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Quality Control Outcomes of Pharmaceuticals and Allied Products Analyzed in the Mission for Essential Drugs and Supplies (MEDS) Laboratory: 2018-2020

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Quality control data was compiled for samples analyzed in the Mission for Essential Drugs and Supplies (MEDS) laboratory in the 2018-2020 period. During this interval, the laboratory received and processed 6,059 samples from Kenya and international sources. These samples comprised domestic (31.9%) and internationally manufactured (67.0%) products while 1.1% were of undeclared origin. Analysis was performed using compendial and/or in-house specifications. The non-compliance rate was 8.0% consisting of 3.2 % local, 4.5% imports and 0.3% for samples of unknown origin. The top 20 drug classes with high failure rates were: environmental monitoring samples (100.0%), joint lubricants (50.0%), dialysis solutions (50.0%), microscopy stains (50.0%), herbal preparations (43.2%), nootropics (33.3%), solvents (33.3%), waters (32.0%), antiseptics/disinfectants (29.8%), medical devices (28.4%), hormones (23.7%), nutrient mixtures (20.9%), disease modifying antirheumatic drugs (20.0%), anti-incontinence drugs (16.7%), uterotonics (13.8%), vitamins (13.0%), anti-ulcer drugs (12.6%), vasopressor agents (12.5%), anthelmintics (12.2%) and hypolipidemics (10.8%). Full compliance was however, recorded with antiflatulants, digestive enzymes, antidiarrheals, prokinetics, anti-arrhythmics, anti-anginals, choleretics, antimycobacterials, anaesthetics, antimigraine drugs, bisphosphonates, antimyaesthenics thyroid/antithyroid drugs, erectile dysfunction drugs, ovulants, uricosurics, osmotic diuretics, vaginal lubricants, tocolytics, histaminics, lozenges, ear drops, detergents, radiopharmaceuticals, proteins, probiotics, acaricides, sterilization validation swabs and excipients. There was a significant increase in the overall non-compliance rate compared to the previous report for 2013-2017. These results add impetus towards the need for regulatory stringency to curb the occurrence of substandard and falsified products in the market.

Key words: MEDS, drug product, assay, dissolution, substandard and falsified medicine, specification

INTRODUCTION

The quality of pharmaceuticals and medical devices in circulation is contingent on an effective regulatory framework supported by a robust quality control system. This depends on functional quality control (QC) laboratories capable of performing analyses under streamlined operations.[1] Consequently, these vital establishments require strengthening for the attainment of a well-controlled pharmaceuticals market profuse with quality assured products for guaranteed safety and efficacy of the same.[2]

In Kenya, pharmaceutical QC laboratories perform analysis for both human and veterinary

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medicines despite the dual regulatory regime in operation for the two categories.[3,4] Additionally, herbals, foods, cosmetics, agrochemicals and other borderline products draw analytical services from the same laboratories. Publication of QC results of samples processed in individual laboratories over specified periods provides data, which may elicit realignments of policy and practice towards enhanced consumer protection. Instinctively, consumers of pharmaceuticals and allied products heavily rely on stringent regulation for quality assurance of these commodities.[5] Thus, it is imperative that governments support testing frameworks for pharmaceuticals, agrochemicals, cosmetics and foods.

Contemporarily, the One Health (OH) approach is geared towards a sustainable balance and optimization of the health of people, animals, environment and ecosystems.[6] The OH campaign recognizes the interdependence, hence pertinent collaboration among players in the constituent sectors for improved planetary health. Likewise, the attainment of universal health coverage (UHC) is intricately connected to quality of medicines supported by an optimal quality assurance system and secure supply chain management impervious to substandard and falsified medicines.[7-,9]

The advent of Covid-19 in the year 2020 triggered widespread use of alcohol based hand sanitizers (ABHS) as a preventative measure against spread of the infection. This caused entry of unqualified producers and vendors of these products seeking to exploit the spike in demand, without due regard to good manufacturing practices (GMP), and QC standards. Consequently, the Kenyan market experienced entry of substandard ABHS products as evidenced by market survey reports.[10,11]

The Mission for Essential Drugs and Supplies (MEDS) laboratory is World Health Organization (WHO) prequalified to perform quality control of medicines and related products. A detailed description of the laboratory's context and operations has been reported previously.[12] This is the second report of the quality performance of samples analyzed in the laboratory covering a three-year period, 2018-2020.

