतिरोध (AMR) रोकथाममा महत्वपूर्ण योगदान पुऱ्याउने कार्य गर्दै आईरहेको छ ।

निष्कर्ष

प्रतिजैविक औषधि आधुनिक स्वास्थ्य सेवामा रोगको उपचारका लागि महत्वपुर्ण आधारभूत औषधिहरु हुन । यिनको अनुचित तथा अत्यधिक प्रयोगले दिनानुदिन प्रतिजैविक प्रतिरोध (AMR) को गम्भीर संकट सिर्जना गरिरहेको छ । नेपालमा प्रतिजैविक औषधिको आयात, दर्ता, वितरण तथा प्रयोग प्रणालीलाई अझ वैज्ञानिक, जिम्मेवार, व्यवस्थित तथा प्रभावकारी बनाउनु अहिलेको आवश्यकता हो । औषधि व्यवस्था विभाग, औषधि आयातकर्ता, औषधि उद्योग, चिकित्सक, फर्मासिस्ट, नर्स तथा अन्य स्वास्थ्यकर्मीले तथा सम्पूर्ण सरोकारवालाहरूबीचको सहकार्यबाट मात्र प्रतिजैविक औषधिको उपभोग (AMC) मा नियन्त्रण तथा प्रतिजैविक प्रतिरोध (AMR) नियन्त्रण सम्भव छ । MIAN गुणयुक्त, असरयुक्त, जनसुरक्षित तथा वैज्ञानिक रूपमा प्रमाणित प्रतिजैविक औषधिहरुको आपूर्ति, वितरण, तथा समुचित प्रयोग सुनिश्चित गर्दै भविष्यका पुस्ताका लागि प्रभावकारिता सुरक्षित कायम राख्न कार्य गर्दै आईरहेको छ । आउदो पुस्तालाई अनुचित प्रतिजैविक औषधि प्रतिरोध (AMR) मुक्त बनाएर स्वस्थ नेपाल निर्माणमा नेपाल औषधि आयातकर्ता संघ (Medicine Importers Association of Nepal, MIAN) राज्य, नागरिक तथा सरोकारवालासङ्ग हातेमालो गर्न सधै तत्पर रहनेछ । धन्यवाद ।

प्रतिजैविक औषधिको बढ्दो प्रयोग र प्रतिरोध (Antimicrobial Resistance): नेपालका लागि गम्भीर सार्वजनिक स्वास्थ्य चुनौती

प्रकाश कुमार खण्डेवाल
केन्द्रीय अध्यक्ष
नेपाल औषधि व्यवसायी संघ

१. प्रस्तावना:

मानव इतिहासमा प्रतिजैविक (Antimicrobial) औषधिको आविष्कारले चिकित्सा विज्ञानमा ठूलो क्रान्ति ल्यायो । तर, पछिल्ला दशकहरूमा यसको अत्यधिक, अव्यवस्थित र अनुचित प्रयोगका कारण विश्वव्यापी रूपमा "प्रतिजैविक प्रतिरोध" (Antimicrobial Resistance - AMR) तीव्र रूपमा बढिरहेको छ । विश्व स्वास्थ्य संगठन (WHO) ले यसलाई विश्वका शीर्ष १० सार्वजनिक स्वास्थ्य खतरामध्ये एक मानेको छ ।

नेपालमा पनि बिना चिकित्सकीय सल्लाह एन्टिबायोटिकको प्रयोग, स्व-औषधोपचार (Self-medication), बिना प्रेस्क्रिप्सन सहज उपलब्धता, पशुपालनमा दुरुपयोग र जनचेतनाको अभावले AMR गम्भीर संकटका रूपमा देखापरेको छ । विभिन्न अध्ययनहरूले नेपालमा बहुऔषधि प्रतिरोधी जीवाणु (Multi-Drug Resistant Organisms) तीव्र रूपमा बढेको देखाएका छन् । यसै पृष्ठभूमिमा प्रस्तुत लेखमा नेपालमा प्रतिजैविक औषधिको वर्तमान अवस्था, यसका कारण, प्रभाव, चुनौती र नियन्त्रणका उपायहरूबारे विस्तृत चर्चा गरिएको छ ।

२. प्रतिजैविक औषधि र AMR के हो?

प्रतिजैविक (Antimicrobial) औषधि भन्नाले ब्याक्टेरिया, भाइरस, फङ्गस तथा परजीवीका कारण हुने संक्रमण नियन्त्रण वा उपचार गर्न प्रयोग हुने औषधिलाई बुझिन्छ । ब्याक्टेरियाविरुद्ध प्रयोग गरिने एन्टिबायोटिक यसको एउटा प्रमुख भाग हो ।

जब सूक्ष्मजीवहरूले औषधिविरुद्ध प्रतिरोध क्षमता विकास गर्छन्, तब पहिले प्रभावकारी रहेका औषधिहरू निष्प्रभावी बन्छन् । यस अवस्थालाई "Antimicrobial Resistance-AMR" भनिन्छ, जसले गर्दा सामान्य संक्रमणको उपचार पनि कठिन हुन्छ ।

उदाहरणका रूपमा:

साधारण मूत्रमार्गको संक्रमण (UTI), निमोनिया वा सेप्सिसको उपचार कठिन भई मृत्युको जोखिम बढ्छ भने शल्यक्रिया, क्यान्सर उपचार र अङ्ग प्रत्यारोपणजस्ता आधुनिक चिकित्सा सेवाहरू अत्यन्तै जोखिमपूर्ण बन्छन् ।

३. विश्वव्यापी अवस्था:

विश्व स्वास्थ्य संगठन (WHO) तथा अन्य अन्तर्राष्ट्रिय संस्थाहरूका अनुसार AMR ले विश्वभर प्रत्येक वर्ष लाखौं मानिसको ज्यान लिइरहेको छ । यदि यसलाई समयमै नियन्त्रण गरिएन भने सन्

२०५० सम्ममा AMR का कारण करोडौं मानिसको मृत्यु हुन सक्ने चेतावनी दिइएको छ ।

दक्षिण एसियाली क्षेत्र AMR को उच्च जोखिममा रहेको मानिन्छ । यस क्षेत्रमा बिना प्रेस्क्रिप्सन औषधिको जथाभावी प्रयोग, कमजोर नियमन, अस्पतालहरूमा संक्रमण नियन्त्रणको कमी र पशुपालनमा अत्यधिक एन्टिबायोटिकको प्रयोग जस्ता कारणले समस्या झन् गम्भीर बनेको छ ।

४. नेपालमा प्रतिजैविक प्रयोगको अवस्था:

नेपालमा प्रतिजैविक औषधिको प्रयोग विगत केही वर्षमा उल्लेखनीय रूपमा बढेको छ । यसका प्रमुख कारणहरूमा जनसंख्याको वृद्धि, निजी स्वास्थ्य संस्थाहरूको विस्तार, औषधिको सहज पहुँच, स्व-औषधोपचारको प्रवृत्ति, संक्रमणजन्य रोगहरूको उच्च भार र फितलो नियमन रहेका छन् ।

नेपालमा धेरै व्यक्तिहरू चिकित्सकको सल्लाह बिना नै फार्मेसीबाट सोझै प्रतिजैविक औषधि खरिद गर्ने गर्छन् । एउटा अध्ययन अनुसार करिब ५३% व्यक्तिले बिना प्रेस्क्रिप्सन एन्टिबायोटिक प्रयोग गरेको पाइएको छ । सामान्य रुघाखोकी, भाइरल ज्वरो, घाँटी दुख्ने, पखाला वा अन्य भाइरल संक्रमणमा पनि अनावश्यक रूपमा एन्टिबायोटिक प्रयोग गर्ने प्रवृत्ति व्यापक छ । धेरै बिरामीहरूले औषधिको पूरा मात्रा (ऋयगचकभ) सेवन नगर्ने, अलिकति निको हुनासाथ बीचमै औषधि बन्द गर्ने, पुरानो प्रेस्क्रिप्सन दोहोऱ्याउने वा आफन्त र छिमेकीको सल्लाहमा औषधि खाने गर्छन् । यसले जीवाणुहरूमा प्रतिरोध क्षमता विकास प्रक्रियालाई तीव्र बनाइरहेको छ ।

५. नेपालमा AMR को वर्तमान अवस्था:

नेपालमा सन् १९९९ देखि नै AMR निगरानीको प्रयास सुरु भए पनि अझै पर्याप्त राष्ट्रिय डेटा उपलब्ध हुन सकेको छैन । तथापि, हालसम्मका अध्ययनहरूले धेरै सामान्य जीवाणुहरूमा उच्च स्तरको प्रतिरोध क्षमता विकास भइसकेको देखाएका छन् ।

नेपालमा विशेष गरी E. coli, Klebsiella pneumoniae, Staphylococcus aureus र Pseudomonas aeruginosa जस्ता जीवाणुहरूमा उच्च प्रतिरोध देखिएको छ। केही अनुसन्धानहरूमा Fluoroquinolone प्रतिरोधी E. coli, MRSA (Methicillin-Resistant Staphylococcus aureus), तेस्रो पुस्ताका Cephalosporin प्रतिरोधी जीवाणु र Carbapenem प्रतिरोधी संक्रमण समेत बढ्दै गएको उल्लेख छ । WHO को प्रतिवेदन अनुसार नेपालमा सन् २०१९ मा मात्रै AMR का कारण प्रत्यक्ष रूपमा करिब ६,४०० मानिसको मृत्यु भएको थियो भने २३,००० भन्दा बढी मृत्युमा AMR योगदानकारी कारकको रूपमा रहेको थियो ।

६. AMR बढ्नुका प्रमुख कारणहरू:

१. आवश्यकता नभए पनि वा उचित प्रयोगशाला परीक्षण नगरी 'Broad-spectrum antibiotic' को अत्यधिक र गलत प्रयोग गरिनु ।

२. कानुनी नियमहरू भए पनि अनुगमन कमजोर हुँदा फार्मेसी तथा औषधि पसलहरूबाट बिना प्रेस्क्रिप्सन सजिलै एन्टिबायोटिक उपलब्ध हुनु ।

३. बिरामीले रोगको लक्षण अलिकति कम हुनासाथ औषधिको पूरा मात्रा सेवन नगरी बीचमै खान छोड्नु ।

४. अस्पतालजन्य संक्रमण रोक्नका लागि आवश्यक पर्ने Hand hygiene, Sterilization र Isolation जस्ता अभ्यासहरू पर्याप्त रूपमा लागू नहुनु ।

५. कुखुरापालन, पशुपालन र मत्स्यपालनमा जीवहरूको शारीरिक वृद्धि प्रवर्द्धक (Growth promoter) का रूपमा अनियन्त्रित एन्टिबायोटिक प्रयोग गरिनु ।

६. एन्टिबायोटिकले भाइरल रोगमा काम गर्दैन र यसको गलत प्रयोगले भविष्यमा औषधि निष्प्रभावी हुन्छ भन्नेबारे आम नागरिकमा चेतनाको कमी हुनु ।

७. AMR को प्रभावहरू:

१. प्रतिरोधी संक्रमण भएपछि त्यसको उपचारका लागि महँगा औषधि, लामो समय अस्पताल बसाइ र सघन उपचार कक्ष (ICU Care) को आवश्यकता पर्छ ।

२. सामान्य संक्रमणले पनि औषधि काम नगर्दा मानिसको ज्यान लिन सक्ने भयावह अवस्था सिर्जना हुन्छ ।

३. AMR का कारण आम नागरिकको स्वास्थ्य खर्च र औषधि खर्च बढ्न गई समग्र देशको अस्पताल व्यवस्थापनमा ठूलो भार थपिन्छ ।

४. एन्टिबायोटिक निष्प्रभावी हुँदा शल्यक्रिया (Surgery), अंग प्रत्यारोपण, क्यान्सरको केमोथेरापी र नवजात शिशु सघन उपचार (NICU) जस्ता जटिल उपचारहरू अत्यन्तै जोखिमपूर्ण बन्छन् ।

५. कम स्रोत साधन भएका मुलुकहरूमा प्रयोगशालाको सुविधा सीमित हुने, निगरानी कमजोर हुने र गुणस्तरीय औषधिको पहुँच कम हुने भएकाले यो समस्या झन् घातक बन्दै गएको छ ।

८. WHO को ब्यबच्म अवधारणा:

विश्व स्वास्थ्य संगठन (WHO) ले प्रतिजैविक औषधिको जिम्मेवार र बुद्धिमानीपूर्ण प्रयोगका लागि AWaRe Classification विकास गरेको छ:

- Access Group: सुरक्षित र पहिलो रोजाइका रूपमा प्रयोग गरिने आधारभूत एन्टिबायोटिकहरू ।
- Watch Group: उच्च प्रतिरोधको जोखिम भएका र विशेष अवस्थामा मात्र प्रयोग गरिने औषधिहरू ।
- Reserve Group: अन्य औषधिले काम नगर्दा अन्तिम विकल्पका रूपमा मात्र प्रयोग गरिने महत्वपूर्ण औषधिहरू ।

WHO ले देशहरूले आफ्नो कुल एन्टिबायोटिक खपतको कम्तीमा ६०% हिस्सा 'Access' समूहबाट हुनुपर्ने सिफारिस गरेको छ । नेपालमा पनि यो AWaRe अवधारणालाई राष्ट्रिय उपचार निर्देशिकामा प्रभावकारी रूपमा समावेश गर्न आवश्यक छ ।

९. नेपाल सरकारले गरेका प्रयासहरू:

AMR नियन्त्रणका लागि नेपाल सरकारले केही सकारात्मक पहलहरू सुरु गरेको छ:

१. विश्व स्वास्थ्य संगठन (WHO) को विश्वव्यापी कार्ययोजना अनुरूप National Action Plan on AMR तयार गरी कार्यान्वयन ।

२. राष्ट्रिय जनस्वास्थ्य प्रयोगशाला (NPHL) मार्फत देशका विभिन्न स्वास्थ्य संस्थाहरूबाट AMR को निगरानी (Surveillance) कार्य विस्तार ।

३. मानव, पशु तथा वातावरणीय स्वास्थ्यलाई एकीकृत रूपमा सम्बोधन गर्न One Health Approach अवधारणा लागू गर्ने प्रयास भइरहेको ।

४. सुरक्षित र व्यवस्थित औषधि प्रयोगका लागि 'National Antibiotic Treatment Guidelines' (उपचार निर्देशिका) लागू गरिएको ।

५. प्रत्येक वर्ष World AMR Awareness Week लगायतका विभिन्न सचेतनामूलक कार्यक्रमहरू सञ्चालन गरिँदै आएको ।

१०. नेपालमा रहेका चुनौतीहरू:

विभिन्न प्रयासहरू भइरहे तापनि नेपालमा अझै धेरै चुनौतीहरू विद्यमान छन्:

१. कानुनी नियमन र अनुगमन प्रणाली कमजोर,

२. पर्याप्त र आधुनिक प्रयोगशालाहरूको अभाव हुनु, विशेष गरी ग्रामीण क्षेत्रमा परीक्षण सुविधा नहुन,

३. फार्मेसीहरूको नियमित निरीक्षण प्रभावकारी हुन नसक्नु,

४. राष्ट्रिय स्तरमा गुणस्तरीय र भरपर्दो डेटाको अभाव,

५. पशु स्वास्थ्य र कृषि क्षेत्रमा एन्टिबायोटिकको प्रयोगमा निगरानी अत्यन्तै न्यून हुनु,

६. दक्ष तथा प्रशिक्षित जनशक्तिको कमी र आम समुदायमा चेतनाको स्तर कमजोर हुनु ।

११. AMR नियन्त्रणका लागि आवश्यक कदमहरू:

१. चिकित्सक तथा स्वास्थ्यकर्मीले अनिवार्य आवश्यकतामा मात्र 'Culture and sensitivity testing' का आधारमा 'Narrow-spectrum' एन्टिबायोटिक सिफारिस गर्ने बानी बसाल्ने ।

२. चिकित्सकको वैध प्रेस्क्रिप्सन बिना एन्टिबायोटिक बिक्री वितरण गर्ने कार्यलाई कानुनी रूपमा पूर्ण नियन्त्रण गर्ने ।

३. प्रत्येक अस्पतालमा एन्टिबायोटिक नीति, कमिटी र अडिट प्रणाली (Antimicrobial Stewardship Program) लागू गरी उपचार निर्देशिकाको पालना सुनिश्चित गर्ने ।

४. अस्पतालहरूमा Hand hygiene, सफा वातावरण, समयमै खोप सेवा र सुरक्षित शल्यक्रियामार्फत संक्रमण फैलिनै नदिने व्यवस्था गर्ने ।

५. राष्ट्रिय AMR निगरानी प्रणालीलाई समयसापेक्ष, प्रविधिमैत्री, डिजिटल र वैज्ञानिक रूपमा सुदृढ बनाउने ।

६. पशुपालन, कुखुरापालन र कृषि क्षेत्रमा व्यावसायिक हितका लागि भइरहेको एन्टिबायोटिकको अनियन्त्रित प्रयोग रोक्न कडा मापदण्ड लागू गर्ने ।

७. विद्यालय, समुदाय र आम सञ्चार माध्यममार्फत एन्टिबायोटिकको सही प्रयोग र यसको कोर्स पूरा गर्नेबारे देशव्यापी जनचेतना अभियान चलाउने ।

८. नेपालको स्थानीय परिवेश सुहाउँदो डेटा उत्पादन, चिकित्सा अनुसन्धान र नयाँ उपचारका विकल्पहरूको विकासलाई प्रोत्साहन गर्ने ।

१२. औषधि व्यवसायी र स्वास्थ्यकर्मीको भूमिका:

AMR नियन्त्रण गर्ने महाअभियानमा चिकित्सक, फर्मासिस्ट, नर्स, माइक्रोबायोलोजिस्ट र औषधि व्यवसायी सबैको भूमिका उत्तिकै महत्वपूर्ण रहन्छ ।

विशेष गरी फर्मासिस्ट तथा औषधि व्यवसायीहरूले व्यावसायिक मर्यादा जोगाउँदै बिना प्रेस्क्रिप्सन एन्टिबायोटिक बिक्री नगर्ने, औषधि दिँदा बिरामीलाई यसको सही प्रयोग र अवधिको बारेमा उचित परामर्श (Counseling) दिने र औषधिको पूरा मात्रा सेवन गर्नुको महत्त्व बुझाउने जिम्मेवारी इमानदारिताका साथ निभाउनुपर्छ ।

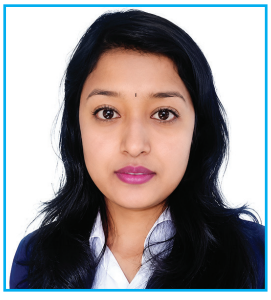
निष्कर्ष:

प्रतिजैविक प्रतिरोध (AMR) नेपालका लागि एक सुस्त तर गम्भीर सार्वजनिक स्वास्थ्य चुनौती हो । यदि समयमै ठोस कदम चालिएन भने भविष्यमा सामान्य संक्रमणको पनि उपचार असम्भव हुने "Post-Antibiotic Era" को भयावह अवस्था आउन सक्छ, जसले समग्र स्वास्थ्य र अर्थतन्त्रमा दीर्घकालीन संकट निम्त्याउने निश्चित छ ।

यस जटिल समस्याको समाधान स्वास्थ्य क्षेत्रको एक्लो प्रयासबाट मात्र सम्भव छैन । सरकार, नियामक निकाय, चिकित्सक, फर्मासिस्ट, औषधि व्यवसायी, पशु स्वास्थ्य क्षेत्र र आम नागरिकको संयुक्त प्रतिबद्धता आवश्यक छ । "One Health Approach" लाई प्रभावकारी रूपमा कार्यान्वयन गर्दै जिम्मेवार प्रतिजैविक प्रयोग, कडा नियमन र देशव्यापी जनचेतना जगाउन सकेमा मात्र हाम्रा भावी पुस्तालाई यो ठूलो संकटबाट जोगाउन सकिनेछ ।

Pharmacovigilance

Adverse Drug Reaction Reporting in Nepal- Progress Report 2025



Binala Joshi
Pharmacy Officer, DDA

In 2025, Nepal's Pharmacovigilance Program achieved a significant accomplishment. A total of 287 Adverse Drug Reaction (ADR) reports were submitted to the national database — the highest annual number recorded since the program began. This notable success highlights the increasing awareness and continued strengthening of drug safety culture across healthcare institutions in the country.

Introduction

Adverse Drug Reactions (ADRs) represent one of the most significant yet preventable causes of morbidity and mortality worldwide. The pre-marketing evaluation of pharmaceutical products, while rigorous, is inherently limited in its capacity to detect rare adverse events, delayed reactions, or effects arising from long-term exposure or drug-drug interactions in diverse real-world populations.

The Department of Drug Administration (DDA) initiated its National Pharmacovigilance Program in 2002, recognizing that pharmacoepidemiological data from other countries may not be directly applicable to the Nepalese population due to genetic, environmental, and lifestyle differences. DDA serves as the National Centre for Pharmacovigilance and the designated focal point for liaison with the Uppsala Monitoring Centre (UMC) — the WHO Collaborating Centre for International Drug Monitoring based in Sweden. Nepal is a full member of the WHO Programme for International Drug Monitoring.

The DDA maintains the national ADR database using the VigiFlow online reporting platform and forwards collated reports to UMC for incorporation into VigiBase, the global database of individual case safety reports. Through its network of Regional Pharmacovigilance Centres, DDA facilitates spontaneous reporting, conducts awareness programs, and promotes rational use of medicine across the country.

National Pharmacovigilance Network- 2025

As of 2025, Nepal's national pharmacovigilance network comprises 20 Regional Pharmacovigilance Centres spanning tertiary hospitals, private medical colleges, and specialist institutions.

S.N.	Regional Pharmacovigilance Centre
1	Dhulikhel Hospital
2	Nepal Cancer Hospital and Research Centre
3	Nepal Medical College
4	Manipal Teaching Hospital
5	KIST Medical College (KIST Hospital)
6	Bharatpur Hospital

S.N.	Regional Pharmacovigilance Centre
7	Hetauda Hospital
8	B.P. Koirala Institute of Health Science
9	Tribhuvan University Teaching Hospital
10	National Academy of Medical Sciences, Bir Hospital
11	College of Medical Science Teaching Hospital (CoMSTH)
12	Civil Service Hospital of Nepal
13	Norvic International Hospital
14	Chitwan Medical College
15	Nepal Mediciti Hospital
16	Nepalese Army Institute of Health Science
17	Patan Academy of Health Science
18	Bhaktapur Cancer Hospital
19	Kanti Children's Hospital
20	Kathmandu Cancer Centre

ADR Reporting – 2025 Analysis

In 2025, a total of 287 ADR reports were entered into the national VigiFlow.

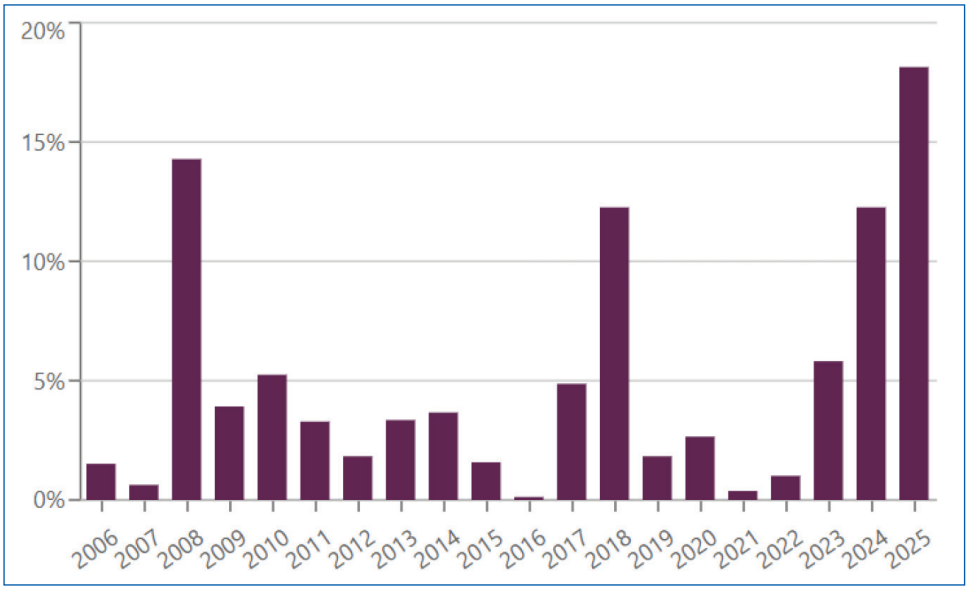


Fig: Trend of ADR Reporting (2006–2025)

Dhulikhel Hospital emerged as the highest reporter in 2025, contributing 84 reports, followed by Nepal Cancer Hospital and Research Centre (75 reports) and Nepal Medical College (31 reports). The strong performance of these institutions exemplifies the impact of institutional PV champions and structured reporting protocols.

Nepal's cumulative ADR reports submitted to UMC VigiBase stand at 1,561 as of the end of 2025, representing a steady and growing contribution to the global repository of individual case safety reports. Each case report contributes to the international signal detection process and enhances the understanding of drug safety in South Asian populations.

Of the 1561 ADRs reported in the national database till date, the graphical representation of healthcare professionals, patient age, sex and the types of ADR reported along with the drug, reaction and reported are mentioned below.

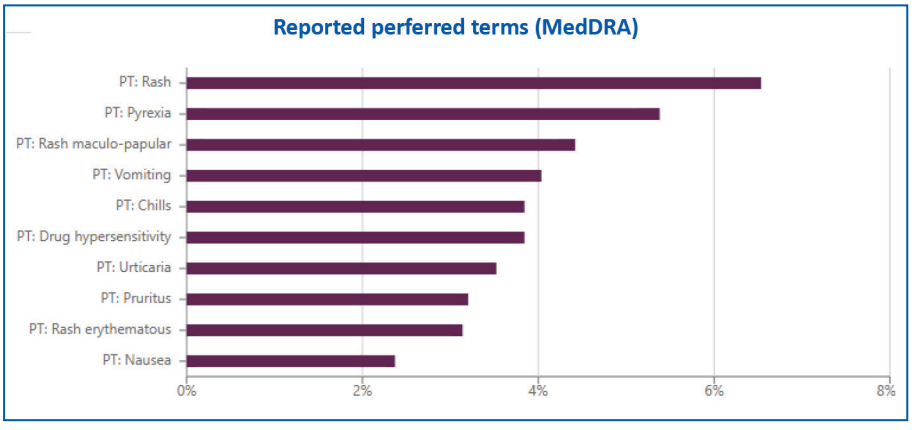


Fig: ADR distribution as per preferred MedDRA terms

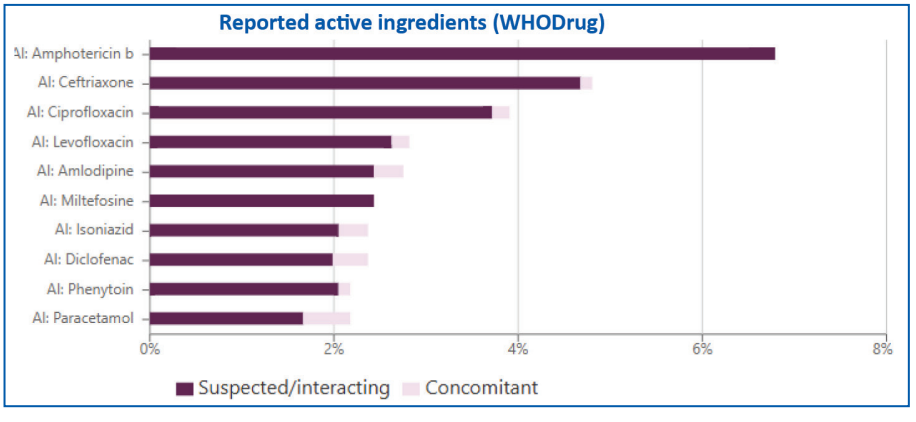


Fig: ADR distribution as per ATC codes and active ingredient

Current Issues with PV Program:

- Absence of a dedicated Pharmacovigilance Unit within the Department of Drug Administration.
- Lack of legal provisions mandating ADR reporting by pharmaceutical manufacturers and healthcare practitioners.
- Inadequate communication and coordination between the Department of Drug Administration and Regional Pharmacovigilance Centres.
- Absence of a functional Technical Working Group to provide strategic and technical guidance for pharmacovigilance activities.
- Low reporting rates and limited participation from Regional Pharmacovigilance Centres.
- Insufficient training and capacity-building opportunities for pharmacovigilance personnel and staff of Regional Pharmacovigilance Centres.

