औषधि बिक्री वितरण संहिता, २०८०

प्रस्तावनाः नेपाल राज्यभर औषधिको बिक्री-वितरण प्रक्रियालाई थप व्यवस्थित गरी औषधिहरुको गुणस्तरियता, जनसुरक्षितता एवं प्रभावकारिता कायम गर्दै जनस्वास्थ्यमा टेवा पुऱ्याउने अभिप्रायले औषधि दर्ता नियमावली, २०३८ को नियम ११ को प्रयोजनको लागि यो संहिता जारी गरीएको छ।

परिच्छेद-१

प्रारम्भिक

१. संक्षिप्त नाम र प्रारम्भः (१) यो संहिताको नाम "औषधि बिक्री-वितरण संहिता, २०८०" रहेको छ।
(२) यो संहिता तुरुन्त प्रारम्भ हुनेछ ।

२. परिभाषाः विषय वा प्रसंगले अर्को अर्थ नलागेमा यस संहितामा,-

(१) "ऐन" भन्नाले औषधि ऐन, २०३५ सम्झनु पर्छ ।

(२) "नियमावली" भन्नाले औषधि ऐन अन्तर्गतका नियमावली भन्ने सम्झनु पर्छ ।

(३) "विभाग" भन्नाले औषधि व्यवस्था विभाग सम्झनु पर्छ ।

(४) "सेवा" भन्नाले तयारी औषधिको खुद्रा वा थोक बिक्री वितरण एवं प्रेशक्रिप्सन अनुसार तत्काल औषधि बनाई वा अर्धप्रशोधन गरी बिरामीलाई बिक्रि-वितरण गर्ने कार्यका साथै वितरित औषधि बारेमा सुचना र परामर्श दिने कार्यलाई सम्झनु पर्छ ।

(५) "प्रणाली" भन्नाले बिरामी (मानव र पशुपन्छी) को उपचारमा प्रयोग हुने एलोपेथिक, आयुर्वेदिक, होमियोपेथिक र युनानी प्रणालीहरु वा नेपाल राजपत्रमा प्रकाशित हुने थप प्रणाली समेत लाई सम्झनु पर्छ।

(६) "औषधि पसल" भन्नाले बिरामी (मानिस वा पशुपन्छी) वा बिरामीको प्रतिनिधि वा सेवाग्राहीलाई औषधि बिक्रि वितरण गर्नको लागि ऐन बमोजिम दर्ता रहेको खुद्रा पसल वा फर्म सम्झनु पदर्छ र सो शब्दले उक्त सेवा प्रदान गर्ने सरकारी, गैरसरकारी तथा निजि अस्पतालबाट संचालित फार्मेसी समेतलाई बुझाउँछ।

(७) "थोक बिक्रेता वा वितरक" भन्नाले स्वदेश वा विदेशका कुनै उत्पादक वा वितरकको तर्फबाट औषधि बिक्रीवितरणको लागि ऐन बमोजिम दर्ता भएका थोक बिक्रि वितरण गर्ने वा पैठारी गरी थोक बिक्रि वितरण गर्ने पसल वा फर्मलाई सम्झनु पर्छ।

(८) "प्रेशक्रिप्सन" भन्नाले मान्यता प्राप्त चिकित्सक वा स्वास्थ्यकर्मीले बिरामी (मानिस वा पशुपंक्षी) लाई हुने रोगको निदान, उपचार, रोकथाम, रोग निको पार्न वा साम्य गर्नको लागि दिइने आवश्यक औषधि र निर्देशन सहितको लिखत विवरण सम्झनु पर्छ।

(९) "औषधीय सतर्कता वा फार्मकोभिजिलेन्स"भन्नाले औषधि वा खोपको दुष्प्रभाव वा प्रतिअसरहरुको पहिचान, मूल्यांकन, बुझाई र रोकथाम गर्ने कार्य भन्ने सम्झनु पर्छ।

(१०) "पुनर्पूर्ति" भन्नाले बिरामीलाई दिईएको औषधि पूर्जिमा लेखिएका औषधिहरु चिकित्सकको सल्लाहमा पूर्ण वा आंशिकरुपमा फेरि पनि दिने प्रक्रिया सम्झनु पर्छ ।

परिच्छेद-२

संरचनात्मक प्रावधानहरु

३. औषधि पसल वा थोक बिक्रेताको कोठा/भवन र परिसर सम्बन्धी प्रावधानः

(१) कोठा/भवन र परिसर सफा, स्वच्छ हुनुका साथै मुसाजस्ता जीवहरु प्रवेश गर्न नसक्ने गरी निर्माण भएको हुनु पर्नेछ ।

महानिर्देशक

(२) प्रत्यक्ष सुर्यको किरण, धुलो, धुँवा, औषि (ग्यास, धास्फ) र अत्याधिक तापबाट जोगिने गरी औषधिहरुको संचय गर्न मिल्ने हुनु पर्नेछ। साथै भवनको भित्ता र छतबाट पानी नचुहिने वा नरसाउने गरी निर्माण भएको हुनु पर्नेछ।

(३) संचय गरिने औषधिको परिमाण र प्रकृतिको आधारमा औषधिको गुणस्तरमा कुनै असर नपर्ने र सजिलै पहिचान गर्न सकिने गरी पर्याप्त ठाउँको व्यवस्था गरिएको हुनु पर्नेछ।

(४) थोक बिक्रेताको संचयकोठा तथा औषधि पसलमा कुनै पनि असम्बन्धित व्यक्तिको सहज प्रवेश हुन नसक्ने गरी निर्माण भएको हुनु पर्नेछ ।

(५) म्याद नाघेका, बिग्रेका, फिर्ता गर्नु पर्ने वा कुनै समस्या भई फिर्ता आएका औषधिको संचयको लागि पुनः प्रयोग हुन नसक्ने गरी सुरक्षित तवरले अलग्गै संचय गर्न प्रबन्ध मिलाईएको हुनु पर्नेछ।

(६) ऐन तथा नियमावली बमोजिम सुरक्षित राख्नुपर्ने भनि तोकिएका लागु तथा मनोदिपक र बिषालु औषधिको लागि सुरक्षित तवरले (तालाबन्द/Digital Lock) संचय र बिक्रीवितरण हुने व्यवस्था गरिएको हुनु पर्नेछ।

(७) औषधि पसल वा थोक बिक्रेताले प्रष्टरुपमा बुझिने गरी औषधि पसल वा थोक बिक्रेताको नाम (नेपाली, अंग्रेजी) र विभागबाट जारी भएको दर्ता नम्बर उल्लेखित साईनबोर्ड राखिएको हुनु पर्नेछ ।

(८) औषधि पसल तथा थोक बिक्रेताले शौचालय, फोहोर राख्ने भाँडो र स्वच्छ पिउने पानीको प्रबन्ध गरीएको हुनु पर्नेछ ।

(९) प्रेशक्रिप्सन अनुसार तत्काल औषधि बनाई वा अर्धप्रशोधन गरी बिरामीलाई बिक्रि-वितरण गर्ने कार्यको विभागबाट अनुमति प्राप्त गरेको औषधि पसलले औषधि निर्माणको लागी अलग्गै कोठाको व्यवस्थाका साथै कुशल उत्पादन अभ्यासको पालना गरेको हुनु पर्नेछ ।

(१०) औषधि पसलले औषधिको प्रयोग सम्बन्धि परामर्शको लागि कोठा वा निश्चित स्थानको व्यवस्था गरेको हुनु पर्नेछ।

(११) औषधि पसल तथा थोक बिक्री केन्द्रमा धुम्रपान र मध्यपान पूर्णतया निषेध गर्नु पर्नेछ ।

४. <u>औषधि पसलको फर्निचर र औजार उपकरण सम्बन्धि प्रावधानः</u>

(१) औषधिको गुण, नाप, प्रकार समेतलाई उपयुक्त हुने गरी संचय गर्न पर्याप्त फर्निचरको व्यवस्था गरीएको हुनुपर्नेछ।

(२) चिसो वा तोकिएको न्यून तापक्रममा संचय गर्नुपर्ने औषधिहरुको लागि संचय हुने परिमाण र आवश्यकता अनुसार तोकिएको मापदण्ड बमोजिमको रेफ्रिजिरेटर वा चिस्यान कोठा (कोल्ड रुम) को व्यवस्था हुनुका साथै तापक्रम सूचकको व्यवस्था भएको हुनु पर्नेछ।

(३) सेवाग्राही वा बिरामीहरु सजिलोसँग बस्न र सेवा प्रदायकले सेवा प्रदान गर्नको लागी पर्याप्त फर्निचरको व्यवस्था भएको हुनु पर्नेछ ।

(४) परामर्श सेवा प्रदान गर्नको लागि आवश्यक पर्ने औजार तथा उपकरण (जस्तै रोटाहेलर, ईन्हेलर, ईन्सुलिन कलम, पेसरी ईन्सर्टर) लगायतका सामग्रीको व्यवस्था भएको हुनु पर्नेछ ।

(५) सेवा प्रदान गर्दा आवश्यक पर्न सक्ने श्रोत सामग्रीहरुको व्यवस्था भएको हुनु पर्नेछ ।

(६) औषधि पसलमा प्राप्त हुने औषधिको खरिद/बिक्री बिल, भौचर, लागू तथा मनोद्धिपक औषधिको रेकर्ड, प्रमाणपत्र सुरक्षित तवरले राख्ने व्यवस्था भएको हुनु पर्नेछ ।

(७) औषधि पसलमा रक्तचाप, अक्सिमीटर, तापक्रम, शरीरको तौल र उचाई लगायत नापजाँच गर्ने साधन आवश्यकता हेरी राख्न सकिनेछ।

५. <u>थोक बिक्रेताको फर्निचर र औजार उपकरण सम्बन्धि प्रावधानः</u>

महानिर्देशक

(१) चिसो वा न्यून तापक्रममा संचय गर्नुपर्ने औषधिको लागि संचय गर्नु पर्ने परिमाण र आवश्यकता अनुसार रेफ्रिजिरेटर वा चिस्यान कोठा (कोल्ड रुम) को व्यवस्था भएको हुनु पर्नेछ ।

