

Annex I: Registration Fees Structure

REGISTRATION AND RETENTION	Fees Payable
1. Initial registration for foreign manufactured products	US\$1,000
2. Annual retention for foreign manufactured products	US\$300
3. Initial registration for locally manufactured products from large scale manufacturers	US\$200
4. Annual retention for locally manufactured products from large scale manufacturers	US\$100
5. Initial registration for locally manufactured products from small scale manufacturers	UShs.150,000
6. Annual retention for locally manufactured products from small scale manufacturers	UShs.75,000
7. Initial registration of EDLU* items of low commercial value with no registered equivalent	US\$250
8. Annual retention of EDLU* items of low commercial value with no registered equivalent	US\$125
9. Registration of foreign manufactured traditional/herbal medicines including ayurvedic and homeopathic remedies	US\$500
10. Notification of locally manufactured traditional/herbal products	No charge
11. Notification of foreign manufactured dietary/nutritional supplements	See below
12. Notification of locally manufactured dietary/nutritional supplements	See below
13. Notification of foreign manufactured public health products	US\$50
14. Notification of locally manufactured public health products	UShs.20,000
15. Annual retention for foreign traditional/herbal medicines including ayurvedic and homeopathic Remedies	US\$150

AMENDMENTS	Fees Payable
1. Change in formulation (Inactives)	US\$500
2. Change in manufacturing site**	US\$500
3. Additional manufacturing site**	US\$500
4. Change in Local Technical Representative (LTR) ***	US\$1,000
5. Extension/reduction of shelf life	US\$200
6. New scientific information/literature	US\$200
7. Finished product specification	US\$200
8. Trade name change	US\$100
9. Change in name of manufacturer**	US\$100
10. Additional pack size	US\$100
11. Pack design - Primary pack - Secondary pack	US\$50 US\$50
12. Change in packing material	US\$100
13. Additional accessories	US\$50
14. Change of label design	US\$50
15. Change of licence holder **	US\$500

*EDLU - Essential Drugs List of Uganda

** - Fees are applicable to each individual product

*** - Fees covers entire product range (lump sum).

1. Fees for dietary supplements notification:

Description	Amount (US\$)
1. New application – imported Human DS*	\$500
2. Annual retention – imported Human DS*	\$200
3. New application – imported Vet DS*	\$300
4. Annual retention – imported Vet DS*	\$120
5. New application – Local Human/Vet DS*	\$50
6. Annual retention – Local Human/Vet DS*	\$20

2. Amendment Fees (Nutritional Supplements):

Description	Amount (US\$)
A. Amendments for imported Human DS*	
1. Change in formulation (Inactive)	\$250
2. Extension of shelf life	\$100
3. New scientific information /literature	\$100
4. Finished product specification	\$100
5. Trade name change	\$50
6. Change in name of manufacturer	\$50
7. Additional pack size	\$50
8. Pack design	
- Primary pack	\$25
- Secondary pack	\$25
9. Change in packing material	\$50
10. Additional accessories	\$25
11. Change of label design	\$25
12. Change of licence holder	\$250
B. Amendments for imported Vet DS* (dietary supplements)	60% of the above fees
C. Amendments for locally produced DS* (dietary supplements)	Can be exempted

* DS – Dietary Supplement