ITEKA RYA MINISITIRI Nº 002/17/10/TC RYO KU WA 27/10/2017 RIGENA IGICIRO CYO KWANDIKA IMITI, IBIKORESHO BYO MU BUVUZI N'IZINDI SERIVISI BIJYANYE	MINISTERIAL ORDER Nº 002/17/10/TC OF 27/10/2017 DETERMINING THE FEES FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES AND OTHER RELATED SERVICES	ARRETE MINISTERIEL Nº 002/17/10/TC DU 27/10/2017 DETERMINANT LES FRAIS D'ENREGISTREMENT DES PRODUITS PHARMACEUTIQUES, DES DISPOSITIFS MEDICAUX ET AUTRES SERVICES CONNEXES
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ITEKA RYA MINISITIRI Nº 002/17/10/TC RYO KU WA 27/10/2017 RIGENA IGICIRO CYO KWANDIKA IMITI, IBIKORESHO BYO MU BUVUZI N'IZINDI SERIVISI BIJYANYE	MINISTERIAL ORDER Nº 002/17/10/TC OF 27/10/2017 DETERMINING THE FEES FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES AND OTHER RELATED SERVICES	ARRETE MINISTERIEL Nº 002/17/10/TC DU 27/10/2017 DETERMINANT LES FRAIS D'ENREGISTREMENT DES PRODUITS PHARMACEUTIQUES, DES DISPOSITIFS MEDICAUX ET AUTRES SERVICES CONNEXES
Ministiri w'Imari n'igenamigambi;	**The Minister of Finance and Economic Planning;**	**Le Ministre des Finances et de la planification économique;**
Ashingiye ku Itegeko Nshinga rya Repubulika y'u Rwanda ryo mu 2003 ryavuguruwe mu 2015, cyane cyane mu ngingo zaryo, iya 121, 122 n'iya 176;	Pursuant to the Constitution of the Republic of Rwanda of 2003 revised in 2015, especially in Articles 121, 122 and 176;	Vu la Constitution de la République du Rwanda de 2003 révisée en 2015, spécialement en ses articles 121, 122, et 176;
Ashingiye ku Itegeko nº 47/2012 ryo ku wa 14/01/2013 rigenga imicungire n'igenzura ry'ibiribwa n'imiti, cyane cyane mu ngingo yaryo ya 26;	Pursuant to Law nº 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, especially in Article 26;	Vu la Loi nº 47/2012 de la 14/01/2013 portant règlementation et inspection des produits alimentaires et pharmaceutiques, spécialement en son article 26;
Inama y'Abaminisitiri yateranye ku wa 04/10/2017 imaze kubisuzuma no kubyemeza;	After consideration and approval by the Cabinet, in its session of 04/10/2017;	Après examen et approbation par le Conseil des Ministres en sa séance du 04/10/2017;
ATEGETSE:	**HEREBY ORDERS:**	**ARRETE:**
Ingingo ya mbere: Icyo iri teka rigamije	**Article one: Purpose of this Order**	**Article premier: Objet du présent arrêté**
Iri teka rigena igiciro cyo kwandika imiti, ibikoresho byo mu buvuzi n'izindi serivisi bijyanye.	This Order determines fees for registration of pharmaceutical products, medical devices and other related services.	Le présent arrêté détermine les frais d'enregistrement des produits pharmaceutiques, des dispositifs médicaux et autres services connexes.

