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Drug Quality Control in Kenya: Observation in the Drug Analysis and Research Unit During the Period 2001-2005

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During the five-year period January 2001 to December 2005, the Drug Analysis and Research Unit received and analyzed 394 drug samples. Samples were received from regulatory authorities, local industry, non-governmental organizations, hospitals and private practitioners. The samples analyzed constituted 37.8 % locally manufactured and 62.2 % imported products. In contrast to previous years when failure rates of over 20 % were recorded, the overall rate of failure to comply with compendial quality specifications was 6.1 %, comprising of 8.7 % locally manufactured and 4.5 % imported drugs.

Key Words: Quality control, active pharmaceutical ingredient content, dissolution.

INTRODUCTION

For medicines to be effective in prevention and treatment of diseases, they have to be safe, efficacious and of acceptable quality. In Kenya, many of the drugs in circulation are generics and they are either locally manufactured or imported. Most of the imported drugs are from India and the Asian continent. Quality control of drugs in the Kenyan market has been going on at the Drug Analysis Research Unit (DARU) since 1980. Previous studies have shown that the quality varies with the therapeutic classification, the manufacturer and whether the drugs are locally manufactured or imported [1-8]. The therapeutic classes that have raised quality concerns over the last three decades are antimalarials, antituberculars, parenteral electrolytes, skin preparations and vitamins/mineral preparations.

The present paper gives the findings of drug analysis carried out at DARU between January 2001 and December 2005.

MATERIALS AND METHODS

Samples

Samples were received from regulatory authorities, local industry, non-governmental organizations, hospitals and private practitioners. Procedures for receiving the samples have been reported previously [1,2]. The products were either locally manufactured or imported.

Methods

Tablets were subjected to the tests of uniformity of weight, content of active pharmaceutical ingredient (API) and dissolution, depending on the clients' requests. Oral drops and liquid mixtures were tested for microbial load and content of active pharmaceutical ingredient (assay), while parenteral injections were tested for sterility and content. Wherever possible, methods from official compendia, British Pharmacopoiea (BP), European Pharmacopoiea (EP) and the United States Pharmacopoiea (USP) were used [9-11]. In cases where no compendial methods were available, in-house methods of DARU or the manufacturers were used.

RESULTS AND DISCUSSION

A total of 394 samples were analysed during the period 2001-2005. The failure rate of locally manufactured and imported products was calculated separately as shown in table 1. Unlike in previous DARU studies where the overall

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failure rate ranged from 17.6 to 31.4 %, the failure rate of the drugs analysed in the period under study was surprisingly low (6.1 %). However, as in previous years, local products had a higher failure (8.7 %) than imported ones (4.5 %).

None of the drugs acting on the alimentary, cardiovascular, endocrine and respiratory systems failed the analysis. Drugs for eye and allergic disorders as well as those for nutrition also showed nil failure rate.

As in previous studies, the antimalarial drugs had a high failure rate of 26.8 %, with most of those that failed being locally manufactured. Ten of the 11 antimalarial drugs that failed were sulphadoxine-pyrimethamine (SP) preparations. Out of these, six failed in the dissolution test for pyrimethamine, two in the content of the APIs and two in both pyrimethamine dissolution and API content. An artemether suspension failed in the content of the API. This analysis was done when SP was the recommended first line medicine for treatment of uncomplicated malaria [12]. In 2006, the recommended first line treatment for uncomplicated malaria in Kenya was changed from SP to artemisinin combination therapy (ACT) in accordance with WHO guidelines. Indeed, since then, many ACT products are in the market, some of which have been found to be substandard [13].

Six of the antibiotics analyzed (5.3 %) failed in the content of the API, while two failed in the dissolution test. Majority of these products (seven) were imported. This is in contrast to previous years when failure rates of antibiotics ranged from 10.7 to 31.5 % [1-8]. One out of the ten anthelmintic agents analyzed failed in the assay, while one (4.3 %) of the analgesics, paracetamol tablets, failed in the dissolution test.

One out of the 29 antiretroviral (ARV) products analyzed (3.4 %) failed to comply with pharmacopoeial requirements. This represented 6.2 % of locally manufactured ARVs. Previously reported data for ARVs analyzed in DARU showed a failure rate of 9.1 % [14].

CONCLUSION

Over the period 2001 to 2005 the overall failure rate of drugs analyzed at DARU was much lower (6.1 %) than in the period 1996 to 2000 (23.6 %). Antimalarial drugs had the highest failure rate (26.8 %), followed by antibiotics (5.3 %). During this study, most of the drug categories that previously caused quality concerns, such as antifungals, antiprotozoals and electrolytes did not record any failure. Most of the samples submitted were pre-registration drugs. This might account for the lower failure rate than in previous studies.