(२) बाकस खोल्ने, बन्द गर्ने, सुरक्षित प्याकिङ्ग तथा लेवलिंग गर्ने साधनको व्यवस्था भएको हुनु पर्नेछ ।

(३) आवश्यकता अनुसार औषधिहरु ओसार पसार गर्ने ट्रलीको व्यवस्था भएको हुनु पर्नेछ ।

(४) आधिकारिक सफ्टेवयरमा आधारित बिलिंगको लागि कम्पुटर र प्रिन्टरको व्यवस्था भएको हुनु पर्नेछ ।

(५) औषधिको परिमाण र आवश्यकता अनुसारको संख्यामा सुरक्षित ढुवानी गर्न आवश्यक संख्यामा उपयुक्त सवारी साधनको व्यवस्था वा प्रणाली लागू भएको हुनुपर्दछ ।

परिच्छेद-३

आवश्यक जनशक्ति र सेवा सम्बन्धी प्रावधान

६. <u>औषधि पसल र थोक बिक्रेता केन्द्रमा हुनुपर्ने जनशक्ति:</u>

(१) औषधि पसल र थोक बिक्रेतामा नेपाल फार्मेसी परिषदमा दर्ता भएको कम्तिमा एक जना पूर्णकालीन फर्मासिष्ट वा फार्मेसी सहायक वा ऐनको प्रावधान अनुरुप औषधि सल्लाकार समितिबाट मान्यता प्राप्त व्यवसायी हुनु पर्नेछ ।

(२) अस्पताल फार्मेसीको लागि अस्पताल फार्मेसी निर्देशिकामा तोकिए बमोजिम जनशक्ति हुनु पर्नेछ।

(३) आयुर्वेदिक, होमीयोपेथिक, युनानी र पशु औषधि औषधि पसल वा थोक बिक्रेताहरुमा विभागले तोकेबमोजिमको जनशक्तिको व्यवस्था भएको हुनु पर्नेछ ।

(४) सेवाको प्रकृति, कार्यबोझ र सेवा प्रदान गर्ने समयका आधारमा थप फर्मासिष्ट, फार्मेसी सहायक, व्यवसायी र अन्य जनशक्तिको व्यवस्था भएको हुनु पर्नेछ ।

७. <u>व्यवसायिक आचारसंहिता पालन गर्नु पर्ने</u>: औषधि पसल र थोक बिक्रेतामा कार्यरत फर्मासिष्ट, फार्मेसी सहायक, व्यवसायी र अन्य कर्मचारीले प्रचलित कानून बमोजिम तोकिएको व्यवसायिक आचारसंहिताको पालना गर्नु पर्नेछ।

८. <u>औषधि पसलबाट दिइने सेवा सम्बन्धी प्रावधान:</u>

(१) प्रेशक्रिप्सन अनुसार बिक्रि वितरण गर्नुपर्ने औषधि अधिकार प्राप्त चिकित्सकको प्रेशक्रिप्सनमा मात्र बिक्री वितरण गर्नुपर्दछ ।

(२) प्रेशक्रिप्सन बमोजिम बिक्रि वितरण गर्नुपर्ने औषधि डिस्पेसिंग गर्दा बिरामीलाई उचित परामर्श सहित प्रेशक्रिप्सनमा "डिस्पेन्स्ड बाइ" भन्ने छाप सहित औषधि डिस्पेसिंग गर्ने व्यक्तिको नाम थर/नेपाल फार्मेसी परिषद नं/व्यवसायी नं उल्लेख गरी सही छाप गर्नुपर्नेछ ।

(३) औषधि वितरण गर्नु अघि प्रेशक्रिप्सनमा उल्लेखित औषधि, परिमाण, मात्रा, सेवन गर्ने विधि र अवधि, औषधिको प्रति असर, औषधिहरु बिचको अन्तरक्रिया लगायतको सम्बन्धमा कुनै त्रुटी भए नभएको एकिन गर्नु पर्दछ र सो सम्बन्धमा कुनै शंका वा द्विविधा भएमा सम्बन्धित सिफारिसकर्ता लाई सम्पर्क गरी एकिन गर्नु पर्नेछ ।

(४) प्रेशक्रिप्सनमा लेखिएका निर्देशनहरु पूर्णरुपमा बिरामी वा सेवाग्राही वा निजको प्रतिनिधिलाई स्पष्ट रुपमा सम्झाउनु/बुझाउनु पर्दछ। यस अन्तर्गत औषधिको परिमाण, मात्रा, सेवन गर्ने विधि र अवधि अनिवार्य बुझाउनु पर्नेछ । साथै औषधिको अपेक्षित वा संभावित प्रतिअसरहरु र औषधीहरु बिचको अन्तरक्रिया समेत बिरामी वा सेवाग्राही वा निजको प्रतिनिधिलाई जानकारी गराउनु पर्दछ।

(५) प्रेशक्रिप्सनमा उल्लेख नभएको तर औषधि सेवन गर्दा अपनाउनु पर्ने कुनै विशेष सावधानी भए सो सम्बन्धि जानकारीका साथै कुनै कारणबस औषधिको मात्रा छुट्न गएमा के गर्ने ? पुनःपूर्ति गर्न मिल्ने नमिल्ने ?, औषधि कसरी सुरक्षित तवरले संचय गर्ने भन्ने सम्बन्धमा प्रष्टरुपमा बुझाउनु पर्दछ ।

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(६) औषधिको प्रयोग विधि/मात्रा सम्बन्धमा थप जानकारी दिएपछि बिरामीको नाम, उमेर, औषधिको नाम (ब्रान्ड र जेनेरिक), मात्रा, सेवनको विधि र अवधि सम्बन्धि विवरण सम्भव भएसम्म लिखित रुपमा दिनु पर्नेछ।

(७) बिरामीको आवश्यकता बमोजिम तथा गर्भवती, स्तनपान, दिर्घ रोगी, बृद्ध वृद्धा, संवेदनशिल तथा औषधि सेवनमा बिशेष प्राविधिक ज्ञान आवश्यक पर्ने औषधि सेवन गर्ने बिरामीलाई परामर्श सेवा उपलब्ध गराउनु पर्नेछ ।

(८) औषधि बिक्रि वितरण गर्दा गर्भवती, दिर्घ रोगी, बृद्धवृद्धा, र अपांगता अशक्तता भएका व्यक्तिलाई प्राथमिकता दिनु पर्दछ ।

(९) औषधि पसलले औषधि बिक्रि गर्दा अनिवार्य रुपमा बिल विजक जारी गर्नु पर्नेछ बिलमा जसमा औषधिको नाम, प्यान न. फोन न., विभागको दर्ता नम्बर उल्लेख हुनुपर्नेछ र बिलमा औषधिको इकाई, बनावट, शक्ति, परिमाण, ब्याच नम्बर, मूल्य, औषधिको म्याद नाघ्ने मिति, बिक्रेताको नाम र हस्ताक्षर हुनु पर्नेछ ।

(१०) औषधि पसलले आनलाइन सेवा प्रदान गर्न विभागले व्यवस्था गरेको मापदण्ड पुरा गरी अनुमति लिनु पर्नेछ।

९. <u>थोक बिक्रि केन्द्रबाट दिईने सेवा सम्बन्धी प्रावधानः</u>

(१) औषधिहरुको बिक्रि वितरणको सम्बन्धमा उत्पादक वा पैठारीकर्ता र थोक बिक्रेता बीच लिखित सम्झौता हुनु पर्नेछ र लिखित सम्झौता नभएको उत्पादक वा पैठारीकर्ताको औषधिहरु बिक्रि वितरण गर्नु हुदैन ।

(२) थोक बिक्रेताले विभागमा दर्ता भएका बिक्रि केन्द्र/औषधि पसल, सरकारी कार्यालय, तथा प्रचलित कानून बमोजिम दर्ता भएको संस्थालाई मात्र औषधिहरु बिक्रि वितरण गर्नुपर्दछ ।

(३) औषधिको गुणस्तरमा आशंका हुनसक्ने आधारहरु जस्तैः टुटेको, फुटेको, भिजेको,लेबल बिग्रेको, ट्याब्लेट, क्याप्सुल ओसिएको,फुटेको तथा इन्जेक्सन तथा झोल औषधिको रंग परिवर्तन तथा ढुसी र Foreign Particle आदि देखिएमा/भेटिएमा सोको पहिचान र पहिचान भएको अवस्थामा अवलम्वन गर्नुपर्ने प्रक्रिया सम्बन्धि विवरण अभिलेखीकरण गरी राख्नु पर्दछ ।

(४) औषधि बिक्रि गर्दा अनिवार्य रुपमा बिल विजक जारी गर्नु पर्नेछ र बिक्रि गरीएको बिल/विजकहरुमा औषधि पसलको नाम, ठेगाना, फोन न., दुवै फर्मको प्यान न. र विभागको दर्ता नम्बर र बिलमा औषधिको नाम, शक्ति, बनावट, ईकाई, परिमाण, ब्याच नम्बर, म्याद नाघ्ने मिति, मुल्य र उल्लेख गर्नु पर्दछ ।

(५) औषधिको प्याकिंग गर्दा परिवहनको क्रममा टुटफुट नहुने र औषधिको गुणस्तरमा कुनै असर नगर्ने गरी प्याकिंग तथा ढुवानी गरीएको हुनु पर्दछ ।

(६) औषधिको प्राप्ति, संचय, प्याकिंग, बहिर्गमन/प्रस्थान, प्रशासनिक/लेखा र अभिलेखीकरण सम्बन्धि हरेक कार्यको लागि अलग स्थानको व्यवस्था भएको हुनु पर्नेछ ।

(७) गुणस्तरबारे गुनासो प्राप्त गर्न र विभाग, उत्पादक तथा औषधि पसललाई सुचित गर्नका लागि उपयुक्त व्यवस्था भएको हुनुपर्दछ ।

