East and Central African Journal of Pharmaceutical Sciences
Vol. 5(2002) 28 - 32

Drug Quality Control in Kenya: Observation in Drug Analysis and Research Unit during the Period 1996-2000

G.N. THOITHI, K.O. ABUGA, J.M. NGUYO, G. MUKINDIA, O. KINGONDU, J.K. NGUGI AND I.O. KIBWAGE*

Drug Analysis and Research Unit, Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Nairobi, P. O. Box 19676-00202 KNH, Nairobi, Kenya.

The Drug Analysis and Research Unit received and analyzed 261 drug samples over a five-year period, 1996 to 2000. Samples were received from regulatory authorities, local industry, non-governmental organizations, hospitals and private practitioners. The samples analyzed constituted 59.8 % locally manufactured and 40.2 % imported products. The overall rate of failure to comply with quality specifications set out in the respective monographs was 21.1 %. This represents 24.6 % and 16.2 % of the locally manufactured and imported drugs, respectively.

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

INTRODUCTION

Good quality drugs are essential for effective healthcare delivery. In recognition of this, official compendia, such as the European Pharmacopoeia [1], the British Pharmacopoeia [2] and the United States Pharmacopoeia [3], among others, give the minimum requirements of a good drug. It is the onus of a drug manufacturer to follow good manufacturing practices and to release quality products to the consumers. On the other hand, drug regulatory authorities have the responsibility of ensuring that this happens.

Previous studies of drug products in the Kenyan market show that quality varies with type of drug, the manufacturer and whether the drugs are locally manufactured or imported [4-9]. Certain products, like locally manufactured intravenous infusions [10], tetracyclines [11], cotrimoxazole [12] and ampicillin [13] have attracted more attention because of their nature, use and consequences of their poor quality. The antitubercular agents, antimalarial drugs, especially the sulphonamide/pyrimethamine (SP) products, and the antiretroviral drugs comprise another important category because of the magnitudes of tuberculosis, malaria and HIV/AIDS in Sub-Saharan Africa. Besides, there is the threat of emerging resistance to many of these drugs. The development of a liquid chromatographic method for analysis of fixed-dose combination products containing isoniazid, pyrazinamide and rifampicin has been reported elsewhere [14].

The present paper reports on the findings of drug analyses carried out at Drug Analysis and Research Unit (DARU) between January 1996 and December 2000.

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 [4,5]. The products were either locally manufactured or imported.

Methods

Drugs were analyzed according to specifications given in the European Pharmacopoeia, the United States Pharmacopoeia or the British Pharmacopoeia. Products which are not subject to official compendia were analyzed according to the manufacturer's method and specifications.

* Author to whom correspondence may be addressed

RESULTS AND DISCUSSION

Samples were evaluated for quality with regard to appearance, identification, disintegration, content of active pharmaceutical ingredient, dissolution and dissolution profile, microbial load and sterility. Out of 261 samples that were analyzed, 156 (59.8 %) were locally manufactured while 105 (40.2 %) were imported (table 1). The overall failure to meet one or more of the specifications was 21.1 % (55 samples). Local products had a higher failure (24.6 %, 38 samples) than imported ones (16.2 %, 17 samples).

The major quality problem was the content of the active ingredients, which was often too low and occasionally too high. Some products did not meet dissolution, sterility and particulate matter specifications. None of the products analyzed was found to have the wrong or no active pharmaceutical ingredients (counterfeit).

The anthelmintic drugs had the highest failure (37.5 %) and these failed in the content of active ingredient. Most of these products were for veterinary use and all came from the same local company. The manufacturer concerned eventually solved the problem following advice on product development.

The failure of the antimalarial drugs was 27.7 %, with sulphadoxine/pyrimethamine and chloroquine (CQ) having a failure rate of 40.5 and 13.3 %, respectively. The quality of sulphadoxine/pyrimethamine products in Kenya has been discussed elsewhere [15]. As opposed to other classes of drugs, which had a problem with the content of the active ingredients, the sulphadoxine/pyrimethamine and CQ products mostly had a problem with dissolution and sometimes with both dissolution and content.

The Ministry of Health in Kenya changed the first line antimalarial drugs from CQ to SP products in 1998 [16]. Many local pharmaceutical companies immediately started manufacturing these products and hence the problems of quality may be attributed to poor pharmaceutical product development. Samples of sulphamethoxypyrazine /pyrimethamine, amodiaquine and quinine were too few for inferences to be made.

Other groups of drugs that had quality problems, especially in the content of active ingredients, include skin preparations (25.0 %, both local and imported), electrolytes (23.1 %, all imported), antiprotozoal agents (14.3 %, all local), antibiotics/antibacterial agents (10.3 %, local and imported) and analgesics (9.8 %, local and imported). The bronchodilators had a failure rate of 20.0 %, but the sample size was not big enough to make conclusions.

CONCLUSION

The failure rate (23.6 %) of drugs analyzed in DARU over the period 1996-2000 is higher compared to those analyzed in the same laboratory in the period 1991-1995 (17.5 %) [9]. This calls for strict market surveillance of drugs, especially antimalarial agents. Other drugs requiring close surveillance include antibiotics/antibacterial agents, antiprotozoal agents, anthelmintic agents, skin preparations and electrolytes.

ACKNOWLEDGEMENTS

The authors acknowledge financial support from the Belgian government (VLIR-ABOS Grant No. JH 107) and thank Mr. D. Samoei, Mr. H. Mugo and Mr. G. K. Kaptich for technical assistance.