- Limited awareness and understanding of the importance of ADR reporting among healthcare professionals and the general public.

Way Forward

Building on the achievements of 2025, the following priorities have been identified for 2026:

- Institutionalize bi-monthly virtual coordination meetings with all Regional Pharmacovigilance Centres to ensure continuous engagement, facilitate timely feedback, and strengthen real-time review of ADR data quality.
- Expand the pharmacovigilance network beyond the current 20 Regional Centres by enrolling additional hospitals and healthcare institutions across the country.
- Strengthen capacity-building initiatives through regular training, mentoring, and technical support for healthcare professionals and focal persons involved in pharmacovigilance activities.
- Enhance public awareness of adverse drug reaction (ADR) reporting through mass media campaigns and community outreach activities in collaboration with provincial and local governments.
- Integrate pharmacovigilance activities into routine hospital practices, including orientation programmes for newly recruited healthcare professionals and incorporation into continuing professional development (CPD) activities.
- Strengthen collaboration with academic institutions to incorporate pharmacovigilance education and ADR reporting practices into undergraduate and postgraduate health science curricula.
- Increase patient and consumer participation in pharmacovigilance by promoting direct patient reporting mechanisms and community-based awareness programmes.

Conclusion

The year 2025 has been a progressive year for pharmacovigilance in Nepal. The achievement of 287 ADR reports, the highest annual total is a testament to the growing dedication of healthcare professionals, the expanding network of Regional Pharmacovigilance Centres, and the sustained commitment of the Department of Drug Administration.

However, the stark contrast between contributing and non-contributing centres underscores the need for continued capacity building and institutional engagement. A comprehensive and well-coordinated pharmacovigilance program is not only essential for patient safety in Nepal but also for Nepal's contribution to global post-market drug surveillance.

औषधि सुरक्षालाई सुदृढ बनाउने रणनीतिक मार्गचित्र

शुभमान श्रेष्ठ
महासचिव
नेपाल औषधि व्यवसायी संघ, काठमाडौं

नेपालको स्वास्थ्य प्रणाली तीव्र रूपमा परिवर्तनको चरणमा छ । नयाँ औषधिहरूको प्रयोग, antimicrobial resistance (AMR) को बढ्दो चुनौती, self–medication को प्रवृत्ति, online तथा uncontrolled medicine access, polypharmacy, chronic disease burden र aging population जस्ता कारणहरूले औषधि सुरक्षालाई आजको सार्वजनिक स्वास्थ्यको अत्यन्त संवेदनशील विषय बनाएको छ । यस्तो अवस्थामा Pharmacovigilance (PV) केवल regulatory activity मात्र होइन, यो patient safety, rational medicine use र public health protection को आधारभूत संयन्त्र हो ।

विश्व स्वास्थ्य संगठन (WHO) का अनुसार Pharmacovigilance भन्नाले औषधिको प्रतिकूल असर (Adverse Drug Reactions – ADRs) तथा अन्य औषधि सम्बन्धी समस्याहरूको पहिचान, मूल्यांकन, बुझाइ तथा रोकथामसँग सम्बन्धित विज्ञान र गतिविधिहरूलाई जनाउँछ । Clinical trial हरूले औषधिको efficacy र limited safety profile मात्र देखाउँछन्; तर वास्तविक जीवनमा (real–world use) विभिन्न उमेर समूह, comorbidities, nutritional status, genetic diversity, polypharmacy र irrational use जस्ता कारणले औषधिको असर फरक रूपमा देखापर्न सक्छ । त्यसैले post–marketing surveillance कुनै पनि औषधि प्रणालीको अपरिहार्य अंग हो ।

विश्वव्यापी अध्ययनहरूले देखाएका छन् कि करिब ५ देखि १० प्रतिशत अस्पताल भर्ना ADR का कारण हुने गर्दछन् भने ठूलो संख्यामा भएका ADR हरू preventable हुन्छन् । विकसित देशहरूमा समेत ADR हरू mortality तथा morbidity को प्रमुख कारणमध्ये पर्दछन् । यसले औषधि सुरक्षालाई केवल चिकित्सकीय विषय नभई आर्थिक, सामाजिक र नीतिगत विषयको रूपमा पनि स्थापित गरेको छ । औषधि सम्बन्धी त्रुटि, irrational antibiotic use, counterfeit medicines, substandard products तथा uncontrolled dispensing जस्ता समस्याले low and middle–income countries मा थप जटिलता सिर्जना गरेका छन् ।

नेपालले पनि औषधि सुरक्षाको महत्त्वलाई आत्मसात गर्दै Pharmacovigilance प्रणाली स्थापना गरिसकेको छ । Department of Drug Administration अन्तर्गत राष्ट्रिय Pharmacovigilance Programme सञ्चालनमा रहेको छ र नेपाल WHO Programme for International Drug Monitoring सँग पनि आबद्ध छ । केही teaching hospitals तथा regional centres मार्फत ADR reporting भइरहे पनि ground–level reporting अझै अत्यन्त न्यून रहेको विभिन्न अध्ययन तथा संस्थागत अनुभवहरूले देखाउँछन् ।

नेपालमा हाल विद्यमान मुख्य चुनौतीहरू निम्न प्रकारका छन्:

- ADR underreporting
- Weak reporting culture
- Community pharmacy exclusion
- Limited digital reporting mechanism
- Inadequate professional training
- Fragmented coordination among stakeholders.

विशेषगरी "No report" लाई "No adverse reaction" का रूपमा बुझ्ने प्रवृत्ति अत्यन्त खतरनाक छ। धेरै adverse events कहिल्यै documentation नै हुँदैनन् । यसले regulatory decision-making कमजोर बनाउँछ, irrational use बढाउँछ र patient safety मा प्रत्यक्ष असर पार्छ।

यस्तो अवस्थामा नेपालको सबैभन्दा ठूलो तर कम उपयोग गरिएको स्वास्थ्य संरचना भनेको community pharmacy network हो । देशभर रहेका हजारौं community pharmacies ग्रामीण तथा शहरी दुवै क्षेत्रमा स्वास्थ्य सेवाको पहिलो सम्पर्क बिन्दुका रूपमा कार्यरत छन् । धेरै बिरामीहरू अस्पताल वा चिकित्सकसम्म पुग्नुभन्दा पहिले pharmacy मा पुग्छन् । OTC medicines, antibiotics, chronic disease medicines तथा symptomatic उपचारका लागि pharmacy नै पहिलो सल्लाह केन्द्र बन्ने गरेको छ ।

यसकारण community pharmacists वास्तविक अर्थमा "frontline medicine safety professionals" हुन् । उनीहरू बिरामीसँग प्रत्यक्ष सम्पर्कमा हुन्छन्, medicine adherence, side effects, allergy, drug interaction, misuse तथा therapeutic failure जस्ता संकेतहरू दैनिक रूपमा अवलोकन गर्न सक्छन् । यदि यही network लाई व्यवस्थित रूपमा Pharmacovigilance system सँग जोड्न सकियो भने नेपालको औषधि सुरक्षा प्रणालीमा ऐतिहासिक परिवर्तन ल्याउन सकिन्छ ।

विश्वका धेरै देशहरूले pharmacist–led pharmacovigilance model लाई सफलतापूर्वक कार्यान्वयन गरेका छन् ।

उदाहरणका लागि:

- United Kingdom मा Yellow Card Scheme मार्फत pharmacists र public दुवैलाई ADR reporting मा सहभागी गराइएको छ ।
- India मा Pharmacovigilance Programme of India (PvPI) अन्तर्गत community–level engagement विस्तार हुँदै गएको छ ।
- European Medicines Agency अन्तर्गत EudraVigilance system ले real–time digital safety monitoring लाई सुदृढ बनाएको छ ।

यी सबै सफल प्रणालीहरूको साझा विशेषता भनेको digital reporting infrastructure, pharmacist engagement र strong regulatory coordination हो ।

नेपालमा पनि यस्तै मोडेल व्यवहारिक, लागत-प्रभावकारी तथा scalable हुन सक्छ । यसको लागि बहुआयामिक रणनीति आवश्यक छ ।

1. Pharmacist–Led ADR Reporting System:

प्रत्येक community pharmacy लाई "ADR Reporting Point" का रूपमा विकास गर्न सकिन्छ । Standardized ADR reporting forms, QR–enabled reporting mechanism तथा simplified reporting guideline विकास गरिनुपर्छ । Reporting लाई अत्यधिक जटिल बनाइयो भने frontline participation कमजोर हुन्छ । त्यसैले सहज, छरितो र user–friendly प्रणाली आवश्यक छ ।

2. Digital Transformation of Pharmacovigilance:

नेपालको PV प्रणालीलाई digital ecosystem मा रूपान्तरण गर्नु आजको आवश्यकता हो । Mobile application, web portal, SMS–based reporting तथा QR–code integration जस्ता प्रणालीले reporting dramatically बढाउन सक्छ । Real–time data aggregation ले signal detection, trend analysis तथा rapid regulatory action लाई सम्भव बनाउँछ ।

Artificial intelligence तथा data analytics आधारित भविष्यको PV framework ले antibiotic misuse patterns, counterfeit medicine clusters तथा region–specific adverse events पहिचान गर्न समेत सहयोग पुऱ्याउन सक्छ ।

3. Professional Capacity Building:

Pharmacovigilance लाई academic syllabus र Continuing Professional Development (CPD) सँग जोड्न आवश्यक छ । ADR detection, causality assessment, medication error reporting, vaccine safety monitoring तथा antimicrobial stewardship सम्बन्धी नियमित तालिम सञ्चालन गरिनुपर्छ ।

Nepal Chemists and Druggists Association (NCDA), pharmacy colleges, professional councils तथा regulatory agencies बीच institutional collaboration निर्माण गर्न सकिए National competency framework विकास गर्न सहज हुनेछ ।

4. Regulatory and Policy Reform:

Community pharmacy लाई औपचारिक रूपमा national PV system को integral component को रूपमा मान्यता दिनुपर्छ । Reporting encouragement mechanism, recognition system वा minimum reporting expectation जस्ता regulatory measures अपनाउन सकिन्छ ।

यसका साथै DDA, hospitals, academia, pharmacists, NCDA तथा public health institutions बीच data–sharing coordination mechanism विकास गर्न आवश्यक छ ।

5. Public Participation and Consumer Awareness:

विश्वव्यापी रूपमा patient–reported ADR system प्रभावकारी साबित हुँदै गएको छ । नेपालमा पनि "Report Side Effects" public awareness अभियान सञ्चालन गर्न सकिन्छ । यदि बिरामी स्वयंले adverse reactions report गर्न सक्ने प्रणाली विकास गरियो भने medicine safety intelligence अझ बलियो बन्नेछ ।

Pharmacovigilance and Antimicrobial Resistance (AMR) नेपालमा irrational antibiotic use तथा self–medication AMR को प्रमुख कारणमध्ये पर्दछन् । Pharmacovigilance system लाई antimicrobial stewardship सँग जोड्न सकियो भने antibiotic–related adverse events, treatment failure तथा resistance patterns को surveillance सुदृढ बनाउन सकिन्छ ।

यसले "One Health" approach लाई समेत समर्थन गर्छ, जहाँ मानव स्वास्थ्य, पशुपंक्षी स्वास्थ्य र environmental safety परस्पर सम्बन्धित मानिन्छन् ।

नेपालको community pharmacy network geographically widespread, socially accessible / economically sustainable platform हो । धेरै ग्रामीण क्षेत्रमा pharmacy नै de facto primary healthcare access point बनेको छ । यही संरचनालाई औषधि सुरक्षा प्रणालीसँग जोड्नु भनेको नयाँ structure निर्माण गर्नु होइन, विद्यमान प्रणालीलाई strategic रूपमा mobilize गर्नु हो । यो नै नेपालको लागि रणनीतिक अवसर पनि हो ।

यदि सरकार, regulatory bodies, professional organizations तथा private sector–NCDA बीच सहकार्य हुन सक्यो भने नेपालले comparatively कम लागतमा robust pharmacovigilance ecosystem निर्माण गर्न सक्छ ।

यसले निम्न लाभहरू दिन सक्छ:

- ADR reporting rate मा उल्लेखनीय वृद्धि
- Early safety signal detection
- Rational medicine use promotion
- AMR control support
- Patient trust strengthening
- Evidence–based regulatory decision making
- National health security enhancement

नेपालमा Pharmacovigilance को भविष्य केवल tertiary hospitals वा regulatory offices भित्र सीमित छैन । यसको वास्तविक शक्ति community pharmacy network मा निहित छ । Frontline pharmacists लाई medicine safety surveillance को केन्द्रीय भूमिकामा ल्याउन सकियो भने नेपालको औषधि सुरक्षा प्रणाली गुणात्मक रूपमा रूपान्तरण हुन सक्छ ।

आजको आवश्यकता नयाँ संरचना निर्माणको मात्र होइन, existing healthcare network लाई intelligent रूपमा integrate गर्ने हो । Community pharmacists लाई "medicine dispensers" को सीमित भूमिकाबाट बाहिर ल्याएर "guardians of drug safety" का रूपमा संस्थागत मान्यता दिनु समयको माग हो ।

Drug safety is not merely a regulatory responsibility; it is a shared national public health commitment र नेपालमा यस अभियानको सबैभन्दा बलियो आधार Community Pharmacy Network (CPN) र नेपाल औषधी व्यवसायी संघ बन्न सक्छ ।

Artificial intelligence in Pharmacovigilance

Sachita Joshi
Senior Drug Administrator, DDA

Artificial Intelligence (AI), a term first introduced by John McCarthy in 1955 at the Dartmouth Conference, which marked the birth of AI as a field of study, is the science and engineering of creating intelligent machines. AI enables computer systems to emulate human intelligence for problem-solving, decision-making, creativity, and autonomous operation. Advances in large datasets, computing power, and algorithms have made AI increasingly feasible. As noted by Dr. Ball (FDA), machines should perform tasks they do efficiently, while human experts should focus on tasks requiring human expertise.

Artificial intelligence (AI) is reshaping pharmacovigilance (PV), shifting it from a largely reactive discipline to one that is increasingly proactive, predictive, and automated. By leveraging large and diverse datasets, AI facilitates faster adverse event detection, improved signal identification, and real-time safety monitoring. Technologies such as machine learning (ML) and natural language processing (NLP) have found widespread applications in PV, enabling the automation of routine and labor-intensive tasks, rapid extraction of meaningful insights from complex data, and support for document preparation, thereby allowing experts to focus on higher-value analyses. AI has been successfully applied to various aspects of Individual Case Safety Report (ICSR) management, including case intake, assessment, follow-up, distribution, and causality evaluation. Its utility has been particularly evident in high-volume settings, such as the capture of adverse events associated with coronavirus disease 2019 (COVID-19) vaccines from social media and other sources, where manual processing may be time-consuming and susceptible to human error. Furthermore, AI has been employed to predict adverse drug reactions (ADRs) during drug discovery, underscoring its potential to strengthen drug safety throughout the development continuum.

The application of AI in pharmacovigilance, particularly in the management of Individual Case Safety Reports (ICSRs), has been well documented, although standardized performance metrics are yet to be fully established. AI enables the efficient handling of large volumes of ICSRs through Natural Language Processing (NLP), which extracts and structures relevant patient information from unstructured sources such as Electronic Health Records (EHRs) and social media, thereby improving the accuracy and efficiency of adverse event reporting. AI models are also capable of identifying duplicate reports and automating routine quality checks, reducing the manual burden on safety teams. In addition, AI enhances signal detection and

analysis by identifying new, rare, or unexpected adverse drug reactions (ADRs) more rapidly than conventional methods. Machine learning techniques, including k-means clustering, random forest, and gradient boosting, have demonstrated improved pattern recognition compared with traditional frequentist approaches, while Bayesian networks provide greater transparency and reduce subjectivity in causality assessment. AI further supports continuous, real-time post-licensure surveillance and predictive safety management by forecasting potential side effects and integrating real-world evidence from sources such as social media, wearable devices, and telehealth platforms. Machine learning also assists in signal validation and prioritization, enabling experts to focus on the most clinically relevant findings. These applications offer significant advantages, including increased speed and efficiency, improved accuracy, enhanced detection of rare events, and faster decision-making. Nevertheless, challenges related to data quality, privacy, the lack of transparency associated with "black box" models, regulatory considerations, and the continued requirement for human oversight remain important considerations.

In conclusion, the future of drug development is expected to be increasingly knowledge-driven, emphasizing smarter rather than harder approaches. AI is poised to provide novel insights, enhance efficiency through automated workflows, and transform regulatory and health authority processes. Realizing the full potential of these advancements will require close collaboration between the pharmaceutical industry and health authorities to ensure the safe and effective integration of AI into drug development and pharmacovigilance.

WHO Certification Scheme and Regulatory Reliance

Shiwani Khadgi
Act. Director General, DDA

The World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was developed to facilitate international trade in pharmaceutical products by promoting transparency, regulatory cooperation, and the exchange of reliable information between national regulatory authorities (NRAs). Under the Scheme, the competent regulatory authority of the exporting country issues a Certificate of a Pharmaceutical Product (CPP), which provides information on the product's marketing authorization status, the manufacturer's GMP compliance, and the regulatory oversight exercised by the exporting authority. The Scheme is intended to support importing countries in their regulatory decision-making, particularly where regulatory capacity may be limited.

In recent years, WHO has further promoted regulatory reliance as an efficient and science-based approach to medicine regulation. Regulatory reliance enables an NRA to consider and make use of the assessments, inspections, or regulatory decisions performed by another trusted regulatory authority while retaining full responsibility and accountability for its own regulatory decisions. Reliance helps optimize regulatory resources, avoid unnecessary duplication of work, facilitate timely access to quality-assured medicines, and strengthen international regulatory collaboration.

The WHO Certification Scheme serves as one of the important tools that supports regulatory reliance by providing standardized and internationally recognized information on pharmaceutical products. However, the Scheme is not intended to replace an independent regulatory assessment or automatically guarantee product registration. Importing countries remain responsible for ensuring that medicines placed on their market meet national requirements for quality, safety, and efficacy.

Accordingly, the level of reliance should be determined using a risk-based approach. Regulatory authorities may rely on the CPP, GMP certificates, inspection reports, or decisions from trusted regulatory authorities when sufficient confidence exists in the regulatory oversight of the exporting country. Conversely, where there are concerns regarding product risk, manufacturing complexity, previous GMP compliance, limited regulatory oversight, or insufficient information, the importing authority may undertake additional documentary assessments or conduct its own GMP inspection of domestic

or foreign manufacturing sites before granting or maintaining marketing authorization.

Domestic and Foreign GMP Inspections

While the WHO Certification Scheme and regulatory reliance provide valuable tools for regulatory decision-making, physical GMP inspection remains an essential regulatory function for assuring the quality of medicines. Documentary evidence such as a Certificate of a Pharmaceutical Product (CPP), GMP certificate, or inspection report can support regulatory assessment, but these documents cannot always provide complete assurance that manufacturing operations continue to comply with GMP requirements. An on-site inspection allows regulatory inspectors to directly verify facilities, equipment, quality management systems, manufacturing processes, documentation practices, data integrity, and implementation of corrective and preventive actions.

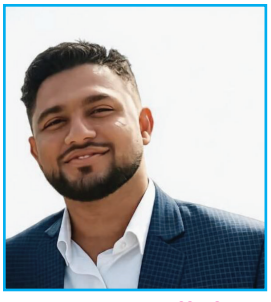
For domestic manufacturers, periodic physical GMP inspections are indispensable to ensure continuous compliance with national regulatory requirements and WHO GMP standards. Similarly, for foreign manufacturing sites supplying medicines to the national market, reliance on regulatory decisions of trusted authorities may be appropriate in certain circumstances; however, it should not replace the authority's ability to conduct its own inspections when justified. Foreign GMP inspections are particularly important for high-risk products, manufacturers with limited inspection history, facilities located in jurisdictions with less mature regulatory systems, or where quality concerns or compliance issues have been identified.

Therefore, a risk-based approach should determine when reliance is appropriate and when an independent physical inspection is necessary. While reliance can improve regulatory efficiency and reduce duplication of effort, physical GMP inspection should remain a mandatory regulatory tool where required to provide confidence that medicines are consistently manufactured in compliance with GMP and meet the required standards of quality, safety, and efficacy.

This balanced approach combines the benefits of international cooperation with national regulatory responsibility. By integrating the WHO Certification Scheme, regulatory reliance, and risk-based GMP inspections, regulatory authorities can strengthen oversight, make efficient use of available resources, avoid duplication of regulatory activities, and ensure that only quality-assured medicines are supplied to patients while maintaining a high level of public health protection.

Veterinary Drug Regulation in Nepal: Challenges, International Practices, and Future Directions

1. Introduction



Dr. Manoj Adhikari
Veterinary Doctor, DDA

Veterinary drugs play a crucial role in the prevention, diagnosis, and treatment of animal diseases. They also have a significant contribution in animal welfare, food security, and public health. Regulatory systems are essential to ensure that veterinary drugs available in the market meet the standard criteria for quality, safety, and efficacy.

Globally, veterinary medicine includes Pharmacological products, biologicals, vaccines, Antimicrobial agents, antiparasitic agents, and diagnostic products. International Organizations such as the World Organization for Animal Health (WOAH), previously known as the OIE, International Cooperation on Harmonization of Technical Requirements for Veterinary Medicinal Products (VICH), and the European Medicines Agency (EMA) have developed guidelines and standards to facilitate effective regulation of veterinary drugs. The regulation of veterinary drugs is linked with the One Health framework because inappropriate use of veterinary drugs may affect animal health, human health, as well as environmental sustainability through the emergence of Antimicrobial resistance and the presence of Drug residue in products of food animals.

2. Regulatory Framework for Veterinary Medicines in Nepal

The Drug Act, 2035, is the guiding document of legislation that controls drugs in Nepal. The Department of Drug Administration (DDA) was established by the Act as the national regulatory body regulating the production, import, export, distribution, sale, and use of pharmaceutical products.

Under the same statutory framework, the DDA controls veterinary, traditional (Ayurvedic) drugs, and human drugs. The DDA regulates the registration, licensing, quality control, inspection, and post-marketing surveillance procedures for veterinary products entering the Nepali market. However, the Drug Act was enacted before the emergence of many modern veterinary products and therefore lacks explicit provisions addressing contemporary veterinary pharmaceutical challenges.

It is the statutory obligation of DDA to ensure the safety, efficacy, and standard quality of drugs that are available in Nepal. Product registration, manufacturing plant inspection, import authorization, market monitoring, and enforcement actions against substandard and counterfeit goods are all examples of regulatory control activities of the Department.

3. Major Regulatory Challenges

3.1 Absence of Dedicated Veterinary Drug Legislation

Although the Drug Act, 2035, has provided the foundation for the regulation of veterinary medicines in Nepal, the rapid evolution of veterinary pharmaceutical products, including biologicals, biotechnology-derived products, and other advanced therapeutics, has introduced regulatory considerations.This emphasizes the importance of regularly assessing and enhancing regulatory rules to deal with new technologies and current veterinary healthcare demands.

3.2 Antimicrobial Resistance

The growing global concern regarding antimicrobial resistance has highlighted the importance of effective regulation of veterinary antimicrobial products. Given the widespread use of antimicrobial substances in management of animal diseases, it is crucial to ensure they are approved, distributed, and utilized responsibly. Strong regulatory supervision plays a key role in promoting responsible use of antimicrobials and backing efforts at national and global levels to reduce the threats linked with antimicrobial resistance.

3.3 Drug Residues in Food-Producing Animals

Ensuring the safety of food from animals involves thoroughly evaluating the use of veterinary drugs in animals raised for food. Animal-derived products like meat, milk, and eggs could contain traces of veterinary drugs if not used according to approved guidelines, such as recommended doses and withdrawal periods. Excessive residues can pose a risk to consumer health and affect the trade of livestock products domestically and internationally. Therefore, regulatory authorities globally prioritize setting maximum residue limits (MRLs), establishing withdrawal periods based on scientific evidence, and implementing effective monitoring mechanisms. The safe and responsible use of veterinary drugs can be supported while maintaining food safety by enhancing residue surveillance and raising awareness among veterinarians, animal health professionals, and livestock producers.

3.4 Substandard and Falsified Veterinary Medicines

The existence and distribution of low-quality, falsified and unregistered veterinary drugs continue to be a significant concern for regulators in maintaining the quality, safety, and effectiveness of veterinary healthcare. These medications might have inaccurate concentration of active ingredients, unsuitable additives, resulting in treatment failure, emergence of drug resistance, side effects, and potential harm to animals. These consequences not only jeopardize animal health and performance but also have indirect effects on public health, especially in animals raised for food, where drug residues and treatment failures can impact food safety and consumer trust.

3.5 Limited Veterinary Pharmacovigilance

Within Nepal's drug regulatory framework, veterinary pharmacovigilance is still a developing field. Currently, the systematic gathering, analysis, and interpretation of safety-related data pertaining to veterinary medical products is restricted by the lack of a specialized and thorough veterinary reporting system. Because of this, potential adverse drug reactions, treatment failures, or unexpected safety issues might not be frequently documented or reported through official regulatory channels, which would restrict regulatory authorities' capacity to recognize and react quickly to emerging safety signals.

3.6 Resource Constraints

Insufficient human resources and limited opportunities for ongoing professional development may limit regulatory personnel's ability to keep up with rapidly evolving veterinary pharmaceutical technologies, such as biological products, combination formulations, and novel therapeutic agents. Furthermore, the absence or restricted development of integrated digital information systems could hinder effective data management, traceability, and regulatory decision-making.

Insufficient human resources and limited opportunities for continued professional development may make it difficult for regulatory professionals to keep up with rapidly evolving veterinary pharmaceutical technology such as biological products, combination formulations, and innovative therapeutic agents. Furthermore, efficient data management, traceability, and quick regulatory decision-making may be hampered by the lack of or limited development of integrated digital information systems.

4. International Best Practices

International regulatory frameworks for veterinary pharmaceutical goods serve as useful reference points for enhancing and upgrading national regulatory systems. Among these, the European Union Veterinary Medicinal Products Regulation (EU 2019/6) is considered widely as a thorough and relevant model that reflects evolving standards of veterinary medicine regulation. A lifecycle approach to veterinary medications is emphasized by the regulation, which covers every phase from post-marketing surveillance to product development and authorization. Enhancing prompt access to safe and effective veterinary medications, lowering administrative and regulatory burdens, encouraging innovation in veterinary pharmaceuticals, strengthening pharmacovigilance systems, and supporting the global campaign against antimicrobial resistance are among its key objectives. Additionally, the framework emphasizes risk-proportionate regulatory constraints and evidence-based decision-making, especially for several veterinary medical product categories.

From the perspective of regulatory development, this approach is essential to take

account of in nations like Nepal, where veterinary medicine regulation is being carried out inside a more comprehensive pharmaceutical regulatory framework. The European Union's structured approach emphasizes the importance of species-specific considerations, dedicated regulatory pathways for veterinary biologicals, and well-established post-authorization monitoring systems, all of which are becoming more relevant in the context of a growing livestock and poultry sector.

Similarly, the World Organisation for Animal Health (WOAH) develops globally acknowledged standards and guidelines to help countries establish effective veterinary regulatory systems. WOAH strongly advocates for the implementation of prudent and responsible antimicrobial use policies, the establishment of pharmacovigilance and adverse event reporting systems, regular residue monitoring in food-producing animals, and effective enforcement mechanisms to prevent the circulation of substandard and falsified veterinary products. These concepts are strongly aligned with the One Health strategy and are especially important for countries dealing with antimicrobial resistance and food safety.

Furthermore, the International Cooperation on Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) plays a key role in promoting global harmonization of technical guidelines for veterinary medicine registration. The VICH recommendations address important aspects of veterinary pharmaceutical product quality, safety, efficacy, and environmental impact evaluation. Adoption or alignment with such harmonized technical requirements can help with regulatory convergence, product evaluation efficiency, and regulatory decision-making predictability. For Nepal, gradually harmonizing with selected VICH standards could help to modernize regulatory processes, increase technical uniformity in dossier evaluation, and enhance stakeholder confidence in the regulatory system.