(८) कुनै औषधिको गुणस्तरका कारण वा अन्य कारणले विभागले वा उत्पादकले सूचना जारी गरी वा जानकारी गरी औषधि फिर्ता (रिकल) गरेमा तुरुन्त बिक्रि वितरण रोकि, बिक्रि गरिएका औषधिहरु औषधि पसलबाट फिर्ता लिनु पर्नेछ र सो प्रक्रियालाई प्रभावकारी बनाउन नेपाल औषधि व्यवसायी संघ लाई पनि जानकारी दिन सकिनेछ ।

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(९) थोक बिक्री केन्द्रले कुशल अभ्यासका सिद्धान्तको कार्यान्वयन र परिपालना गरे नगरेको अनुगमन गरी सुधारात्मक तथा रोकथाम मुलक कदम चालेको लागि कम्तिमा वर्षको १ पटक स्वनिरीक्षण गरी अभिलेख राख्नुपर्नेछ ।

१०. <u>आयात अनुमति प्राप्त गरेका थोक बिक्रेता सम्बन्धि विशेष व्यवस्था:</u>

(१) उत्पादक/कम्पनीसँगको लिखित सम्झौता मार्फत अधिकार प्राप्त थोक बिक्रेताले मात्र औषधि पैठारी गर्नु पर्नेछ।

(२) आधिकारीक पैठारीकर्ताले उत्पादकबाट आधिकारिक पत्र (लेटर अफ एटोर्नी) प्राप्त गरेको औषधिमात्र पैठारी, संचय र वितरण गर्नुपर्नेछ ।

(३) आधिकारिक सम्झौता गर्दा पैठारी गरिने भन्सार बिन्दु, भन्सार बिन्दुमा औषधिको संचय तथा ढुवानीका साधन, सिपर कार्टून, प्याकिंग लगायतका विवरण खुलाएको हुनु पर्नेछ ।

(४) लागू तथा मनोदिपक, खोप र विभागबाट तोकिएका प्रतिजैविक औषधिहरुको पैठारी गर्दा पैठारी हुने औषधिको परिमाण, पैठारी हुने औषधिको ब्याचको परीक्षण प्रतिवेदन, भन्सार बिन्दु, ब्याच सम्बन्धि सम्पूर्ण विवरण अभिलेखीकरण गर्ने र आवश्यक परेमा विभागमा पेश गर्नु पर्नेछ ।

(५) पैठारीकर्ताले जीवन रक्षक र अत्यावश्यक भनी तोकिएका औषधिहरुको अभाव हुन नदिन आवश्यक सजगता अपनाउनु पर्दछ ।

(६) कुनै निश्चित तापक्रम कायम गरी परिवहन/भण्डारण गर्नुपर्ने औषधि तथा खोप पैठारी गर्दा सोको लागि निश्चित तापक्रम कायम हुने गरी मात्र पैठारी गर्नु पर्नेछ ।

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भण्डारण र अभिलेख सम्बन्धी प्रावधान

११. <u>औषधि पसलको भण्डारण:</u>

(१) निश्चित बैज्ञानिक संचय प्रणाली अपनाई औषधि र औषधिको परिमाण तत्कालै एकिन गर्न सकिने गरी औषधिको व्यवस्थित भण्डारण गरिनु पर्दछ ।

(२) औषधि राखिएको डिब्बा वा भाडोमा प्रष्ट रुपमा लेबल गरीएको हुनु पर्नेछ ।

१२. <u>थोक बिक्रेताको भण्डारण:</u>

(१) औषधि भण्डारण गर्दा भुइको चिसो, तापक्रम तथा सापेक्षित आद्रता, सुर्यको प्रत्यक्ष किरणले असर नगर्ने गरी भण्डारण गर्नु पर्दछ ।

(२) निश्चित वैज्ञानिक संचय प्रणाली अपनाई औषधि र औषधिको परिमाण तत्कालै एकिन गर्न सकिने गरी औषधिको व्यवस्थित भण्डारण गरिनु पर्दछ ।

(३) बजारबाट फिर्ता भएका औषधि अलग्गै संचय गरी बिक्रि वितरण नहुने गरी लेबल लगाई भण्डारण गर्नु पर्दछ । पुनः बिक्रि वितरण हुन सक्ने अवस्था भएमा सो सम्बन्धि विधि र निर्णय गर्ने आधिकारीक व्यक्ति तोकिनु पर्दछ ।

(४) औषधि प्राप्त गर्दा र पठाउनु अघि बिल/बिजक बमोजिम परिमाण, भौतिक गुणस्तर, औषधिको ब्याच नं र म्याद नाघ्ने मिति रुजु गर्नु पर्दछ र रुजु नभएसम्म अलग्गै संचय (क्वारेन्टाइन) गरी राख्नु पर्नेछ ।

(५) संचय वा भण्डारण गरिने स्थानको विस्तृत विवरण विभागमा पेस गरेको हुनु पर्नेछ र स्थानान्तरण/थप भएको खण्डमा विभागमा जानकारी दिनुपर्नेछ ।

१३. <u>औषधि मौज्दात व्यवस्थापन सम्बन्धि व्यवस्था:</u> औषधि बिक्रि वितरण गर्दा औषधि मौज्दात व्यवस्थापनको उपयुक्त वैज्ञानिक प्रणाली (FEFO, FIFO, LIFO इत्यादी) अवलम्बन गर्नु पर्नेछ।

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१४. <u>औषधि पसल र थोक बिक्रेता दर्ता सम्बन्धित अभिलेख सम्बन्धी विशेष व्यवस्था:</u> औषधि पसल र थोक बिक्रेताले देहायका अभिलेख कम्तिमा ३ वर्ष सम्म सुरक्षित राख्नु पर्नेछ।

(१) खरिद र बिक्री वितरण सम्बन्धि बिल/विजकहरु,

(२) टुटफुट भएमा, म्याद नाघेका, फिर्ता भई आएका, प्रचलित नियमानुसार हुनेगरी मुचुल्का उठाई नष्ट गरिएमा औषधिको परिमाण सहितको विवरण,

(३) लागु, मनोदिपक र बिषालु औषधिको बिक्रि वितरण सम्बन्धमा औषधि स्तर नियमावलीमा उल्लेख भए बमोजिमको अभिलेख,

(४) विभागबाट जारी गरिएका अध्यावधिक नविकरण भएका प्रमाणपत्र, सिफारिस पत्र र निर्देशन पत्र तथा परिपत्रहरु एंव सूचनाहरु,

(५) तापक्रम र सापेक्षिक आद्रता सम्बन्धि अभिलेख,

(६) थोक बिक्रेताको ग्राहक सम्बन्धि अभिलेख,

(७) औषधीय सतर्कता तथा औषधीय दुस्प्रभाव सम्बन्धमा प्राप्त सूचना,

(८) औषधि पसल वा बिक्रेतामा कार्यरत कर्मचारीको विवरण र प्रत्येक कर्मचारीको व्यक्तिगत कार्य विवरण,

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विविध

१५. <u>औषधि सतर्कता (फार्मकोभिजिलेन्स) तथा गुणस्तर निगरानी सम्बन्धी व्यवस्था:</u> (१)औषधिको असामान्य तथा गम्भीर प्रकृतिको दुष्प्रभावको सूचना प्राप्त हुन साथ तत्कालै सम्बन्धित उत्पादक, पैठारीकर्ता र विभागमा लिखित वा मैखिक वा दुवै माध्यमबाट जानकारी गराउनु पर्नेछ।

(१) औषधीय सतर्कतामा (फार्मकोभिजिलेन्स) सक्रिय रही औषधिबाट हुन सक्ने अपेक्षित एवम् अनपेक्षित असरहरुको अनुगमन र रिपोर्टिंग कार्यमा सक्रियता जनाउनु पर्दछ र प्राप्त भएका सूचना सम्बन्धित उत्पादक, पैठारीकर्ता र विभागमा यथासिघ्रं पठाउनु पर्दछ ।

(२) औषधिको गुणस्तर सम्बन्धमा कुनै शंका भएमा सो को सूचना तत्काल विभागलाई यथाशिघ्र जानकारी गराउनु पर्नेछ ।

१६. <u>प्रयोग योग्य नभएका औषधीय पदार्थको बिसर्जन</u> : म्याद नाघेका, टुटफुट भएका, बिग्रेका औषधीय पदार्थको बिसर्जन गर्ने जिम्मेवारी उत्पादक, पैठारीकर्ता, थोक बिक्रेता र औषधि पसलको छुट्टाछुट्टै वा संयुक्त जिम्मेवारी हुनेछ । यस्ता पदार्थको बिसर्जन गर्दा राष्ट्रिय तथा अन्तराष्ट्रिय निकायले तोकेको मापदण्डको पालना गरेको हुनु पर्नेछ ।

१७. <u>कुशल फार्मेसी अभ्यास वा कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरण सम्बन्धी व्यवस्था:</u> (१) औषधि पसलले यस संहिता बमोजिमको कुशल फार्मेसी अभ्यास कायम गरेको प्रमाणपत्र लिन चाहेमा संहिताको व्यवस्थाका साथै अनुसूची १ मा उल्लेख भए बमोजिमका प्रावधानहरु समेतको पालना गरेको हुनु पर्नेछ ।

२) थोक बिक्रेताले यस संहिता बमोजिमको कुशल भण्डारण तथा वितरण अभ्यास कायम गरेको प्रमाणपत्र लिन चाहेमा संहिताको व्यवस्थाका साथै अनुसूची २ मा उल्लेख भए बमोजिमका प्रावधानहरु समेतको पालना गरेको हुनु पर्नेछ ।

(३) कुशल फार्मेसी अभ्यास वा कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरणका लागि निम्न बमोजिमको विधि अवलम्बन गर्नु पर्नेछ:

(क) यस संहिता बमोजिम कुशल अभ्यास प्रमाणीकरणको लागि विभागले तोकेको ढांचामा स्वः निरीक्षणको प्रतिवेदन र अनुसूची ३ बमोजिमको ढांचामा निबेदन पेश गर्नु पर्नेछ ।

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(ख) खण्ड (क) बमोजिम निवेदन उपर विभागबाट आवश्यक जाँचबुझ, स्थलगत अवलोकन तथा निरीक्षण गरी संहिता बमोजिम कुशल अभ्यास कायम गरेको पाइएमा अनुसूची ४ बमोजिम ढाँचामा कुशल अभ्यासको प्रमाणपत्र दिनेछ।