REFERENCES

[1] C.K. Maitai, W.M. Kofi-Tsekpo, E. Wakori, C. Wangia, L. Mkoji and I.M. Githiga, E. Afr. Med. J. 59 (1982) 399-403.

[2] J. Ogeto, C.K. Maitai, C. Wangia, M.L. Mkoji, E. Wakori, G.K. Rutere, R.W. Mithamo, A. Ochieng' and I.M. Githiga, E. Afr. Med. J. 60 (1983) 438-443.

[3] I.O. Kibwage, J.O. Ogeto, C.K. Maitai, G. Rutere, J.K. Thuranira and A. Ochieng, E. Afr. Med. J. 69 (1992) 577-580.

[4] K.O. Mang'era, G.K. Rutere, J.K. Thuranira, R. Mithamo, A. Ochieng', S. Vugigi, E. Ogaja and I.O. Kibwage, Pharm. J. Kenya 4 (1992) 66-69.

[5] S. Vugigi, I.O. Kibwage, E. Ogaja, K.O. Mang'era, H.K. Chepkwony, A.N. Machine and J. Kathanzu, Pharm. J. Kenya 8 (1997) 23-25.

[6] I.O. Kibwage, J.K. Thuranira, L. Gathu, I.M. Githiga, J.M. Nguyo, J.K. Ngugi and O. King'ondu, East Cent. Afr. J. Pharm. Sci. 2 (1999) 32-36.

[7] G.N. Thoithi, K.O. Abuga, J.M. Nguyo,

G. Mukindia, O. King'ondu, J.K. Ngugi and I.O. Kibwage, East Cent. Afr. J. Pharm. Sci. 5 (2002) 28-32.

[8] I.O Kibwage and J.K. Ngugi, East Cent. Afr. J. Pharm. Sci. 3 (2000) 14-19.

[9] British Pharmacopoeia, HMS, London, U.K. 2001.

[10] European Pharmacopoeia 4. Council of Europe, Strasbourg. France. 2002.

[11] United States Pharmacopeia. U. S. Pharmacopeial Convention, Inc., Rockville, MD, U.S.A. 2002.

[12] National Guidelines for Diagnosis, Treatment and Prevention of Malaria for Health Workers. Ministry of Health, Nairobi. Kenya. 1998.

[13] H.K. Chepkwony, N. Mwaura, E. Guantai, E. Gathoni, F.N. Kamau, E. Mbae, G. Wang'ang'a, S. Muteru, N. Birgen and M. Wandeto, East Cent. Afr. J. Pharm. Sci. 10 (2007) 59-62.

[14] K.O. Abuga, P.M. Mwagiru, G.N. Thoithi, J.M. Nguyo, J.K. Ngugi, O.K. King'ondu, H.N. Mugo and I.O. Kibwage, East Cent. Afr. J. Pharm. Sci. 6 (2003) 20-23.

Table 1. Results of drugs analysis in the Drug Analysis and Research Unit during the period 2001-2005

Drug class and name	Total number of analyses	Number of samples passed		Number of samples failed	
		Local	Imported	Local	Imported
1. Alimentary system					
a) Antacids					
Aluminium hydroxide powder[a]	1	-	1	-	-
Magnesium trisilicate powder[a]	1	-	1	-	-
b) Antispasmodic drugs					
Atropine sulphate injection	2	2	-	-	-
2. Allergic disorders					
Antihistamines					
Adrenaline injection	1	-	1	-	-
Cetirizine infusion	2	-	2	-	-
Cetirizine powder[a]	1	-	1	-	-
Chlorpheniramine injection	1	1	-	-	-
Promethazine hydrochloride injection	1	-	1	-	-
Promethazine powder[a]	1	-	1	-	-
3. Cardiovascular system					
Frusemide injection	1	1	-	-	-
4. Endocrine system					
a) Corticosteroids					
Beclomethasone powder[a]	1	-	1	-	-
Betamethasone powder[a]	1	-	1	-	-
Dexamethasone injection	1	1	-	-	-
Hydrocortisone powder[a]	2	-	2	-	-
b) Oral hypoglycaemic agents					
Chlorpropamide tablets	1	1	-	-	-
5. Eye preparations					
Dexamethasone metasulfobenzoate eye drops	1	-	1	-	-
Gentamycin/Prednisolone/Benzylkonium chloride eye drops	1	1	-	-	-
Prednisone acetate eye drops	1	-	1	-	-
Dexpanthenol eye drops	1	-	1	-	-
6. Infections					
a) Antibiotics/antibacterial agents					
Amoxicillin trihydrate capsules	1	1	-	-	-
Amoxycillin suspension	1	1	-	-	-
Amoxycillin/Clavulanate suspension	2	-	2	-	-
Amoxycillin/Clavulanate tablets	2	1	1	-	-
Ampicillin sodium injection	2	1	1	-	-
Ampicillin capsules	1	1	-	-	-