5. Future Directions for Nepal

5.1 Development of Veterinary-Specific Regulatory Framework

Nepal may consider the progressive strengthening of its regulatory framework for veterinary medicinal products through the development of dedicated veterinary medicine provisions within the existing regulatory system or, where appropriate, through the establishment of a more specialized veterinary regulatory framework. Veterinary medications, biologicals, vaccines, feed additives, and emerging technologies like veterinary items produced from biotechnology would all be subject to more organized regulation under such a system. Addressing the variations in pharmacokinetics, safety assessment, dose forms, and residue considerations between human and veterinary medications would also be aided by a species-specific regulatory approach. Enhancing this area. would enable more focused regulatory monitoring and compliance to changing global standards..

5.2 Strengthening Veterinary Pharmacovigilance

The establishment of a structured veterinary pharmacovigilance system is critical for assuring continued monitoring of the safety and efficacy of veterinary drugs following market authorization. Such a system should allow for the systematic reporting, evaluation, and management of adverse drug reactions, treatment failures, and other medical problems. The development of standardized reporting tools, clear standardized reporting pathways, and centralized data management systems would improve signal detection and regulatory response. Strengthening pharmacovigilance will also help guide evidence-based regulatory decisions and promote the safe and rational use of veterinary pharmaceuticals in the field.

5.3 Enhancing Post-Marketing Surveillance

Post-marketing surveillance is an essential regulatory function that ensures veterinary pharmaceuticals on the market continually meet set standards of quality, safety, and efficacy. A risk-based surveillance system that focuses on high-risk items, essential therapeutic classes like antimicrobials, and products with a large market circulation can boost regulatory effectiveness. Improving laboratory testing capacity, inspection methods, and sampling techniques will aid in finding substandard, fraudulent, or noncompliant veterinary products. The integration of field monitoring, laboratory findings, and regulatory enforcement will improve the system's overall performance.

5.4 Strengthening Antimicrobial Stewardship

Given the critical function of antimicrobials in veterinary medicine and their link to antimicrobial resistance (AMR), regulatory measures should prioritize their safe and ethical application. To improve antimicrobial stewardship, promotion on prescription-only access to veterinary antimicrobials, regulation of their distribution routes, and ensuring rational application based on veterinary professional judgment should be made. Furthermore, monitoring antimicrobial consumption patterns and resistance developments in animal populations are critical components of an overall stewardship plan. These strategies collectively promote both animal health and public health objectives within the One Health concept..

5.5 Adoption of One Health Approaches

The One Health concept acknowledges the link between human health, animal health, and the environment. The Department of Drug Administration (DDA), Department of Livestock Services (DLS), public health authorities, food safety organizations, academic institutions, and environmental agencies are some of the stakeholders that must work together to effectively regulate veterinary pharmaceuticals. Improving collaboration among organizations can improve monitoring systems, increase information exchange, and promote integrated

responses to challenges including antibiotic resistance, drug residues, and zoonotic disease concerns. Adopting this method will improve the overall effectiveness and sustainability of veterinary drug regulation in Nepal.

5.6 Regulatory Harmonization

Nepal's veterinary Drug regulatory system can be greatly strengthened by harmonization with globally accepted regulatory standards, such as those published by the World Organization for Animal Health (OIE) and the VICH effort. Regulatory decision-making can become more standardized and consistent by adopting certain rules related to quality, safety, efficacy, and environmental risk assessment. Additionally, regulatory convergence promotes alignment with international best practices and enables improved technical evaluation of veterinary pharmaceuticals. While considering into account national capacity and priorities, a progressive and context-appropriate adoption of these standards will help modernize Nepal's regulatory system.

6. Conclusion

Veterinary medicines are crucial for ensuring animal health, increasing livestock productivity, assuring food security, and safeguarding public health. The Department of Drug Administration in Nepal established a basic regulatory framework for drugs; however, the regulatory framework needs to be strengthened further considering the growing complexity of veterinary pharmaceutical products and evolving public health issues.

Modernizing veterinary-specific product regulations, creating a functional pharmacovigilance system, strengthening post-marketing surveillance, and improving antimicrobial use control to combat antimicrobial resistance are important issues that need to be addressed. Building a more strong and efficient regulatory system will also require implementing a One Health strategy and adhering to international regulatory norms.

To ensure that veterinary drugs in Nepal are safe, effective, and of reliable quality throughout their lifecycle, future standards and regulations should concentrate on evidence-based decision-making, institutional capacity building, and gradual regulatory harmonization. These initiatives will eventually lead to better animal health outcomes, increased food safety, and public health protection.

Transforming Laboratory Efficiency through LIMS: Strengthening Quality Control Systems for Regulatory Advancement

Barsha Shakya
Quality Control Officer, NML

In Nepal's evolving governance landscape, recent policy directions have emphasized the need for faster public service delivery, improved transparency, and enhanced citizen satisfaction. Central to this transformation is the continued implementation of the Digital Nepal Framework, which envisions the integration of digital technologies across public institutions. Within this context, the National Medicines Laboratory (NML), as a drug quality control laboratory engaged in critical pharmaceutical testing, is uniquely positioned to benefit from digital modernization. The adoption of a Laboratory Information Management System (LIMS) represents a critical step for NML toward achieving these national objectives while significantly strengthening the reliability, traceability, and efficiency of its laboratory operations.

Understanding LIMS in Laboratory Systems

A LIMS is a specialized digital platform designed to manage laboratory workflows, including sample registration, tracking, analysis, data storage, and reporting. By replacing paper-based systems and fragmented data management practices, LIMS enables laboratories to operate with greater precision, consistency, and accountability. Internationally, regulatory laboratories operating under agencies such as the U.S. Food and Drug Administration have successfully integrated LIMS into their operations, resulting in improved turnaround times, enhanced data integrity, and stronger compliance with regulatory standards.

As Nepal's drug quality control laboratory, NML's analytical results directly influence regulatory decisions and public health outcomes regarding product safety, efficacy, and quality. A LIMS will play a vital role in ensuring NML generates high-quality, defensible laboratory reports by minimizing manual transcription errors, enforcing standardized pharmacopeial workflows, and incorporating secure audit trails. Ultimately, these features will uphold strict data integrity principles, ensuring NML's laboratory results remain transparent, traceable, and fully defensible during regulatory reviews and inspections.

Challenges in Existing Systems

Despite the global shift toward automated laboratories, many facilities in developing environments continue to rely on manual or semi-digital frameworks. Paper-based recordkeeping can cause prolonged turnaround times, difficult data retrieval, and complex data tracking across laboratory sections. In NML, the implementation of LIMS is essential for several critical functions, such as sample entry, reference standard management, chemicals and glassware inventory management, preparation of analytical data sheets, internal report

preparation, Certificate of Analysis (COA) preparation and so on. Currently, the same data often needs to be recorded at multiple stages and by different personnel, which increases the possibility of errors and creates additional administrative workload.

However, the successful adoption of LIMS is contingent upon the establishment of a strong foundational system within the laboratory. Digital transformation cannot be achieved through software implementation alone; it requires careful preparation in terms of infrastructure, processes, human resources, and data governance. Reliable power supply, stable internet connectivity, and appropriate hardware are essential prerequisites for system functionality. Equally important is the standardization of laboratory procedures, including the development and documentation of clear standard operating procedures aligned with international quality standards such as ISO/IEC 17025. Human capacity building is another critical component, as laboratory personnel must be adequately trained in both digital tools and data integrity principles to ensure effective system utilization. Additionally, robust data management and cyber security measures must be established to protect sensitive information and maintain system integrity. A phased implementation in NML beginning with institutional readiness, followed by pilot testing, and eventual full-scale rollout ensures effective integration while minimizing disruption.

Foundational Requirements for Implementation

Transitioning NML to a digital system requires careful financial planning. The initial budget shall cover the procurement and implementation of the Laboratory Information Management System (LIMS), including software licenses, database configuration, hardware upgrades, and integration with laboratory instruments used in NML's testing activities. Long-term sustainability depends on allocating an annual budget of approximately 15% to 20% of the initial system cost for an Annual Maintenance Contract (AMC). This funding supports technical assistance, server hosting, software updates, security enhancements, and routine system maintenance.

LIMS is best regarded as a long-term infrastructure investment rather than a one-time purchase. Maintaining a dedicated annual budget for system maintenance and future expansion helps ensure continued reliability, scalability, and compliance with international ISO/IEC 17025 quality standards.

Conclusion

In conclusion, the implementation of a Laboratory Information Management System represents a strategic investment in the future of quality control laboratories. It is not merely a technological upgrade but a comprehensive approach to improving the accuracy, efficiency, and credibility of laboratory services. By ensuring the production of reliable and high-quality laboratory reports, LIMS strengthens the foundation of regulatory systems and supports the overarching goal of protecting public health. As Nepal continues its journey toward digital governance and institutional reform, the integration of LIMS within NML stands as a critical enabler of regulatory excellence and sustainable development.

Recent Advances in the Treatment of *Helicobacter pylori* Infection: A review in Effectiveness of Updated Therapies

Introduction

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Helicobacter pylori is a Gram-negative, spiral-shaped bacteria that colonizes the human gastric mucosa and has adapted to survive in the harsh acidic environment of the stomach (Howden et al., 2024). It is the leading cause of infection-associated cancer globally and is classified as a Group I carcinogen by the World Health Organization (WHO). *H. pylori* infection is causally linked to dyspepsia, peptic ulcer disease, mucosa-associated lymphoid tissue (MALT) lymphoma, and gastric adenocarcinoma (Chey et al., 2024). The global prevalence of *H. pylori* infection is estimated at 43.9% in adults and 35.1% in children and adolescents (Chen et al., 2024). The burden is disproportionately higher in developing nations, with South Asia reporting a prevalence of 57.7% (Ranjan et al., 2024). In Nepal, *H. pylori* infection was detected in 28.41% of patients undergoing upper gastrointestinal endoscopy at Tertiary Care Center of Nepal (Sharma et al., 2024). The current established treatments for *H. pylori* infection are numerous and include triple and quadruple therapy, both of which utilize two antibiotics (metronidazole, amoxicillin, tetracycline, or clarithromycin) in addition to either a proton pump inhibitor (PPI) (triple therapy) or a PPI and bismuth (quadruple therapy) (Benites et al., 2018). Different treatment regimens of varying duration with varying success rates are used for *H. pylori* eradication. There is a rising concern about ever-increasing antimicrobial resistance to these regimens (Thung et al., 2016). Rising antimicrobial resistance has significantly compromised the efficacy of traditional eradication regimens. The ACG Clinical Guideline 2024 represents a landmark update that introduces novel treatment options including rifabutin-based triple therapy and PCAB-based dual therapy while reaffirming bismuth quadruple therapy as the most robust empirical option. This review critically examines recent advances in *Helicobacter pylori* treatment and discusses their significance in the context of Nepal's healthcare system.

Previous Treatment Protocol: ACG Clinical Guideline 2017

The ACG Clinical Guideline 2017 recommended the following first-line treatment options:

- **Clarithromycin triple therapy:** A proton pump inhibitor (PPI), clarithromycin, and amoxicillin or metronidazole for 14 days, recommended in regions where *H. pylori* clarithromycin resistance is known to be <15% and in patients with no prior macrolide exposure.
- **Bismuth-based quadruple therapy:** A preferred option for individuals with prior macrolide exposure or penicillin hypersensitivity.
- **Concomitant therapy:** A PPI, clarithromycin, amoxicillin, and a nitroimidazole for 10–14 days, recommended as a first-line option.

National Antimicrobial Treatment Guidelines 2023, Nepal: *H. pylori* Treatment Regimens

The National Antimicrobial Treatment Guidelines 2023 of Nepal recommend the following regimens:

- **Preferred Treatment: Clarithromycin-Based Triple Therapy**

  Clarithromycin 500 mg PO every 12 hours Plus Amoxicillin 1 g PO every 12 hours (Metronidazole 400 mg PO every 12 hours may be substituted if amoxicillin cannot be used)

- **Alternative Preferred Treatment: Levofloxacin-Based Triple Therapy**

  Levofloxacin 500 mg PO every 24 hours Plus Amoxicillin 1 g PO every 12 hours

- **Alternative Treatment: Bismuth-Based Quadruple Therapy**

  Metronidazole 200 mg PO every 6 hours Plus Tetracycline 500 mg PO every 6 hours Plus Bismuth subsalicylate 300 mg PO every 6 hours

- **Proton Pump Inhibitor (PPI) Therapy** (to be used with all regimens): Pantoprazole 40 mg, Omeprazole 20 mg, Esomeprazole 20 mg, Rabeprazole 20 mg, or Lansoprazole 30 mg all PO every 12 hours

- **Duration:** 14 days

Note: *Metronidazole is not preferred as a first-line component of triple therapy due to common resistance in Nepal. When used, it may be administered at 400 mg every 8–12 hours depending on clinical circumstances and local guidelines.*

Antimicrobial Resistance: A Growing Challenge

Antimicrobial resistance is the principal driver of eradication failure in *H. pylori* management. A ten-year trend analysis cited in the ACG Clinical Guideline 2024 demonstrated increasing resistance rates for clarithromycin (21% to 30%), ciprofloxacin (3% to 16%), and tetracycline (5% to 20%) from 2003 to 2022 (Chey et al., 2024). A meta-analysis further revealed a high prevalence of resistance to commonly used antibiotics among *H. pylori* isolates in South Asian countries (Shrestha et al., 2023).

In Nepal specifically, Miftahussurur et al. (2016) documented emerging levofloxacin resistance and identified novel genetic mutations in Nepalese *H. pylori* strains, raising concerns about the sustained efficacy of levofloxacin-based regimens recommended by the National Antimicrobial Treatment Guidelines 2023. Macrolide resistance, driven primarily by point mutations in the 23S rRNA gene, is also recognized as common in Nepal, further limiting the utility of clarithromycin-based triple therapy as a first-line option.

Rationale for Revised Treatment Protocols: ACG Clinical Guideline 2024

The ACG Clinical Guideline 2024 was driven by two principal factors:

- **Rising antibiotic resistance:** Resistance to clarithromycin and levofloxacin has

rendered conventional regimens increasingly ineffective in many regions, including South Asia.

- **Emergence of novel therapeutic options:** Recent studies have evaluated novel treatment regimens featuring new antibiotic options (i.e., rifabutin) or more potent, next-generation gastric acid-suppressing agents (i.e., potassium-competitive acid blockers (PCABs) in treatment-naive individuals, demonstrating comparable or superior eradication rates with improved tolerability.

Evidence for PCAB-Based Therapies in treatment of *H.pylori* infection

- Vonoprazone Amoxicillin (VA) dual therapy provided a higher eradication rate, enhanced compliance, decreased adverse events, and lowered cost relative to bismuth-containing quadruple therapy (BQT) for patients with *H. pylori* infection (Li et al., 2025).
- A study showed a similar eradication rate of *H. pylori* but a significantly lower incidence of adverse events in the vonoprazan and amoxicillin (VA) group compared with the bismuth-based therapy (BBT) group. The analysis suggests that a VA-based regimen is an acceptable treatment option for *H. pylori* patients who cannot tolerate BBT (Abosheaishaa et al., 2025).
- Vonoprazan–amoxicillin (VA) dual therapy achieved comparable *H. pylori* eradication rates to those achieved with esomeprazole, bismuth, amoxicillin, and clarithromycin (EBAC), while offering better safety and a more convenient regimen, supporting it as a preferred first-line treatment for *H. pylori* infection (Fan et al., 2025).

Evidences for Rifabutin-based therapies in treatment of *H.pylori* infection

- Gugnani et al. (2023) concluded that rifabutin-based regimens represent a promising and effective alternative for *H. pylori* eradication, especially in patients who have failed multiple prior treatment attempts or in regions where resistance to conventional antibiotics is prevalent.
- Chen et al., 2023 concluded that rifabutin-containing triple therapy is an effective and better-tolerated alternative to bismuth quadruple therapy for rescue *H. pylori* eradication, offering clinicians a simplified option particularly useful in patients with prior treatment failures or intolerance to standard regimens.
- Vonoprazan-based regimens performed comparably or better than conventional PPI-based therapies, achieving eradication rates of 83.3% to 89.5%, while maintaining a similar adverse event profile. The potassium-competitive acid-blocking mechanism of vonoprazan appears to offer a meaningful pharmacological advantage over standard PPIs in achieving consistent gastric acid suppression regardless of meal timing or CYP2C19 metabolizer status. Rifabutin-containing triple therapy emerged as particularly valuable for patients with a history of multiple prior treatment failures, with efficacy ranging from 80.7% to 100%. Importantly, it was associated

with fewer adverse events compared to bismuth-containing quadruple regimens, making it an attractive option in heavily pre-treated patients where tolerability and compliance are ongoing concerns (Liu & Nahata, 2024).

Conclusion

Helicobacter pylori eradication strategies have evolved significantly in response to rising antimicrobial resistance. Recent evidence supports the use of bismuth quadruple therapy as the preferred empiric treatment, while vonoprazan-based dual therapy and rifabutin-based triple therapy have emerged as effective and well-tolerated alternatives. Given the increasing resistance to clarithromycin and levofloxacin in Nepal, continued reliance on traditional triple therapies may compromise eradication success. Therefore, updating national treatment guidelines to incorporate newer evidence-based regimens and strengthening antimicrobial resistance surveillance are essential to improve treatment outcomes and reduce the burden of *H. pylori* associated diseases in Nepal.

Recommendation

In view of the increasing resistance to clarithromycin and levofloxacin in Nepal, the National Antimicrobial Treatment Guidelines should be updated to recommend optimized bismuth quadruple therapy as the preferred first-line empiric treatment for *Helicobacter pylori* infection. Efforts should also focus on expanding antimicrobial susceptibility testing, facilitating access to newer therapies such as vonoprazan and rifabutin-based regimens, and conducting local research on resistance patterns and treatment outcomes. Strengthening antimicrobial stewardship programs is equally important to preserve the effectiveness of available treatment options and improve eradication success.

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Role of National Medicines Laboratory (NML) as the National Reference Laboratory of Nepal

Introduction

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The National Medicines Laboratory (NML) is Nepal's principal government laboratory for scientific testing, analysis, and research of medicines. Established under the Section-6(1) of Drug Act-1978, NML serves as the national authority for laboratory-based quality assurance of medicines and health products. Over the years, NML has evolved into a key institution supporting medicine regulation, public health protection, and quality surveillance in Nepal.

The recent achievement of ISO/IEC 17025:2017 accreditation has further strengthened NML's credibility and demonstrated its technical competence in laboratory testing. This accreditation provides international recognition of test results and supports confidence in Nepal's pharmaceutical quality assurance system.

Current Functions of NML

At present, NML performs the following major functions:

- Quality testing and analysis of medicines for regulatory purposes.
- Pre-marketing and post-marketing surveillance testing.
- Method validation for non-pharmacopoeial products.
- Vaccine and biological product lot release and verification.
- Laboratory audit and Good Laboratory Practice (GLP) oversight.
- Capacity building and training of laboratory professionals.

The laboratory currently operates through specialized sections including Testing & Analysis, Microbiology, Biological Testing, Quality Control & Management and Method Validation.

NML as the National Reference Laboratory

As Nepal moves toward strengthening its regulatory system, NML should be positioned as the **National Reference Laboratory under the Ministry of Health and Food safety**. Regardless of the future regulatory structure, a strong national reference laboratory is essential for evidence-based regulatory decision-making.

NML should serve as the highest scientific authority for laboratory testing and verification of:

- Medicines and pharmaceutical products.
- Vaccines and biological products.
- Medical devices and diagnostic products.

- Traditional and herbal medicines.
- Nutraceuticals and other health-related products.

As the national reference laboratory, NML would provide scientific evidence for regulatory actions, quality assurance programs, surveillance activities, and public health interventions.

Expansion of Testing Capacity

To meet future national requirements, NML should progressively expand its laboratory scope beyond conventional pharmaceutical testing. Strengthening laboratory infrastructure and human resources will enable testing of:

- Biological products and vaccines.
- Medical devices and diagnostic kits.
- Traditional and herbal medicines.
- Nutraceutical and health products.
- Cytotoxic and specialized pharmaceutical products.

Such expansion will improve Nepal's ability to independently evaluate product quality, safety, and performance.

1. Vaccine and Biological Product Verification

NML plays a critical role in vaccine lot release and verification. Independent testing of vaccines and biological products helps ensure that products entering the Nepalese market meet required quality, potency, and safety standards.

With increasing use of vaccines and biological products, strengthening this function will remain a national priority for safeguarding public health.

2. Detection of Substandard and Falsified Medical Products

The circulation of substandard and falsified medical products remains a significant public health concern. NML provides scientific evidence through laboratory analysis to identify:

- Substandard products.
- Falsified medicines.
- Counterfeit health products.
- Quality defects affecting patient safety.

A strengthened NML will enhance national surveillance systems and support timely regulatory interventions to protect the public from poor-quality products.

3. Research, Method Development, and Analytical Method Validation

Scientific research and analytical method development should remain a core mandate of NML. The laboratory should lead the development and validation of testing methods for products that are not adequately covered by international pharmacopoeias.

Rather than functioning through a temporary committee structure, **Analytical Method Validation (AMV) should be established as a dedicated and strong**

technical section within NML, supported by qualified experts, standardized procedures, and quality systems. This approach will provide long-term institutional sustainability and strengthen national laboratory capacity.

The AMV function should support:

- Development of validated analytical methods.
- Verification and transfer of testing methods.
- Standardization of laboratory procedures.
- Scientific support for future Nepal Pharmacopoeia initiatives.

4. Strengthening Private and External Laboratories

Private analytical laboratories and pharmaceutical industry laboratories play an important role in Nepal's quality assurance ecosystem. Since regulatory authorities frequently depend on reports generated by these laboratories, strengthening their technical capacity is essential.

NML should provide technical leadership through:

- Proficiency testing and inter-laboratory comparison programs.
- Technical guidance and mentorship.
- Laboratory audits and quality assessments.
- Promotion of Good Laboratory Practices (GLP).
- Capacity-building and training activities.

A stronger network of competent private laboratories will improve national testing capacity and complement the work of NML.

Key Requirements for Strengthening NML

To effectively function as the National Reference Laboratory, NML requires:

- Strengthened legal and regulatory provisions.
- Expansion of skilled human resources.
- Modern laboratory infrastructure and equipment.
- Sustainable financing mechanisms.
- Advanced research and method development capacity.
- Strong collaboration with provincial, academic, and private laboratories.

Conclusion

The National Medicines Laboratory is the scientific foundation of Nepal's medicine quality assurance system. Strengthening NML as the National Reference Laboratory under the Ministry of Health and Population will enhance regulatory decision-making, improve surveillance of medicines and health products, support private laboratory development, and protect public health. A robust NML will ensure that Nepal has the scientific capacity necessary to maintain high standards of quality, safety, and effectiveness for health products nationwide.

Common Pitfalls in Analytical Method Validation

1. Introduction

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Analytical methods are the foundation of quality control and regulatory compliance in pharmaceutical laboratories. Whether testing active pharmaceutical ingredients (APIs), finished pharmaceutical products, raw materials, laboratories must ensure that analytical methods generate accurate, reliable, and reproducible results.

Method validation establishes documented evidence that an analytical procedure is fit for its intended purpose. Regulatory frameworks including the International Council for Harmonization guideline Q2(R2), United States Pharmacopeia General Chapter <1225>, and International Organization for Standardization/IEC 17025 provide guidance on validation requirements.

Despite the availability of comprehensive guidelines, many manufacturer or laboratories encounter challenges that compromise the validity of their studies and the reliability of test results. Common pitfalls include poor validation planning, inadequate sample selection, inappropriate statistical evaluation, insufficient robustness testing, and incomplete documentation. Understanding these pitfalls is essential for maintaining data integrity and ensuring product quality.

2. Common Pitfalls in Analytical Method Validation

2.1 Unsuitable Selection of analytical method: The analytical method should be stability-indicating, with the ability to detect changes in the quality attributes of a product throughout storage. Instrumental techniques such as high-performance liquid chromatography (HPLC) and gas chromatography (GC) are generally preferred over titration and colorimetric methods due to their superior specificity and sensitivity. Suitable analytical methods may be selected based on recognized pharmacopoeias or published scientific literature.

Furthermore, the analytical method should be thoroughly optimized before initiating method validation. An inadequately developed method is unlikely to satisfy validation requirements, often resulting in repeated experiments, increased resource utilization, and delays in the analytical process.

2.2 Inadequate Validation Planning: Conducting method validation without a comprehensive and well-defined validation protocol is one of the most common mistakes made by manufacturers. The validation plan should clearly specify the method's scope and intended purpose, validation parameters, acceptance criteria, experimental design, statistical evaluation methods, and the roles, responsibilities, and approval requirements.

Inadequate planning can lead to incomplete validation studies, unnecessary repeat testing, inefficient use of resources, and inconsistent or unreliable conclusions. Upon completion of the validation study, the findings should be compiled and documented in a comprehensive validation report.

2.3 Failure to Understand Regulatory Requirements: A common mistake in analytical method validation is the failure to recognize that different types of analytical methods require different validation parameters. Applying validation characteristics that are not relevant to the intended analytical procedure can lead to unnecessary testing, inefficient use of resources, and the generation of redundant data. Therefore, validation requirements should be selected in accordance with the purpose of the analytical method and applicable regulatory guidelines. The table below outlines the performance characteristics recommended for different types of analytical procedures.

Table 1

Type of Analytical Procedures; Characteristics	Identification	Testing for Impurities Quantitation Limit		Assay; Dissolution (measurement only); content/potency
Accuracy	-	+	-	+
Precision	-	+	-	+
Repeatability	-	+	-	+
Intermediate Precision	-	+	-	+
Specificity	+	+	-	+
Detection Limit	-	- *	+	-
Quantitation Limit	-	+	+	-
Linearity	-	+	-	+
Range	-	+	-	+

**May be needed in some case*

2.4 Inappropriate Sample Selection: Selecting unsuitable samples for method validation can compromise the demonstration of method specificity and selectivity. To adequately establish the specificity of a stability-indicating analytical method, the validation study should include samples spiked with target analytes and known interfering substances, samples subjected to relevant physical and chemical stress conditions to generate degradation products, and actual product samples that have been naturally aged or stored under accelerated or stressed conditions. The inclusion of these representative samples ensures that the method can reliably distinguish the analyte of interest from degradation products, impurities, and other potential interferences.

2.5 Different Standard and Sample concentration: During analytical method validation, the concentrations of the standard and sample solutions should ideally be the same. When different concentrations are used, the method's linearity, range, and accuracy must be demonstrated across both concentration levels. This approach increases the complexity of the validation study and requires additional experimentation. In practice, many manufacturers evaluate linearity, range, and accuracy only within 80–120% of the

nominal standard concentration. Consequently, if the sample concentration falls outside this validated range, the method may not be demonstrated to be suitable for its intended purpose.

Example: If the standard concentration is 8 ppm and the sample concentration is 12 ppm, and the validation range is established at 80–120% of the standard concentration (6.4–9.6 ppm), the sample concentration lies outside the validated analytical range. In such cases, the method has not been validated at the concentration used for sample analysis, potentially affecting the reliability of the analytical results.

2.6 Insufficient Specificity Studies: Many laboratories demonstrate chromatographic separation but do not adequately establish that the analytical method can accurately quantify the analyte in the presence of impurities, degradation products, excipients, and other matrix components. For stability-indicating methods, forced degradation studies are essential to confirm method specificity. In products containing multiple APIs, potential interference between the APIs should also be evaluated to ensure that each API can be accurately measured without affecting the determination of the other.

2.7 Overreliance on Correlation Coefficients: A correlation coefficient (R^2) greater than 0.999 alone is not sufficient to demonstrate acceptable linearity. While a high R^2 indicates a strong linear relationship, it does not confirm the absence of systematic bias, consistent analytical response across the calibration range, or the suitability of the calibration model. A comprehensive assessment of linearity should also include evaluation of residual plots, calibration slope and intercept, and the accuracy of back-calculated concentrations to ensure reliable method performance.