MATERIALS AND METHODS

Samples

During the study period, samples for analysis were submitted by manufacturers, importers, regulatory authorities, non-governmental organizations, donor-funded programmes, government agencies and hospitals operating in Kenya and other African countries. Furthermore, internal MEDS samples were processed as described previously.[12] Testing was requested for purposes of product registration, batch release, manufacturing inputs, supplier prequalification, post market surveillance and pharmacovigilance investigations. The procedure for receipt and tracking of samples in the MEDS laboratory was earlier reported by Abuga et al.[12]

Therapeutic categories

A total of 5,670 (93.6%) pharmaceutical samples for human use incorporating drug products, raw materials and laboratory standards were processed during the study period. On the other hand, fewer veterinary drugs (187, 3.1%), comprising of anti-infectives (147), nutritionals (1), vaccines (7), milking salve (25), antidotes (1) and acaricides (6). Likewise, 203 (3.3%) non-drug samples consisting of excipients (12), solvents (3), medical devices (102), environmental monitoring (3), laboratory testing kits (79), microscopy stains (2), detergents (1) and sterilization validation swabs (1) were tested. Notably, a higher number of medical devices were submitted compared to the 2013 - 2017 period, probably due to boosted demand during the COVID-19 period.

Specifications

Samples were subjected to official and/or in-house specifications. For this purpose, monographs from current editions of the British Pharmacopoeia (BP), United States Pharmacopeia (USP), International Pharmacopoeia (Ph. Int.) and European Pharmacopoeia (Ph. Eur.) were employed.[13-16] In addition, the GPHF-Minilab[17] was used for post market surveillance (PMS) samples while borderline products were subjected to the International Standards Organization (ISO), Kenya Bureau of Standards (KS), Association of Official Analytical

Chemists (AOAC) and United States Environmental Protection Agency (EPA) standards.[18-21] In all other cases, in-house methods were utilized.

RESULTS AND DISCUSSION

The QC results for the different classes of samples analyzed in 2018-2020 are presented in Table 1 whilst the detailed data are available at: https://uonjournals.uonbi.ac.ke/ojs/index.php/ecajps/libraryFiles/downloadPublic/22. A total of 6,059 samples were processed consisting of 1,933 (31.9%) domestic and 4,061 (67.0%) imported products while 65 samples (1.1%) were of undeclared origin. The underlying causes and impacts of Kenya's low manufacturing capacity for pharmaceuticals has been discussed in previous reports.[12,22-24] The number of internal MEDS samples was 2,079 (34.3%) while 3,978 (65.7) were clients' submissions. In addition, two reference standards were tested.

Pharmacopoeial methods were applied in 4,190 samples (69.1%) while 463 samples (7.6%) were subjected to GPHF minilab (156), KS (85), AOAC (132), ISO (87) and EPA (3) specifications. Conversely, 1,615 (26.7%) were analyzed using client's in-house specifications. In 89 cases (1.5%), a combination of two or more official specifications were applied.

The overall non-compliance rate was 8.0% comprising 3.2 % local, 4.5% imported and 0.3% of unknown origin. This failure level was higher than previously reported for the same laboratory and the Drug Analysis and Research Unit (DARU).[12,24]

All three samples (100.0%) for environmental monitoring of laboratory effluent failed the pH test. The other drugs with more than 10% non-compliance were; joint lubricants (50.0%), dialysis solutions (50.0%), microscopy stains (50.0%), herbal preparations (43.2%), nootropics (33.3%), solvents (33.3%), waters (32.0%), antiseptics/disinfectants (29.8%), medical devices (28.4%), hormones (23.7%), nutrient mixtures (20.9%), disease modifying antirheumatic drugs (20.0%), anti-incontinence drugs (16.7%), uterotonics (13.8%), vitamins (13.0%), anti-ulcer drugs (12.6%), vasopressor agents (12.5%), anthelmintics (12.2%), hypolipidemics (10.8%), vaccines (10.5%) and anti-inflammatory agents (10.1%).