Ampicillin/Cloxacillin capsules	3	-	-	-	3
Bacitracin/Gramicidin/Neomycin powder	1	-	1	-	-
Benzathine penicillin injection	1	-	1	-	-
Benzylpenicillin injection[a]	3	2	1	-	-
Cefatoxin (Cefazolin) injection	2	-	2	-	-
Cefixime tablets	1	-	1	-	-
Cefixime suspension	1	-	1	-	-
Cefpodoxime proxedtil tablets	1	-	-	-	1
Ceftazidine injection	2	-	2	-	-
Ceftriaxone injection	8	4	4	-	-
Cefuroxime injection	2	-	2	-	-
Cefuroxime axetil tablets	2		2	-	-
Cephalexin capsules	1	1	-	-	-
Cephalexin suspension	1	1	-	-	-
Chloramphenicol capsules	2	1	1	-	-
Chloramphenical injection	3	3	-	-	-
Chloramphenical suspension	1	1	-	-	-
Ciprofloxacin infusion	2	-	2	-	-
Ciprofloxacin powder[a]	2	-	1	-	1
Ciprofloxacin tablets	2	-	2	-	-
Cloxacillin injection	3	3	-	-	-
Debenzacin injection	1	1	-	-	-
Doxycycline capsules	2	1	1	-	-
Erythromycin estolate powder[a]	2	-	2	-	-
Erythromycin stearate powder[a]	4	-	4	-	-
Erythromycin suspension[b]	16	2	14	-	-
Erythromycin tablets	26	8	17	1	-
Flucloxacillin injection	4	-	4	-	-
Fugentin tablets	1	-	1	-	-
Gentamicin sulphate injection[b]	3	3	-	-	-
Gentamycin sulphate powder	1	-	1	-	-
Kanamycin injection	1	-	1	-	-
Longacillin injection	1	1	-	-	-
Meofloxin suspension	3	-	3	-	-
Nalidixic acid tablets	1	1	-	-	-
Norfloxacin tablets	1	1	-	-	-
Oxytetracycline oral powder[b]	1	-	1	-	-
Oxytetracycline powder[a]	2	-	2	-	-
Oxytetracycline injection	3	-	3	-	-
Penicillin powder	1	1	-	-	-
Penicillin G injection	1	1	-	-	-
Procaine penicillin injection	2	2	-	-	-
Pefloxacin infusion	1	-	1	-	-
Roxithromycin tablets	2	-	2	-	-
Spectinomycin injection	1	-	1	-	-
Streptomycin injection	3	3	-	-	-
Streptomycin sulphate injection	2	1	1	-	-
Sulphamethoxazole powder[a]	1	-	1	-	-
Sulphamethoxazole/trimethoprim tablets	2	2	-	-	-
Tetracycline capsules	2	1	1	-	-
Tetracycline powder[a]	1	-	1	-	-

Tetracycline tablets	3	1	-	-	2
Ceftriaxone injection	1	1	-	-	-
Trimethoprim powder[a]	2	-	2	-	-
b) Antifungals					
Clotrimazole cream	1	-	1	-	-
Clotrimazole powder[a]	1	-	1	-	-
Fluconazole capsules	4	4	-	-	-
Fluconazole tablets	2	2	-	-	-
Fluconazole suspension	1	-	1	-	-
Ketoconazole tablets	1	-	1	-	-
Nystatin tablets	5	1	4	-	-
Nystatin oral drops	1	-	1	-	-
Nystatin powder[a]	4	-	4	-	-
Nystatin suspension	7	-	7	-	-
c) *Anthelmintic drugs*					
Albendazole suspension	1	-	1	-	-
Albendazole drench[c]	1	1	-	-	-
Levamisole suspension	3	2	-	1	-
Levamisole/oxyclozanide suspension[c]	3	3	-	-	-
Mebendazole tablets	1	-	1	-	-
Pyrantel pamoate powder[b]	1	1	-	-	-
d) Antiprotozoal drugs					
Metronidazole infusion	1	1	-	-	-
Metronidazole injection	2	-	2	-	-
Metronidazole powder[a]	1	-	1	-	-
Metronidazole suspension	1	1	-	-	-
e) Antimalarial drugs					
Amodiaquine powder[a]	1	-	1	-	-
Amodiaquine syrup	2	2	-	-	-
Amodiaquine tablets	1	1	-	-	-
Artemether suspension	1	-	-	-	1
Artemether tablets	1	-	1	-	-
Dihydroartemisinin suspension	1	-	1	-	-
Pyrimethamine powder	1	-	1	-	-
Sulfadoxine/pyrimethamine suspension	4	4	-	-	-
Sulfadoxine/pyrimethamine tablets	20	6	4	10	-
Sulphadoxine powder [a]	1	-	1	-	-
Sulphamethoxypyrazine tablets	1	-	1	-	-
Sulphamethoxypyrazine powder	1	-	1	-	-
Quinine injection	6	4	2	-	-
f) Antituberculosis drugs					
Ethambutol tablets	3	-	3	-	-
Isoniazid tablets	1	-	1	-	-
Isoniazid/Rifampicin tablets	3	-	3	-	-
Isoniazid/Pyrazinamide/Rifampicin tablets	5	3	2	-	-