2.8 Inadequate Accuracy Assessment: According to the WHO guideline on analytical method validation, accuracy should be demonstrated across the entire specified range of the analytical procedure. For example, if the validated range is 50%–150% of the target concentration, accuracy should be evaluated throughout this range. However, many laboratories routinely perform accuracy studies only at 80%, 100%, and 120% of the test concentration, regardless of the validated range, which does not adequately establish method accuracy.

When preparing placebo-spiked samples, only the API concentration should be varied while maintaining a constant placebo composition. In some cases, both the API and placebo concentrations are varied simultaneously, which is not an appropriate approach for accuracy assessment.

Furthermore, accuracy should be established using independently prepared replicate samples at each concentration level. Performing multiple injections of a single prepared sample does not demonstrate accuracy; instead, separate replicate sample preparations (e.g., triplicates) should be analyzed at each concentration level.

2.9 Insufficient Precision Studies: During intermediate precision studies, many laboratories prepare only triplicate samples at the 100% test concentration. However, standard validation guidelines recommend either six independent determinations at the 100% test concentration or nine determinations covering the entire specified analytical range to adequately demonstrate precision.

Intermediate precision should also assess the impact of normal analytical variations, such as different analysts, instruments, days of analysis, reagent lots, and other relevant laboratory conditions, to confirm the reproducibility of the method under routine use.

In addition, precision should be evaluated based on the final analytical results (e.g., assay values or percentage drug release) rather than on instrument responses such as chromatographic peak areas or UV absorbance values. The %RSD should therefore be calculated using the reported test results, not the raw detector responses.

2.10 Poor Determination of LOD and LOQ: In many laboratories, LOD and LOQ are estimated theoretically using signal-to-noise ratios derived from high-concentration standards. However, a more appropriate approach is to assess noise and variability using samples close to the expected detection limit. It is also necessary to experimentally confirm that the LOD yields a clearly detectable signal and that the LOQ demonstrates acceptable accuracy and precision. In addition, these determinations should be verified using actual sample matrices rather than relying solely on standard solutions.

2.11 Neglecting Robustness Studies: Robustness studies for an analytical method should evaluate the effect of small, deliberate variations in critical parameters such as mobile phase composition, flow rate, column temperature, detection wavelength, and pH. For dissolution testing methods, factors including medium composition, volume, agitation speed, sampling time, and temperature should also be systematically assessed. Failure to perform robustness testing can result in methods that appear valid during development but may perform unreliably under routine laboratory conditions.

2.12 Incorrect Stability studies of Standard & Sample Solution: The stability of standard and sample solutions should be evaluated by comparing solutions stored at room temperature and under refrigeration against freshly prepared standard solutions at defined time intervals. This ensures that any changes in solution integrity over time are properly assessed.

2.13 Inadequate Statistical Analysis: In some cases, statistical evaluation is restricted to basic calculations such as mean values and percent recovery. However, a complete validation should incorporate more robust statistical tools, including standard deviation, relative standard deviation (%RSD), confidence intervals, regression analysis, and, where appropriate, analysis of variance (ANOVA). Insufficient statistical evaluation may result in misleading or incorrect conclusions about the performance of the analytical method.

2.14 Acceptance criteria not as per guideline: According to the AMV guideline (AMVP/076-77-02), the recommended acceptance range for assay by HPLC is a recovery of 98%–102%. However, some validation reports use wider limits, such as 95%–105%, which do not align with the specified criteria. Similarly, the acceptance criteria for precision are typically set at %RSD $\leq$ 2.0% for repeatability and %RSD $\leq$ 3.0% for intermediate precision, whereas some submitted validation documents apply a broader limit of %RSD $\leq$ 5.0%.

2.15 Poor Documentation and Data Integrity Practices: During document reviews, it is common to encounter missing raw data, calculations, and chromatograms. In addition, there is often insufficient traceability, particularly regarding the use of reference standards and equipment calibration records, which undermines overall data integrity.

2.16 Failure to Revalidate After Method Changes: A validated method should be revalidated whenever significant changes occur, such as modifications to the method itself, alterations in the sample matrix, or changes in the manufacturing process. If the impact of these changes is not properly assessed through revalidation, the reliability and performance of the method may be compromised.

3. Recommendations for Best Practice

The validation programme can be improved by implementing the following measures:

1. Developing comprehensive validation protocols prior to initiating experiments.
2. Adhering to international guidelines such as ICH Q2(R2), USP, and ISO/IEC 17025, as well as relevant national requirements.
3. Defining scientifically sound and justified acceptance criteria.
4. Using representative samples and relevant matrices for evaluation.
5. Conducting thorough robustness studies to assess method reliability under small deliberate variations.
6. Applying appropriate and robust statistical tools for data evaluation.
7. Ensuring complete documentation with full traceability of all data and procedures.
8. Performing periodic reviews of method performance throughout its lifecycle.
9. Providing adequate training to analysts on validation principles and statistical evaluation.
10. Implementing a risk-based approach to manage the entire analytical method lifecycle.

4. Conclusion

Analytical method validation is not merely a regulatory obligation but a critical scientific exercise that establishes the reliability and credibility of analytical results. Issues such as inadequate study planning, limited evaluation of specificity, excessive dependence on correlation coefficients, insufficient robustness assessment, and incomplete documentation can compromise method performance and data quality. Addressing these challenges through a structured and comprehensive validation approach enhances analytical reliability, facilitates regulatory compliance, and ensures the generation of accurate, high-quality, and scientifically defensible data.

References

1. ICH Q2(R2): Validation of Analytical Procedures.
2. USP General Chapter <1225>: Validation of Compendial Procedures.
3. ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories.
4. WHO Guideline: Appendix 4, Analytical Method Validation
5. FDA Guidance for Industry: Analytical Procedures and Methods Validation.
6. Guideline on Analytical Method Validation on Non-pharmacopoeial Products for Regulatory Approval (AMVP/076-77-02)

आयुर्वेद उद्योग: अवसर, चुनौती र भविष्य

सुमन प्रसाद पाण्डेय
निवर्तमान अध्यक्ष
नेपाल आयुर्वेद औषधि उत्पादक संघ (AMPAN)

नेपालमा आयुर्वेद चिकित्सा पद्धति हजारौं वर्षदेखि जनस्वास्थ्यको महत्वपूर्ण आधारका रूपमा रहँदै आएको छ । विशेषगरी ग्रामीण क्षेत्रमा अझै पनि करिब ६०-७० प्रतिशत जनसंख्या प्राथमिक स्वास्थ्य सेवाका लागि परम्परागत तथा आयुर्वेदिक उपचार प्रणालीमा निर्भर रहेको विभिन्न अध्ययनहरूले देखाएका छन् । पछिल्ला वर्षहरूमा विशेषगरी कोभिड-१९ महामारीपछि रोग प्रतिरोधात्मक क्षमता अभिवृद्धि गर्ने तथा विभिन्न नसर्ने रोगहरूको व्यवस्थापनमा आयुर्वेद औषधि र जडीबुटीजन्य उत्पादनहरूको प्रयोग उल्लेखनीय रूपमा बढेको छ । यसले आयुर्वेदप्रतिको जनविश्वास तथा बजार विस्तार दुवैलाई संकेत गर्दछ ।

हाल नेपालमा आयुर्वेद औषधि उत्पादन गर्ने ७२ वटा उद्योग औषधि व्यवस्था विभागमा दर्ता रहेका छन् । साथै औषधि व्यवस्था विभागमा एलोपेथिक, आयुर्वेदिक/हर्बल तथा अन्य श्रेणीका गरी करिब २५,००० भन्दा बढी औषधि तथा स्वास्थ्यसम्बन्धी उत्पादनहरू दर्ता रहेको अनुमान छ । यसले नेपालको औषधि बजार निरन्तर विस्तार भइरहेको देखाउँछ । तथापि अझै पनि केही उद्योग तथा उत्पादनहरू घरेलु तवरमा सञ्चालन तथा अनधिकृत बिक्री-वितरणमा संलग्न रहेका कारण गुणस्तर र उपभोक्ता सुरक्षामा चुनौती देखिएको छ । त्यसैले उत्पादनदेखि बजारसम्म प्रभावकारी नियमन र अनुगमन प्रणालीको आवश्यकता रहेको छ ।

आयुर्वेद औषधिको प्रभावकारिता यसको गुणस्तरमा निर्भर रहन्छ । उत्पादन प्रक्रियामा Good Manufacturing Practice (GMP), WHO-GMP मापदण्ड तथा औषधि व्यवस्था विभागले तोकेका निर्देशिकाहरूको पूर्ण पालना हुनुपर्छ । नेपालमा ध्ज्इ-न्ए मापदण्ड अपनाउने उद्योगहरूको संख्या क्रमशः बढ्दै गएको छ, जसले नेपाली आयुर्वेद औषधिको अन्तर्राष्ट्रिय विश्वसनीयता अभिवृद्धि गरेको छ । साथै आवश्यकता अनुसार औषधिको गुणस्तर सुनिश्चित गर्न आधुनिक प्रयोगशाला, Stability Study, Microbial Test तथा Heavy Metal Test जस्ता परीक्षण प्रणालीलाई थप सुदृढ र प्रभावकारी बनाउँदै लैजान आवश्यक छ ।

यसका अतिरिक्त दक्ष फर्मासिस्टको निगरानी तथा GMP मापदण्डअनुसार उत्पादन गरिएका, निर्धारित मात्रा (Prescribed Dose) स्पष्ट उल्लेख भएका र स्वदेशमै उत्पादित आयुर्वेद औषधिहरूको बिक्री-वितरणमा देखिएका केही नीतिगत समस्याहरू पनि सम्बोधन गर्न आवश्यक छ । उदाहरणका लागि आयुर्वेद औषधि एलोपेथिक फार्मेसीमार्फत बिक्री-वितरण गर्न नपाइने व्यवस्थाले उपभोक्ताको पहुँच सीमित बनाएको छ । यस्ता विषयमा औषधि व्यवस्था विभागले समयानुकूल नीतिगत सुधार गरी बिरामी तथा उपभोक्तालाई सहज उपलब्धताको व्यवस्था गर्न सके आयुर्वेद उद्योगलाई थप प्रोत्साहन मिल्नुका साथै विद्यमान समस्याहरूको समाधान हुन सक्ने देखिन्छ ।

आयुर्वेद उद्योगहरूले प्रत्यक्ष तथा अप्रत्यक्ष रूपमा हजारौं व्यक्तिलाई रोजगारी प्रदान गरिरहेका छन् । पछिल्लो समयमा जडीबुटी संकलन, खेती, प्रशोधन, प्याकेजिङ तथा वितरण प्रणालीमार्फत ग्रामीण अर्थतन्त्रमा समेत सकारात्मक प्रभाव परेको छ । यदि सरकारले सातै प्रदेशमा Herb Collection Center, Processing Hub तथा Quality Testing Laboratory स्थापना गर्ने नीति अघि बढायो भने यस क्षेत्रको विकास अझ तीव्र गतिमा अगाडि बढ्न सक्छ । साथै जडीबुटी खेतीलाई व्यावसायिक कृषि कार्यक्रमसँग जोडेर किसानलाई प्रोत्साहन गर्दै स्वास्थ्य-उद्योग-कृषि र बन बीचको साझेदारी र सहकार्यले समग्र क्षेत्रको बिकासको सम्भावना नकार्न सकिदैन ।

आयुर्वेद औषधिको सही प्रयोग-उपयोग पनि अत्यन्त महत्वपूर्ण पक्ष हो । धेरै व्यक्तिहरूले आयुर्वेद औषधिलाई पूर्ण रूपमा सुरक्षित ठानी चिकित्सक, स्वास्थ्यकर्मी वा विशेषज्ञको सल्लाहबिना सेवन गर्ने प्रवृत्ति देखिन्छ जुन उचित होइन । औषधिको मात्रा, सेवन विधि, समय तथा रोगअनुसार यसको प्रयोग फरक-फरक हुन्छ । गलत प्रयोगले अपेक्षित लाभ नदिनुका साथै स्वास्थ्यमा प्रतिकूल असर समेत पर्न सक्छ । पछिल्लो समय सामाजिक सञ्जाल तथा अनधिकृत माध्यमबाट चिकित्सकीय सल्लाहबिना औषधि सेवन गर्ने प्रवृत्ति बढ्दै गएको छ जसले स्वास्थ्य जोखिम निम्त्याउन पनि सक्छ । त्यसैले आयुर्वेद औषधिहरु पनि स्वास्थ्यकर्मी एवं विशेषज्ञको सल्लाह र निर्धारित मात्रा अनुसार मात्र प्रयोग गर्नुपर्छ भन्ने जनचेतना विस्तार गर्न आवश्यक छ । यसकालागि औषधि व्यवस्था बिभाग तथा आयुर्वेद विभागको सयुक्त सचेतना कार्यक्रम निर्माण हुनु अपरिहार्य छ ।

बर्तमान समयमा विश्वव्यापी रूपमा Antimicrobial Resistance (AMR) तथा औषधिको दुरुपयोग स्वास्थ्य क्षेत्रका प्रमुख चुनौतीका रूपमा देखापरेका छन् । यस्तो अवस्थामा वैज्ञानिक अनुसन्धानमा आधारित गुणस्तरीय तथा सुरक्षित आयुर्वेद औषधिको प्रयोगले स्वास्थ्य क्षेत्रमा सकारात्मक योगदान दिन सक्छ । विश्वविद्यालय अनुसन्धान संस्था तथा उद्योगबीच सहकार्य गरी Evidence–Based Ayurvedic Research लाई प्राथमिकता दिन आवश्यक छ ।

अन्त्यमा; उचित नीति, वैज्ञानिक अनुसन्धान, गुणस्तर सुनिश्चितता तथा अन्तर्राष्ट्रिय ब्रान्डिङमार्फत नेपालले "Nepalayan Ayurved Brand" का रूपमा विश्व बजारमा आफ्नो विशिष्ट पहिचान स्थापित गर्न सक्ने प्रबल सम्भावना रहेको छ । यसका लागि सरकार, उद्योग, अनुसन्धान संस्था तथा स्वास्थ्य क्षेत्रका सबै सरोकारवालाबीच प्रभावकारी सहकार्य अपरिहार्य छ । गुणस्तरीय उत्पादन, जिम्मेवार प्रयोग र दीर्घकालीन दृष्टिकोणमार्फत आयुर्वेद क्षेत्रलाई राष्ट्रिय समृद्धिको एक महत्वपूर्ण आधारका रूपमा विकास गर्न सकिन्छ ।

नेपालमा दम रोग: व्यवस्थापनका चुनौतीहरु, इनहेलेसन थेरापीको महत्त्व तथा फर्मासिस्टको भूमिका

परिचय

श्वासप्रश्वास सम्बन्धी रोग दम (Asthma), दीर्घकालीन दम रोग (COPD) नेपालमा बढ्दो सार्वजनिक स्वास्थ्य समस्याका रूपमा रहेका छन् । वायु प्रदूषण, धूम्रपान, जैविक इन्धनको प्रयोग, शहरीकरण तथा जनचेतनाको कमीका कारण यी रोगहरूको भार निरन्तर बढिरहेको छ । यद्यपि प्रभावकारी औषधि तथा उपचार उपलब्ध भए पनि गलत इनहेलर प्रयोग, कमजोर औषधि अनुपालन तथा पर्याप्त परामर्शको अभावले उपचारको अपेक्षित परिणाम प्राप्त हुन सकेको छैन । यस सन्दर्भमा इनहेलेसन थेरापी र फार्मासिस्टद्वारा प्रदान गरिने उपकरण (Device) सम्बन्धी परामर्शले रोग नियन्त्रणमा महत्वपूर्ण भूमिका खेल्न सक्छ ।

Renu Paudel
Pharmacy Supervisor, DDA

नेपालमा दम (COPD / Asthma) को वर्तमान अवस्था

विशेषगरी COPD तथा Asthma नेपालमा जनस्वास्थ्यका प्रमुख समस्यामध्ये पर्दछन् र यी रोगहरुले जनस्वास्थ्यमा उल्लेखनीय भार सिर्जना गरेका छन् । हालसम्म उपलब्ध राष्ट्रिय अध्ययनहरूका अनुसार नेपालमा COPD को प्रकोप (prevalence) करिब ११-१२% रहेको अनुमान गरिएको छ । एक अध्ययनले नेपालमा COPD को प्रकोप ११.७% रहेको देखाएको छ । उमेर बढ्दै जाँदा, धूम्रपान गर्ने व्यक्तिहरूमा, कम शैक्षिक स्तर भएका मानिसहरूमा तथा जैविक इन्धनको धुवाँमा लामो समयसम्म रहने व्यक्तिहरूमा COPD बढी देखिन्छ । नेपालमा COPD हाल मृत्यु तथा Disability Adjusted Life Years (DALYs) का प्रमुख कारणहरूमध्ये एक मानिन्छ । विशेष गरी ग्रामीण क्षेत्रमा दाउरा, गोबर तथा अन्य बायोमास इन्धन प्रयोगका कारण महिलाहरू उच्च जोखिममा रहेका छन् । दम रोग (Asthma) को अवस्था विभिन्न अध्ययन अनुसार फरक देखिए पनि नेपालमा बालबालिका तथा वयस्क दुवै समूहमा यसको भार उल्लेखनीय रहेको छ । वातावरणीय प्रदूषण, धुलो, एलर्जी, धूम्रपान तथा मौसमीय परिवर्तन प्रमुख जोखिम कारकतत्व का रूपमा रहेका छन् । विश्व स्वास्थ्य संगठन (WHO) तथा Global Initiative for Asthma (GINA) का अनुसार उचित उपचार तथा इनहेलेसन थेरापीमार्फत अधिकांश दम रोगीहरूले सामान्य जीवनयापन गर्न सक्छन् ।

नेपालमा रोग व्यवस्थापनका प्रमुख चुनौतीहरू

ढिलो निदान :

नेपालमा धेरै बिरामीहरू रोगको प्रारम्भिक चरणमा स्वास्थ्य संस्थासम्म पुग्दैनन् । COPD भएका धेरै बिरामीहरू फोक्सोको कार्यक्षमता निकै घटिसकेपछि मात्र अस्पताल पुग्ने गर्दछन् ।

स्पाइरोमेट्रीको सीमित उपलब्धता :

COPD र दमको सही निदानका लागि स्पाइरोमेट्री अत्यावश्यक परीक्षण हो । तर ग्रामीण तथा दुर्गम क्षेत्रमा यसको पहुँच सीमित छ ।

वायु प्रदूषण र धूम्रपान :

काठमाडौं लगायतका शहरी क्षेत्रहरूमा वायु प्रदूषण उच्च स्तरमा रहेको छ। यसका अतिरिक्त सक्रिय तथा निष्क्रिय धूम्रपान COPD र दम दुवैका लागि प्रमुख जोखिम कारक हुन् ।

औषधि अनुपालनको (Adherence) कमी :

धेरै बिरामीहरूले लक्षण कम भएपछि औषधि प्रयोग बन्द गर्ने, नियमित प्रयोग नगर्ने वा चिकित्सकको सल्लाहअनुसार औषधि नलिने समस्या देखिन्छ ।

गलत इनहेलर प्रयोग गर्ने तरिका :

विश्वव्यापी अध्ययनहरूले केवल करिब ३१% बिरामीहरूले मात्र इनहेलर सही तरिकाले प्रयोग गर्ने देखाएका छन् । नेपालमा गरिएको एक व्यवस्थित समीक्षाले ६४% देखि १००% बिरामीहरूले इनहेलर प्रयोग गर्दा कम्तीमा एउटा चरण गलत गर्ने गरेको देखाएको छ ।

इनहेलेसन थेरापीको महत्त्व

दम तथा COPD उपचारको आधारभूत स्तम्भ इनहेलेसन थेरापी हो ।

इनहेलेसनमार्फत औषधि सिधै फोक्सोमा पुग्ने भएकाले:

- औषधिको प्रभाव छिटो देखिन्छ ।
- कम मात्रा (Low dose) पर्याप्त हुन्छ ।
- शरीरमा औषधिको अनावश्यक दुष्प्रभाव कम हुन्छ ।
- रोग नियन्त्रण राम्रो हुन्छ ।
- आकस्मिक आक्रमण (Exacerbation) कम हुन्छ ।

दम र COPD का अधिकांश अन्तर्राष्ट्रिय तथा राष्ट्रिय गाइडलाइनहरूले इनहेल्ड कोर्टिकोस्टेरोइड (ICS), Long Acting Beta २ Agonist (LABA) तथा Long Acting Muscarinic Agent (LAMA) आधारित उपचारलाई प्राथमिकता दिएका छन् ।

हाल प्रयोगमा रहेका प्रमुख इनहेलर उपकरणहरू:

Metered Dose Inhaler (MDI)

- औषधि प्रेसरयुक्त क्यानिस्टरमा हुन्छ ।
- प्रेस गर्ने र सास तान्ने समयको समन्वय आवश्यक हुन्छ ।
- स्पेसरसँग प्रयोग गर्दा प्रभावकारिता बढ्छ ।

Dry Powder Inhaler (DPI)

- औषधि सुक्खा पाउडरको रूपमा हुन्छ ।
- बिरामीले बलियो र गहिरो सास तान्नुपर्छ ।
- समन्वयको आवश्यकता कम हुन्छ ।

यस्ता उपकरण छनोट गर्दा बिरामीको उमेर, शारीरिक क्षमता, फोक्सोको अवस्था तथा प्रयोग क्षमता विचार गर्नुपर्छ ।

MDI र DPI सम्बन्धी परामर्शमा फर्मासिस्टको भूमिका

फर्मासिस्ट स्वास्थ्य सेवा प्रणालीको अत्यन्त महत्वपूर्ण सदस्य हुन् । इनहेलर औषधिको प्रभावकारिता केवल सही औषधिमा मात्र निर्भर हुँदैन; सही प्रविधि पनि उत्तिकै आवश्यक हुन्छ । फार्मासिस्टद्वारा प्रत्यक्ष प्रदर्शन (Demonstration) तथा पुनः प्रदर्शन (Return Demonstration) गराउँदा इनहेलर प्रयोगमा उल्लेखनीय सुधार हुन्छ ।

MDI प्रयोग गर्दा सिकाउनुपर्ने मुख्य चरणहरू:

१. क्यानिस्टर राम्ररी हल्लाउने ।
२. पूर्ण रूपमा सास बाहिर निकाल्ने ।
३. मुखमा इनहेलर राख्ने ।
४. प्रेस गर्दै बिस्तारै गहिरो सास तान्ने ।
५. कम्तीमा १० सेकेन्ड सास रोक्ने ।
६. बिस्तारै सास फेर्ने ।
७. मुख कुल्ला गर्ने

DPI प्रयोग गर्दा सिकाउनुपर्ने मुख्य चरणहरू:

१. उपकरण सही तरिकाले तयार गर्ने ।
२. पूर्ण रूपमा सास बाहिर निकाल्ने ।
३. बलियो तथा गहिरो सास तान्ने ।
४. १० सेकेन्डसम्म सास रोक्ने ।
५. उपकरण सफा राख्ने ।
६. मुख कुल्ला गर्ने

नेपालमा गरिएको एक अध्ययनअनुसार फार्मासिस्टको सहि परामर्श पछि इन्हेलर प्रयोग गर्ने बिरामीहरूको इन्हेलर प्रयोग गर्ने तरिकामा महत्वपूर्ण सुधार देखिएको थियो ।

अर्को नेपाली अध्ययनले पनि फर्मासिस्टद्वारा गरिएको प्रत्यक्ष प्रशिक्षणपछि ७०% बिरामीहरूले सबै चरण सही रूपमा पूरा गर्न सकेको देखाएको छ ।

सही इनहेलेसन प्रयोगको परिणाम :

प्रभाबकारी रोग नियन्त्रण

औषधि फोक्सोको लक्षित स्थानमा पुग्दा दम तथा COPD का लक्षणहरू उल्लेखनीय रूपमा घट्छन् ।

Exacerbation (दमको आकस्मिक आक्रमण) कम हुने

सही इनहेलेसन प्रविधिले आकस्मिक श्वासप्रश्वास बिग्रिने घटनाहरू कम गर्छ ।

अस्पताल भर्ना हुने दर घट्ने

रोग राम्रोसँग नियन्त्रणमा हुँदा आपतकालीन कक्ष तथा अस्पताल भर्नाको आवश्यकता कम हुन्छ ।

जीवनस्तरमा सुधार

सही प्रविधि अपनाउने बिरामीहरूमा शारीरिक गतिविधि, निद्रा, कार्यक्षमता तथा दैनिक जीवनको गुणस्तरमा सुधार देखिएको छ ।

उपचार खर्च कम हुने

रोगको जटिलता तथा अस्पताल भर्ना कम हुँदा दीर्घकालीन स्वास्थ्य खर्च घट्छ ।

औषधि अनुपालनमा (Adherence) सुधार

फार्मासिस्टको नियमित परामर्शले बिरामीको आत्मविश्वास बढाउने तथा औषधि नियमित प्रयोग गर्ने बानी विकास गराउने गर्दछ ।

निष्कर्ष

नेपालमा COPD र दमको भार उल्लेखनीय रूपमा बढिरहेको छ । धूम्रपान, वायु प्रदूषण, जैविक इन्धनको प्रयोग, ढिलो निदान तथा गलत इनहेलर प्रविधि रोग नियन्त्रणका प्रमुख अवरोधहरू हुन् । इनहेलेसन थेरापी दम र COPD व्यवस्थापनको सबैभन्दा प्रभावकारी माध्यम हो, तर यसको पूर्ण लाभ प्राप्त गर्न बिरामीले सही प्रविधि अपनाउनु आवश्यक छ । यस सन्दर्भमा फार्मासिस्टको भूमिका अत्यन्त महत्वपूर्ण छ । MDI र DPI उपकरणहरूको सही प्रयोगबारे परामर्श, प्रदर्शन तथा नियमित पुनर्मूल्यांकनले उपचारको प्रभावकारिता उल्लेखनीय रूपमा बढाउन सक्छ । नेपालमा भएका अध्ययनहरूले समेत फर्मासिस्टद्वारा प्रदान गरिएको प्रशिक्षणले इनहेलर प्रविधि, रोग नियन्त्रण तथा बिरामीको जीवनस्तरमा महत्वपूर्ण सुधार ल्याउने प्रमाण दिएका छन् । त्यसैले "Right Drug, Right Device, Right Technique" को अवधारणालाई व्यवहारमा लागू गर्दै चिकित्सक, फार्मासिस्ट र बिरामीबीचको सहकार्य सुदृढ गर्न सकिएमा नेपालमा दम र COPD को भार उल्लेखनीय रूपमा घटाउन सकिनेछ ।

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Bridging Education and Regulation: Strengthening Medicine Product Recall through Academic–Regulatory Collaboration

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Medicine product recalls are a critical public health safeguard that remove defective, substandard, or potentially harmful pharmaceutical products from the distribution chain. In Nepal, the Department of Drug Administration (DDA) serves as the national regulatory authority responsible for ensuring the quality, safety, and efficacy of medicines. However, the complexity of modern pharmaceutical supply chains, coupled with the evolving nature of drug-related risks, demands a more robust and scientifically grounded approach to recall management. This article explores how academic institutions particularly Pharmacy college and Universities can collaborate with regulatory bodies to strengthen medicine recall systems.

1. Introduction

The safety of medicines is a cornerstone of public health. When pharmaceutical products fail to meet quality standards whether due to manufacturing defects, contamination, incorrect labeling, or stability issues effective recall action becomes essential for patient safety. A medicine recall is defined as the process of withdrawing specific batches of a medicinal product from the distribution chain due to deficiencies in quality, safety, or efficacy. In Nepal, the Department of Drug Administration (DDA) is entrusted with this responsibility under the Drug Act 2035 B.S., issuing public alerts and warnings when substandard, falsified, or unregistered medicine incidents are detected.