Ingingo ya 2: Ibisobanuro by'amagambo	**Article 2: Definitions**	**Article 2: Définitions**
Muri iri teka, amagambo akurikira afite ibisobanuro bikurikira:	For the purpose of this Order, the following terms have the following meanings:	Aux fins du présent arrêté, les termes ci-après ont les significations suivantes:
1° **uruganda:** isosiyete ikora ibintu birimo nko gukora, gufunika, kongera gufunika, gushyiraho ikirango no kongera gushyira ikirango ku miti;	1° **manufacturer:** company that carries out operations such as production, packaging, repackaging, labeling and, re-labeling of pharmaceutical products;	1° **fabricant:** entreprise qui réalise des opérations telles que la production, l'emballage, le reconditionnement, l'étiquetage et le ré-étiquetage de produits pharmaceutiques;
2° **umuti:** ikintu cyose gifite ubushobozi bwo gukingira, kuvura indwara z'abantu cyangwa iz'inyamaswa ndetse n'ikindi kintu cyose cyagenewe guhabwa umuntu cyangwa inyamaswa kugira ngo hasuzumwe indwara, gusana, gukosora cyangwa guhindura imikorere y'umubiri cyangwa iy'ubwenge n'ibintu bikoreshwa mu gusukura inyubako zikorerwamo, zitegurirwamo n'izibikwamo ibiribwa n'imiti;	2° **pharmaceutical product:** any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions and products used in disinfecting premises in which food and drugs are manufactured, prepared or stored;	2° **produit pharmaceutique:** toute substance capable de prévenir, traiter les maladies humaines ou animales et toute autre substance destinée à être administrée à un être humain ou à un animal afin de diagnostiquer des maladies, de restaurer, de corriger ou de modifier des fonctions organiques ou mentales ainsi que les produits utilisés pour désinfecter les locaux où sont fabriqués, préparés ou stockés les aliments et médicaments;
3° **igikoresho cyo mu buvuzi:** ikintu cyose gikoreshwa mu buvuzi hagamijwe gusuzuma, gupima, kuvura, kubaga cyangwa kurinda ubuzima;	3° **medical device:** any device used in the medical field for the purpose of diagnosis, testing, cure, surgery or health protection;	3° **dispositif médical:** tout article utilisé dans le domaine médical à des fins de diagnostic, de dépistage, de guérison, de chirurgie ou de protection de la santé;
4° **imenyekanisha:** impinduka mu ikorwa cyangwa mu bigize umuti bishobora gutera ingaruka nke cyangwa kudatera ingaruka mbi ku mutekano, ku buziranenge no ku ireme ry'umuti watunganyijwe;	4° **notifications:** changes in manufacturing or compositions that could have minimal or no adverse effects on the overall safety, efficacy and quality of the finished pharmaceutical products;	4° **notifications:** modifications dans la fabrication ou composition qui pourraient avoir peu ou pas d'effets néfastes sur la sécurité, l'efficacité et la qualité globale des produits pharmaceutiques finis;

5° **impinduka zikomeye:** ivugurura ryimbitse mu mikorere cyangwa mu bigize umuti bishobora gutera ingaruka zikomeye ku mutekano, akamaro no ku buziranenge rusange bw'umuti watunganyijwe; 6° **impinduka zorohereje:** ivugurura rishobora kugira ingaruka zoroheje ku mutekano, akamaro no ku buziranenge rusange bw'umuti watunganyijwe; 7° **amafaranga yo kwandika umuti buri mwaka:** amafaranga atuma icyemezo cyo gucuruza umuti kandi atuma ikigo gishinzwe ibiribwa n'imiti gikora igenzura no gukurikirana ireme n'imikoreshereze myiza y'imiti cyangwa ibikoresho byo kwa muganga ku isoko kigumaho; 8° **kwandika umuti:** igikorwa cyo gusuzuma no kwiga kuri dosiye y'umuti kugira ngo uhabwe uburenganzira bwo gucuruzwa ku isoko, guhabwa uburenganzira bwo gutumiza cyangwa koherezwa hanze y'igihugu no guha uburenganzira sosiyete zikora imiti.	5° **major variation:** changes that could have major effects on the overall safety, efficacy and quality of the finished pharmaceutical products; 6° **minor variation:** changes that may have minor effects on the overall safety, efficacy and quality of the finished pharmaceutical products; 7° **annual retention fees:** fees to maintain market authorization and enable the regulatory authority to carry out inspection and monitor the quality and rational use of the pharmaceutical product or medical devices on market; 8° **registration of pharmaceutical products:** process of reviewing and assessing the file to support medical product in view of its marketing authorization, licensing of its import or export and granting operational approval to establishments manufacturing pharmaceutical products.	5° **modification majeure:** changements qui pourraient avoir des effets majeurs sur la sécurité globale, l'efficacité et la qualité des produits pharmaceutiques finis; 6° **modification mineure:** changements qui peuvent avoir des effets mineurs sur la sécurité globale, l'efficacité et la qualité des produits pharmaceutiques finis; 7° **frais de rétention annuelle:** frais pour maintenir l'autorisation de mise sur le marché et permettre à l'autorité de réglementation de procéder à l'inspection et contrôler la qualité et l'utilisation rationnelle du produit pharmaceutique ou des dispositifs médicaux sur le marché; 8° **enregistrement de produits pharmaceutiques:** processus d'examen et d'évaluation du dossier d'un médicament en vue de garantir son autorisation de mise sur le marché, l'octroi d'une licence pour son importation ou exportation et l'octroi d'une autorisation opérationnelle aux établissements pharmaceutiques engagés dans sa production.
Ingingo ya 3: Ibiciro byo kwandikisha imiti n`ibikoresho byo mu buvuzi Ibiciro byo kwandikisha imiti n'ibikoresho byo mu buvuzi n'izindi serivisi zijyanye na byo biri ku mugereka w'iri teka.	**Article 3: Registration fees for pharmaceutical products and medical devices** Registration fees for pharmaceutical products and medical devices and other related services are annexed to this Order.	**Article 3: Frais d'enregistrement des produits pharmaceutiques et des dispositifs médicaux** Les frais d'enregistrement des produits pharmaceutiques et des dispositifs médicaux et autres services y relatifs sont en annexe du présent arrêté.