(ग) खण्ड (ख) बमोजिम निरीक्षण गर्दा फार्मेसी काउन्सिल संग आवश्यक समन्वय गर्न सकिनेछ ।

(घ) कुशल फार्मेसी अभ्यास र कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरण सम्बन्धि विभागले थप व्यवस्था गर्न सक्नेछ ।

१८. **कुशल अभ्यास प्रमाणपत्रको मान्य अवधि र नविकरण** : (१) यस संहिताको बमोजिमको कुशल अभ्यास प्रमाणपत्रको अवधि ३ बर्षको हुनेछ ।

(२) उपदफा १ बमोजिमको प्रमाणपत्रको नविकरण गराउनको लागि अवधि समाप्त हुने मिति भन्दा तिन महिना अगाडी विभाग समक्ष निवेदन दिनु पर्नेछ ।

(३) उपदफा (२) बमोजिम प्राप्त निवेदन उपर जांचबुझ, स्थलगत अवलोकन र निरीक्षण गर्दा यस संहिता बमोजिम कुशल अभ्यास कायम गरिरहेको पाइएमा विभागले कुशल अभ्यासको प्रमाणपत्र नविकरण गर्न सक्नेछ ।

१९. <u>संशोधन र हेरफेरः</u> (१) यस संहिताको व्यवस्थामा विभागले संशोधन गर्न सक्नेछ ।

२) यस संहिता बमोजिमको अनुसूचीहरु विभागले सूचना जारी गरी हेरफेर गर्न सक्नेछ।

२०. <u>खारेजी र बचाउः</u> (१) औषधि बिक्रि वितरण संहिता, २०७१ खारेज गरीएको छ ।

(२) औषधि बिक्रि वितरण संहिता, २०७१ बमोजिम भए गरिएका कार्यहरु यसै संहिता बमोजिम भए गरिएको मानिने छ ।

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नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

(दफा १७ उपदफा (३) को संग सम्बन्धित)

कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरणको लागी निवेदन

श्री व्यवस्थापक,
औषधि व्यवस्था विभाग

बिषय : **कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरण गरी पाँउ ।**

महोदय,

यस फार्मेसी/थोक बिक्रि केन्द्रले कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण अभ्यास पालना गरी सेवा प्रदान गरीरहेकोले कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण अभ्यास पालना भएको स्व निरीक्षण प्रतिवेदन संलग्न गरी यो निवेदन पेस गरेको छौ ।

निवेदकको नाम :.....

फार्मेसी/थोक बिक्रि केन्द्रको नामः.....

फार्मेसी/थोक बिक्रि केन्द्र दर्ता नम्बरः .....

ठेगाना : .....

सम्पर्क फोनः .....

ईमेल : .....

महानिर्देशक

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

(दफा १७उपदफा (३) ख संग सम्बन्धित)

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरणको प्रमाणपत्र

प्रमाण पत्र नम्बर : मितिः

श्री *(फार्मेसी वा थोक बिक्रेताको नाम र ठेगाना)*

फार्मेसी/थोक बिक्रिकेन्द्र दर्ता नम्बरः

त्यस फार्मेसी/थोक बिक्रेताले कुशल फार्मेसी अभ्यास /कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरणको लागि आफ्नो फार्मेसी/थोक *बिक्रेता*को स्वनिरीक्षण प्रतिवेदन सहित यस विभागमा निवेदन पेश गर्नु भएकोमा यस विभागबाट मिति ..... मा त्यस फार्मेसी/थोक *बिक्रेता*को निरीक्षण/अवलोकन गर्दा कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण अभ्यास पालना भएको पाईएकोले यो प्रमाणपत्र प्रदान गरिएको छ । औषधि बिक्रि वितरण संहिता, २०८० तथा सो साथ संलग्न कुशल फार्मेसी अभ्यास/कुशल भण्डारण तथा वितरण निर्देशिका अनुरुपको अभ्यास कायम भएको नपाईएका बखत यो प्रमाणीकरण स्वतः निस्क्रिय भएको मानिने छ ।

प्रमाणपत्र जारी गर्ने अधिकारीको

दस्तखत : ..... कार्यालयको

छाप

नामः .....

पदः .....

मिति .....

महानिर्देशक

अनुसूची १

(दफा १७ को उपदफा (१) सँग सम्बन्धित)

कुशल फार्मेसी अभ्यास प्रमाणीकरणको लागि आवश्यक प्रावधानहरु

Contents

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1 PREMISES, FURNITURE, FIXTURES, AND EQUIPMENT

1.1 Premises

1.1. The pharmacy location should be easy for the public to identify. A neat and clean exterior and interior environment should be maintained.

1.2. The word "pharmacy" should be part of the pharmacy name and it should be clearly visible.

1.3. The background, design, content, and colors of the signboard (Nepali and English) shall be as prescribed by the department.

1.4. The pharmacy registration certificates must be displayed in a prominent place in the pharmacy that is visible to customers.

1.5. The pharmacy should be accessible to differently abled people.

1.6. The pharmacy environment should be clean with minimum dust and should be maintained as per the cleaning schedules outlined in the standard operating procedures (SOPs). Cleaning records should be maintained.

1.7. The pharmacy should be free from rodents and insects, and pest control measures should be taken as per the defined schedule.

1.8. Dispensing should be provided from an area separate from other activities.

1.9. Based on the personnel, activities, and volume of products, there should be enough space for holding shelves for medicines and adequate movement of personnel.

1.10. There should be a separate area for counselling with counselling resources. Client/patient can talk freely with the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist /byawasaayi and maintain privacy.

1.11. The pharmacy should have communication technology (i.e., telephone, internet) and uninterrupted electricity, especially for the refrigerator.

1.12. The pharmacy must provide toilets, a hand-washing facility, and access to drinking water for the staff and for clients.

1.13. Waste collection baskets/boxes should be available for personnel and for clients.

1.14. There must be sufficient space for clients to stand comfortably at the dispensing counter and for some to sit comfortably while they wait.

1.2 Furniture, Fixtures, and Equipment

1.2.1 The pharmacy should have sufficient, appropriately designed, and labelled shelving to store medicines of various shape and sizes and in various dosage forms in a systematic manner (e.g., therapeutic categorization, alphabetical order, dosage form) and protected from moisture, dust, and direct sunlight.

1.2.2 The pharmacy should have lockable cupboards for storing of narcotics, psychotropics and poisonous medicines.

1.2.3 A separate rack/cabinet should be available for records, files and documents.

1.2.4 Adequate provisions should be available for storing various medicines at prescribed temperatures. The pharmacy should be equipped with refrigerated storage (available for medicines requiring storage at cold temperatures (i.e., 2-8°C) and freezing temperature where required).

1.2.5 The pharmacy shall have computers for medicines information and counselling, inventory management, billing, adverse drug reaction reporting, communication purposes, and record keeping.

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1.2.6 The pharmacy should have arrangement for fire safety.

2 PERSONNEL

2.1.1 A pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist /asst. pharmacists/pharmacy assistants/professionalists/pharmacy assistants/ professionalist/ byawasaayi should supervise overall pharmacy management and have final responsibility for all the professional activities and operations.

2.1.2 Based on the service hours and workload, adequate numbers of pharmacists/pharmacy assistants/professionalists and other personnel should be available.

2.1.3 Pharmacy personnel should follow good documentation practice.

2.1.4 All pharmacy personnel must wear a neat apron/coat and name tag as prescribed by Nepal Pharmacy Council (NPC).

2.1.5 All personnel should be periodically medically examined and adequately immunized recorded.

2.1.6 All personnel should have clearly assigned job descriptions and responsibilities.

3 QUALITY POLICY

3.1.1 The pharmacy should formulate quality policy, quality manual, and SOPs.

3.1.2 The policy should be publicly available and include a commitment to satisfy statutory requirements and to continuously improve the quality management system.

3.1.3 The quality manual and SOPs should be accessible to the pharmacy personnel for their easy reference.

3.1.4 The pharmacy should have well-defined and documented systems and formats for all key operations carried out in the pharmacy.

3.1.5 All pharmacy personnel should be aware of pharmacy's quality policy and should understand their role in delivering health care to patients.

4 SERVICE STRATEGY

4.1.1 The service strategy should state in detail the necessary steps to carry out for providing each service offered and list the details of the activities, routines, authority delegations, work procedures, and instructions that are necessary for provision of the services in day-to-day operations of the pharmacy.

4.1.2 The pharmacy should have a well-documented service policy and policy implementation strategy based on its customer service goals.

4.1.3 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should be easily accessible to the public to provide information and counselling promptly in the service operating hours which should be mentioned in the service strategy.

4.1.4 The service strategy should state issues like home delivery of medicines and the nature and level of attention to be given to patient groups (e.g., elderly, disabled).

4.1.5 The strategy should also include a provision for using a "Prescription Filled" stamp to prevent refilling the prescription without prescriber's recommendation.

4.1.6 If the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist suspects that delivery of medicine from the pharmacy was inadequate, he/she should take immediate measures to minimize the risk of danger to the patient(s).

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5 TRAINING

5.1.1 All staff members including newly recruited staff should be trained as per the staff training SOP of the pharmacy.

5.1.2 Training SOP should include provision for induction and continuous professional education.

5.1.3 There should be adequate resources (books, current periodicals, software, etc.) in the pharmacy for staff to update their knowledge and skills as a fundamental requirement of the training process.

5.1.4 The program should ensure that all pharmacy personnel are kept abreast of the developments in their fields. Upgrading communication and interpersonal skills should form the core of the training program, so that pharmacy personnel can collaborate with other health care providers on one end and can form relationships with clients on the other.

5.1.5 The pharmacy professional must ensure that they have adequate training, knowledge, and skills to provide the designated services.

5.1.6 All staff should be trained on personal hygiene as well as the level of hygiene to maintain when storing and handling medicines.

5.1.7 Training should include different aspects relevant to pharmacy practice, legal provisions, communication and inter-personal skills, documentation, etc.