Research indicates that approximately 10.5% of medicines worldwide are either substandard or falsified, with prevalence significantly higher in low- and middle-income countries (Ozawa et al., 2018). Nepal, sharing open borders with major pharmaceutical producers, faces unique challenges in ensuring drug quality. A comprehensive analysis of DDA recall notices from 2010 to 2020 revealed that antimicrobial medicines had the highest frequency of recall incidents, followed by vitamins, non-steroidal anti-inflammatory drugs, and antidiabetic medicines. Common reasons for recall included failure in laboratory tests such as microbial assay, content uniformity, dissolution, and sterility tests many of which can be traced to inadequate quality control during manufacturing and inappropriate storage and transportation conditions (Neupane et. al., 2022). As pharmaceutical products and supply chains grow more complex, the DDA's existing recall systems require a more evidence-driven, scientific framework. Academic institutions-equipped with research facilities, specialized knowledge, and training capabilities-are well-positioned to assist regulators in evaluating risks, designing recall strategies, building staff competencies, and informing policy. This article explores how partnerships between universities and the DDA can enhance medicine recall systems in Nepal, drawing on global standards and guidelines.

2. The Regulatory Framework for Medicine Recalls: International Guidelines

2.1 ICH Q9: Quality Risk Management

The International Council for Harmonisation (ICH) Q9 guideline on Quality Risk Management (QRM) is widely regarded as the gold standard for systematic risk assessment in the pharmaceutical sector. ICH Q9 provides a structured framework for identifying, analyzing, evaluating, and controlling quality risks across the drug product lifecycle-from development and manufacturing to distribution and post-marketing surveillance (International Council for Harmonisation, 2023).

ICH Q9 outlines a four-phase QRM process: risk assessment (identification, analysis, and evaluation), risk control (reduction and acceptance), risk communication, and risk review. These principles are directly applicable to medicine recalls. The guideline also encourages the use of tools such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), and fault tree analysis to systematically evaluate recall scenarios (World Health Organization, 2013).

2.2 WHO Good Manufacturing Practice (GMP) Guidelines

The WHO GMP guidelines provide the foundational quality standards against which pharmaceutical manufacturing is evaluated. According to WHO GMP, recall procedures should be understood by all responsible personnel, and records must be maintained to ensure complete traceability of products from raw materials to finished goods (World Health Organization, 1996). The guidelines mandate that manufacturers conduct mock recalls at least annually to test the effectiveness of recall arrangements, particularly for products with the longest distribution chains.

2.3 WHO Quality Risk Management Guidelines

Complementing ICH Q9, the WHO published its own guidelines on Quality Risk Management (WHO TRS 981, Annex 2), which adapt the ICH framework for use in diverse regulatory environments, including resource-limited settings. The WHO guidelines explicitly state that QRM outputs can serve as reference documents to support product development, control strategy discussions, and regulatory filings (World Health Organization, 2013).

3. The Current Landscape of Medicine Recalls in Nepal

The DDA Nepal operates within a challenging environment characterized by a growing pharmaceutical market, porous borders, and limited regulatory resources. The domestic market for medical products was estimated at approximately 70 billion Nepali rupees in 2019, encompassing drugs, raw materials, and surgical equipment (Neupane et. al., 2022). With this expanding market comes increased exposure to quality risks.

Analysis of DDA recall data reveals several concerning patterns. First, a significant proportion of recalls involve essential medicines, including antibiotics, which raises serious concerns about antimicrobial resistance. Suboptimal dosing or poor manufacturing quality of antibiotic medicines can accelerate resistance development,

undermining treatment efficacy for entire populations (Neupane et. al., 2022). Second, many recalled products fail basic quality parameters such as dissolution, assay, and microbial limits suggesting systemic weaknesses in manufacturing quality control and supply chain management. Third, the presence of unregistered and falsified medicines in the market indicates gaps in pre-market surveillance and border control. DDA's makes recall process through initiation (notification and problem identification, hazard/risk assessment, and decision to recall), implementation (issuance of recall circulars and public warnings) and evaluation for assessment of recall effectiveness. The DDA has only around two dozen drug inspectors tasked with monitoring over 24,000 registered pharmacies and thousands of unregistered ones. Laboratory testing capacity is severely limited.

4. Effective Medicine Recall System

An effective medicine recall system is one that promptly identifies defective products, rapidly communicates risks to all stakeholders, efficiently removes affected products from the market, and prevents recurrence through systematic learning and improvement. The effectiveness of a recall system can be measured through several key metrics that provide quantitative and qualitative indicators of performance.

4.1 Metrics for Measuring Recall Effectiveness

Drawing on international regulatory practices, particularly those of the U.S. Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC), the following metrics can be used to evaluate the effectiveness of a medicine recall system:

- Recall Effectiveness Rate.
- Time to Detection.
- Time to Recall Completion.
- Stakeholder Notification Rate.
- Patient Harm Incidence.
- Mock Recall Performance.
- CAPA Implementation Rate.
- Public Awareness Index.

In the Nepalese context, current data suggests significant gaps across most of these metrics.

4.2 Current Gaps in Nepal's Recall System

Despite the DDA's efforts, several critical gaps persist in Nepal's medicine recall system:

- Inadequate Laboratory Infrastructure.
- Insufficient Human Resources.
- Weak Traceability Systems.

- Limited Post-Market Surveillance.
- Ineffective Enforcement Mechanisms.
- Poor Coordination with Border Controls.
- Lack of Systematic Data Analysis.
- Limited Public Communication.

5. Benefits of an Improved Medicine Recall System

Strengthening the medicine recall system in Nepal would yield substantial benefits across multiple dimensions of public health, regulatory capacity, and economic stability:

- Enhanced Patient Safety.
- Reduced Antimicrobial Resistance.
- Increased Public Trust in the Regulatory System.
- Economic Protection.
- Improved Regulatory Reputation.
- Data-Driven Policy Development.
- Strengthened Supply Chain Integrity.
- Accelerated Emergency Response Capacity.

6. The Role of Academia in Strengthening Medicine Recalls

6.1 Education and Workforce Development

Regulatory science is an emerging discipline that bridges pharmaceutical sciences, public health, law, and policy. Despite its importance, formal training in regulatory science remains limited in many low- and middle-income countries. The Institute of Medicine (now National Academy of Medicine) has emphasized that effective regulatory science training programs must cover scientific methodology, pharmacology, clinical trial design, biostatistics, decision theory, and food and drug law (Institute of Medicine, 2012). Pharmacy curricula in Nepal can be strengthened by integrating modules on regulatory science, quality risk management, and recall management procedures.

Universities can develop specialized courses on pharmaceutical regulatory affairs, drawing on international models such as the European Centre for Pharmaceutical Medicine (ECPM) modular training program, the University of California, San Francisco (UCSF) Center for Drug Development Science, and the University of Southern California (USC) Regulatory Science Program (Institute of Medicine, 2012). These programs typically combine didactic instruction with case-based learning, using real-world recall scenarios to teach risk assessment, communication strategies, and post-recall evaluation. By embedding such content into Bachelor of Pharmacy (B. Pharm) and Master of Pharmacy (M. Pharm) curricula, Nepalese universities can produce a generation of pharmacists who are not only clinically competent but also regulatory-literate.

Furthermore, universities can serve as venues for continuing professional development (CPD) for practicing regulators, pharmacists, and industry quality assurance personnel. Short courses, workshops, and certificate programs on ICH Q9, WHO GMP, and recall management can help bridge the knowledge gap among current workforce members. The International Pharmaceutical Federation (FIP) has called for globally shared visions in pharmaceutical education, emphasizing the need for workforce development that meets the challenges of global health and patient care (International Pharmaceutical Federation, 2016).

6.2 Research and Innovation

Academic research can address critical knowledge gaps in medicine recall management. For example, researchers can conduct epidemiological studies to identify risk factors for drug quality failures in the Nepalese market, analyze the cost-effectiveness of different recall strategies, or develop rapid analytical methods for detecting substandard medicines at border entry points. A recent study applying fuzzy DEMATEL methodology to pharmaceutical drug recalls identified the top five causative criteria for recalls as product contamination, subpotency or superpotency, patient injury, lack of sterility, and inadequate system detectability of hazards (Lin & Hertig, 2023).

Universities can also support the DDA in developing and validating risk assessment tools tailored to the Nepalese context. While ICH Q9 provides general frameworks, their application must be adapted to local conditions-including the types of products most commonly used, the structure of the distribution chain, and the capacity of healthcare facilities. Collaborative research between university faculty and DDA officers can produce context-specific risk matrices, decision trees, and recall classification systems that improve the speed and accuracy of regulatory decision-making.

In addition, academic institutions can contribute to post-recall analysis and learning. Systematic investigation of recall root causes, trend analysis of quality failures, and evaluation of recall effectiveness are research activities that generate actionable intelligence for regulators. Published research on drug recalls in Nepal has already begun to illuminate patterns in therapeutic categories, failure types, and manufacturer origins (Neupane et. al., 2022). Expanding this research agenda through academic-regulatory partnerships can transform recall data into preventive knowledge.

6.3 Policy Support and Advocacy

Academic experts can serve as independent advisors to regulatory bodies, providing scientific input on policy formulation, guideline development, and regulatory harmonization. The National Institutes of Pharmaceutical Education and Research (NIPERs) in India exemplify this model, where academic institutions actively contribute to pharmaceutical policy on drug pricing, quality control, intellectual property, and research and development (Department of Pharmaceuticals, India, 2022). Similarly, Nepalese pharmacy schools can establish regulatory science centers or chairs that provide ongoing policy support to the DDA.

Academia can also play a crucial role in public communication and health literacy. When recalls occur, clear, accurate, and accessible public messaging is essential to ensure

compliance and prevent panic. University faculty with expertise in health communication can assist the DDA in crafting public alerts, developing patient information materials, and training pharmacists to counsel patients during recall events. Research has shown that consumer understanding of recall information is influenced by message design, media channel, and cultural context-factors that benefit from academic expertise in communication science (CPSC, 2003).

7. A Proposed Model for Academic-Regulatory Collaboration

Building on international precedents and the specific needs of Nepal, this article proposes a structured model for collaboration between the DDA and academic institutions. The model comprises four interconnected pillars:

Pillar 1: Joint Research Centers. Establish dedicated research centers or units within pharmacy schools that focus on pharmaceutical quality assurance, regulatory science, and recall management. These centers would conduct collaborative research with the DDA, access funding from national and international sources, and publish findings in peer-reviewed journals. Research priorities could include: prevalence and patterns of substandard medicines in Nepal; development of low-cost analytical methods for quality screening; evaluation of recall effectiveness metrics; and risk modeling for supply chain vulnerabilities.

International examples demonstrate the value of such centers. In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) sponsors seven Centers of Excellence for Regulatory Science and Innovation (CERSIs), including partnerships with the University of Birmingham for AI and Digital Health Technologies, and Brunel University of London for regulatory science in transformative digital health. These centers provide the MHRA with valuable academic insight and access to cutting-edge research, enabling the agency to identify and solve emerging regulatory problems (MHRA, 2025). Similarly, the U.S. FDA has established multiple academic partnerships through its Centers of Excellence in Regulatory Science and Innovation (CERSI) program, collaborating with universities such as Johns Hopkins, the University of Maryland, and Stanford to advance regulatory science research and education.

Pillar 2: Integrated Education Programs. Revise pharmacy curricula to include mandatory courses on regulatory science, quality risk management, and recall procedures. Develop internship and fellowship programs that place pharmacy students and graduates within the DDA for hands-on regulatory experience. Create continuing education programs for DDA staff, industry personnel, and community pharmacists, delivered through university platforms.

The MHRA in the UK provides an excellent model for integrated education. The agency has developed e-learning modules in collaboration with academic partners such as the Centre for Postgraduate Pharmacy Education (CPPE) and the Wales Centre for Pharmacy Professional Education, providing accredited continuing professional development for pharmacists, doctors, and nurses on adverse drug reaction reporting and medicine safety (MHRA, 2021). These modules count toward continuing professional development credits and have been endorsed by professional bodies, ensuring widespread uptake

among healthcare professionals.

Pillar 3: Technical Advisory Services. Form a standing technical advisory committee comprising senior pharmacy faculty, DDA officials, industry representatives, and clinical experts. This committee would meet regularly to review emerging quality risks, advise on recall classifications, and provide scientific input on policy decisions. During active recall events, the committee could be convened rapidly to provide expert risk assessment.

India's National Institutes of Pharmaceutical Education and Research (NIPERs) illustrate how academic institutions can serve as policy advisors. NIPERs actively contribute to pharmaceutical policy discussions on drug pricing, quality control standards, intellectual property frameworks, and research and development strategies-providing independent scientific input that strengthens regulatory decision-making (Department of Pharmaceuticals, India, 2022). Similarly, in the United States, the FDA's Science Board, which includes academic experts from leading universities, provides independent advice on complex scientific and technical issues, including product recalls and emerging safety concerns.

Pillar 4: Data and Knowledge Sharing. Develop secure, shared databases for recall information, quality testing results, and adverse event reports. Universities can assist in data analysis, trend monitoring, and predictive modeling. Regular joint publications such as annual recall reports, policy briefs, and bulletin articles which would disseminate findings to stakeholders and the public, enhancing transparency and accountability.

8. Potential Challenges of Academic-Regulatory Collaboration

While academic-regulatory collaboration offers substantial benefits, several challenges must be anticipated and addressed to ensure successful implementation in Nepal:

- Resource Constraints and Funding Limitations.
- Regulatory Hurdles and Bureaucratic Complexity.
- Intellectual Property Concerns.
- Cultural and Organizational Barriers.
- Limited Time for Academics Due to Work Overload
- Data Confidentiality and Security.
- Political and Institutional Commitment.
- Capacity Asymmetries.
- Limited Research Infrastructure.

9. Implementation Considerations

Realizing this collaborative model requires attention to several practical considerations. First, funding mechanisms must be established. The DDA could allocate a portion of its budget for academic partnerships, while universities could seek research grants from international bodies such as the WHO, World Bank, and Global Fund. Second, memoranda of understanding (MoUs) should formalize the roles, responsibilities, and

intellectual property arrangements of each party. Third, capacity building is essential-not only for university faculty to understand regulatory processes but also for DDA staff to engage effectively with academic research methodologies.

Fourth, political and institutional commitment is necessary to sustain collaboration beyond individual projects or leadership tenures. The success of academic-regulatory partnerships in countries like the United States, the United Kingdom, and India demonstrates that long-term commitment yields cumulative benefits in workforce quality, regulatory capacity, and public health outcomes (Institute of Medicine, 2012). Finally, international collaboration can amplify local efforts. Partnerships with regional regulatory networks, WHO prequalification programs, and international pharmacy education bodies can provide technical assistance, training opportunities, and peer learning platforms.

10. Conclusion

Medicine product recalls are essential for protecting public health, but their effectiveness depends on strong scientific, regulatory, and technical capacity. In Nepal, closer collaboration between the Department of Drug Administration (DDA) and academic institutions can strengthen recall systems through education, research, technical expertise, and evidence-based decision-making. By incorporating international standards such as WHO GMP and ICH Q9 into pharmacy education and fostering partnerships in research and data sharing, academia can support regulators in ensuring the quality, safety, and effectiveness of medicines. While challenges exist-including funding limitations, bureaucratic complexity, and capacity asymmetries, the benefits of an improved recall system in terms of patient safety, antimicrobial resistance containment, public trust, and regulatory reputation are substantial. Building this bridge between education and regulation is crucial for a stronger pharmaceutical system and improved patient safety.

औषधि उत्पादन कुशल अभ्यास र WHO GMP Guideline बमोजिम प्रमाणीकरण गरिएका स्वदेशी औषधि उद्योगको सूची

S.N	NAME OF MANU-FACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
1	AADEE REMEDIES PVT. LTD, LALITPUR				2085-04-21	2082-04-22	Tablet (Non Penicillin, Non Cephalosporin) Ointment/Cream/ Gel/Lotion (Non Penicillin and Non Cephalosporin) ORS (Non Penicillin and Non Cephalosporin)
2	ALIVE PHARMA-CEUTICAL PVT. LTD, SUNSARI	12-Oct-2027	13-Oct-2025	Tablet (Non Penicillin & Non Cephalosporin) Capsule (Non Penicillin & Non Cephalosporin) Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)	2084-03-13	2081-03-14	Tablet (Non Penicillin & Non Cephalosporin) Capsule (Non Penicillin & Non Cephalosporin) Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
3	ALLIANCE PHAR-MACEUTICAL PVT. LTD, BARA				2080-09-26	2078-09-27	Tablet(Non Penicillin & Non Cephalosporin) Capsule (Non Penicillin & Non Cephalosporin) Oral Liquid (Non Penicillin & Non Cephalosporin)
4	AMTECH MED PVT. LTD, MORANG	06-Nov-2027	07-Nov-2025	Tablet (Non Penicillin and Cephalosporin) Capsule(Non Penicillin and Non Cephalosporin) Ointment/Cream/Lotion/External Liquid (Non Penicillin and Non Cephalosporin) Oral Liquid (Non Penicillin and Non Cephalosporin) Powder for Oral Suspension (Cephalosporin) ORS(Non Penicillin and Non Cephalosporin)	2085-07-20	2082-07-21	Tablet(Non Penicillin and Cephalosporin) Capsule(Non Penicillin and Non Cephalosporin) Ointment/Cream/Lotion/External Solution (Non Penicillin and Non Cephalosporin) Oral Liquid (Non Penicillin and Non Cephalosporin) ORS (Non Penicillin & Non Cephalosporin) Powder for Oral Suspension (Cephalosporin) ORS(Non Penicillin and Non Cephalosporin)
5	APEX PHARAM-CEUTICAL PVT. LTD, BARA	28-Nov-2026	29-Nov-2024	Tablet (Non Penicillin and Cephalosporin) Capsule (Non Penicillin and Cephalosporin) Powder for Oral Suspension (Cephalosporin) Ointment/Cream/Gel/Lotion (Non Penicillin Non Cephalosporin) Oral Lquid (Non Penicillin Non Cephalosporin)	2084-08-13	2081-08-14	Tablet (Non Penicillin and Cephalosporin) Capsule (Non Penicillin and Cephalosporin) Powder for Oral Suspension (Cephalosporin) Ointment/Cream/Gel/Lotion (Non Penicillin Non Cephalosporin) Oral Lquid (Non Penicillin Non Cephalosporin)

S.N	NAME OF MANU-FACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
6	ARROW PHAR-MACERUTICAL PVT. LTD, BHAKTAPUR	03-Apr-2027	04-Apr-2025	Tablet (Non Penicillin and Cephalosporin)	2082-11-15	2079-11-16	Tablet (Non Penicillin and Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
							Ointment/Cream/Gel (Non Penicillin and Cephalosporin)
7	ARYA PHARMALAB PVT. LTD, BARA	12-Oct-2027	13-Oct-2025	Tablet(Non Penicillin and Non Cephalosprine , Penicillin and Cephalosporin)	2083-04-24	2080-04-25	Tablet(Non Penicillin and Non Cephalosporin, Penicillin and Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosprorin, Penicillin and Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin , Penicillin and Cephalosporin)
				Oral Liquid (Non Penicillin and Non Cephalosporin)			Oral Liquid (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin and Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin and Non Cephalosporin)
				ORS (Non Penicillin & Non Cephalosporin)			ORS (Non Penicillin & Non Cephalosporin)
				Powder for Oral Suspension (Penicillin and Cephalosporin)			Powder for Oral Suspension (Penicillin and Cephalosporin)
8	ASIAN PHARMA-CEUTICAL PVT. LTD, RUPANDEHI	3-Apr-2027	4-Apr-2025	Tablet (Non Penicillin and Cephalosporin)	2083-03-14	2080-03-24	Tablet (Non Penicillin and Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin And Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin Non Cephalosporin)
				Powder for Oral Suspension (Non Penicillin and Cephalosporin)			Powder for Oral Suspension (Non Penicillin and Cephalosporin)
				Dental preparation(Non Penicillin and Non Cephalosporin),			Dental preparation(Non Penicillin and Non Cephalosporin),
				Oral Liquid (Non Penicillin and Non Cephalosporin)			Oral Liquid (Non Penicillin and Non Cephalosporin)
							Tablet, Bolus, Powder for Oral use and Oral Liquid for veterinary use (Non Penicillin & Non Cephalosporin)

S.N	NAME OF MANUFACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
9	ASIAN PHARMACEUTICAL PVT. LTD, UNIT-I, RUPANDEHI	19-Jul-2027	20-Jul-2025	Tablet (Non Penicillin and Cephalosporin)	2085-04-03	2082-04-04	Tablet (Non Penicillin and Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Oral Liquid (Non Penicillin and Non Cephalosporin)			Oral Liquid (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin Non Cephalosporin)
10	ACCORD PHARAMCEUTICALS LIMITED, LALITPUR	06-Nov-2027	07-Nov-2025	Tablet (Non Penicillin & Non Cephalosporin)	2083-01-25	2080-02-26	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin),			Capsule (Non Penicillin and Non Cephalosporin),
				Oral Liquid (Non Penicillin & Non Cephalosporin)			Oral Liquid (Non Penicillin and Non Cephalosporin)
				Ointment/ Cream (Non Penicillin& Non Cephalosporin)			Ointment/ Cream (Non Penicillin and Non Cephalosporin)
10	APPLE INTERNATIONAL PHARMACEUTICAL PVT. LTD, RUPENDEHI	21-Feb-2028	22-Feb-2026	Tablet (Non Penicillin & Non Cephalosporin)	2085-11-09	2082-11-10	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel/Lotion (Non Penicillin Non Cephalosporin)			Ointment/Cream/Gel/Lotion (Non Penicillin Non Cephalosporin)
				Oral Liquid(Non Penicillin & Non Cephalosporin)			Oral Liquid(Non Penicillin & Non Cephalosporin)
11	BIOGAIN REMEDIES PVT. LTD. RUPANDEHI	8-Jun-2027	9-Jun-2025	Tablet (Non Penicillin and Non Cephalosporin)	2082-08-18	2079-08-20	Tablet (Non Penicillin and Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
							External Liquid (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin and Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin and Non Cephalosporin)
				Powder for External use (Non Penicillin and Non Cephalosporin)			Powder for External use (Non Penicillin and Non Cephalosporin)

S.N	NAME OF MANUFACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
12	BHASKAR HERBACEUTICALS PVT. LTD	12-Jan-2028	12-Jan-2026	Tablet (Ayurvedic)	2083-04-01	2080-04-02	Tablet (Ayurvedic)
				Capsule (Ayurvedic)			Capsule (Ayurvedic)
				External Preparation (Medicated oil/Ointment/Cream)(Ayurvedic)			External Preparation (Medicated oil/Ointment/Cream) (Ayurvedic)
				Churna (powder)(Ayurvedic)			Churna (powder)(Ayurvedic)
				Oral Liquid (Ayurvedic)			Oral Liquid(Ayurvedic)
				Avaleha & Pak, Vati, and Gutika (Ayurvedic)			Avaleha & Pak, Bhasma, Vati, Ras and Gutika (Ayurvedic)
							Oral Liquids for veterinary use (Ayurvedic)
13	CTL PHARAMCEUTICAL PVT. LTD, BHAKTAPUR	17-Jul-2025	18-Jul-2023	Tablet (Non Penicillin and Non Cephalospotin, Penicillin and Cephalosporin)			
				Capsule (Non Penicillin and Non Cephalosporin, Cephalosporin and Penicillin)			
				Ointment/Cream/Gel (Non Penicillin and Non Cephalosporin)			
				Powder for Oral Suspension (Penicillin and Cephalosporin)			
				ORS (Non Penicillin and Non Cephalosporin)			
				Oral Liquids (Non Penicillin and Non Cephalosporin)			
14	CHEMIDRUG INDUSTRIES PVT. LTD, KATHMANDU	4-Dec-2024	6-Dec-2022	Tablet (Penicillin)	2082-08-18	2079-08-20	Tablet (Penicillin)
				Capsule (Penicillin)			Capsule (Penicillin)
				Powder for Oral Suspension (Penicillin)			Powder for Oral Suspension (Penicillin)

S.N	NAME OF MANUFACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
15	CUREX PHARMACEUTICAL PVT. LTD, KAVRE	17-Sep-2027	18-Sep-2025	Tablet (Non Penicillin & Non Cephalosporin)	2083-03-14	2080-03-24	Tablet (Non Penicillin and Non Cephalosporin, Penicillin and Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin, Penicillin and Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Oral Liquid (Non Penicillin & Non Cephalosporin)			Oral Liquid (Non Penicillin & Non Cephalosporin)
		8-Jun-2027	9-Jun-2025	Tablet (Penicillin and Cephalosporin)			Powder for Oral Suspension(Penicillin &Cephalosporin)
				Capsule (Penicillin and Cephalosporin)			
				Powder for Oral Suspension(Penicillin &Cephalosporin)			
16	DEURALI JANATA PHARMACEUTICALS PVT. LTD , DHAPASI, KATHMANDU	19-Jul-2027	20-Jul-2025	Tablet (Non Penicillin & Cephalosporin)	2085-04-03	2082-04-04	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel/External Liquid (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel/External Liquid (Non Penicillin & Non Cephalosporin)
17	DIVINE HEALTHCARE PVT. LTD, CHITWAN	12-Oct-2027	13-Oct-2025	Tablet (Non Penicillin & Non Cephalosporin)	2083-03-14	2080-03-24	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
18	EVEREST PHARMACEUTICALS PVT. LTD, BHAKTAPUR	16-Apr-2025	18-Apr-2023	Tablet (Non Penicillin & Cephalosporin)	2083-01-03	2080-02-26	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)