Ibiciro bishyirwa mu byiciro hakurikijwe serivisi zitangwa. Ibiciro biri mu Madolari y'Abanyamerika bishobora kwishyurwa mu mafaranga y'u Rwanda hakurikijwe agaciro k'ivunjisha ka Banki Nkuru y'u Rwanda. **Ingingo ya 4: Ivanwaho ry'ingingo zinyuranyije n'iri teka** Ingingo zose z'amateka abanziriza iri kandi zinyuranyije na ryo zivanyweho. **Ingingo ya 5: Igihe iri teka ritangira gukurikizwa** Iri teka ritangira gukurikizwa mu minsi mirongo itatu (30) nyuma y'igihe ritangarijwe mu Igazeti ya Leta ya Repubulika y'u Rwanda.	Fees are classified by category of services provided. The rates set in American Dollars may be paid in Rwandan francs at the exchange rate of the National Bank of Rwanda. **Article 4: Repealing provision** All prior provisions contrary to this Order are repealed. **Article 5: Commencement** This Order comes into force thirty (30) days after its publication in the Official Gazette of the Republic of Rwanda.	Les frais sont classés par catégorie de services fournis. Les frais fixés en Dollars Américains peuvent être payés en franc rwandais au taux de change de la Banque Nationale du Rwanda. **Article 4: Disposition abrogatoire** Toutes les dispositions antérieures contraires au présent arrêté sont abrogées. **Article 5: Entrée en vigueur** Le présent arrêté entre en vigueur trente (30) jours après sa publication au Journal officiel de la République du Rwanda.
Kigali, ku wa **27/10/2017** (sé) **GATETE Claver** Minisitiri w'Imari n'Igenamigambi	Kigali, on **27/10/2017** (sé) **GATETE Claver** Minister of Finances and Economic Planning	Kigali, le **27/10/2017** (sé) **GATETE Claver** Ministre des Finances et de la Planification Economique
Bibonywe kugira ngo bishyirweho Ikirango cya Repubulika: (sé) **BUSINGYE Johnston** Minisitiri w'Ubutabera/Intumwa Nkuru ya Leta	**Seen and sealed with the Seal of the Republic:** (sé) **BUSINGYE Johnston** Minister of Justice/Attorney General	**Vu et scellé du Sceau de la République:** (sé) **BUSINGYE Johnston** Ministre de la Justice/Garde des Sceaux

UMUGEREKA W'ITEKA RYA MINISITIRI Nº 002/17/10/TC RYO KU WA 27/10/2017 RIGENA IGICIRO CYO KWANDIKA IMITI, IBIKORESHO BYO MU BUVUZI N'IZINDI SERIVISI BIJYANYE	**ANNEX TO MINISTERIAL ORDER Nº 002/17/10/TC OF 27/10/2017 DETERMINING FEES FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES**	**ANNEXE A L'ARRETE MINISTERIEL Nº 002/17/10/TC DU 27/10/2017 DETERMINANT LES FRAIS D'ENREGISTREMENT DES PRODUITS PHARMACEUTIQUES ET DES DISPOSITIFS MEDICAUX**

LIST OF PAYABLE SERVICES AND THEIR FEES

PART 1: FEES FOR REGISTRATION OF MEDICINES, RETENTION, NOTIFICATION AND AMENDMENT

REGISTRATION/RETENTION/NOTIFICATION/AMENDMENTS	Fees in US $ or in Rwandan Francs
1. Registration	
a) registration of imported pharmaceutical products and medical devices;	US $ 1,250
b) registration of locally manufactured pharmaceutical products or medical devices;	FRW 150.000
c) registration of imported pharmaceutical products and preparations which are repackaged or labeled in Rwanda;	US $ 300
d) registration of foreign herbal medicines or traditional products;	US $ 500
e) registration of locally manufactured herbal medicines or traditional products.	FRW 75,000
2. Annual fees for keeping pharmaceutical products, medical devices on register	
a) annual fees for keeping imported human pharmaceutical products, medical devices on the register;	US $ 250
b) annual fees for keeping foreign herbal medicines on the register;	US $ 250
c) annual fees for keeping locally manufactured pharmaceutical products or medical devices;	FRW 37,500
d) annual fees for keeping locally manufactured herbal medicines on the register.	FRW 37,500