5.1.8 Training processes should be recorded and reviewed periodically.

5.1.9 Management and the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist shall be responsible for continuously training pharmacy personnel to ensure maximum benefits to the community.

6 CLIENT COMPLAINTS AND PRODUCT RECALLS

6.1 Client complaints

6.1.1 The pharmacy should have a procedure to receive and review complaints and evaluate them to find the underlying causes.

6.1.2 The complaint procedure should be publicly available.

6.1.3 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist must immediately address all complaints-oral or written-and take action to amend the situation. Complaints should be documented in the complaint register, and reported to the Department if applicable.

6.1.4 Appropriate steps should be taken to amend SOPs or other guidelines to prevent the recurrence of the same or similar events.

6.2 Product recalls and returns

6.2.1 The pharmacy should have a well-documented product recall procedure in place, where information on dispensed prescription medicines can be traced to the client.

6.2.2 The pharmacy should actively participate in a nationwide recall process for any substandard medicines. All such recalls should be initiated upon receiving official information from the Department or the supplier/manufacturer.

6.2.3 The start, progress, and completion of the recall process should be well documented.

6.2.4 If any medicine looks suspicious or falsified, the pharmacists/pharmacy assistants/ professionalists/pharmacy assistants/professionalist should take immediate steps to stop selling the medicine and notify the relevant parties and the Department.

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7 DOCUMENTATION

7.1.1 The overall responsibility for documentation rests with an authorized pharmacy personnel. All necessary statutory documents (pharmacy registration certificate, name registration certificate, permanent account number (PAN), etc.) for operating a pharmacy must be adequately maintained, displayed, and easily accessible.

7.1.2 Operational documents such as purchase invoices, sales invoices, and other statutory documents should be maintained and archived for at least 3 years.

7.1.3 Documents that form a part of the pharmacy's quality management system should be adequately controlled and maintained.

7.1.4 Apart from the regulatory documents, the following system documents should be in place:

- Quality policy and manual
- Health promotional policy
- Dispensing records
- Records of drugs specified by the Department
- Complaint-handling
- Training records
- Standard treatment guidelines
- Cleaning and maintenance processes
- Stock management (stock cards or ledger books) and storage systems
- Records of expired medicines and supplies
- Records of temperature monitoring
- Return and recall policy and procedures
- Internal quality audit and inspection reports
- Personnel and job descriptions
- Sales of poisons, narcotics, and psychotropics
- Related to wholesalers and medicines procurement

There should be SOPs for the following pharmaceutical care processes:

- Document control system
- Prescription handling
- Dispensing
- Labelling
- Patient counselling
- Medication records
- Drug information
- Vendor selection
- Receipt of goods
- Storage of goods
- Handling of narcotic, psychotropic, and poisonous drugs
- Stock/inventory management
- Handling of expired/rejected/broken goods
- Rodent and pest control
- Complaint handling

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- Recall
- Return
- Cleaning and maintenance procedures and records
- Dress code
- Training
- Internal quality audit and management review meeting procedure
- Extemporaneous compounding

8 VENDOR SELECTION AND PROCUREMENT

8.1 General

8.1.1 The pharmacy should develop and maintain an effective procurement and inventory management process that ensures quality of products.

8.1.2 The pharmacy must ensure the authenticity of the invoice/bill the suppliers generate. As much as possible, the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/ professionalist should ensure that medicines and health technology products are available in the pharmacy in sufficient quantities.

8.2 Vendor selection

8.2.1 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should ensure that the selected wholesaler has a valid license and the medicines sold are registered as per the prevailing law so to ensure that the pharmacy sell only authorized/ registered products. The authorized bill/invoice can be considered as a basis for this provision.

8.2.2 The pharmacy should maintain and have available a list of wholesalers for medicines procured.

8.2.3 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should be confident in the adequacy of the wholesaler's supply chain to ensure that all medicines have been handled under appropriate storage and transit conditions.

8.3 Procurement

8.3.1 Only medicines registered with the Department shall be procured and only from registered and licensed wholesalers.

8.3.2 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should inform the regulatory authorities if he/she believes the supplier has carried out dubious activities and/or if error or malpractice occurs.

8.3.3 All products received from wholesalers should be tallied against their invoice and checked for correctness of dosage form, label, quantity, price, batch number, and expiry date and visually inspected for quality.

8.3.4 The wholesaler should be informed as soon as possible about errors and their nature, repetition of errors, and how and by when the pharmacy expects the wholesaler to rectify the error. All errors made by the wholesalers should be documented and reviewed periodically to prevent their recurrence and be acknowledged by an authorized wholesaler representative.

9 STORAGE MANAGEMENT

9.1.1 All medicines coming into the pharmacy should initially be quarantined, preferably in a separate area, before they are checked for correctness of quantity, batch number, expiry, integrity, etc. After the necessary checks, they should be transferred to their respective storage locations.

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9.1.2 All medicines should be stored at stipulated temperatures and protected from direct sunlight, dust, and humidity. Temperatures in the various areas including the refrigerator should be monitored and recorded daily and records should be preserved for two years. Medicines should be stored on the shelves of the refrigerator and not in the door.

9.1.3 A systematic method of storage should be defined and adopted for different dosage forms of medical products.

9.1.4 Narcotic, psychotropic, and poisonous drugs shall be kept under lock and key, separate from other medical products. Only the pharmacy personnel should keep the key. The dispensing and inventory record of such drugs should be maintained in the format prescribed by the department.

9.1.5 The medicine packets/bottles and shelves should be kept clean and dust free at all times by following cleaning schedules and SOPs.

9.1.6 Medicines and health technology products should be kept out of reach of the clients.

9.1.7 Shelves should be checked routinely to remove medicines with approaching expiry dates. In-house threshold periods before expiry should be set and followed to retrieve those medicines from the shelves.

9.1.8 Expired medicines and health technology products should be stored separately and securely with the label "Expired Goods - Not for Sale". Care should be taken that such goods are not dispensed.

9.1.9 Clients should not receive medicines that expire during the prescribed treatment duration.

9.1.10 The pharmacy should follow a scientific inventory management (FEFO/FIFO) to minimize medicines expiry.

9.1.11 Expired and damaged medicines should be returned to the wholesaler or destroyed as per in-house procedures.

9.1.12 The pharmacy should not store any items that are unrelated to the medicines and health technology products.

10 PRESCRIPTION HANDLING, FILLING, AND DISPENSING

10.1 Prescription handling

10.1.1 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should create a climate so that clients feel comfortable to talk to the dispenser. Communication should encourage the client to convey his / her needs by producing a prescription or by asking for other medicines or advice.

10.1.2 Upon receiving the prescription, the pharmacists/pharmacy assistants/professionalists/ pharmacy assistants/professionalist or person instructed by the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should confirm the client's identity and whether the client is the patient or is there on someone's behalf.

10.1.3 The client may be politely requested to wait while the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist evaluates the prescription for the therapeutic aspects, validity, completeness, and appropriateness/correctness of the prescription, which may require questions to the client or the prescriber.

10.1.4 Any incompleteness, ambiguities, shortcomings, or anomalies in the prescription should be brought to the prescriber's notice.

10.1.5 The prescription should be considered incomplete if any of the following information is missing:

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- Name of the prescriber, his/her address, and council registration number
- Name, address, age, gender of the patient
- Name(s) of the medicine(s), strength, route of administration, dosage form, frequency, and duration
- Instructions to the client/pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist
- Refill information if any
- Prescribers' signature and date

10.2 Correctness of prescribed medicines

10.2.1 **The prescription should be checked for the following information:**

- Dosage regimen: Whether the dosage prescribed is within the standard minimum or maximum dosage range
- Multiple medication: Same medicine or different medicine with same pharmacotherapeutic effect concurrently prescribed by the same prescriber or by two or more prescribers to the same patient.
- Interactions between the prescribed medicines with other medicines the client is taking such as over-the-counter medicines; medicines from past prescriptions (record of which may be in the patient's medication records); vitamins; tonics; or any other herbal medicines. Any medicine interactions likely to render the therapy ineffective or cause undesirable effects to the patient should be brought to notice of the prescriber and the client.
- Contraindications: Age, gender, disease(s), conditions, or other patient characteristics that may cause prescribed medicines to be contraindicated.
- History of overuse, under use, or misuse of medicines by the patient.
- Any of the above as well as handwriting legibility problems should be brought to the prescriber's notice. Any changes the prescriber makes should be recorded on the prescription, with the words "Changes made in consultation with the prescriber (name) at (time) on (date)" and should be signed and stamped by the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist .

10.3 Filling/dispensing prescriptions

10.3.1 The pharmacy is responsible for dispensing prescription-only medicines only when the client presents a valid prescription.

10.3.2 The dispensing should be on first-come-first-serve basis; however, priority should be given to the severely ill, elderly, women, and differently abled clients.

10.3.3 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should ensure correctness of the dispensed medicines, dosage form, strength, dose, quantity, and dose regime against the prescription, verify the patient's name, and generate an invoice.

10.3.4 Medicines should be packed neatly so that their integrity is maintained (i.e., in an appropriate dispensing envelop) and labelled appropriately as per the labelling requirements. The envelope should include the name of the patient, medicine and quantity dispensed, how often to take the medicine, and any special directions for administration.

10.3.5 Appropriate information must be given to the client. If detailed counselling is not required, the client should be advised on administration and other appropriate information and advice

(storage, refill, possible side effects, etc.).

10.3.6 It must be ensured that the information and advice given is correct, clear, explicit, up-to-date, and understandable to the client. The client should be asked if the information was clear and if she/he has further questions.

10.3.7 Prescriptions with controlled substances (narcotics and psychotropics) should be stamped "Prescription filled" and duly signed by the pharmacists/pharmacy assistants/ professionalists/pharmacy assistants/professionalist or retained after dispensing the medicines.

10.3.8 The pharmacy must generate an invoice/bill for medicines sold or dispensed patient information, medicine name, dosage form, strength, quantity dispensed, batch number, expiry date, price, dispenser's name, and signature.

11 CLIENT INFORMATION AND COUNSELLING

11.1 Client information

11.1.1 Pharmacy personnel must help the client to make well-informed decisions about the proper use of medicines and other health technology products and about self-care.