S.N	NAME OF MANUFACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
19	EVEREST PARENTERALS PVT. LTD, BARA	19-Jul-2027	20-Jul-2025	SVP (Ampoule & Vials) (Non Penicillin & Non Cephalosporin)	2083-04-01	2080-04-02	SVP (Ampoule & Vials) (Non Penicillin & Non Cephalosporin)
				LVP (Non Penicillin & Non Cephalosporin)			LVP (Non Penicillin & Non Cephalosporin)
				Eye/ Ear drop (Non Penicillin & Non Cephalosporin)			Eye/ Ear drop (Non Penicillin & Non Cephalosporin)
20	FLORID LABORATORIES PVT. LTD, LALITPUR	8-Jan-2027	9-Jan-2025	Tablet (Non Penicillin & Non Cephalosporin)	2084-09-24	2081-09-25	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
21	GENETICA LABORATORIES PVT. LTD, BARA	03-Apr-2027	04-Apr-2025	Tablet (Non Penicillin & Cephalosporin)	2084-12-21	2081-12-22	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin, Steroid			Oral liquid (Non Penicillin & Non Cephalosporin, Steroid)
				Powder for oral suspension (Cephalosporin)			Powder for oral suspension (Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
22	GRACE PHARMACEUTICALS PVT. LTD. RUPANDEHI	08-June-2027	09-June-2025	Tablet (Ayurvedic)	2085-02-25	2082-02-26	Tablet (Ayurvedic)
				Capsule (Ayurvedic)			Capsule (Ayurvedic)
				Oral Liquid (Ayurvedic)			Oral Liquid (Ayurvedic)
				Ointment (Ayurvedic)			ointment/ Cream /Gel (Ayurvedic)
							External Liquid (oil) (Ayurvedic)
23	GRACE PHARMACEUTICALS PVT. LTD. (UNIT II) (ALLOPATHIC UNIT), RUPANDEHI	8-Jan-2027	9-Jan-2025	Tablet (Non Penicillin & Non Cephalosporin)	2084-09-24	2081-09-25	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
24	HESTER BIOSCIENCES NEPAL PVT. LTD	27 Nov, 2025	28 Nov, 2023	Live and inactive Vaccine (Veterinary use only)	2085-04-21	2082-04-22	Live and inactive Vaccine (Veterinary use only)
25	HUKAM PHARMACEUTICALS PVT. LTD				2079-11-27	2077-11-28	Tablet (Non Penicillin and Cephalosporin)
							Capsule (Non Penicillin and Non Cephalosporin)
							ORS (Non Penicillin and Non Cephalosporin)
							Oral Liquid (Non Penicillin and Non Cephalosporin)
							Powder for Oral Suspension (Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
26	KASTURI PHARMACEUTICALS PVT. LTD, CHITWAN	28-Mar-2028	29-Mar-2026	Tablet (Non Penicillin & Non Cephalosporin)	2085-12-14	2082-12-15	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
27	KEVA PHARMACEUTICALS PVT. LTD, CHITWAN	4-Dec-2024	6-Dec-2022	Tablet (Non Penicillin & Non Cephalosporin)	2082-08-18	2079-08-20	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Powder for Oral use, Sachet (Non Penicillin & Non Cephalosporin)			Powder for Oral use, Sachet (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
28	LIVE CARE PHARMACEUTICALS PVT. LTD, CHITWAN				2080-10-25	2078-10-26	Tablet (Non Penicillin & Non Cephalosporin) (for Veterinary use only)
							Capsule (Non Penicillin & Non Cephalosporin)(for Veterinary use only)
							Oral liquid (Non Penicillin & Non Cephalosporin) (for Veterinary use only)
							Powder for Oral Use (Non Penicillin & Non Cephalosporin) (for Veterinary use only)
29	LOMUS PHARMACEUTICALS PVT. LTD, GOTHATAR, KATHMANDU	28-April-2028	29-April-2026	Tablet (Non-Penicillin / Non-Cephalosporin, Penicillin, Cephalosporin, Hormone, Steroid)	2083-10-01	2080-10-02	Tablet (Non-Penicillin / Non-Cephalosporin, Penicillin, Cephalosporin, Hormone, Steroid)
				Capsule (Non-Penicillin / Non-Cephalosporin, Cephalosporin, Penicillin)			Capsule (Non-Penicillin / Non-Cephalosporin, Cephalosporin, Penicillin)
				Oral Liquid ((Non-Penicillin / Non-Cephalosporin)			Oral Liquid ((Non-Penicillin / Non-Cephalosporin)
				Ointment/Cream/Gel/Lotion (Non-Penicillin / Non-Cephalosporin)			Ointment/Cream/Gel/Lotion (Non-Penicillin / Non-Cephalosporin)
				External Liquid (Non-Penicillin / Non-Cephalosporin)			External Liquid (Non-Penicillin / Non-Cephalosporin)
				ORS (Non-Penicillin / Non-Cephalosporin)			ORS (Non-Penicillin / Non-Cephalosporin)
				Powder for Oral Suspension (Penicillin and Cephalosporin)			Powder for Oral Suspension (Penicillin and Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
30	MAGNUS PHARMA PVT. LTD, BARA	22-Aug-2026	23-Aug-2024	Tablet (Non Penicillin & Non Cephalosporin)	2084-05-06	2081-05-07	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Semisolid (Oitment/Cream/gel)			Semisolid (Oitment/Cream/gel)
31	MARK FORMULATION PVT. LTD, KATHMANDU				2083-01-03	2080-02-26	Tablet (Non Penicillin & Cephalosporin)
							Capsule (Non Penicillin & Non Cephalosporin)
							Oral Liquid (Non Penicillin and Non Cephalosporin)
							Powder for Oral Suspension (Cephalosporin)
32	MARUTI PHARMA PVT. LTD, BARA	30-Nov-2027	1-Dec-2025	Tablet (Non Penicillin & Non Cephalosporin)	2083-06-09	2080-06-24	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/ Gel/Lotion/ Topical Solution/Dusting Powder (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
33	Medrik Pharmaceuticals Pvt. Ltd, Chitwan	16-Mar-2026	17-Mar-2024	Tablet (Non Penicillin & Non Cephalosporin)	2083-12-03	2080-12-04	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
34	Meera Biotech Pvt. Ltd. Changunarayan 6, Bhaktapur,	20-Dec-2025	21-Dec-2023	Tablet (Non Penicillin & Non Cephalosporin)	2083-09-04	2080-09-05	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
35	NATIONAL HEALTH-CARE PVT. LTD, BARA	30-Nov-2027	01-Dec-2025	SVP (Liquid, Lyophilized) (Non Penicillin & Non Cephalosporin)	2083-07-02	2080-07-03	SVP (Liquid, Lyophilized) (Non Penicillin & Non Cephalosporin)
				Dry powder for Injection (Cephalosporin & Penicillin)			Dry powder for Injection (Cephalosporin & Penicillin)
				Eye /Ear drop (Non Penicillin & Non Cephalosporin)			Eye /Ear drop (Non Penicillin & Non Cephalosporin)
				Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)			Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin and Penicillin)
				Powder for Oral Suspension (Cephalosporin & Penicillin)			Powder for Oral Suspension (Cephalosporin & Penicillin)
				Capsule (Non Penicillin & Non Cephalosporin and Penicillin)			Capsule (Non Penicillin & Non Cephalosporin, Cephalosporin and Penicillin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				External Liquid (Non Penicillin and Non Cephalosporin)			External Liquid (Non Penicillin and Non Cephalosporin)
36	NEPAL PHARMA-CEUTICAL LAB. PVT. LTD, PARSA	22-Aug-2026	23-Aug-2024	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin and Penicillin)	2084-05-06	2081-05-07	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin and Penicillin)
				Powder for Oral Suspension (Cephalosporin & Penicillin)			Powder for Oral Suspension (Cephalosporin & Penicillin)
				Capsule (Non Penicillin & Non Cephalosporin, Cephalosporin and Penicillin)			Capsule (Non Penicillin & Non Cephalosporin, Cephalosporin and Penicillin)
				Ointment/Cream/Gel/Lotion (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel/Lotion (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				External Liquid (Non Penicillin and Non Cephalosporin)			External Liquid (Non Penicillin and Non Cephalosporin)
							Tablet (Non Penicillin and Non Cephalosporin) (For Veterinary use only)
							Oral Liquid (Non Penicillin and Non Cephalosporin) (For Veterinary use only)
							Powder for Oral use (Non Penicillin and Non Cephalosporin) (For Veterinary use only)

S.N	NAME OF MANUFACTURER	WHO GMP GUIDELINE बमोजिमको प्रमाणीकरण			औषधि उत्पादन कुशल अभ्यास संहिता २०७२ बमोजिमको प्रमाणीकरण		
		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
37	NEPAL REMEDIES LTD, RUPANDEHI	28-Mar-2028	29- Mar-2026	Tablet (Non Penicillin & Non Cephalosporin, Hormone)	2085-12-14	2082-12-15	Tablet (Non Penicillin & Non Cephalosporin, Hormone)
				Capsule (Non Penicillin & Non Cephalosporin, Hormone)			Capsule (Non Penicillin & Non Cephalosporin, Hormone)
				Oral Liquid			Oral Liquid
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
38	NOVA GENETICA PVT. LTD, DHADING	18-Mar-2027	19-Mar-2025	Tablet (Non Penicillin & Non Cephalosporin and Cephalosporin)	2084-12-05	2081-12-06	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin,)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Hemodialysis Fluid (Part A and Part B) (Non Penicillin & Non Cephalosporin)			Hemodialysis Fluid (Part A and Part B) (Non Penicillin & Non Cephalosporin)
39	OHM PHARMACEUTICALS LABORATORIES PVT. LTD, BHAKTAPUR	9-May-2026	10-May-2024	Tablet (Non Penicillin & Non Cephalosporin and Cephalosporin, Hormone)	2084-01-27	2081-01-28	Tablet (Non Penicillin & Non Cephalosprorin and Cephalosporin, Hormone)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Oral Liquid (Non Penicillin and Non Cephalosporin)			Oral Liquid (Non Penicilline and Non Cephalosporin)
		28-Mar-2028	29-Mar-2026	Tablet (Steroid)	2085-12-14	2082-12-15	Tablet (Steroid)
40	OMNICA LABORATORIES PVT. LTD, BHAKTAPUR	28-Nov-2026	29-Nov-2024	Tablet (Non penicillin & Non Cephalosporin and Steroid)	2084-08-13	2081-08-14	Tablet (Non penicillin & Non Cephalosporin and Steroid)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				ORS (Non Penicillin and Non Cephalosporin)			ORS (Non Penicillin and Non Cephalosporin)
41	PANAS PHARMACEUTICALS PVT. LTD, NEPALGUNJ	18-Mar-2027	19-Mar-2025	Tablet (Non Penicillin & Non Cephalosporin)	2083-03-14	2080-03-24	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
42	PRIME PHARMACEUTICALS PVT. LTD, BIRGUNJ	27-Feb-2025	1-Mar-2023	Capsule (Non Penicillin & Non Cephalosporin)	2082-11-15	2080-02-26	Capsule (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel/lotion (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel/lotion (Non Penicillin & Non Cephalosporin)
				Powder for External use (Non Penicillin and Non Cephalosporin)			Powder for External use (Non Penicillin and Non Cephalosporin)
43	PHARMACO INDUSTRIES PVT. LTD, KATHMANDU	12-Jan-2028	13-Jan-2026	Tablet (Non Penicillin & Non Cephalosporin)	2085-09-28	2082-09-29	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				ORS(Non Penicillin and Non Cephalosporin)			ORS(Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
44	QbD PHARMACEUTICAL PVT. LTD, KAVRE	29-Jul-2026	30-Jul-2024	Tablet (Non Penicillin & Non Cephalosporin)	2084-04-14	2081-04-15	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
45	QMED FORMULATION PVT. LTD, BHAKTAPUR	6-Aug-2027	7-Aug-2025	Tablet (Non Penicillin & Non Cephalosporin and Cephalosporin)	2085-04-21	2082-04-22	Tablet (Non Penicillin & Non Cephalosporin and Cephalosporin)
				Capsule (Non Penicilline and Cephalosporin)			Capsule (Non Penicilline & Non Cephalosporin and Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
				Tablet (Bolus) (Non Penicillin & Non Cephalosporin)(for Veterinary use)			Tablet (Bolus) (Non Penicillin & Non Cephalosporin)(for Veterinary use)
				Oral Liquid (Non Penicillin & Non Cephalosporin) (for Veterinary use)			Oral Liquid (Non Penicillin & Non Cephalosporin) (for Veterinary use)
				Oral Powder (Non Penicillin & Non Cephalosporin) (for Veterinary use)			Oral Powder (Non Penicillin & Non Cephalosporin) (for Veterinary use)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
46	QUEST PHARMACEUTICAL PVT. LTD, BARA	30-Nov-2027	1-Dec-2025	Tablet (Non Penicillin & Non Cephalosporin)	2083-04-01	2080-04-02	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Ointment/Cream/Gel/Lotion/ Topical Solution (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel/Lotion (Non Penicillin & Non Cephalosporin)
				Softgel Capsule (Non Penicilline and Non Cephalosporin)			Softgel Capsule (Non Penicilline and Non Cephalosporin)
47	ROYAL PHARMACEUTICALS PVT. LTD, CHITWAN	4-Dec-2024	6-Dec-2022	Tablet (Non Penicillin & Non Cephalosporin)	2082-08-18	2079-08-20	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Softgel Capsule (Non Penicilline and Non Cephalosporin)			Softgel Capsule (Non Penicilline and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
48	SAMAR PHARMA COMPANY PVT. LTD, PARSA	8-Jan-2027	9-Jan-2025	Tablet (Non Penicillin & Non Cephalosporin)	2084-09-24	2081-09-25	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
49	SIDDHARTHA PHARAMCEUTICAL PVT. LTD, RUPANDEHI	26-Mar-2026	27-Mar-2024	Tablet (Non Penicillin & Non Cephalosporin)	2083-12-13	2080-12-14	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
50	SIMCA LABORATORIES PVT. LTD, BHAKTAPUR	17-Sep-2027	18-Sep-2025	Tablet (Non Penicillin & Cephalosporin)	2082-08-18	2079-08-20	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Powder for oral Suspenion (Cephalosporin)			Powder for oral Suspenion (Cephalosporin)
				External Liquid (Non Penicillin and Non Cephalosporin)			External Liquid (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
51	SR DRUG LABORATORIES PVT. LTD	12-Jan-2028	13-Jan-2026	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)	2083-04-24	2080-04-25	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)
				Capsule (Non Penicillin and Non Cephalosporin, Penicillin)			Capsule (Non Penicillin and Non Cephalosporin, Penicillin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				External Liquid (Non Penicillin and Non Cephalosporin)			External Liquid (Non Penicillin and Non Cephalosporin)
				ORS(Non Penicillin and Non Cephalosporin)			ORS (Non Penicillin and Non Cephalosporin)
				Powder for Oral Suspension (Penicillin and Cephalosporin)			Powder for Oral Suspension (Penicillin and Cephalosporin)
52	SUMMY PHARMACEUTICAL PVT. LTD, NAWALPARASI	11-Mar-2023	12-Mar-2021	Tablet (Non Penicillin & Non Cephalosporin and Cephalosporin)	2079-11-17	2077-11-28	Tablet (Non Penicillin & Non Cephalosporin and Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Powder for oral Suspension (Cephalosporin)			Powder for oral Suspension (Cephalosporin)
				Sterile Eye /Ear drop (Non Penicillin & Non Cephalosporin)			Sterile Eye /Ear drop (Non Penicillin & Non Cephalosporin)
53	SUPREME HEALTHCARE PVT. LTD, BARA	19-Oct-2025	20-Oct-2023	Tablet (Non Penicillin & Non Cephalosporin)	2083-10-13	2080-10-14	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel/lotion (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel/lotion (Non Penicillin & Non Cephalosporin)
				External Liquid (Non Penicillin and Non Cephalosporin)			External Liquid (Non Penicillin and Non Cephalosporin)
54	TAURUS PHARMA PVT. LTD, DHARKE, DHADHING	24-May-2028	25-May-2026	Tablet (Non Penicillin & Non Cephalosporin)	2083-10-13	2080-10-14	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Semisolid (Cream/Ointment/Gel)			
				ORS (Non Penicillin and Non Cephalosporin)			ORS (Non Penicillin and Non Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
55	TIME PHARMACEUTICALS PVT. LTD, NAWALPARASI	12-Oct-2027	13-Oct-2025	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)	2083-03-14	2080-03-15	Tablet (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)
				Powder for Oral Suspension (Cephalosporin & Penicillin)			Powder for Oral Suspension (Cephalosporin & Penicillin)
				Capsule (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)			Capsule (Non Penicillin & Non Cephalosporin, Cephalosporin, Penicillin)
				Ointment/Cream/Gel/Lotion (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel/Lotion (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Eye/Ear/Nasal Drops(Non Penicillin & Non Cephalosporin)			
56	UNIQUE PHARMACEUTICAL PVT. LTD, BARA	18-Apr-2024	19-Apr-2022	Tablet (Non Penicillin & Non Cephalosporin)	2081-01-05	2079-01-07	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Oral liquid (Non Penicillin & Non Cephalosporin)			Oral liquid (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
58	VEGA PHARMACEUTICAL PVT. LTD	28-Nov-2026	29-Nov-2024	Tablet (Non Penicillin & Non Cephalosporin)	2084-08-13	2081-08-14	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
59	VIJAYADEEP LABORATORIES PVT. LTD	31-Aug-2024	2-Sep-2022	Tablet (Non Penicillin & Non Cephalosporin)	2081-05-15	2079-05-17	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin & Non Cephalosporin)			Capsule (Non Penicillin & Non Cephalosporin)
60	Nepal Ausadhi Limited				2084-10-20	2081-10-21	Tablet (Non Penicillin & Non Cephalosporin)
							ORS (Non Penicillin & Non Cephalosporin)
							Haemodialysis Fluid (Non Penicillin & Non Cephalosporin)
61	Pharmonics Life-sciences Pvt Ltd	29-Jul-2026	30-Jul-2024	Tablet (Thyroxine)	2084-04-14	2081-04-15	Tablet (Thyroxine)
		27-Jun-2026	28-Jun-2024	Tablet (Non Penicillin & Non Cephalosporin)	2084-03-13	2081-03-14	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
62	Elixir Lifesciences Pvt Ltd	26-Mar-2026	27-Mar-2024	Tablet (Non Penicillin & Non Cephalosporin)	2083-12-13	2080-12-14	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
63	Royal Sasa Nepal Pharmaceuticals	06-Aug-2027	07-Aug-2025	Tablet (Non Penicillin & Cephalosporin)	2085-04-21	2082-04-22	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)			Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
64	Sopan Pharmaceuticals Ltd	08-Oct-2026	09-Oct-2024	Tablet (Non Penicillin & Cephalosporin)	2084-06-22	2081-06-23	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicillin & Cephalosporin)			Capsule (Non Penicillin & Cephalosporin)
				Ointment/Cream/Gel (Non-Penicillin & Non-Cephalosporin)			Ointment/Cream/Gel (Non-Penicillin & Non-Cephalosporin)
				Oral Liquid (Non-Penicillin & Non-Cephalosporin)			Oral Liquid (Non-Penicillin & Non-Cephalosporin)
				Powder for Oral Suspension (Cephalosporin)			Powder for Oral Suspension (Cephalosporin)
65	Tizig Pharma Pvt. Ltd.,Kavre	02-Feb-2027	03-Feb-2025	Tablet (Oncology)	2084-10-20	2081-10-21	Tablet (Oncology)
				Capsule (Oncology)			Capsule (Oncology)
66	National Healthcare Pvt. Ltd., Unit V, Bara	19-Jul-2027	20-Jul-2025	Tablet (Non Penicillin & Non Cephalosporin)	2085-04-03	2082-04-04	Tablet (Non Penicillin & Non Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
67	Lomus Parenterals and Formulation Pvt Ltd, Dhanusa	12-Jan-2028	13-Jan-2026	Large Volume Parenterals (Non Penicillin and Non Cephalosporin)			
68	MDH Pharmaceuticals Pvt Ltd, Bhaktapur	12-Jan-2028	13-Jan-2026	Tablet (Veterinary)			
				Bolus (Veterinary)			
				Powder for Oral Use (Veterinary)			
				Oral liquid (Veterinary)			
				Dry Powder for Inhalation (Human)			

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
69	Arogya Bhawan Works Pvt Ltd, Palpa	21 Feb 2028	22 Feb 2026	Tablet (Ayurvedic) Capsule (Ayurvedic) Oral Liquid (Ayurvedic) External Preparation (Medicated oil/ Lotion) (Ayurvedic) Churna (Powder) (Ayurvedic) Granules (Ayurvedic) Vati & Guti (Ayurvedic) Semisolids (Avaleha, Pak) (Ayurvedic)	2085-11-09	2082-11-10	Tablet (Ayurvedic) Capsule (Ayurvedic) Oral Liquid (Ayurvedic) External Preparation (Medicated oil/ Lotion) (Ayurvedic) Churna (Powder) (Ayurvedic) Granules (Ayurvedic) Vati & Guti (Ayurvedic) Semisolids (Avaleha, Pak) (Ayurvedic)
70	Nivix Pharmaceuticals Ltd, Tanahun	21 Feb 2028	22 Feb 2026	Tablet (Non Penicillin & Non Cephalosporin) Capsule (Non Penicillin and Non Cephalosporin)	2085-11-09	2082-11-10	Tablet (Non Penicillin & Non Cephalosporin) Capsule (Non Penicillin and Non Cephalosporin)
71	Corel Pharmaceuticals Pvt Ltd, Rupandehi	21 Feb 2028	22 Feb 2026	Tablet (Non Penicillin & Cephalosporin) Capsule (Non Penicilline and Non Cephalosporin) Ointment/Cream/Gel/Lotion (Non Penicillin & Non Cephalosporin)	2085-11-09	2082-11-10	Tablet (Non Penicillin & Cephalosporin) Capsule (Non Penicilline and Non Cephalosporin) Ointment/Cream/Gel (Non Penicillin & Non Cephalosporin)
72	JJ Laboratories Pvt Ltd, Bhaktapur	21 Feb 2028	22 Feb 2026	Tablet (Veterinary) Bolus (Veterinary) Powder for oral use (Veterinary) Oral liquid (Veterinary)			
73	Ideal Pharmaceuticals Company Pvt. Ltd., Banke	28 Mar 2028	29 Mar 2026	Sterile Eye/Ear Drop Sterile Ointment	2085-12-14	2082-12-15	Sterile Eye/Ear Drop Sterile Ointment
74	Classical Herbal Products Pvt Ltd, Kathmandu	28 Mar 2028	29 Mar 2026	Tablet (Ayurvedic) Capsule (Ayurvedic) Oral Liquid (Ayurvedic) External Preparation (Medicated oil/ Ointment) (Ayurvedic) Churna (Powder) (Ayurvedic) Vati & Guti (Ayurvedic) Semisolids (Avaleha, Pak)	2085-12-14	2082-12-15	Tablet (Ayurvedic) Capsule (Ayurvedic) Oral Liquid (Ayurvedic) External Preparation (Medicated oil/ Ointment) (Ayurvedic) Churna (Powder) (Ayurvedic) Vati & Guti (Ayurvedic) Semisolids (Avaleha, Pak)

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		VALID UP TO	ISSUE DATE	CATEGORY	VALID UP TO	ISSUE DATE	CATEGORY
75	Shivam Pharmaceutical Ltd, Bara	28 Mar 2028	29 Mar 2026	Tablet (Non Penicillin & Cephalosporin)	2085-12-14	2082-12-15	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicilline and Non Cephalosporin)			Capsule (Non Penicilline and Non Cephalosporin)
				Oral Powder/Granules (Non Penicillin & Non Cephalosporin)			Oral Powder/Granules (Non Penicillin & Non Cephalosporin)
				Enema (Non Penicillin & Cephalosporin)			Enema (Non Penicillin & Cephalosporin)
76	Lifestar Pharmaceuticals Pvt Ltd, Parsa	07 April 2028	06 April 2026	Tablet (Non Penicillin & Cephalosporin)	2085-12-23	2082-12-24	Tablet (Non Penicillin & Cephalosporin)
				Capsule (Non Penicillin and Non Cephalosporin)			Capsule (Non Penicillin and Non Cephalosporin)
				Cream/Ointment(Non Penicillin and Non Cephalosporin)			Cream/Ointment(Non Penicillin and Non Cephalosporin)

Upto date: 2083/03/05

यो प्रमाणीकरण सूचीमा समावेश उद्योगमा निरन्तर सुधार र स्वः परीक्षण गरी असल अभ्यास कायम गर्ने सर्त लागू हुनेछ।

औषधि सल्लाहकार समितिको मिति २०८२/०९/३० गते बसेको ५८ औं बैठकको निर्णयानुसार अनुमोदन भएका नयाँ औषधि तथा नयाँ समिश्रणहरुको सूची

S.No.	Generic Name	Indication(s)
1	Thalidomide 100mg Capsule	Newly diagnosed multiple myeloma (MM); acute treatment of moderate to severe erythema nodosum leprosum (ENL) in adults ≥18 years.
2	Lurasidone Hydrochloride 20 mg Tablet	Bipolar depression
3	Fulvestrant 250 mg/5ml PFS	HR-positive, HER2-negative advanced breast cancer in postmenopausal women
4	Saxagliptin 2.5mg/5mg tablets	Type 2 diabetes mellitus (as adjunct to diet and exercise)
5	Tapinarof 1% w/w cream	Plaque psoriasis in adults ≥18 years
6	Zolmitriptan Nasal Spray 5mg/dose	Acute treatment of migraine with or without aura in adults
7	Dimethyl fumarate (DMF) 120mg/240mg (as enteric coated micro tablets in a capsule)	Relapsing-remitting multiple sclerosis (RRMS) in adults ≥18 years
8	Vigabatrin Powder for Oral solution, 500mg per sachet	Infantile spasms (including TSC); refractory complex partial seizures
9	Brivaracetam injection 50mg/5ml	Partial onset seizures in epilepsy (≥4 years)
10	Vonoprazan 20mg tablets	Gastric ulcer, duodenal ulcer, reflux esophagitis; H. pylori eradication adjunct
11	Bempedoic acid 180mg tablet	Heterozygous Familial Hypercholesterolemia or atherosclerotic CVD (with statin)
12	Tylvalosin Tartarate Oral Powder 62.5 % w/w	Porcine proliferative enteropathy, swine enzootic pneumonia, swine dysentery
13	Vitamin A soft gelatin capsule	Vitamin A supplementation
14	Ertapenem for Injection 1g	Intra-abdominal infections, community-acquired pneumonia, gynecological & diabetic foot infections
15	Leucovorin 5mg tablets	Antidote to folic acid antagonists; megaloblastic anemia due to folate deficiency
16	Flurbiprofen 50mg/100mg tablets	Rheumatoid disease, osteoarthritis, ankylosing spondylitis, musculoskeletal disorders
17	Desidustat tablets	Anemia associated with chronic kidney disease (CKD)
18	Daprodustat tablets 1/2/4/6/8 mg	Anemia due to CKD in adults on dialysis ≥4 months
19	Tirzepatide in 0.5 ml PFS (2.5, 5, 7.5, 10, 12.5, 15 mg in 0.5ml PFS)	Type 2 diabetes mellitus (glycemic control & weight management)
20	Daprodustat tablets 1/2/4/6/8 mg	Anemia due to CKD in adults on dialysis ≥4 months
21	Lansoprazole Gastro Resistant Capsules 30mg, Clarithromycin 500mg and Amoxicillin Capsules 500mg	H. pylori infection with duodenal ulcer
22	Semaglutide 0.25 mg Injection	Type 2 diabetes mellitus (glycemic control)
23	L Arginine Zinc and Folic Acid Granules	Nutritional supplement for cardiovascular health, immune support, reproductive health and pregnancy

औषधि सल्लाहकार समितिको मिति २०८२/०५/३० गते बसेको ५८ औं बैठकको निर्णयानुसार स्तर अनुमोदन भएका औषधिहरुको सूची

S.No.	Product Name	Analytical Profile No.
1.	Lurasidone HCl Tablets	Luras 081/082/AP 170
2.	Sulphamethoxazole & Trimethoprim Powder	Cotri 081/082/AP 171
3.	Meloxicam & Paracetamol Bolus	Para Melo 081/082/AP 172
4.	Finerenone Tablets	Finere 081/082/AP 173
5.	Mecobalamin Dispersible Tablets	Mecoba 081/082/AP 174
6.	Albendazole Bolus	Alben B 082/083 AP 175

आ.व. २०८२/८३ मा भएका औषधि फिर्ता (Recall) को सूची

S. N.	Product Name	Manufacturer	Batch No.	Mfg date	Exp date	Type of Medicine	Parameter failed
1.	Heliclar-500 (Clarithromycin Tablets IP)	Nova Genetica Pvt. Ltd., Dhading	HL 5-77	Jan. 2024	Dec. 2025	Allopathy	Dissolution
2.	TIDZ-1000 (Tinidazole Tablets IP)	Lomus Pharmaceuticals P.L., Kathmandu	TZ3-0123	May 2023	Apr-25	Allopathy	Disintegration
3.	Cetophen 500 (Paracetaol Tablets BP)	Lomus Pharmaceuticals, Kathmandu	CT-1123	April 2023	Mar- 26	Allopathic	Disintegration
4.	Rexamol 500 (Paracetamol Tablets)	Curex Pharmaceuticals Pvt. Ltd, Kavre	TRX-695	Nov 2024	Oct 2026	Allopathic	Dissolution
5.	Cetophen 500 (Paracetamol Tablets BP)	Curex Pharmaceuticals Pvt. Ltd. Kavre, Nepal	CT-2723	Jun. 2023	May-26	Allopathy	Dissolution
6.	Levoflox-500 (Levofloxacin 500 mg) Tablet	Magnus Pharma Pvt.Ltd., Bara, Nepal	BB 24001	Mar. 2024	Feb. 2026	Allopathy	Dissolution
7.	SUPRAMOX CV BID Suspension (Amoxycillin Trihydrate 200 mg Potassium Clavulanate 28.5 mg)	Arya Pharmalab, Bara	FSBD 12016	Mar. 2025	Aug. 2026	Allopathy	Assay of Amoxycillin
8.	Enclave-OD Tablet (Amoxycillin 875 mg, Clavulanic acid 125 mg)	Curex Pharmaceuticals Pvt. Ltd., Kavre	TEOD-026	Dec. 2024	May. 2026	Allopathy	Assay and Disssolution
9.	Axapara, 100 ml Infusion, Paracetamol IP 1.0% w/v	Mfg: Axa Parenterals Ltd, India Importer: Axadeep Pharma Distributiors Pvt. Ltd., Lalitpur, Nepal	AB5 0335	Feb. 2025	Jan. 2027	Allopathy	Sterility
10.	Abamol, 100 ml, Infusion, Paracetamol IP 1.0% w/v	Mfg: Abaris Healthcare Pvt. Ltd, India Importer: RB Pharmaceuticals Pvt.Ltd. Kathmandu, Nepal	RB 544502	Jul. 2024	Jun. 2026	Allopathy	Sterility
11.	Ondatron-4 (Ondansetron HCl 4 mg)	Deurali Janta Pharmaceuticals Pvt.Ltd., Dhapasi, Kathmandu	ONDT 2901	Aug. 2025	Jul. 2027	Allopathy	Assay
12.	Fexadine -180 (Fexofenadine HCL Tablets IP)	Simca Laboratories Pvt. Ltd., Bhaktpur	T25/ 071	May-25	Apr. 2027	Allopathy	Dissolution (Self Recall)
13.	Espro-40 (Esomeprazole Tablets IP - 40 mg)	Panas Pharmaceuticals Pvt. Ltd., Nepalgunj	TEO 048'R'	Apr. 2025	Mar. 2027	Allopathy	Dissolution (Buffer) (Self Recall)
14.	Adopin-L (Amlodipine & Losartan Potassium Tablets IP)	Panas Pharmaceuticals Pvt. Ltd., Nepalgunj	TADD 011	Aug. 2025	Jul. 2027	Allopathy	Dissolution (Self Recall)
15.	MARBLE (Calcium and Vitamin D3 Tablets BP)	Grace Pharmaceuticals Pvt Ltd, Rupandehi	TMA-025	Jun 2025	May 2027	Allopathy	Assay of Cholecalciferol
16.	LINARCE M 850 Tablets (Linagliptin and Metformin HCl Tablets)	Grace Pharmaceuticals Pvt Ltd, Rupandehi	TLMS-006	Nov 2024	Oct 2026	Allopathy	Assay
17.	AGLOCEF 1G (Ceftriaxone Injection IP)	Aglowmed Ltd, India	N45 2501	April 2025	Sep 2027	Allopathy	Bacterial Endotoxin Test
18.	ADOXY 100 (Doxycycline Capsules IP)	Apex Pharmaceuticals Pvt Ltd, Birgunj	C-81 060	Dec 2024	Nov 2026	Allopathy	Uniformity of weight
19.	Reditux (Rituximab 500 mg) 500 mg vial	Dr. Reddy's Laboratories Ltd., Bachupally Mandal, Telangana, India	N230 662C	Nov. 2023	Oct. 2026	Allopathy	Out of Trend in % Monomer and aggregates impurities in drug substance (Self Recall)
20.	Reditux (Rituximab 500 mg) 500 mg vial		N230 633C	Nov. 2023	Oct. 2026	Allopathy	
21.	Sinex Tablet	Time Pharmaceuticals Ltd., Nawalpur	SN 839	Oct. 2025	Sep. 2027	Allopathy	Physical: Hair was seen in Tablet (Self Recall)