Complete compliance with specifications was however, recorded with antiflatulants, digestive enzymes, antidiarrheals, prokinetics, anti-arrhythmics, anti-anginals, choleretics, anti-mycobacterials, anaesthetics, antimigraine drugs, bisphosphonates, antimyaesthenics thyroid/ antithyroid drugs, erectile dysfunction drugs, ovulants, uricosurics, osmotic diuretics, vaginal lubricants, tocolytics, histaminics, lozenges, ear drops, detergents, radiopharmaceuticals, proteins, probiotics, acaricides, sterilization validation swabs and excipients.

Among the gastrointestinal drugs, anti-ulcers registered non-compliance of 12.6% followed by anti-emetics (6.0%), laxatives (4.2%) and spasmolytics (4.0%) while all other drugs in this category complied with specifications. For cardiovascular drugs, vasopressors (12.5%), and hypolipidemics (10.8%) recorded higher than 10% failure rate, while the anti-arrhythmics, anti-anginals and choreletics complied with specifications. Eight (6.5%) eye preparations, all imported and consisting of combination preparations except dexamethasone suspension failed diverse quality tests.

The anti-infectives exhibited a wide range of failure rates, ranging from 12.2% (antihelminthics) down to 0.6% for antivirals. Conversely, all antimycobacterial samples complied with specifications. Similar to the previous report, antiretroviral (ARV) drugs (94.8%) formed the majority of antiviral samples submitted.[12] These products are produced by prequalified manufacturers for Global Fund supported infection programmes to mitigate against the impact of the HIV-AIDS pandemic.[25] Metronidazole suspension accounted for 57% of failed samples among the antiprotozoals.

Antimalarials showed a failure rate of 7.3% with quinine (9) and artemether-lumefantrine (3) tablets accounting for 60.0% of the non-compliant samples. However, two samples of quinine tablets were of unknown origin.

Table 1: Quality control results of samples analyzed in MEDS laboratory in the years 2018 - 2020

	Body system/Drug class	Number of samples	Compliant Samples		Non-Compliant Samples	
			Local	Imported	Local	Imported
1.	**Gastrointestinal system**					
	a. Anti-ulcer drugs	159	27	112	3	17
	b. Antiflatulants	1	-	1	-	-
	c. Digestive enzymes	2	-	2	-	-
	d. Anti-emetics	67	3	60	1	3
	e. Spasmolytics	25	11	13	1	-
	f. Laxatives	24	10	13	1	-
	g. Anti-diarrheals	4	2	2	-	-
	h. Antihaemorrhoidals	6	-	6	-	-
	i. Prokinetics	3	3	-	-	-
2.	**Cardiovascular system**					
	a. Hemostatics	32	-	29	-	3
	b. Antihypertensives	263	59	182	4	18
	c. Anticoagulants	31	5	24	-	2
	d. Antithrombotics	20	5	13	-	2
	e. Vasopressor agents	8	-	7	-	1
	f. Anti-arrhythmic drugs	3	-	3	-	-
	g. Anti-anginal drugs	8	-	8	-	-
	h. Hypoglycemic agents	88	39	43	-	6
	i. Hypolipidemics	37	12	21	-	4
	j. Choleretics	4	-	4	-	-
3.	**Eye preparations**	123	10	105	-	8
4.	**Anti-infectives**					
	a. Antibacterials	1167	411	716	12	28
	b. Antimycobacterials	91	-	91	-	-
	c. Anthelmintics	180*	126	31	9	13
	d. Antiprotozoals	144	79	51	10	4
	e. Mixed antimicrobials	21	-	19	-	2
	f. Antimalarials	247*	18	207	1	17
	g. Antivirals	538	13	522	1	2
	h. Antifungals	99	45	51	-	3
5.	**Nervous system**					
	a. Analgesics	383	129	234	6	14
	b. Anti-inflammatory drugs	69	16	46	2	5
	c. DMARD	5		4		1
	d. Opioid analgesics	63	-	58	-	5
	e. Anti-epileptics	72	20	47	-	5
	f. Psychotropics	155	63	82	-	10