Isoniazid/Ethambutol/Pyrazinamide/ Rifampicin tablets	2	2	-	-	-
Pyrazinamide tablets	1	-	1	-	-
g) Antiviral drugs					
Lamivudine oral solution	6	6	-	-	-
Lamivudine tablets	8	6	2	-	-
Lamivudine/Zidovudine capsules	1	-	1	-	-
Nevirapine tablets	1	-	1	-	-
Ribavirin capsules	1	-	1	-	-
Zidovudine capsules	3	1	2	-	-
Stavudine capsules	4	3	-	1	-
Lamivudine/Stavudine capsules	2	-	2	-	-
Lamivudine/Stavudine/Nevirapine capsules	4	-	4	-	-
7. Nervous system					
a) Anaesthetics					
Bupivacaine hydrochloride injection	1	1	-	-	-
Lignocaine injection	4	4	-	-	-
Thiopentone injection	1	1	-	-	-
b) Analgelsics					
Aspirin granules	1	-	1	-	-
Aspirin/paracetamol/caffeine tablets	3	-	3	-	-
Diclofenac tablets	3	-	3	-	-
Diclofenac injection	2	-	2	-	-
Ibuprofen suspension	1	1	-	-	-
Ibuprofen tablets	1	1	-	-	-
Ibuprofen/Paracetamol tablets	1	-	1	-	-
Indomethacin suspension	1	-	1	-	-
Paracetamol powder	5	-	5	-	-
Paracetamol suspension	4	4	-	-	-
Paracetamol tablets	1	-	-	-	1
c) *Antidepressants*					
Fluoxetine capsules	1	-	1	-	-
d) Antiepileptic drugs					
Carbamazepine tablets	1	-	1	-	-
e) Antipsychotics					
Chlorpromazine tablets	1	1	-	-	-
8. Nutrition					
a) Electrolytes and Dextrose infusions					
Compound sodium lactate infusion	2	-	2	-	-
Darrow's solution	2	-	2	-	-
Dextrose 5 % infusion	4	1	3	-	-
Dextrose 10 % infusion	1	-	1	-	-
Dextrose powder [a]	1	-	1	-	-

Glucose intravenous solution	3	-	3	-	-
Hartmann's solution	2	2	-	-	-
Normal saline infusion	2	-	2	-	-
Normal saline/dextrose 5 % infusion	1	-	1	-	-
Oral rehydration salt [b]	1	-	1	-	-
b) Vitamins/minerals					
Ascorbic acid powder [a]	2	-	2	-	-
Vitamin B Complex injection	1	1	-	-	-
9. Respiratory system					
Aminophylline injection	2	1	1	-	-
Bromhexine powder	1	-	1	-	-
Carbocysteine powder	1	-	1	-	-
Dextromethorphan suspension	1	1	-	-	-
Ephedrine powder [a]	1	-	1	-	-
Salbutamol solution	1	1	-	-	-
10. Skin preparations					
Cetrimide powder	1	-	-	-	1
Sulphur ointment	1	1	-	-	-
Tretinoin powder	1	-	1	-	-
11. Miscellaneous					
Corn starch	1	-	1	-	-
Glacial acetic acid	1	-	1	-	-
Glycerol	1	-	1	-	-
Lactose anhydrous	1	-	1	-	-
Magnesium stearate	1	-	1	-	-
Polypropylene glycol	1	-	1	-	-
Sodium methylhydroxybenzoate powder [a]	1	-	-	-	1
Sodium stibogluconate	1	-	1	-	-
Starch (pregelatinised)	1	-	1		
Vincristine injection	1	-	1	-	-
Purified water	1	1	-	-	-
Water for injection	17	-	17	-	-
Water for pharmaceutical use	1	1	-	-	-
Total number of products	**394**	**136**	**234**	**13**	**11**

a = raw material powder, b = powder for reconstitution, c = veterinary product