Appendix 3: Pharmaceutical Regulatory Authority Schedule of Fees, 2010

A. RETAIL / HOSPITAL PHARMACY			
NO.	**DESCRIPTION**	**FEE UNITS (1 fee Unit = K180)**	**APPLICATION FEES (ZMK)**
1	Application for registration certificate to operate a retail pharmacy	5,000	900,000.00
2	Application for registration certificate to operate a hospital pharmacy	2,834	510,000.00
3	Inspection fee to operate a retail / hospital pharmacy	4,223	760,000.00
4	Application for change of premises	2,500	450,000.00
5	Reinspection fee for retail / hospital pharmacy	2,500	450,000.00
6	(A) Application for renewal of a retail pharmacy registration certificate	6,667	1,200,000.00
	(B) Application for renewal of hospital pharmacy registration certificate	4,445	800,000.00
	Hospital pharmacy - any institution established as a hospital and includes a clinic, nursing home, health centre, surgery, consulting room, hospice and any facility authorised to dispense medicines and drugs		

B. IMPORT / WHOLESALE DEALER'S LICENCES			
NO.	**DESCRIPTION**	**FEE UNITS (1 fee Unit = K180)**	**APPLICATION FEES (ZMK)**
1	(i) Application for import licence	5,556	1,000,000.00
	(ii) Application for Wholesale dealer's licence	5,000.00	900,000.00
2	Inspection fees		
	(i) wholesale dealing	4,223.00	760,000.00
3	Renewal for import licence	5,000.00	900,000.00
	Renewal for wholesale dealer's licence	7,778.00	1,400,000.00

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4	Application for change of premises for wholesale dealing	4,445.00	800,000.00
5	Re-inspection fee	2,778.00	500,000.00

C. MANUFACTURER'S LICENCE

NO.	DESCRIPTION	FEE UNITS (1 fee Unit = K180)	APPLICATION FEES (ZMK)
1	Application for licence to manufacture	10,000	1,800,000.00
	Inspection fee (local manufacture)	20,000	3,600,000.00
2	Renewal for manufacture licence	10,000	1,800,000.00
3	Application for change of premises	5,000	900,000.00
4	(i) Issue of licence to manufacture (5 years)	50,000	9,000,000.00
5	Application for manufacturer's licence :		
	(i) To repackage medicines	10,000	1,800,000.00
	(ii) Inspection fee	11,112	2,000,000.00
	(iii) Annual renewal	7,778	1,400,000.00
	(iv) Re-inspection fee	5,000	900,000.00
	(v) Change of premises	4,445	800,000.00

D. OTHER SERVICES

NO.	DESCRIPTION	FEE UNITS (1 fee Unit = K180)	FEES (ZMK)
1	Screening fees for import authorisation		2% of invoice value
2	Screening for export authorisation	278	50,000.00

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3	Application for clinical trial certificate	2,778	500,000.00
4	Application for product licence of an investigational product	16,889	3,040,000.00
5	Application for issue of GMP certificate	2,223	400,000.00
6	Application for import of narcotic drugs and psychotropic substances	278	50,000.00
7	Minor Amendments to dossier / labeling	1,389	250,000.00
8	Major amendments to dossier	2,778	500,000.00
9	Issue of Certificate of a Pharmaceutical Product (CPP)	278	50,000.00
10	Amendment to product licence (imported)	1,389	250,000.00
11	Amendments to licences and certificates (locally manufactured & locally packaged)	1,389	250,000.00
12	Amendments to import / export authorisation	-	1% of invoice value
13	Application for approval of advertisement, promotion, launch, etc	5,556	1,000,000.00
14	Application for fast track registration	18,334	3,300,000.00
15	Good Clinical Practice inspection	29,445	5,300,000.00
16	inspection and supervision for disposal of expired products	500	90,000.00 per day
17	Application for importation / exportation of a medicine by a person for personal use for that person	278	50,000.00
18	Application for change of category of distribution	5,556	1,000,000.00
19	Inspection of premises for issue of a GMP certificate	2,000	3,600,000.00
20	Application for the importation of small quantities of drugs by an authorised institution for specific patient(s)	2,500	450,000.00

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21	Application for registration for import of a medicine for supply through government public tenders. (Should the medicine be required to be maintained on the market, fresh application fee to be paid as the case may be).	4,223	760,000.00
22	Replacement of lost documents (licences and certificates)	1,389	250,000.00
23	Application for restoration of a product licence	16,667	3,000,000.00