11.1.2 Pharmacy personnel should offer clients sufficient opportunities for personal consultation.

11.1.3 Pharmacy personnel should provide oral and written information to the client about their illnesses, medicines, and other health technology products.

11.1.4 All dispensed medicines should be appropriately labelled, which clearly states:

- Name of the patient
- Medicine's name, strength, batch number, and expiry date
- Dosage and usage instructions for the patient
- Storage instructions if special storage is required
- Date dispensed
- Name and address of the pharmacy

11.1.5 Dosage and usage information must also be given verbally to the clients (e.g., use of dispersible tablets, chewable tablets, inhalers) along with demonstrations and pictograms wherever required.

11.2 Counselling

11.2.1 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist must work out a strategy to provide counselling regarding the use of medicines and health technology products to improve the patient's quality of life. While dispensing, the client should be told:

- How to take the medications
- For how long
- When to take the medicines and whether to take them before, during, or after meals, etc.
- What foods / beverages / tasks to avoid during the therapy
- What side effects to expect and how to manage them
- What to do if one or more doses get skipped
- Refill information wherever applicable
- Any other precautions

11.2.2 Discretion should be exercised while discussing the nature of the illness, its cause, prognosis

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(course of the disease), and the expected outcomes of the therapy.

11.2.3 Client counselling should be done in the counselling area where others cannot overhear the conversation and privacy can be maintained.

11.2.4 Pharmacy personnel should decide whether the client needs counselling. Some conditions that may require counselling include:

- Patient with chronic illness especially a new case
- Patient on multiple medications
- Prescription with complex dosing schedule.
- Prescription requiring a special device or special technique for administration
- Patient requiring modification in lifestyle or dietary habit
- Pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist concern about adherence to the therapy
- Prescription with medicines with high risk of adverse events and/or obvious side effects
- Patient wanting privacy about his/her illness

12 MEDICATION RECORDS & CLIENT FOLLOW-UP

12.1 Medication records

All data and information related to the patients should be stored and maintained in such a way that keeps them confidential and is accessible only to authorized persons. Such data may be shared with other health care professionals, usually at the specific request of the patient or when it is in the patient's best interest.

The pharmacy might have a patient medication record system which allows for easy retrieval of patients' health and medication history when appropriate, especially patients with chronic illness or patients requiring regular follow-up.

12.1.1 The medication record may cover the following information:

- Patient personal details including lifestyle, smoking, alcohol, history of allergy
- Past medication history and illnesses
- Current laboratory and imaging investigation profiles
- Current illness and medication regimen
- Adverse events or side effects
- Counselling records
- Follow-up requirements
- Others as relevant

12.1.2 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should ensure that the patient's confidentiality is maintained and that their information is not accessible to people who do not need it.

12.2 Client follow-up and referral

12.2.1 Pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist s should be able to identify and trace clients who have been dispensed prescription medicines using any means of communication.

12.2.2 If the client reports a serious condition, the pharmacists/pharmacy

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assistants/professionalists/pharmacy assistants/professionalist should provide a referral slip along with a pharmacists/pharmacy assistants/professionalists/pharmacy assistants/ professionalist note to the appropriate clinician.

12.2.3 Possible reasons why the patient may not adhere to treatment should be evaluated and the client counselled accordingly.

12.2.4 Whenever a pharmacists/pharmacy assistants/professionalists/pharmacy assistants/ professionalist has doubts or believes that it would be in the patient's best interest, he/ she must advise the patient to see a doctor or health care provider as soon as possible.

13 HEALTH PROMOTION AND RESPONSE TO SYMPTOMS

13.1.1 The pharmacy should have a clearly stated health promotion policy with pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist s contributing to the activities.

13.1.2 The pharmacy personnel must keep himself/herself aware of national policies and programs related to health promotion. The pharmacy should proactively participate in health promotion campaigns and programs at the local as well as national level.

13.1.3 The pharmacy should give advice and assistance on selected topics such as prevention of noncommunicable diseases (e.g., diabetes), hypertension, arthritis, AIDS, breastfeeding, use of medical devices, rational use of medicines, family planning and reproductive health, immunization, antimicrobial resistance, and lifestyle modification: changing dietary habits, smoking cessation, decreasing alcohol consumption, etc.

13.1.4 Personnel involved in such campaigns should be educated through continuing education programs and regular interactions with other health care providers and should have communication skills.

13.1.5 The pharmacy personnel should be responsible for responding to clients' minor ailments and be able to advise based on the evidence. The pharmacy personnel may suggest non-prescription medicines for such symptoms.

13.1.6 The pharmacy might provide basic onsite rapid testing services such as sugar, HIV, blood pressure, respiratory capacity, pregnancy, etc. The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist must have undergone training for such activities.

14 PHARMACOVIGILANCE

14.1.1 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should be alert to the occurrence of adverse drug events (expected and unexpected) during active conversation with the client and record them in the patient's medication record.

14.1.2 The pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist should give suitable instructions to the client to reduce the potential for future adverse effects such as advising the client how to take the medicine correctly, what other medicines or foods to avoid, any activities that the patient should avoid (e.g., not going out in the sun, not driving, etc.), or consulting the prescriber.

14.1.3 The pharmacy should contribute to the national pharmacovigilance program, and report and record the occurrence of an adverse drug event to the Department or regional pharmacovigilance centres and to the manufacturer.

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15 Self-inspection

15.1 The pharmacy should establish an inspection team to conduct and record **self**-inspection not less than two times a year.

15.1.1 The team may be made up of pharmacy staff or outsiders. However, personnel deployed for internal audit should be adequately trained for the purpose.

15.2 CAPA(s) should be taken based on the findings, and their effectiveness reviewed to improve lapses in different areas.

15.2.1 All audit procedures should be suitably documented. The audit reports should be used to analyse weaknesses and deficiencies so that corrective measures can be taken.

16 GLOSSARY

Corrective and preventative actions (CAPAs)
The response to address complaints, product rejections, non-conformity, recalls, deviations, audits, regulatory inspections, and findings and trends from process performance and product quality monitoring.
Good Pharmacy Practice (GPP) is the practice of pharmacy that responds to the needs of the people who use the services to provide optimal, evidence-based care. To support this practice, it is essential that Nepal has established the national framework of quality standards and guidelines for GPP.
Pharmaceutical care is *the* responsible provision of pharmaco-therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life. It is a collaborative process that aims to prevent or identify and solve medicinal product and health related problems.
Prescriber is a person in health care who is permitted by law to order drugs that legally require a prescription; includes physicians, physician assistants, dentists. The prescriber is not always a medical doctor but can also be a paramedical worker, such as a primary health care practitioner.
Product recall
A process for withdrawing or removing a medical product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be falsified. The recall might be initiated by the manufacturer, importer, wholesaler, wholesaler, or a responsible agency.
Quality policy is a general declaration of the intent of the pharmacy about the level of quality of service and products offered to the public.
Quarantine
Isolation of medical products, physically or by other means, while a decision is awaited on their release, rejection, or reprocessing.
Self-inspection
An internal procedure to evaluate the entity's compliance with GSDP and other good pharmaceutical-related practices to detect any shortcomings and to recommend and implement CAPAs.
Service strategy is a statement of the nature of services provided in the pharmacy and the standards laid down for provision of those services.
Standard operating procedure (SOP)
An authorized written procedure giving instructions for performing general operations that are not necessarily specific to a given product (e.g., equipment operation, maintenance and cleaning, validation, cleaning of premises, environmental control, sampling, and inspection).

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नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

अनुसूची

(दफा १७ को उपदफा (२) सँग सम्बन्धित)

कुशल भण्डारण तथा वितरण अभ्यास प्रमाणीकरणको लागि आवश्यक प्रावधानहरु

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Abbreviations and Acronyms

CAPA	corrective action and preventative action
DDA	Department of Drug Administration
FEFO	first expiry first out
GSDP	Good Storage and Distribution Practices
LIFO	last in first out
QMS	Quality management system
SOP	standard operating procedure

1. Premises, Furniture, and Fixtures

1.15. The premises should have a clearly visible signboard with at least the wholesale firm's name, registration number, and contact information legible in both Nepali and English. The background, design, content, and colors of the signboard (Nepali and English) shall be as prescribed by the department.

1.16. The premises should be in an area unaffected by pollution from waste, garbage, etc.

1.17. Premises and storage facilities should be clean and free from litter and dust. Cleaning equipment and cleaning agents should not be possible sources of contamination.

1.18. Appropriate measures should be taken to control access of rodents, birds, insects, and other animals.

1.19. There should be ample access for vehicles to reach the wholesaler's site and enough space in the premises for receiving and dispatching goods.

1.20. The premises and facilities should be designed or adapted to ensure that required storage conditions are maintained.

1.21. The premises and building should be suitably secure, structurally sound, and of sufficient capacity to allow safe storage and handling of medical products.

1.22. The grounds should have ample security to prevent entry of unauthorized personnel.

1.23. Storage areas should have adequate lighting to enable all operations to be carried out accurately and safely.

1.24. The premises should have an adequate separate area for receipt, quarantine, storage, and dispatch of goods.

1.25. There should be a dedicated area/room for document verification and in-house quality control.

1.26. The wholesaler must have a stable and secure system of communication and uninterrupted electricity with power backup, especially for a refrigerator or cold room.

1.27. There should be a separate and secure area/room to store highly sensitive products such as cytotoxic, poisonous drugs, and narcotics and psychotropics.

1.28. A labeled, dedicated room/area should be available for the storage of expired, damaged, and rejected/recalled goods.

1.29. There should be an appropriate refreshment facility for staff that is separate from storage areas. Food, drink, smoke, or medical products for personal use should be strictly prohibited in the storage areas.

1.30. The premises should be of sufficient size to allow for the cleaning of incoming medical products such as dust and dirt accumulated during storage.

1.31. The wholesaler should have enough shelves/platforms appropriately designed to store various dosage forms.

1.32. Appropriate and adequate furniture must be available for quality control, document verification, and documentation. The furniture must preferably be of stainless steel, or if made of other materials, they should not be broken, chipped, or damaged in any way to affect the products and personnel.