	Body system/Drug class	Number of samples	Compliant Samples		Non-Compliant Samples	
			Local	Imported	Local	Imported
	g. Nootropics	3	-	2	-	1
	h. Anaesthetics	53	-	53	-	-
	i. Antimigraine drugs	4	1	3	-	-
6.	**Musculoskeletal system**					
	a. Muscle relaxants	23	1	20	-	2
	b. Bisphosphonates	4	-	4	-	-
	c. Antimyaesthenics	2	-	2	-	-
	d. Joint lubricants	2	-	1	-	1
7.	**Endocrine system**					
	a. Thyroid/antithyroid drugs	5	-	5	-	-
	b. Hormones	38	-	29	-	9
8.	**Respiratory system**	267	92	160	10	5
9.	**Genitourinary system**					
	a. Erectile dysfunction drugs	21	1	20	-	-
	b. Ovulants	12	-	12	-	-
	c. Anti-BPH drugs	16	-	15	-	1
	d. Anti-incontinence drugs	6	-	5	-	1
	e. Uterotonics	29	-	25	-	4
	f. Contraceptives	21	-	19	-	2
	g. Uricosurics	11	-	11	-	-
	h. Osmotic diuretics	5	-	5	-	-
	i. Dialysis solutions	6	3	-	2	1
	j. Vaginal lubricants	1	1	-	-	-
	k. Tocolytics	1	-	1	-	-
10.	**Anticancer agents**	86	-	84	-	2
11.	**Nutritional products**					
	a. Nutrient mixtures	43	10	24	-	9
	b. Vitamins	100	34	53	4	9
	c. Minerals	44	19	23	-	2
	d. Electrolytes	176	86	88	-	2
	e. Waters	50	21	13	16	-
12.	**Skin preparations**	205	111	89	4	1
13.	**Immunomodulatory agents**	12	-	11	-	1
14.	**Miscellaneous products**					
	a. Histaminics	2	-	2	-	-
	b. Lozenges	2	1	1	-	-
	c. Ear drops	3	-	3	-	-
	d. Antiseptics & disinfectants	359*	203	35	95	3
	e. Detergents	1	1	-	-	-

Body system/Drug class	Number of samples	Compliant Samples		Non-Compliant Samples	
		Local	Imported	Local	Imported
f. Radiopharmaceuticals	20	20	-	-	-
g. Antidotes	16	-	15	-	1
h. Proteins/glycoproteins	1	-	1	-	-
i. Vaccines	19	-	17	-	2
j. Microscopy stains	2	-	1	-	1
k. Environmental monitoring	3	-	-	3	-
l. Medical devices	102*	16	26	8	20
m. Test kits	79*	-	74	-	1
n. Probiotics	2	-	2	-	-
o. Herbal preparations	44	-	25	-	19
p. Acaricides	6	-	6	-	-
q. Sterilization validation swabs	1	1	-	-	-
r. Solvents	3*	-	1	-	1
s. Excipients	12	12	-	-	-
Total	**6,059**	**1,740**	**3,788**	**193**	**273**

*Includes samples of undeclared origin, – not applicable, BPH - Benign prostatic hyperplasia, DMARD – disease modifying antirheumatic drugs, MEDS - Mission for Essential Drugs and Supplies.

The non-compliance level for antibacterials was 3.4% whereby, cotrimoxazole suspension samples recorded five failures in the pH, microbial load and assay tests. Three antifungal samples (3.0%) composed of fluconazole capsules, griseofulvin tablets and itraconazole capsules failed in assay and dissolution.