औषधि व्यवस्था विभाग र अन्तर्गतका कार्यालयबाट आ.ब. २०८२/८३ मा सम्पन्न गरिएका कार्यहरुको विवरण

क्र. स.	कामको विवरण	इकाई	हाल सम्मको जम्मा
१.	औषधि उद्योग निरिक्षण	वटा	१०४
२.	फार्मेसी निरिक्षण	वटा	२८५५
३.	औषधि सूचना प्रवाह	पटक	५५
४.	ड्रग वुलेटिन प्रकाशन	पटक	३
५.	औषधि नमूना परिक्षण	वटा	५१६
६.	नेपाली औषधि उद्योगको प्रयोगशाला निरिक्षण	पटक	१२
७.	नयाँ उत्पादन अनुज्ञापत्र प्रदान (नयाँ) (उद्योग शाखा)	वटा	५६५
८.	उत्पादन अनुज्ञापत्र नवीकरण (उद्योग शाखा)	वटा	८०६४
९.	औषधि बजार बिक्रिवितरण प्रमाणपत्र (नयाँ) उद्योग शाखा	वटा	४९६
१०.	औषधि बजार बिक्रिवितरण प्रमाणपत्र नविकरण (उद्योग शाखा)	वटा	५९७०
११.	नयाँ उद्योग स्थापना सिफारिस (उद्योग शाखा)	वटा	३
१२.	पैठारी सिफारिस पत्र प्रदान (कच्चा पदार्थ) (नयाँ) (उद्योग शाखा)	वटा	९००
१३.	पैठारी सिफारिस पत्र नवीकरण (उद्योग शाखा)	वटा	१४५६९
१४.	औषधि उद्योग नक्सा स्वीकृत (उद्योग शाखा)	वटा	१९
१५.	नयाँ विदेशी औषधि दर्ता (पैठारी शाखा)	वटा	२२२
१६.	पैठारी सिफारिस पत्र नविकरण (पैठारी शाखा)	वटा	२६५०
१७.	नँया विदेशी कम्पनि दर्ता (पैठारी शाखा)	वटा	११
१८.	नयाँ फार्मेसी दर्ता	वटा	४५५७
१९.	फार्मेसी नविकरण	वटा	१४०८८
२०.	फार्मेसी व्यवसायी कार्ड नबिकरण संख्या	वटा	९६९
२१.	फार्मेसी रद्ध संख्या	वटा	३७६२
२२.	मुद्दा दायर संख्या	वटा	१०२
२३.	फार्मेसी निलम्वन संख्या	वटा	३९३
२४.	प्राप्त परिक्षण प्रतिवेदन मध्ये जोखिममा आधारित बजारिकृत औषधि नमूनाहरुको परिक्षण प्रतिवेदन संख्या	वटा	१८२
२५.	न्यून गुणस्तर भएका औषधिको संख्या	वटा	२१
२६.	Vaccine Lot Release	वटा	३०
२७.	औषधि Recall को सूचना	वटा	१५
२८.	सूचना उपलव्ध गराईएको (उजुरी लगायत)	संख्या	११०
२९.	नयाँ औषधि वा समिश्रणको स्तर निर्धारण	संख्या	१५

Highlights of WHO's support to DDA
(July 2025- Feb 2026)

Consultation Workshop on the "Categorization of Medicines"

On 4 July 2025, the Department of Drug Administration (DDA), with support from WHO Nepal, convened a "*Consultation Workshop on the Categorization of Medicines."* The workshop brought together over 40 participants, including representatives from the Association of Pharmaceutical Producers of Nepal (APPON), Nepal Chemists and Druggists Association (NCDA), Nepal Pharmacy Association (NPA), Pharmacy Association of Nepal (PhAN), DDA, the National Medicines Laboratory (NML), and former Director Generals of DDA.

The workshop focused on the revision of Nepal's medicine categorization system established under the Drug Act, 1978 and the Drug Categorization Rules, 1986. Participants recognized that the existing categorization list, which currently includes 434 medicines, no longer reflects the evolving pharmaceutical landscape and requires expansion to encompass all registered medicines.

During the workshop, stakeholders reviewed and refined a revised draft categorization list developed on the basis of therapeutic use, regulatory status, and potential for misuse or abuse. The discussions provided valuable feedback to strengthen and finalize the categorization framework.

The initiative represents a significant milestone in strengthening Nepal's pharmaceutical regulatory framework, supporting the development of a comprehensive national medicines database, and promoting the rational, safe, and appropriate use of medicines across the country.

Consultation Workshop on the Categorization of Medicines

“Public Health Sensitive Patent Provisions in Nepal’s Industrial Property Bill”

The Department of Drug Administration (DDA), with support from WHO and Third World Network, convened a two-day workshop on 29–30 August 2025 to examine public health-sensitive patent provisions in Nepal’s Industrial Property Bill. Held at a pivotal time as Nepal prepares for graduation from Least Developed Country (LDC) status in 2026, the workshop focused on aligning intellectual property obligations with national public health priorities.

The event brought together 104 participants from Parliament, government institutions, academia, legal bodies, the pharmaceutical sector, and civil society. Discussions centered on the effective use of TRIPS flexibilities, safeguards against patent evergreening, and provisions related to compulsory licensing and early working to protect access to medicines.

The workshop facilitated broad stakeholder consensus on the importance of a balanced intellectual property framework that fosters innovation while safeguarding equitable access to affordable medicines. Key recommendations included further refinement of the Industrial Property Bill and the establishment of a national roster of experts to support evidence-based policy development.

Workshop to finalize DDA five-year strategy

With technical support from WHO, the Department of Drug Administration (DDA) convened a two-day consultation workshop on 25–26 December 2025 to finalize its Five-Year Strategic Plan. The workshop brought together over 55 representatives from the Ministry of Health and Population (now Ministry of Health and Food Safety), DDA, Department of Health Services, National Medicines Laboratory, Department of Food Technology and Quality Control, Department of Ayurveda and Alternative Medicine, academia, and professional and industry associations.

The workshop provided a platform for stakeholders to review and refine the draft strategy, ensuring its alignment with national health priorities and emerging regulatory needs. Discussions focused on strengthening regulatory systems, enhancing medicine quality assurance, and improving compliance mechanisms across the pharmaceutical sector.

The workshop concluded with consensus on strategic priorities, key interventions, and implementation pathways that will guide DDA's work over the next five years, contributing to a stronger regulatory system and improved access to safe, effective, and quality-assured medicines in Nepal.

Workshop to finalize DDA five-year strategy, 25-26 December 2025

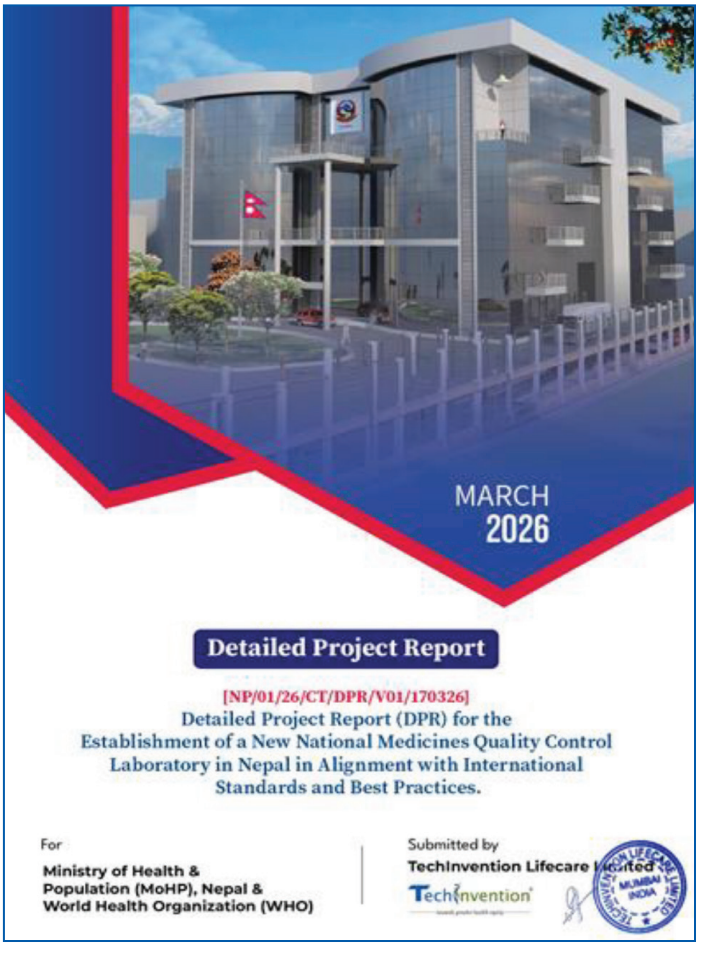
Workshop on Regulatory System Strengthening

The Department of Drug Administration (DDA), in collaboration with WHO, organized a two-day workshop on 17–18 February 2026 to strengthen Nepal's drug regulatory and quality assurance systems. The event brought together more than 90 participants, including the Honorable Minister for Health and Population, senior government officials, experts from WHO SEARO and the WHO Country Office, representatives from CDSCO, Thai FDA, the Indian Pharmacopoeial Commission, TechInvention Lifecare Pvt. Ltd., and key pharmaceutical stakeholders.

The workshop reviewed Nepal's existing regulatory and laboratory capacities, identified priority gaps, and explored international and regional best practices. Participants also discussed on the preliminary Detailed Project Report (DPR) for establishing a new national quality control laboratory with expanded services. The meeting concluded with consensus on priority actions, implementation timelines, and collaboration mechanisms to advance a practical roadmap, with WHO reaffirming its commitment to supporting the process.

Detailed Project Report for establishing a new National Quality Control Laboratory developed

WHO Nepal supported DDA and NML to develop the Detailed Project Report (DPR) for the establishment of a new National Quality Control Laboratory (NQCL) in Nepal. The DPR presents evidence-based recommendations on infrastructure, laboratory design, equipment, quality management systems, and accreditation readiness required to develop a modern, internationally compliant drug testing facility. As a strategic roadmap, it informs policy decisions, resource mobilization, and phased implementation, while supporting the Ministry of Health and Food Safety in strengthening the national quality assurance system through expanded testing capacity and enhanced regulatory oversight, thereby ensuring the quality, safety, and efficacy of medical products.



आ.ब. २०८२/८३ मा विभागबाट जारी गरिएका महत्वपूर्ण सूचनाहरु

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
प्रकाशित मिति: २०८२/०४/१५

झुट्टा, भ्रामक, प्रचारप्रसार तथा बिक्रिवितरण सम्बन्धि अत्यन्त जरुरी सूचना।

सामाजिक संजालहरू फेसबुक, टिकटक लगायत अन्य अनलाइन प्लेटफर्महरू मार्फत झुट्टा तथा भ्रामक प्रचारप्रसार गरी मधुमेह निको पार्ने, मोटोपन घटाउने, प्रोस्टेट (Prostate) ठीक पर्ने, थाइराइड (Thyroid) निको पार्ने, युरिक एसिड (Uric Acid) निको पार्ने, यौनशक्ति/उत्तेजना बढाउने, जौड-रक्सी छुटाउने, र क्यान्सर जस्ता प्राण घातक रोगहरू निको पार्ने दावी गर्दै अनाधिकृत रुपमा नक्कली औषधिहरु बिक्री-वितरण भइरहेको पाईएकोमा विभागको गम्भीर ध्यानाकर्षण भएको छ।

चिकित्सकको सिफारिस (Prescriptions) विना नै विज्ञापनको आधारमा प्रयोग गरिने यस्ता प्रकारका सामग्रीहरु वैज्ञानिक रुपमा प्रमाणित नभएको हुदाँ सोको प्रयोगले जनस्वास्थ्यमा गम्भीर हानी पुर्याउनुका साथै अङ्गभङ्ग समेत हुने गर्दछ। साथै भविष्यमा अन्य स्वास्थ्य सम्बन्धि जटिल समस्या निम्त्याउन पनि सक्दछ।

यस विभागको निरीक्षणका क्रममा देहायका नक्कली औषधिहरु जस्तै डीफ्यूजल-एल, कायाप्लस, 100 Horse Power, 30 Minutes Plus Stops, बूजी लगायत औषधिहरुको बरामद गरी कानुनी कारवाहीको प्रक्रियामा रहेको छ। यस्ता किसिमका सामग्रीहरु उत्पादन, ओसारपसार र बिक्री-वितरण कानुनविपरीत भएकाले उक्त गतिविधिहरु तत्काल रोक्न साथै सामाजिक सञ्जालबाट भ्रामक विज्ञापनहरू हटाउन अनुरोध गरिन्छ। स्वास्थ्य सम्बन्धि कुनै पनि समस्या भएमा वा देखिएमा चिकित्सकको सिफारिसमा मात्र आधिकारिक फार्मेसीबाट खरिद गरि प्रयोग गर्नुहुन सम्पूर्ण उपभोक्ताहरु लगायत सम्बन्धित सरोकारवालाहरुको जानकारीका लागि यो सूचना प्रकाशित गरिएको छ।

महानिर्देशक

तपसिलः

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रमाणपत्र र सिफारिसपत्रको अवधि र नवीकरण सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः २०८२/०४/१८

केही नेपाल ऐनलाई संसोधन गर्न बनेको ऐन, २०८२ को दफा १२ मा औषधि ऐन २०३५ मा संसोधन सम्बधि व्यवस्था उल्लेख भएकोले औषधि ऐन को दफा ११ बमोजिम विभागबाट जारी उत्पादन अनुज्ञापत्र, सिफारिसपत्र र प्रमाणपत्रको अवधि र नवीकरण अवधि सम्बन्धि नयाँ संसोधित व्यवस्था नेपाल राजपत्र खण्ड ७५ अतिरिक्तांक २१ भाग २ मिति २०८२/०४/१४ मा प्रकाशन भएकोले सोहि व्यवस्था अनुसार गर्न/गराउनु हुन सरोकारवाला सबैमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

संलग्नः

नेपाल राजपत्र खण्ड ७५ अतिरिक्तांक २१ भाग २ मिति २०८२/०४/१४ मा प्रकाशन भएको औषधि ऐन २०३५ को दफा ११ मा संशोधन सम्बन्धि सूचना पाना ३

२०८२/०४/१८
महानिर्देशक

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति : २०८२/०४/२१

औषधि उत्पादन कुशल अभ्यास संहिता, २०७२ को संसोधन सम्बन्धि जरुरी सूचना

उपरोक्त सम्बन्धमा औषधि दर्ता नियमावली २०३८ को नियम ११ बमोजिम औषधि उत्पादन प्रयोजनको लागि औषधि उत्पादन संहिता, २०४१ लागू भएकोमा सो संहितालाई समय सापेक्ष रुपमा परिमार्जन गर्दै नेपाल सरकार, माननीय मन्त्री स्तर (मिति २०७२/०९/०२) निर्णयानुसार औषधि उत्पादन कुशल अभ्यास संहिता, २०७२ स्वीकृत भै कार्यान्वयन भएको व्यहोरा अनुरोध छ।

उक्त संहिता बमोजिम कार्यसम्पादन गर्दा देखिएका समस्या एवं औषधि उत्पादनमा अन्तराष्ट्रिय स्तरमा भएका असल अभ्यास समेत समेटी नेपाल सरकार, माननीय मन्त्री स्तरबाट मिति २०७९/०६/२५ (पहिलो संसोधन) र मिति २०८२/०३/२२ (दोस्रो संसोधन) मा स्वीकृत भई जारी गरिएको व्यहोरा सरोकारवाला सबैको जानकारीको लागि यस विभागको मिति २०८२/०४/२१ को निर्णयानुसार अनुरोध छ।

संलग्नः

औषधि उत्पादन कुशल अभ्यास संहिता, २०७२ (पहिलो र दोस्रो संसोधन सहित) : पाना १०५।

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उत्पादन अनुज्ञापत्र र औषधि विक्रिवितरण दर्ता प्रमाणपत्र DAMS मा प्रविष्ट गर्ने सम्बन्धि अत्यन्त जरुरी सूचना।

उपरोक्त सम्बन्धमा यस विभागले औषधि ऐन, २०३५ र औषधि दर्ता नियमावली, २०३८ बमोजिम स्वदेशी औषधि उद्योगहरुलाई औषधि उत्पादन र विक्रिवितरणको लागि आवश्यक प्रमाणपत्रहरु प्रदान गर्दै आएको विदितै छ। साथै, हाल औषधि ऐन २०३५ मा भएको संसोधनमा रहेको प्रावधान बमोजिम नविकरण नभएका अनुज्ञापत्र/प्रमाणपत्र म्याद सकिएको एक महिना पछि स्वतः रद्द हुने र सो को जानकारी सरोकारवालालाई दिनुपर्ने अनिवार्यतालाई समेत ध्यानमा राखी विभागबाट प्रदान हुने सेवालाई चुस्त दुरुस्त बनाई विद्युतीय माध्यमबाट सेवा प्रवाह गर्न DAMS प्रणाली मार्फत उत्पादन अनुज्ञापत्र (अनुसूची ५) र औषधि विक्रिवितरण दर्ता प्रमाणपत्र (अनुसूची ४ ख) प्रदान गर्दै आएकोमा कतिपय उत्पादकले सो अनुज्ञापत्र र प्रमाणपत्रहरुको विवरण DAMS मा प्रविष्ट गरेको नदेखिएकोले अब उप्रान्त, नविकरण DAMS मार्फत गरिने हुँदा तिस (३०) दिन भित्र अध्यावधिक गर्नुहुन सम्बन्धित स्वदेशी उत्पादकहरुको जानकारीको लागि सूचित गरिन्छ।

यसरी, अध्यावधिक गर्दा निम्न बमोजिमको कागजातहरु DAMS मा प्रविष्ट गर्नुपर्ने व्यहोरा समेत जानकारीका लागि अनुरोध गरिन्छः

- अनुसूची ५ र अनुसूची ४ (ख) को नविकरणको अवस्था खुल्ने गरि छायाँ प्रति
  - अनुसूची ५ प्रविष्टको लागि Home > List of Products > Add new products > If pre-registered both side scanned copy अनुसार गर्न
  - अनुसूची ४ (ख) प्रविष्टको लागि Home > List of Products > Add new products > If pre-registered both side scanned copy अनुसार गर्न
- Updated Product specification
- Certificate of Analysis
- औषधिको नमुनाको फोटो

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खोकीको औषधि (Cough Syrup) को सुरक्षितता र प्रयोग सम्बन्धी अत्यन्त जरुरी सूचना।

भारतमा विभिन्न राज्यहरुमा खोकीको औषधि "Coldrif Cough Syrup" प्रयोगपछि बालबालिकाको मृत्यु भएको समाचारहरु प्रति विभागको गम्भीर ध्यानाकर्षण भएको छ । उक्त Coldrif Cough Syrup औषधि भारतको Sresan Pharma, India उत्पादक रहेको जानकारी हुन आएकोमा सो उत्पादक तथा सोका उत्पादनहरु बिभागमा दर्ता नभएको व्यहोरा सबैको जानकारीको लागि अनुरोध छ ।

यस्ता प्रकारका घटनाहरु विगतमा पनि भई सकेकोमा सो प्रति विभाग पहिले नै सचेत रही कार्य गर्दै आएको छ । नेपालमा झोल बनावटको औषधि उत्पादन तथा आयात गर्ने सबै उद्योगहरुलाई आफ्नो उत्पादनमा Propylene Glycol, Polyethylene Glycol, Sorbitol र Glycerol/Glycerine जस्ता सहायक कच्चा पदार्थ प्रयोग गर्दा तिनीहरूमा Ethylene Glycol र Diethylene Glycol को मिसावट नभएको सुनिश्चित गर्न आवश्यक गुणस्तर परीक्षण अनिवार्य गर्दै मिति २०७९/०८/१२ मा सूचना प्रकाशित गरिएको थियो । यस पश्चात मिति २०८२/०४/२१ मा WHO Working Document वमोजिम Liquid Preparation for Oral Use मा Ethylene Glycol र Diethylene Glycol को मात्रा परीक्षण गर्न व्यवस्था मिलाउन भनि सूचना प्रकाशित गरिएको छ । तथापि, सम्बन्धित सबै पक्षलाई यस विषयमा पुनः सचेत रहन निर्देशन दिदै आवश्यक गुणस्तर परीक्षण गर्न निम्न वमोजिमको निर्देशन पालना गर्न गराउन अनुरोध गरिएको छ :

१. औषधि उत्पादकका लागि :
   - कच्चा पदार्थ खरिद गर्दा आधिकारिक आपूर्तिकर्ता (Approved Vendor) हरुबाट फर्माकोपियल स्तरको मात्र खरिद गर्नुहुन
   - उल्लेखित कच्चा पदार्थ तथा सो समिश्रित झोल बनावटको औषधिको निर्धारित विधि वमोजिम Ethylene Glycol र Diethylene Glycol को परीक्षण गरे पश्चात मात्र उत्पादन तथा बिक्री वितरण गर्नुहुन

२. औषधि आयातकर्ताका लागि :
   - नेपालमा आयात हुने उल्लेखित कच्चा पदार्थ मिश्रित झोल बनावटको औषधिको प्रत्येक ब्याचको Ethylene Glycol र Diethylene Glycol मिसावट नभएको सुनिश्चित गरे पश्चात मात्र आयात तथा बिक्री वितरण गर्नुहुन

३. फार्मेसीहरूका लागि :
   - बिभागमा दर्ता भएका औषधिहरु मात्र बिक्री वितरण गर्नुहुन

४. चिकित्सकहरुका लागि :
   - बिभागमा दर्ता भएका औषधिहरु मात्र prescribe गर्नुहुन
   - दुई वर्ष वा सो भन्दा कम उमेरका बालबालिकाहरुलाई खोकीको औषधि सिफारिस गर्दा वैज्ञानिक प्रमाणको आधारमा मात्र सिफारिस गर्न गराउनु हुन

५. सर्वसाधारणका लागि :
   - बालबालिकाका लागि प्रयोग गरिने कुनै पनि औषधि चिकित्सकको सल्लाह वमोजिम मात्र प्रयोग गर्नुहुन
   - बिभागमा दर्ता भएका औषधिहरु मात्र प्रयोग गर्नुहुन
   - औषधिको लेबलमा उल्लेखित जानकारी वमोजिम मात्र प्रयोग गर्नुहुन

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१७४८, मदन भण्डारी पथ-४
विजुलीबजार, काठमाडौं।

पत्र संख्याः- ८२।८३
चलानी नं.:- २४३७

प्रतिनिधि/कर्मचारी तोक्ने सम्बन्धमा अत्यन्त जरुरी सूचना !