PRODUCT REGISTRATION

NO:	DESCRIPTION	FEE UNITS (1 fee Unit = K180)	REGISTRATION FEES (ZMK)	FEE UNITS (1 fee Unit = K180)	RETENTION FEE (ZMK)
1.	**Human medicines**				
	Application for registration				
	(i) Imported as finished product	21,112	3,800,000.00	14,056	2,530,000.00
	(ii) Packaged in Zambia	18,334	3,300,000.00	14,056	2,530,000.00
	(iii)Locally manufactured	4,223	760,000.00	2,778	500,000.00
	(iv) New Chemical Entities	23,334	4,200,000.00	11,278	2,030,000.00
	(v) Biological products including vaccines	23,334	4,200,000.00	11,278	2,030,000.00
2	**Veterinary medicines**				
	Application for registration:				
	(i) Imported as a finished product	12,778	2,300,000.00	10,556	1,900,000.00
	(ii) Packaged in Zambia	8,445	1,520,000.00	10,556	1,900,000.00
	(iii)Locally manufactured	2,834	510,000.00	2,223	400,000.00
3.	**Herbal medicinal product**				
	Application for registration:				
	(i) Imported as a finished product	21,112	3,800,000.00	14,056	2,530,000.00
	(ii) Herbal medicinal product				

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	packaged in Zambia (iii)Herbal medicine locally manufactured	12,778 4,223	2,300,000.00 760,000.00	10,556 2,778	1,900,000.00 500,000.00
4.	**Allied substances** (ii) Registration of an allied substance	4,223	760,000.00	2,778	500,000.00

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Appendix 4: Key Informant Questionnaire Guide

1. Name of institution
2. Name and position of respondent
3. What is your main mandate/role as an organisation/institution?
4. What is your organisation/institution's relationship/link with pharmaceutical manufacturers?
5. What is the historical background of the pharmaceutical industry in Zambia?
6. Do you know how many pharmaceutical products manufacturers we have in Zambia? Number? Is this number increasing or decreasing? If so why?
7. What are the main categories of pharmaceutical manufacturers?
8. What are the top 5 locally manufactured pharmaceutical products?
9. What are the top 5 imported pharmaceutical products?
10. Which countries are the main sources of imported medicines?
11. Where are most local manufacturers based? Why?
12. What kinds of taxes are imposed on local manufacturers? Percentage?
13. What kinds of taxes are imposed for importation of raw materials for manufacturing? Percentage?
14. What kinds of taxes are imposed for importation of finished pharmaceutical products? Percentage?
15. What taxes/fees are imposed on local manufacturers within their operation/manufacturing locality? (Council rates, fire certificates, health and safety, environmental certificates, etc)
16. What is the average contribution of production utility inputs like water and electricity to the production cost?
17. What non tax impediments affect the manufacture of medicines in Zambia? Products registration fees, registration certificates, etc?
18. Are there any pharmaceutical products that are manufactured under licence from a foreign based company? What is the average cost of such a licence?
19. What role does your organisation/institution play in influencing government policy over the pharmaceutical products tax regime and other incentives for local manufacturers?
20. Are local manufacturers capable of meeting the local demand for medicines without having to import?
21. Do they have capacity to manufacture medicines on the essential drugs list?
22. How do locally manufactured medicines compare with imported ones in terms of price, efficacy and safety? Why?
23. Do you know what percentage of medicines bought by the Ministry of Health, are imported? Manufactured locally?
24. What are the requirements to begin manufacturing medicines in Zambia?

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25. What incentives exist for local manufacturing of medicines and pharmaceutical products? Are these adequate? What is missing?
26. What percentage of the MoH's annual budget is spent on procurement of medicines?
27. How do donated medicines and other pharmaceutical products, affect the market for locally manufactured medicines?
28. Who are the major buyers of medicines and pharmaceutical products manufactured by local manufacturers?
29. Are local manufacturers allowed to export medicines? What percentage is exported? To which countries?
30. Are inspections done to ensure adherence to minimum standards? Who inspects?
31. Do manufacturers generally have the necessary technical capacity to manufacture (i.e. staff, equipment, capital)
32. Is there enough demand for locally produced medicines as opposed to imported medicines? If no, why?
33. What is the local source of raw materials used in the manufacture of medicines?
34. Are there any impediments in the procurement of these raw materials? What are these?
35. What is/are the effect of the impediments in manufacturing medicines locally on health delivery?
36. How can the challenges you have raised be addressed?
37. What constraints do manufacturers face in accessing the market?
38. Are manufacturers allowed to advertise medicines? What types of medicines are allowed?
39. What is the effect of advertising on procurement of medicines from manufacturers?
40. Are there any regulatory requirements for local manufacturers? What are these? Are they enforced?
41. Are there any regulatory requirements for foreign suppliers? What are these? Are they enforced?
42. What effect do regulatory requirements have on the cost, efficacy and safety of medicines?
43. What are the current rates for product registration with the Pharmaceutical Regulatory Authority?
44. How does patenting of medicines (especially generic medicines) affect manufacturers' ability to produce medicines?
45. Does the pharmaceutical sub sector face challenges relating to counterfeit medicines? How serious is this problem?
46. Does the pharmaceutical sub sector face challenges relating to pilferage of medicines? How serious is this problem?
47. Is corruption a problem in the manufacture and supply of medicines? At what points does corruption occur? Why?
48. Is industrial unrest common with pharmaceutical manufacturing companies? What is usually the source of unrest?
49. Do you see potential for growth of the local pharmaceutical manufacturing sub sector in Zambia in the next 10 years?

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50. What 3 things need to be addressed urgently to deal with the challenges of local manufacturers?

Thank you for your Time

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