The failure rate for nootropics was 33.3% attributable to one sample of piracetam injection (pH). The other non-compliant drugs in the neurological category were the anti-inflammatories (10.1%), opioid analgesics (7.9%), anti-epileptics (6.9%), psychotropics (6.5%) and analgesics (5.2%). Among the musculoskeletal drugs analyzed, only one sample of joint lubricants failed in the assay test. The non-compliance rate of hormones was 23.7% on account of erythropoietin and vasopressin which failed in assay.

The non-compliant respiratory drugs (5.6%) included, beclometasone, cetirizine, chlorpheniramine, diphenhydramine, salbutamol, roflumilast and cold/cough combination formulations. Notably, these medicines are commonly employed prescription or over-the-counter remedies thus posing a high risk to users if substandard.

Three out of six dialysis fluids (50%) failed in assay, while one sample of solifenacin (16.7%) did not comply with specifications. With regard to uterotonics, two samples each of misoprostol and oxytocin were non-compliant. A commonly used contraceptive, levonorgestrel failed in the quality tests performed. This is a potential threat to family planning campaigns, which heavily depend on quality products and adherence for effectiveness. Among the anti-BPH drugs, one sample of tamsulosin tablets failed the dissolution

test. All anticancer drugs complied with specifications except one sample each of gemcitabine injection (assay) and sunitinib capsules (dissolution).

Nine samples of nutrient mixtures were non-compliant in which one sample suspected of sildenafil adulteration was found to be devoid of the drug. The non-compliant vitamin preparations contained folic acid, mecobalamin, phyto-menadione and pyridoxine while majority (6.5%) were multivitamin mixtures. Two iron containing mineral supplements failed in content uniformity and assay, while two electrolyte solutions did not meet limits for pH and assay. The failure rate for waters was 32.0% due to borehole water (microbial load), de-ionized water (conductivity), distilled water (microbial load) as well as potable and purified waters (microbial load, limit tests).

The non-compliance rate for dermatologicals was 2.4% owing to benzyl benzoate emulsion (microbial load) and an anti-eczema cream (assay). Among the immunomodulatory drugs, only one sample (8.3%) of sirolimus failed in weight variation, content uniformity and assay.

In the antiseptics/disinfectants category, majority of the failures were due to ABHS (56.4%) with respect to the identification, assay, antiseptic challenge tests. These products were promoted by the WHO and national authorities for the prevention of the COVID-19 pandemic that struck in March 2020. This elicited a spike in demand hence many entrants into the sanitizers market with concomitant quality issues as reported elsewhere.[10,11] All six samples of black disinfectant analyzed as well as antibacterial hand wash, antibacterial soap, calcium hypochlorite powder, surgical spirit, chlorhexidine, formaldehyde, glutaraldehyde, hydrogen peroxide, lysol, povidone iodine and sodium hypochlorite solutions failed in the antiseptic challenge test.

The failure rate for antidotes (6.3%) is attributable to one sample of atipamezole injection with assay values outside limits, while that of vaccines (10.5%) arises from two samples of *Brucella abortus* and *Brucella abortus* antigen (identification). Medical devices had a non-compliance rate of 28.4% on account of cotton wool, coveralls, latex/nitrile examination gloves, and surgical face masks. Most of the devices were submitted during the year 2020, when demand for the same increased due to their application during the COVID-19 pandemic. As a result, several local manufacturers submitted samples of their products to the laboratory for premarketing evaluation. Among the test kits, only one sample (1.3%) of *Plasmodium* test cassette failed in the test for identity.

The herbals tested were *Moringa oleifera*, *Panax notoginseng* and *Moringa oleifera*/selenium preparations, whereby majority (84.2%) of the failed samples were *Moringa oleifera*/selenium capsules (assay). One ethanol sample out of three solvents did not meet identification and assay specifications.

CONCLUSION

The MEDS laboratory received and processed 6059 samples from diverse categories, including products that were targeted at management of the COVID-19 pandemic. This underscores the need for capacity strengthening in quality control services within the country for regulatory support and ultimately consumer protection. The study findings add impetus into post-market surveillance and pharmacovigilance frameworks as vital regulatory tools.

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