श्री सबै औषधि उत्पादक कम्पनी/फर्म,
श्री सबै औषधि पैठारीकर्ता कम्पनी/फर्म,

उपर्युक्त सम्बन्धमा यस विभागले प्रवाह गर्ने सेवालाई छिटोछरितो, सहज र प्रभावकारी बनाउन, कार्यालय परिसरभित्र हुन सक्ने अवाञ्छित भिडभाड/गतिविधि कम गर्न तथा असम्बन्धित व्यक्तिलाई प्रवेश कार्यमा नियन्त्रण गर्न यस विभागले मिति २०८३ साल वैशाख २ गतेबाट प्रवेश कार्ड लागु गर्ने भएकोले ताहाँ औषधि उत्पादक कम्पनी/फर्म तथा औषधि पैठारीकर्ता कम्पनी/फर्मको तर्फबाट यस विभागसँग सम्बन्धित कार्यको लागि तोकिएको कुनै एक आधिकारिक प्रतिनिधि/कर्मचारीको परिचय सहितको प्रवेश कार्डका लागि देहाय बमोजिमको विवरण मिति २०८२ साल चैत्र ३० गतेभित्र उपलब्ध गराइ सहयोग गरिदिनुहुन सबै सरोकारवालाहरुको जानकारीको लागि यो सुचना प्रकाशन गरिएको छ।

(पुनश्चः औषधि पसल दर्ता, नवीकरण तथा व्यवसायिक अनुमतिपत्र लिन आउने सेवाग्राही तथा अध्ययन/भ्रमणका लागि आउने विद्यार्थीको हकमा प्रवेश कार्ड लागु हुने छैन्।)

देहायः

प्रतिनिधिको नामः पदः ठेगानाः राष्ट्रिय परिचयपत्र नं./ना.प्र.नं.
फोटो(PP size)- दुई प्रति
कम्पनी/फर्मको नामः ठेगानाः कम्पनी/फर्मको प्रकारः

मनोज कुमार गुप्ता
कानुन अधिकृत

मितिः २०८२/१२/१९

पो.ब.नं १००३८, फोन : ०१-४७८०४३२, फ्याक्स : ०१-४७८०५७२ इ-मेल : druginfo@dda.gov.np, वेभसाइट : www.dda.gov.np

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

प्रकाशित मिति: २०८२/१२/२०

कुशल फार्मेसी अभ्यास (Good Pharmacy Practice) तथा कुशल भण्डारण तथा वितरण अभ्यास (Good Storage and Distribution Practice) परिपालना सम्बन्धी जरुरी सूचना

औषधि ऐन, २०३५ दफा २८ मा भएको व्यवस्था तथा औषधि दर्ता नियमावली, २०३८ को नियम ११ बमोजिम औषधिको विक्री, वितरण तथा भण्डारण प्रक्रियालाई थप व्यवस्थित, गुणस्तरीय, सुरक्षित तथा प्रभावकारी बनाउने उदेश्यले औषधि विक्री-वितरण संहिता, २०८० लागू गरिएको सर्वविदितै छ। उक्त संहिताको दफा १७ मा कुशल फार्मेसी अभ्यास (Good Pharmacy Practice) तथा कुशल भण्डारण तथा वितरण अभ्यास (Good Storage and Distribution Practice) प्रमाणीकरण (Certification) सम्बन्धि स्पष्ट व्यवस्थाहरू उल्लेख गरिएका छन् ।

यसै व्यवस्था अनुसार प्रमाणीकरणका लागि केहि आवेदनहरु प्राप्त समेत भै प्रमाणीकरणको लागि आवश्यक कारवाही अघि बढीरहेको र इच्छुक औषधि पसल तथा थोक विक्रेताहरूले यस संहितामा उल्लेखित मापदण्डहरू अनुरूप आवश्यक पूर्वतयारीहरू सम्पन्न गरी संहिताको अनुसूची-३ बमोजिमको ढाँचामा औषधि व्यवस्था विभाग तथा मातहतका शाखा कार्यालयहरूमा आवेदन पेश गर्नुहुन र प्रमाणीकरण प्रक्रिया, मूल्याङ्कन मापदण्ड तथा अन्य विवरणहरू विभागको निर्णयअनुसार हुने व्यहोरा अनुरोध छ ।

नयाँ थोक तथा खुद्रा पसल (फार्मेसी)का हकमा औषधि विक्री-वितरण संहिता, २०८० मा उल्लेखित कुशल फार्मेसी अभ्यास (GPP) तथा कुशल भण्डारण तथा वितरण अभ्यास (GSDP) सम्बन्धी सम्पूर्ण मापदण्डहरू पूर्ण रूपमा पालना गर्ने गरी आवश्यक पूर्वतयारी सम्पन्न गरेपछि मात्र विभागमा दर्ताका लागि आवेदन दिनुपर्नेछ। साथै यसअघि दर्ता भइसकेका विद्यमान औषधिका थोक तथा खुद्रा विक्रेताहरूले पनि उक्त संहिता अनुसारका व्यवस्थाहरू क्रमिक रूपमा पूर्ण पालना गर्नुपर्नेछ। संहिताको पालना नगरेमा औषधि ऐन, २०३५ तथा प्रचलित कानुन बमोजिम कानुनी कारवाही हुने व्यहोरा यस सूचनामार्फत सबै सरोकारवालालाई जानकारी गराइन्छ।

थप जानकारी तथा सहयोग लागि

- संहिताको पूर्ण पाठ, मापदण्ड, अनुसूची तथा आवेदन ढाँचा औषधि व्यवस्था विभागको आधिकारिक वेबसाइट www.dda.gov.np मा उपलब्ध छ।
- प्रमाणीकरणसम्बन्धी थप जानकारी, परामर्श वा सहयोगका लागि औषधि व्यवस्था विभाग, काठमाडौं वा नजिकको शाखा कार्यालयमा सम्पर्क गर्नुहोस्।

किरण सुन्दर बज्राचार्य
(सूचना अधिकारी)

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
बिजुलीबजार, काठमाडौं

प्रकाशित मिति: २०८३।०१।१५

Immunosuppressant वर्गका औषधिहरुको उत्पादक तथा पैठारीकर्ताका लागि जरुरी सूचना ।

प्रस्तुत विषयमा Immunosuppressant वर्गका औषधिहरु Shared Facility मा उत्पादन गर्ने उद्योगसँग देहाय बमोजिमका कागजात माग गर्ने र सो प्राप्त भए पश्चात कागजात अध्ययन गरी थप राय प्रदान गर्न यस विभागको मिति २०८२/१२/१० को विभागिय निर्णय अनुरुप Immunosuppressant वर्गका औषधि उत्पादन तथा आयात गर्ने उत्पादकहरुसँग देहायको विवरणहरु माग गरिएकामा, केहि उत्पादक/पैठारीकर्ताबाट सो सम्बन्धि विवरण प्राप्त भई नसकेकाले यस सूचना प्रकाशित मितिबाट सात (०७) दिन भित्र विभागमा उक्त विवरण पेश गर्नु हुन सरोकारवाला सबैमा जानकारीका लागि यो सूचना प्रकाशित गरिएको छ।

देहाय:

A comprehensive, science- and risk-based Quality Risk Management (QRM) report shall be submitted to justify the manufacturing of immunosuppressant category products in shared facilities. The report may include:

Product Description & Toxicological Profile:

- Potency, therapeutic dose, and critical toxicological effects
- Health-Based Exposure Limit (HBEL), including PDE/ADE, OEL

Cross-Contamination Risk Assessment:

- Risk evaluation across all manufacturing stages (including details of manufacturing process and equipment)
- Assessment of material attributes (e.g. dust generation potential, solubility etc.) and process characteristics relevant to cross-contamination risk
- Assessment of co-manufactured products in the same facility

Cleaning Validation:

- MACO calculation based on HBEL
- Protocol & Report of cleaning validation studies

Technical and Organizational Control Measures:

- Dedicated or appropriately segregated HVAC systems
- Use of closed or contained manufacturing systems, dedicated equipment or campaign production, where applicable
- Personnel and material flow controls

०१।१५

किरणसुन्दर बज्राचार्य
(सुचना अधिकारी)

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभागको

प्रकाशित मिति: २०८३।०१।२८

"नागरिक सहायता तथा सहजीकरण केन्द्र"

"एकल विन्दु सेवा प्रणाली" संचालन सम्बन्धी जरुरी सूचना

औषधि ऐन, २०३५ को कार्यान्वयन र औषधिहरूको गुणस्तर सुनिश्चित गर्ने सन्दर्भमा यस विभागको सेवा प्रवाहलाई थप पारदर्शी, झन्झटमुक्त र नागरिकमैत्री वनाउने राज्यको नीति अनुरूप आगामी मिति २०८३/०२/०१ देखि विभागको परिसरमा ***"नागरिक सहायता तथा सहजीकरण केन्द्र""(Citizen Assistance & Facilitation Centre) तथा एकल विन्दु सेवा प्रणाली (Single Point Service System)*** संचालन गरिने व्यहोरा सम्पूर्ण सरोकारवालाहरुको जानकारीका लागि यो सूचना प्रकाशित गरिएको छ।

अतः मिति २०८३/०२/०१ पश्चात् विभागमा सेवा लिन चाहनु हुने सम्पूर्ण सेवाग्राही महानुभावहरूले सर्वप्रथम यसै केन्द्रमा सम्पर्क गरी आफ्नो सेवा प्राप्तिको प्रक्रिया अगाडि वढाउनुहुन अनुरोध गरिन्छ।

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शिवानी खड्गी

(नि. महानिर्देशक)

औषधि व्यवस्था विभाग

नेपाल सरकार
स्वास्थ्य तथा खाद्य स्वच्छता मन्त्रालय
औषधि व्यवस्था विभाग
टंकुजुलीवजार, काठमाडौं

औषधि व्यवस्था विभागको

विभागमा दर्ता भएको बिक्रि केन्द्र/ औषधि पसल/ फार्मेसीमा मात्र औषधि बिक्रि वितरण गर्ने सम्बन्धिमा अत्यन्त जरुरि सूचना!!

प्रकाशित मिति : २०८३/०२/०५

औषधि व्यवस्था विभागले औषधि दर्ता नियमावली २०३८ को नियम ११ बमोजिम औषधिको बिक्रि वितरण तथा भण्डारण प्रक्रियालाई थप व्यवस्थित, गुणस्तरीय, सुरक्षित तथा प्रभावकारी बनाउने उद्देश्यले औषधि बिक्रि वितरण संहिता २०८०, लागु गरिएको सर्बविदितै छ । उक्त संहिताको संहिता ९ को उपसंहिता (२) मा थोक बिक्रेताले विभागमा दर्ता भएका बिक्रि केन्द्र/औषधि पसल/ फार्मेसी, सरकारी कार्यालय, तथा प्रचलित कानुन बमोजिम दर्ता भएको संस्थालाई मात्र औषधि बिक्रि वितरण गर्नुपर्दछ भन्ने व्यवस्था रहेकोमा विभागको निरीक्षणका क्रममा केही थोक बिक्रेताहरूले विभागमा दर्ता नभएका बिक्री केन्द्र/औषधि पसल/ फार्मेसीहरूलाई औषधि बिक्री वितरण गरिरहेको पाइएको छ, जसप्रति विभागको गम्भीर ध्यानाकर्षण भएको छ ।

औषधि बिक्रि वितरण संहिता २०८० संहिताको ९ को उपसंहिता (२) सम्पूर्ण थोक बिक्रेताले विभागमा दर्ता रहेको बिक्रि केन्द्र/औषधि पसल/ फार्मेसीमा मात्र औषधि बिक्रि वितरण गर्नुहुन सबैको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ। साथै, थोक तथा खुद्रा बिक्रेता/औषधि पसल/फार्मेसीले औषधि विक्री गर्दा अनिवार्य रुपमा बिल विजक जारी गरी खरिदकर्ताको विवरण उल्लेख गर्नुहुन जानकारी गराईन्छ । औषधि बिक्रि वितरण संहिता २०८० संहिताको व्यवस्था अवज्ञा गरि थोक बिक्रेताले विभागमा दर्ता नरहेको बिक्रि केन्द्र/औषधि पसल/ फार्मेसीमा औषधि बिक्रि वितरण गरेको पाइएमा औषधि ऐन २०३५ बमोजिम कारबाही हुने व्यहोरा जानकारी गराईन्छ।

(किरण सुन्दर भट्टाचार्य)
वरिष्ठ औषधि व्यवस्थापक)

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
स्वास्थ्य सेवा विभाग
औषधि व्यवस्था विभाग
विजुलीबजार, काठमाडौं

IMMUNOSUPPRESSANT वर्गका औषधि उत्पादनमा हुनुपर्ने व्यवस्था सम्बन्धि सूचना।

प्रकाशित मितिः २०८३/०२/२१

Immunosuppressant वर्गका औषधिहरूको गुणस्तर, सुरक्षा र Cross Contamination को जोखिम न्यूनीकरण गर्न विभागले मिति २०८३/०२/१८ को निर्णय बमोजिम Immunosuppressant वर्गका औषधिहरुलाई समूहकृत गरी निम्नानुसार व्यवस्था गर्न सम्बन्धित सबै उत्पादक, पैठारीकर्ता तथा सरोकारवालाहरूको जानकारीका लागि यस सूचना प्रकाशित गरिएको छ ।

निर्णयहरू:

१. Immunosuppressant औषधिहरूको वर्गीकरण सहितको आवश्यक पर्ने व्यवस्था:

Category	Medicine	Provision
Category I	Antimetabolites / Antiproliferatives (Azathioprine, Methotrexate)	कुनै एउटा Category को औषधि उत्पादन गरेपछि अर्को Category को औषधि उत्पादन गर्दा Campaign basis मा उत्पादन गर्नुपर्ने
Category II	Calcineurin Inhibitors (Cyclosporine, Tacrolimus)	
Category III	mTOR Inhibitors (Sirolimus, Everolimus)	
Category IV	Mycophenolate mofetil (MMF) / Mycophenolic acid	
Category V	JAK Inhibitors तथा Leflunomide (Tofacitinib, Leflunomide)	
Category VI	Corticosteroids (Prednisone, Methylprednisolone, Dexamethasone, Hydrocortisone)	
Category VII	Apremilast, Hydroxychloroquine, Pirfenidone	General facility

२. बुँदा नं १ मा उल्लेखित व्यवस्था नयाँ औषधि दर्ताको हकमा तत्काल लागू हुने छ।

३. विभागमा दर्ता भै सलवसाली नवीकरण भैरहेका औषधिहरुका सम्बन्धमा विरामीले दीर्घकालीन रुपमा सेवन गर्नुपर्ने भएकोले सोको बजारमा आपूर्तिको सन्तुलन कायम राख्न विभागले मिति २०८३/०१/१५ गते प्रकाशित सूचनाका आधारमा जोखिम मूल्यांकन कागजात सन्तोषजनक भएका उत्पादनहरुको हकमा **बढीमा ३ महिनासम्म** उत्पादन/आयात अनुमति दिई प्रमाणपत्र नवीकरण गरिएको छ।

४. बुँदा नं. १ मा उल्लेखित औषधिहरुको जोखिम मूल्यांकन कागजात सन्तोषजनक नभएको तथा कागजात पेश नगरेका र तोकेको व्यवस्था नभएको उत्पादकहरुको दर्ता प्रमाणपत्र रद्द गर्ने प्रक्रिया अगाडि बढाइने व्यहोरा समेत अनुरोध छ ।

वि॰ महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा खाद्य स्वच्छता मन्त्रालय
औषधि व्यवस्था विभाग
विजुलीबजार, काठमाडौं

नयाँ औषधि तथा समिश्रणहरुको मूल्यांकन फाराम संशोधन सम्बन्धि सूचना।

प्रकाशित मितिः २०८३/०२/२५

औषधि व्यवस्था विभागद्वारा नेपालको औषधि दर्ता प्रणालीलाई अन्तर्राष्ट्रिय मापदण्ड अनुरूप थप सुदृढ, पारदर्शी तथा वैज्ञानिक बनाउन तथा नेपालमा सुरक्षित, गुणस्तरीय र प्रभावकारी औषधिको उपलब्धता सुनिश्चित गर्ने उद्देश्यले माग गरिने हालको नयाँ औषधि तथा नयाँ समिश्रणहरूको मूल्यांकन लागि आवश्यक कागजात सम्बन्धी व्यवस्था मिति २०८३/०२/२० गतेको विभागीय निर्णयद्वारा संशोधन गरिएको छ।

उक्त संशोधनमार्फत नयाँ औषधि तथा नयाँ समिश्रणको मूल्यांकनको लागि आवश्यक कागजात तथा प्रमाणहरूको व्यवस्था अन्तर्राष्ट्रिय अभ्यास, वैज्ञानिक आधार तथा नियामकीय आवश्यकता अनुसार परिमार्जन गरिएको छ। तसर्थ, नयाँ औषधि तथा नयाँ समिश्रणको मूल्यांकनका लागि निवेदन पेश गर्ने सम्बन्धित आवेदकहरूले संशोधित नयाँ औषधि तथा नयाँ समिश्रणहरूको मूल्यांकन फाराम "New Molecule Evaluation and Assessment Form" बमोजिम आवश्यक विवरण तथा प्रमाणहरू समेत पूर्ण रूपमा पेश गर्नुपर्ने व्यहोरा सम्बन्धित सबैको जानकारीका लागि यो सूचना प्रकाशन गरिएको छ।

साथै, संशोधित व्यवस्था यस सूचना प्रकाशन भएको मितिदेखि लागू हुने व्यहोरा समेत सम्बन्धित सबैको जानकारीका लागि सूचित गरिन्छ र उक्त मूल्यांकन फाराम यसै सूचनासाथ संलग्न गरिएको छ ।

२०८३/२/२५
नि. महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा खाद्य स्वच्छता मन्त्रालय
औषधि व्यवस्था विभाग

Pregabalin,Dicyclomine र Promethazine को उत्पादन,आयात र खपत विवरणको अभिलेख राख्ने सम्बन्धि सूचना।

प्रकाशित मितिः २०८३/०२/२७

औषधि व्यवस्था विभागद्वारा Pregabalin, Dicyclomine र Promethazine समिश्रित औषधिहरुको दुरुपयोगलाई निरुत्साहित गर्न र आपूर्ति, बजार व्यवस्थापन तथा उपलब्धतालाई थप व्यवस्थित बनाउन तपसिल बमोजिमको कार्य गर्न/गराउन मिति २०८३/०२/२२ को विभागीय निर्णय भएको हुँदा सम्पूर्ण उद्योग एवं पैठारीकर्ता लगायत सरोकारवालाहरुमा जानकारीको लागि यो सूचना प्रकाशित गरिएको छ।

तपसिलः

१. कुनै उत्पादकबाट Pregabalin औषधिको अनुसूची ७ मा उल्लेखित परिमाण वृद्धि गर्नका लागि माग भई आएमा सो औषधिको आयात/खपत परिमाण र retail pharmacy Level सम्मको बजार आपूर्तिको विवरण विभागमा पेश गर्नु पर्ने।

२. आयातको हकमा प्रत्येक ६ महिनामा आयात र retail level सम्मको खपत विवरण विभागमा पेश गर्नु पर्ने।

३. Retail Pharmacy बाट Pregabalin बिरामीको पुर्जीको आधारमा बिक्री वितरण गर्दा बिरामीको विवरण र औषधि सिफारिस गर्ने चिकित्सकको विवरण(नाम, NMC नं) को अभिलेख soft वा Hard copy मा राख्नु पर्ने।

४. Dicyclomine र Promethazine औषधिका उत्पादक र आयातकर्ताहरुले distributors Level सम्मको र Distributors हरुले Retail Level सम्मको बिक्री-वितरणको रेकर्ड कायम गर्नु पर्ने।

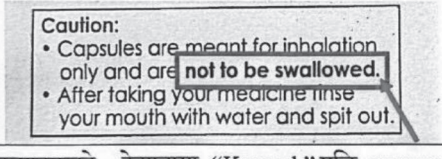
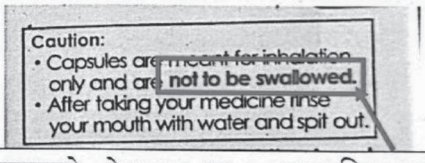
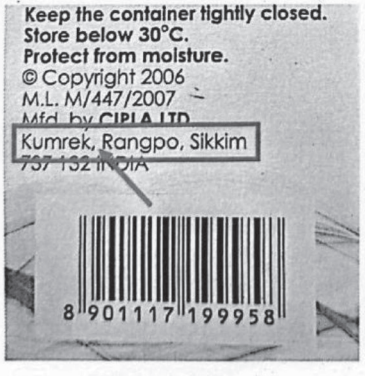
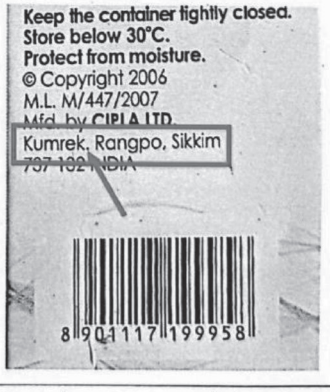
02/26

वरिष्ठ औषधि व्यवस्थापक

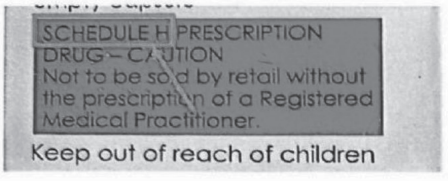
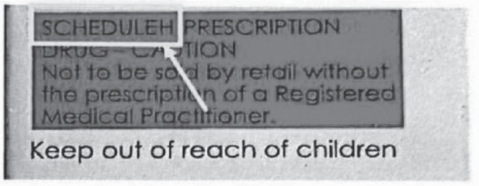
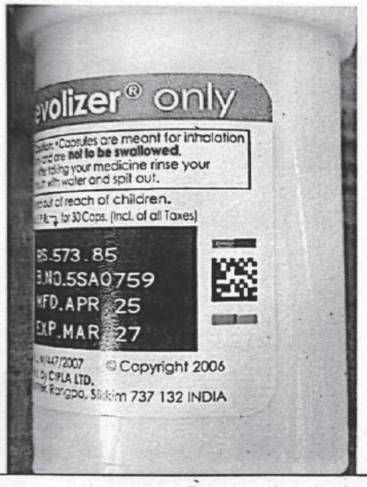
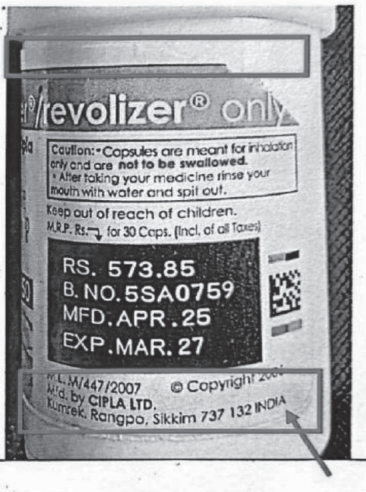
नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

SEROFLO ROTACAP औषधिको नक्कली (Counterfeit) औषधि फेला परेको बारे अत्यन्त जरुरी सूचना (प्रकाशित मितिः २०८३/०३/१०)

औषधि उत्पादक **CIPLA LTD, Kumrek, Rangpo, Sikkim, 737 132, India** बाट उत्पादित **SEROFLO ROTACAPS (Salmeterol and Fluticasone Propionate Powder for Inhalation IP)** को नक्कली औषधि बिक्रि वितरण भई रहेको पाइएकोले उक्त औषधिको सक्कली र नक्कली सम्बन्धि तपसिल बमोजिमको विवरण यकिन गरि साबधानी अपनाई सक्कली औषधिमात्र सिफारिस, बिक्रि वितरण तथा प्रयोग गर्नु हुन सम्पूर्ण चिकित्सक, फार्मसिष्ट, अस्पताल, औषधि व्यवसायी, सर्वसाधारण तथा सरोकारवालाहरुको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ ।

सक्कली औषधिको विवरण	नक्कली औषधिको विवरण
Caution खण्डमा Not to be swallowed को पछाडी कालो रंगको full Stop रहेको	Caution खण्डमा Not to be swallowed को पछाडी रातो रंगको full Stop रहेको
	
उत्पादकको ठेगानामा "Kumrek" पछि comma (,) रहेको	उत्पादकको ठेगानामा "Kumrek" पछि full Stop(.) रहेको
	

महानिर्देशक

लेबलको रातो भागमा "SCHEDULE H PRESCRIPTION DRUG" लेखिएको (SCHEDULE र H छुट्टिएको)	लेबलको रातो भागमा "SCHEDULEH PRESCRIPTION DRUG" लेखिएको (SCHEDULE र H जोडिएको)
	
भित्रको बट्टाको एउटा मात्र लेबल लगाएको	भित्रको बट्टाको लेबल निकाली पुन अर्को लेबल लगाइएको
	

यदि कसैले माथि उल्लेखित विवरण बमोजिमको नक्कली औषधि फेला परेमा तपसिल बमोजिम गर्न/गराउनुहुन अनुरोध छ ।

- बिरामीले प्रयोग बन्द गरि आफुले खरिद गरेको फार्मेसी वा औषधि पसललाई जानकारी गराउनुहुन,
- फार्मेसी वा औषधि पसलले तत्काल बिक्रि-वितरण रोक्का राखी, उक्त औषधिको मौज्दात छुट्टयाइ सम्बन्धित थोक बिक्रेतालाई फिर्ता गर्नुहोस र औषधि व्यवस्था विभागलाई जानकारी गराउनुहुन
- थोक बिक्रेताले उक्त औषधिको बिक्रि वितरण गरेको परिमाण फिर्ता गरि मौज्दात छुट्टयाइ, पुन बिक्रि वितरण नहुने गरि अलग्यै भण्डारण गरि औषधि व्यवस्था विभागलाई जानकारी गराउनुहुन

साथै उक्त औषधि खरिद गर्दा उक्त उत्पादकको अधिकारिक बिक्रेताबाट मात्र खरिद गर्नुहोला ।

नि. महानिर्देशक

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स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

औषधिको आपूर्ति श्रृङ्खला सुनिश्चित गर्ने बारे जरुरी सूचना

(प्रकाशित मितिः २०८३/०३/१८)

नेपाली बजारमा हालै देखिएको **counterfeit** तथा **falsified** औषधिहरूको बिक्री वितरण साथै Recall को सूचना जारी गर्दा त्यस्ता औषधिहरूको बजारबाट न्यून परिमाणमा फिर्ता हुने भएको र उक्त औषधिको सेवनले नकारात्मक असर पर्न सक्ने हुँदा जनस्वास्थ्यलाई जोखिमबाट बचाउन, औषधि आपूर्ति श्रृङ्खलामा सुधार गर्न र बजारलाई व्यवस्थित तथा पारदर्शी बनाउन औषधि बिक्री वितरण संहिता २०८० को मर्म बमोजिम निम्नानुसारका व्यवस्थाहरू लागू गर्न सबैको जानकारीका लागि यो सूचना प्रकाशित गरिएको छ ।

यी व्यवस्थाहरू तत्काल प्रभावकारी रूपमा कार्यान्वयन गर्न सबै स्वदेशी औषधि उत्पादक, पैठारीकर्ता, थोक बिक्रेता तथा खुद्रा बिक्रेताहरूलाई निर्देशन दिइन्छ।

लिखित सम्झौता (Written Agreement)

सबै स्वदेशी उत्पादक तथा औषधि पैठारीकर्ताहरूले आफ्ना आधिकारिक थोक बिक्रेताहरूसँग लिखित सम्झौता गर्नुपर्ने छ। उक्त सम्झौतामा उत्पादक/पैठारीकर्ता तथा थोक बिक्रेताको जिम्मेवारी, क्षेत्राधिकार, गुणस्तर नियन्त्रण, भण्डारण मापदण्ड, आपूर्ति शर्तहरू तथा दुवै पक्षको कानुनी दायित्व स्पष्ट रूपमा उल्लेख हुनु पर्नेछ। लिखित सम्झौता बिना कुनै पनि औषधि आपूर्ति वा वितरण गर्न निषेध गरिएको छ। उत्पादक तथा पैठारीकर्ताले आफ्नो औषधिहरूको उचित भण्डारण र व्यवस्थापन गर्न सक्ने क्षमता भएका योग्य थोक बिक्रेतालाई मात्र थोक बिक्रेता नियुक्त गर्नु पर्नेछ ।

आधिकारिक थोक बिक्रेताहरूको सार्वजनिक सूची

सबै स्वदेशी उत्पादक तथा औषधि पैठारीकर्ताहरूले आफ्ना आधिकारिक थोक बिक्रेताहरूको अद्यावधिक सूची आफ्नो आधिकारिक वेबसाइटमा प्रकाशित गर्नुका साथै औषधि व्यवस्था विभागको आधिकारिक

नि. महानिर्देशक

पोर्टलमा पनि उपलब्ध गराउनु पर्नेछ। सूचीमा थोक बिक्रेताको नाम, ठेगाना, दर्ता नम्बर, सम्पर्क विवरण र सम्झौता मिति उल्लेख हुनु पर्नेछ। यो सूची थपघट भएमा अनिवार्य रूपमा अद्यावधिक गर्नु पर्नेछ।

संस्थागत आपूर्ति (Institutional Supply) सम्बन्धी व्यवस्था

अस्पताल, स्वास्थ्य संस्था तथा अन्य संस्थागत खरिदमा प्रयोग हुने औषधिहरूको प्याकेजिङ/लेबलिङमा **"Institutional Supply Only"** स्पष्ट रूपमा उल्लेख हुनु पर्नेछ। यस्ता औषधिहरू खुद्रा बिक्रीका लागि प्रयोग गर्न निषेध गरिएको छ।

थोक बिक्रेताहरूको बिक्री सीमा

थोक बिक्रेताहरूले औषधि व्यवस्था विभागमा दर्ता भएका खुद्रा औषधि पसल, सरकारी स्वास्थ्य संस्था, अस्पताल तथा प्रचलित कानुनबमोजिम दर्ता भएका अन्य संस्थाहरूलाई मात्र औषधि बिक्री वितरण गर्न सक्नेछन्। अनाधिकृत व्यक्तिलाई औषधि बिक्री वितरण गर्न पूर्ण रूपमा निषेध गरिएको छ ।

खुद्रा बिक्रेताहरूको खरिद दायित्व

सबै खुद्रा बिक्रेताहरूले उत्पादक वा औषधि पैठारीकर्ताद्वारा अधिकृत थोक बिक्रेताबाट मात्र औषधि खरिद गर्नु पर्नेछ। खरिद गर्दा थोक बिक्रेताको नाम, औषधि व्यवस्था विभागको दर्ता नम्बर र Invoice अनिवार्य रूपमा संरक्षण गर्नु पर्नेछ।

लाइसेन्स नवीकरण प्रक्रिया

आर्थिक वर्ष २०८३/८४ देखि थोक बिक्रेताहरूले औषधि बिक्री वितरण प्रमाणपत्र नवीकरण गर्दा उत्पादक/पैठारीकर्तासँग भएको लिखित सम्झौताको प्रमाणित प्रतिलिपि अनिवार्य रूपमा पेश गर्नु पर्नेछ।

उल्लेखित व्यवस्थाको उल्लंघन गर्ने कुनै पनि पक्षलाई औषधि ऐन २०३५ तथा औषधि बिक्री वितरण संहिता २०८० बमोजिम कानुनी कारबाही गरिने व्यहोरा समेत अनुरोध छ।

नेपाल सरकार
स्वास्थ्य तथा खाद्य स्वच्छता मन्त्रालय
औषधि व्यवस्था विभाग
बिजुलीबजार, काठमाडौं

नि. महानिर्देशक