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2. Personnel

2.1. There should be an adequate number of personnel to perform the wholesaler's functions based on the workload.

2.2. Personnel should have appropriate educational qualifications, experience, and training relative to the activities undertaken.

2.3. The wholesaler should be supervised by a pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist present in person, as recognized by the Act, who will have the final responsibility for all professional activities and operations.

2.4. A qualified pharmacists/pharmacy assistants/professionalists/pharmacy assistants/ professionalist should carry out key quality-related activities such as document preparation, record maintenance, self-inspection, etc. All activities should be carried out as per the guidelines and procedures.

2.5. All personnel should have a defined level of autonomy and authority which should be clearly written in a QMS document, and all critical actions and decisions should be recorded.

2.6. An organizational structure should be in place, and each staff person should have a clear job description and clearly assigned responsibilities based on QMS.

2.7. There should be a system to conduct employee health check-ups at the beginning of employment to assure there are no underlying chronic health problems, and then on a routine basis.

2.8. Appropriate personnel safety and hygiene practices relevant to the distribution activity should be established and practiced.

2.9. Codes of conduct should be prepared and implemented to prevent and address cases of product misappropriation, tampering, diversion, or falsification by any personnel.

3. Equipment

3.1. Equipment including electronic/computer systems should be suitable and adequate for its intended use. All equipment should be appropriately designed, located, installed, and maintained.

3.2. Appropriate and adequate refrigerators or cold rooms should be available for the drugs to be stored.

3.3. There should be an appropriate instrument to monitor temperature and humidity in the storage area.

3.4. Billing equipment should ensure traceability and confidence in the supply chain and products.

3.5. Appropriate equipment for moving, storing, releasing, and packaging goods should be available.

3.6. Adequate firefighting equipment should be installed and maintained.

3.7. Calibration/validation of equipment and instruments, as required, should be carried out as per SOPs in a timely manner and recorded.

4. Quality Policy

4.1. The wholesaler should formulate quality policy, quality manual, and SOPs.

4.2. The policy should be publicly available and include a commitment to satisfy statutory requirements and to continuously improve the quality management system.

4.3. The quality manual and SOPs should be accessible to the wholesaler personnel for their easy reference.

4.4. The wholesaler should have well-defined and documented systems and formats for all key operations carried out in the pharmacy.

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4.5. All personnel should be aware of the quality policy and should understand their roles in storage and distribution practices.
4.6. The manager should ensure that the quality policy and quality goals are understood, implemented, and maintained throughout the operations.
4.7. All the activities mentioned in the quality manual should be well-documented.
4.8. There should be a system for periodic management review, and minutes and related documents from such meetings should be available.

5. Service Strategy

5.1. The service strategy should state in detail the necessary steps to carry out for providing each service offered and list the details of the activities, routines, authority delegations, work procedures, and instructions that are necessary for provision of the services in day-to-day operations of the pharmacy.
5.2. The wholesaler should have a well-documented service policy and policy implementation strategy based on its customer service goals.
5.3. The wholesaler should have a service strategy to ensure that unregistered products are not sold and distributed.
5.4. The service strategy should include information for the customers to contact the company regarding the services.

6. Training

6.1. All staff members including newly recruited staff should be trained as per the training SOP.
6.2. Training SOP should include provision for induction and continuous professional education.
6.3. There should be adequate resources (books, current periodicals, software, etc.) for staff to update their knowledge and skills as a fundamental requirement of the training process.
6.4. The program should ensure that all personnel are kept abreast of the developments in their fields.
6.5. The wholesaler must ensure that all personnel have adequate training, knowledge, and skills to provide the designated services.
6.6. All staff should be trained on occupational safety and personal hygiene as well as the level of hygiene to maintain when storing and handling medicines.
6.7. Training should include different aspects relevant to storage and distribution, legal provisions, communication and inter-personal skills, documentation, etc.
6.8. Training processes should be recorded and reviewed periodically for the effectiveness of the trainings.
6.9. Management and the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/ professionalist shall be responsible for continuously training pharmacy personnel to ensure maximum benefits to the community.
6.10. Records of all training sessions, attendance, and assessments should be kept.
6.11. Personnel should be trained to handle poisonous and hazardous materials.

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7. Qualification of Suppliers

7.1. Prior to making any agreement, the wholesaler should verify the validity of the supplier/manufacturer and make sure that the items to be distributed are registered and renewed by the Department.

7.2. The wholesaler should get authorization letter from the manufacturer or importer to present to the Department during registration and renewal of certificates/licenses.

7.3. The wholesaler, with the involvement of or guidance from the Department, should make sure that the supplier (importer/manufacturer) has an adequate facility and the infrastructure to handle medical products. Qualification should be performed according to SOPs.

7.4. The selection, including qualification and approval of suppliers, should be defined in SOPs and the results documented and periodically evaluated.

7.5. The contract should specify which documents the importer/manufacturer are required to provide with the consignment and the transportation conditions.

8. Receipt of Medicines

8.1. The receiving function should include making sure that the arriving consignment is from approved suppliers and were not visibly damaged during transport.

8.2. Each consignment should be carefully checked for possible contamination, tampering, or damage according to SOPs. Any suspect containers, or if necessary, the entire delivery, should be quarantined for further investigation.

8.3. Errors made by the suppliers should be brought to notice as soon as possible, rectified, and recorded.

8.4. Measures should be taken to ensure that rejected medicines are not distributed. They should be segregated and securely stored while awaiting destruction or return to the supplier.

8.5. Medicines and health technology products requiring special storage or security measures should be prioritized for immediate transfer to appropriate storage facilities after the appropriate checks have been conducted.

8.6. The consignment should be checked for container uniformity and subdivided according to the supplier's batch number if the delivery comprises more than one batch. Each batch should be dealt with separately.

8.7. Materials and products requiring transport and storage under controlled temperature and relative humidity conditions should be handled as a priority. Where applicable, cold-chain materials and products should be handled according to manufacturer specified conditions.

8.8. Proper protocols, systems, and space should be available to segregate outgoing and incoming products to avoid mix-up.

9. Review and Quarantine

9.1. The receiver should make sure that everything is verified as per the SOP and checklist.

9.2. All products received from suppliers should be compared to their invoice and checked for correctness of identity, quality, quantity, price, batch number, expiry date, and registration and renewal status at the Department.

9.3. The checklist should be reviewed by the responsible pharmacists/pharmacy assistants/ professionalists/pharmacy assistants/professionalist or designated personnel with authority to approve.

9.4. Products should not be transferred to saleable stock until an authorized release is obtained.

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9.5. Quarantined products should be clearly labeled and segregated to avoid mix-up.

10. Quality Control

10.1. The labelling and packaging specifications of quarantined goods should be evaluated/verified according to the SOPs.
10.2. There should be a document that defines the condition requiring quality testing and/or further verification for products such as quarantined.
10.3. All documents related to quality testing and verification should be complete and signed.
10.4. If the wholesaler notes deviation from the specification or suspects the quality, the wholesaler should hold the goods according to SOP and inform the supplier/manufacturer and the Department.
10.5. A system to maintain retention samples of suspected products should be in place with proper SOPs, facilities, and documentation.

11. Storage/Warehouse and Inventory

11.1. A system should define the storage conditions and location of various dosage forms, and the warehousing method should be defined by the system.
11.2. The storage conditions for medicines should follow their labeling and the information provided by the manufacturer.
11.3. Medicines should be stored separately from other products to ensure the required storage conditions.
11.4. Warehousing operations must maintain security of stock.
11.5. Monitoring is required to protect products from the harmful effects of light, temperature, moisture, and other external factors.
11.6. Periodic stock reconciliation should be performed by comparing the actual and recorded quantities. All significant stock discrepancies should be investigated to check for inadvertent mix-ups and wrong issuances.
11.7. Records of stock levels for all medical products in the store should be maintained, in either paper or electronic format. These records should be updated after each operation.
11.8. Stock should be rotated according to the FIFO/FEFO principle. Any exceptions should be documented.
11.9. Medicines that are nearing their expiry date/end of shelf life should be withdrawn from the saleable stock at least three months prior either physically or through equivalent electronic segregation. But this clause will not be applicable during emergencies and shortage.
11.10. Expired or damaged drugs must be returned or disposed following SOPs within an agreed upon time with the manufacturer or as mentioned by law.
11.11. The products should be handled and stored in a manner that prevents spillage, damage, contamination, and mix-ups. There should not be unlabeled cartons.
11.12. Radioactive materials and hazardous products-as well as products presenting special risks of abuse, fire, or explosion (e.g., combustible, or flammable liquids and solids and pressurized gases)-should be stored in a dedicated area(s) that is subject to additional safety and security measures.
11.13. Drugs classified as narcotic, psychotropic, or poisonous should be stored in a locked cupboard under the supervision of a pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist or designated personnel.
11.14. Damaged containers should be brought to the attention of the person responsible for quality.

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12. Billing and Supply

12.1. The medicines shall be supplied only to pharmacies that have been registered or authorized by the Department, and government institutions and other institutions registered under the prevailing laws.

12.2. The wholesaler should not sell medicines directly to the patient.

12.3. Medicines with an expiration date of less than three months should not be sold, except in the case of emergencies and shortage.

12.4. The billing system should include a warning about short-expiry medicines.

12.5. All records of bills and supplies must be maintained as per the law.

12.6. A sales invoice must be issued with the distributed drug with the following information:

- Name and address of wholesaler and pharmacy/organization with DDA registration number and PAN number
- Name, strength, dosage form, quantity, amount, batch number, manufacturing date, and expiry date of medicine
- Special instructions for storage and handling (if required)

12.7. All received and sold/distributed products should have traceable records in the wholesaler system.

12.8. Delivery from the wholesaler should follow the designated/routine or alternate schedule and plan.

12.9. Packing and transportation should not adversely impact the quality of medicines or the ability to identify the drug.