Table 1. Results of drugs analysis in Drug Analysis and Research Unit during the period 1996-2000

Drug class and name	Total number of requests	Number of samples passed		Number of samples failed	
		Local	Imported	Local	Imported
1. Alimentary system					
a) Antispasmodic drugs					
Atropine sulphate injection	1			1	
b) H_2-receptor antagonists					
Cimetidine tablets	3		3		

* Author to whom correspondence may be addressed

Table 1 Cont'd....

c) Antidiarrhoea drugs					
Attapulgite raw material	1			1	
Loperamide capsules	2		1		1
2. Cardiovascular system					
Atenolol tablets	1		1		
Nifedipine retard tablets	3	1	2		
3. Endocrine system					
a) Corticosteroids					
Dexamethasone injection	1		1		
Prednisolone raw material	1	1			
Prednisolone tablets	1	1			
b) Oral hypoglycaemic agents					
Glibenclamide tablets	2		2		
4. Infections					
a) Antibiotics/antibacterial agents					
Ampicillin/cloxacillin suspension[a]	1		1		
Amoxicillin trihydrate capsules	4	3	1		
Benzyl penicillin injection[a]	2	1	-		1
Chloramphenicol capsules	1		1		
Cloxacillin suspension[a]	1		1		
Doxycycline capsules	2	1			1
Erythromycin suspension[a]	3	3			
Erythromycin tablets	4		4		
Gentamicin sulphate injection[a]	3		2	1	
Norfloxacin tablets	5	2	3		
Sulphamethoxazole/trimethoprim (Co-trimoxazole) tablets	2		2		
Tetracycline capsules	1		1		
b) Antituberculosis drugs					
Ethambutol tablets	1		1		
Rifampicin capsules	1		1		
c) Antiprotozoal drugs					
Metronidazole injection	2		1	1	
Metronidazole tablets	1		1		
Tinidazole raw material	1	1			
Tinidazole tablets	3		3		
d) Antimalarial drugs					
Amodiaquine suspension	1	1			
Amodiaquine tablets	1	1			
Chloroquine tablets	29	25		4	
Chloroquine injection	1		1	-	
Sulfadoxine/pyrimethamine tablets	39	24		15	
Sulfadoxine/pyrimethamine suspension	3	1		2	
Sulfamethoxypyrazine/pyrimethamine tablets	1		1	-	
Sulfamethoxypyrazine/pyrimethamine drops	2	1		1	
Quinine raw material	2	1		1	
Quinine tablets	2	2			
Quinine syrup	1		1		
Quinine injection	1		1		
e) Antifungals					
Clotrimazole pessaries	4		3		1
Nystatin pessaries	2		2		

Table 1 Cont'd....

f) Anthelmintic drugs					
Albendazole tablets	3		3	-	-
Albendazole suspension	1	-	1	-	-
Albendazole bolus (Veterinary)	1	1	-	-	-
Albendazole suspension (Veterinary)	5	3	-	2	-
Levamisole suspension (Veterinary)	2	-	-	2	-
Levamisole/oxyclozanide suspension (Veterinary)	4	2	-	2	-
5. Nervous system					
a) Analgesics					
Aspirin/paracetamol/caffeine tablets	3	3	-	-	
Diclofenac tablets	1	-	1	-	
Ibuprofen tablets	3	1	1	1	
Indomethacin tablets	1		1	-	-
Mefenamic acid capsules	4		3	-	1
Paracetamol tablets	1		1	-	-
Paracetamol suspension	4	-	2	-	2
Paracetamol/caffeine tablets	22	22	-	-	-
Piroxicam capsules	1	-	1	-	
Paracetamol/phenylephrine/caffeine/vitamin	1		1	-	
b) Antidepressants					
Fluoxetine capsules	1	-	1	-	
c) Antipsychotics					
Chlorpromazine tablets	1	1	-	-	
6. Nutrition					
a) Electrolytes and Dextrose infusions					
Compound sodium lactate infusion	2	-	2	-	-
Dextrose 5 % infusion	2	1	-	-	1
Dextrose 10 % infusion	1	1	-	-	-
Dextrose 50 % infusion	1	1	-	-	-
Normal saline infusion	5	4	-	-	1
Normal saline/dextrose 5 % infusion	2	1	-	-	1
b) Vitamins/minerals					
Calcium/vitamin C/vitamin D_3 tablets	1	-	1	-	
Iron with vitamin capsules	1	-	1	-	-
Vitamin B-Complex injection	1	-	-	-	1
7. Respiratory system					
a) Expectorants/Cough suppresants	3		3	-	
b) Bronchodilators					
Ephedrine/theophylline tablets	2	-	1	-	1
Salbutamol tablets	1	1	-	-	-
Salbutamol/bromhexine/guaifenesin syrup	2		2	-	
8. Skin preparations (Ointments or Creams)					
Betamethasone 0.1 %/Gentamycin 0.3 %	3	2	-	1	
Beclomethasone 0.025 %/clotrimazole 1 %/ Gentamicin 0.1 %	1	-	1	-	-
Clotrimazole 1 %	7	-	5	-	2
Gentamicin 0.1 %	1	1	-	-	-
Hydrocortisone 1 %	11		8	-	3
Tretinoin 0.5 %	1		1	-	-

Table 1 Cont'd....

9. Miscellaneous					
Amitraz raw material	2		2		
Camphor crystals	1		1		
Clomiphene	1		1		
Citric acid crystals	1			1	
Ethanol 95.5 %	1	1			
Glycerine	2	2			
Gripe water	2			2	
Human albumin	1		1	-	
Total number of products	**261**	**118**	**88**	**38**	**17**

a: powder for reconstitution

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