12.10. The wholesaler should have an arrangement to supply customers quickly in case of an emergency need.

12.11. Medicines returned to the wholesaler for reasons other than quality such as packaging problems must not be sold until the pharmacists/pharmacy assistants/professionalists/pharmacy assistants/professionalist provides written approval stating that the quality of the drug was not compromised when not under the wholesaler's custody.

13. Importation

13.1. The importer should make sure that all the importation licenses for the medicine are in place and proper agreement is made with the exporter.

13.2. The importer should obtain all required quality control documents guaranteeing the safety, quality, and efficacy of the medicines.

13.3. The importer should ensure that products come only from authorized entities in accordance with the applicable legal and administrative provisions of the country concerned.

13.4. The storage of products at the port of entry should follow storage guidelines and should be for as short a time as possible.

13.5. The products should be imported only through the designated custom point/port.

13.6. The importer should develop and maintain an effective procurement and inventory management system that ensures good-quality products and avoids medicine shortages.

14. Contract Activities

14.1. The contractor must be qualified by the wholesaler. Records of such qualification processes should be maintained.

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14.2. Any activity at the wholesaler that is outsourced should be correctly defined, agreed, and controlled to avoid misunderstandings that could affect product integrity.
14.3. The contract between the purchaser and the contractor should be written and signed by both the contract giver and the contract acceptor.

15. Transportation

15.1. The wholesaler should ensure that the vehicle used for transportation is appropriate to maintain product quality.
15.2. A system to track the vehicle, personnel, and products should be in place during transit.
15.3. The packing in the vehicles should follow last in first out (LIFO) system.
15.4. The packing in the vehicles should avoid over-stacking and have appropriate measures to avoid damage during transit.
15.5. There should be SOPs to inspect, clean, and qualify non-dedicated vehicles for transport.
15.6. The wholesalers/wholesalers should make sure that the shipment containers are appropriate, and the labeling requirements are met.
15.7. There should be written guidelines for handling goods in transit that the transporter must comply with.

16. Falsified Pharmaceutical Products

16.1. The quality system should include procedures to identify and handle medical products that are suspected to be falsified.
16.2. A system should be in place for prompt recall and reporting to the Department and the holder of marketing authorization/manufacturer for the original product when suspected falsified products are identified.
16.3. Suspect products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale. Access should be controlled.
16.4. Upon confirmation of the product being falsified, a formal decision should be taken by the Department on its disposal, ensuring that it does not re-enter the market, and the decision recorded.
16.5. Records should be maintained reflecting the investigations and action taken regarding falsified products, such as disposal. Such products should not re-enter the market.

17. Complaints, Recalls, and Return

17.1. The wholesaler should have a SOP to receive complaints about quality and inform its customers.
17.2. When products are rejected by the customers such as pharmacies and institutions, authorized procedures should be followed, including safe transport.
17.3. Complaints received through any means (i.e., oral, written) must be immediately recorded, investigated, addressed appropriately, and documented.
17.4. The wholesaler should have a well-documented recall procedure in place.
17.5. Recalls should be made only after all the proper protocols have been implemented during investigation.
17.6. Records of information including quantity of broken, expired, returned, and destroyed medicines should be maintained.
17.7. A distinction should be made between complaints about product or its packaging and those relating to distribution.

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17.8. The wholesaler should be available and responsible for receiving information on any complaints about the quality of supplied products.

17.9. If the wholesaler receives any information regarding the quality of supplied goods, the wholesaler should proactively recall the goods immediately after proper procedures and inform Department on such recalls if applicable after proper procedures are applied.

17.10. The recall initiation, progress, and completion should be well-documented. Other batches of the recalled drug should also be verified.

17.11. Recalled items should be stored in a specific location and measures should be in place to avoid access and distribution until a decision has been made. The effectiveness of recalls should be evaluated.

17.12. Products returned should be destroyed unless their quality has been critically assessed in accordance with a written and authorized procedure and deemed satisfactory.

17.13. Destruction and disposal of products should be done in accordance with international, national, and local requirements and with due consideration to protect the environment.

17.14. The wholesaler should provide compensation to its customers as per the law in case of recalls due to expiration and damages, or any harm to the consumers.

18. Documentation

18.1. Documents should be clear, in precise formats, and organized so that it is easy to complete, review, and check. The title, scope, objective, and purpose of each document should be clear.

18.2. Documents related to licenses, registration, agreements, purchase, and sales invoices, import licenses, and other statutory documents related to the products should be maintained and archived for 3 years.

18.3. There should be adequate control and maintenance of documents that are part of the quality system. A periodic review of documents should be carried out.

18.4. All documents should be completed, signed, and dated as required by authorized person(s) and should not be changed without the necessary authorization.

18.5. All records should be stored and retained in a way that prevents unauthorized access, modification, damage, deterioration and/or loss during the record's life cycle.

18.6. Documents related to post-marketing surveillance and pharmacovigilance should be maintained by the wholesalers regarding their dispatched products. They should report any quality and safety issues to the Department.

18.7. Apart from the above documents, the following system documents should be developed, approved, and maintained:

- Quality manual and quality policy
- Physical verification and results
- Personnel and their job descriptions
- Personnel trainings and training evaluation
- Vender selection process and vendor details
- Procurement and inventory management
- Sales and distribution of poisonous drugs, narcotics, and psychotropics
- Calibration and validation of equipment including refrigerator/cold room
- Pharmaceutical product disposal and destruction
- Cleaning and maintenance processes
- Pest control program
- Goods receiving, storage, and dispatch systems

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- Filling, packaging, and dispatching orders
- Complaints, recalls, and returns
- Self-inspection or audit practices
- SOPs for the above practices wherever required
- Others as necessary

19. Self-inspections

19.1. Self-inspections should be conducted to monitor implementation and compliance with GSDP principles and to propose CAPAs.

19.2. The self-inspection program should cover all aspects of and compliance with regulations, guidelines, and procedures within a defined time frame.

19.3. The wholesaler should formulate a competent inspection team which is free of bias and whose members have appropriate knowledge and experience.

19.4. The team may include the wholesaler manager along with a pharmacists/pharmacy assistants/ professionalists/pharmacy assistants/professionalist or person from outside the organization. However, personnel deployed for internal audits should be adequately trained by recognized trainers or organizations.

19.5. Inspections should be conducted according to a pre-planned schedule.

19.6. CAPA(s) should be taken based on the findings, and their effectiveness reviewed to improve lapses in different areas.

19.7. All audit procedures should be suitably documented. The audit reports should be used to analyze weaknesses and deficiencies in the system that can be addressed.

GLOSSARY

Batch
A defined quantity of pharmaceutical products processed in a single process or series of processes that make them homogeneous.

Batch number
A distinctive combination of numbers and/or letters that uniquely identifies a batch of product printed on labels, in batch records, and in corresponding certificates of analysis.

Consignment
A quantity of medical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

Container
The receptacle used to package a medical product. There are primary, secondary, and transportation containers such as shipment containers. Primary containers are in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

Contract
A business agreement for the supply of goods or performance of work at a specified price; quality elements may be included in the contract or in a separate contract.

Corrective and preventative actions (CAPAs)
The response to address complaints, product rejections, non-conformity, recalls, deviations, audits, regulatory inspections, and findings and trends from process performance and product quality monitoring.

Distribution
The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of medical products, except for dispensing medical products directly to a patient or his or her agent.

Expiry date
The date given on the individual container (usually on the label) of a medical product, up to and including the date that the product is expected to remain within specifications if stored correctly. It is established for each batch by adding the shelf life to the date of manufacture.

Falsified product
A product that has been deliberately and/or fraudulently misrepresented as to its identity, composition, or source. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, or reproduction of an authorized product or the manufacture of a product that is not an authorized product.

"Identity" shall refer to the name, labeling, or packaging or to documents that support the authenticity of an authorized product. "Composition" shall refer to any ingredient or component of the product in accordance with applicable specifications authorized/recognized by the national regulatory authority. "Source" shall refer to the identification including name and address of the marketing authorization holder, manufacturer, importer, exporter, wholesaler, or retailer, as applicable.

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First expiry/first out (FEFO)
A distribution procedure where stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

Good distribution practices
Activities that maintain the quality of a pharmaceutical product by controlling the numerous steps during the distribution process as well as secure the distribution system from counterfeit, unapproved, illegally imported, stolen, substandard, adulterated, and/or misbranded pharmaceutical products.

Good storage practices
Activities that maintain the quality of medical products by controlling storage conditions through the distribution process.

Importation
The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

Labeling
Providing information on medical product packaging including the following, as appropriate: name of the product, active ingredient(s), type and amount, batch number, expiry date, special storage conditions or handling precautions, directions for use, warnings and precautions, and names and addresses of the manufacturer and/or supplier.

Product recall
A process for withdrawing or removing a medical product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be falsified. The recall might be initiated by the manufacturer, importer, wholesaler, wholesaler, or a responsible agency.

Quality assurance
A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is a comprehensive system ensuring that medical products are of the quality required for their intended use.

Quality policy
A pharmaceutical service and product-related entity's declaration about the level of service and product quality offered to the public.

Quality system
An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources, and systematic actions necessary to ensure confidence that a product (or services) will satisfy given quality requirements.

Quarantine
Isolation of medical products, physically or by other means, while a decision is awaited on their release, rejection, or reprocessing.

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Self-inspection
An internal procedure to evaluate the entity's compliance with GSDP and other good pharmaceutical-related practices to detect any shortcomings and to recommend and implement CAPAs.

Service strategy
A pharmaceutical service and product-related entity's statement of the nature of services provided and the standards to provide those services.

Shelf life
The period during which a medical product, if stored correctly, is expected to comply with the specifications determined by stability studies on several batches of the product. The shelf life is used to establish the expiry date of each batch.

Standard operating procedure (SOP)
An authorized written procedure giving instructions for performing general operations that are not necessarily specific to a given product (e.g., equipment operation, maintenance and cleaning, validation, cleaning of premises, environmental control, sampling, and inspection).

Storage
The storing of medical products up to the point of use.

Substandard products
"Substandard" medical products (also called "out of specification") are authorized by national medicines regulatory authorities but fail to meet either national or international quality standards or specifications or both.

Transit
The period during which medical products are being carried, conveyed, or transported to reach their destination.

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