3. Fees for application for registration of variation of pharmaceutical products and medical devices	
a) major variation	US$ 700
b) minor variation	US$ 400

PART 2: FEES PAID FOR THE INSPECTION AND LICENSURE OF PHARMACEUTICAL PRODUCTS AND MEDICALDEVICES (COSMETICS, OPTICAL, FOOD AND FOOD SUPPLEMENT ESTABLISHMENTS)

Item	Application for a license		Application for renewal of license	
	City of Kigali	All other Provinces	City of Kigali	All other Provinces
Inspection for suitability of premises and application for license	FRW 150,000	FRW 130,000	FRW 130,000	FRW 90,000

PART 3: FEES FOR RETAIL PHARMACIES

Item	Application for a license		Application for renewal of license	
	City of Kigali	Other Provinces	City of Kigali	Other Provinces
Inspection for suitability of premises and application for license	FRW 250,000	FRW 178,000	FRW 100,000	FRW 100,000

PART 4: FEES PAID BY WHOLESALE PHARMACIES

Item	Application for a license		Application for renewal of a license	
	City of Kigali	Other Provinces	City of Kigali	Other Provinces
Inspection for suitability of premises and application for license	FRW 300,000	FRW 228,000	FRW 178,000	FRW 148,000

PART 5: FEES FOR CHANGING REGISTERED PARTICULARS

Nature of change	Fees in FRW
1. Application for change of name, ownership or management of a pharmacy	50,000

2. Application for change of pharmacist or the in-charge person during the validity of the license	40,000
3. Application for change of a pharmacy technician	20,000

PART 6: FEES PAID FOR A PHARMACEUTICAL PRODUCTS OR MEDICAL DEVICES MANUFACTURING LICENCE

a) Fees paid for operating license and certificate of suitability of premises

License category	**Application for a license to operate**		**Application for renewal of a license**	
	Application for an operating license	**Inspection and Certificate of suitability of premises**	**Application for renewal of an operating license**	**Inspection and Certificate of suitability of premises**
1. license to manufacture external or oral liquids preparations	FRW 150,000	FRW 100,000	FRW 120,000	FRW 100,000
2. license to manufacture external and oral solid preparations	FRW 200,000	FRW 150,000	FRW 140,000	FRW 120,000
3. license to manufacture sterile preparations	FRW 200,000	FRW 150,000	FRW 140,000	FRW 120,000
4. license to manufacture sterile preparations, the preparations in points 1, 2 and other types of pharmaceutical forms	FRW 250,000	FRW 200,000	FRW 150,000	FRW 100,000
5. approval of primary packaging for the local manufacture	FRW 100,000	FRW 100,000	FRW 100,000	FRW 100,000
6. approval of secondary packaging for the local manufacture	FRW 50,000	FRW 50,000	FRW 50,000	FRW 50,000

b) Re-inspection fees for local manufacturer

1. Re- inspection of facilities manufacturing medicines for local manufacturers in point a) categories 1, 2 and 3	FRW 70,000
2. Re-inspection of facilities for manufacturing pharmaceutical products and medical devices for local manufacturers point a) categories 5 and 6	FRW 90,000

c) Application for amendment of conditions of manufacturing license

1. Application for amendment of conditions of manufacturing license with site inspection for local manufacturers point a) categories 1, 2 and 3	FRW 70,000
2. Application for amendment of conditions of a manufacturing license with site inspection for local manufacturers point a), categories 4 and 5	FRW 70,000
3. Application for amendment of conditions of a manufacturing license for all categories without inspection	FRW 50,000

PART 7: FEES PAID FOR IMPORTATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Item	**Fees**
1. Import verification and custom tax clearance	2% of import value
2. Verification fees for donations to non-profit making organisations and charitable NGOs	0.2% of the value of the donation
3. Verification for consignments for disasters and outbreaks	Exempted

PART 8: FEES PAID FOR INSPECTION FOR GOOD MANUFACTURING PRACTICES OF FOREIGN MANUFACTURING FACTORIES

Processes at the site	**Within East Africa**	**Within the rest of Africa**	**Outside Africa(Asia/Europe/America New Zealand/Australia)**
1. Inspection of manufacturing site with all processes at one site for 5 product lines	US$ 3,000	US$ 4,000	US$ 6,000
3. Fee for inspection of any additional production line	US$ 1000 per line	US$ 1000 per line	US$ 1000 per line

PART 9: FEES PAID FOR CLINICAL TRIALS OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Stage of clinical trial	**Fees in US $**
1. Application to undertake clinical trial for registered pharmaceutical products or medical devices	US $ 2500
2. Application to undertake clinical trial for unregistered pharmaceutical products or medical devices	US $ 4000
3. Application to amend clinical trial application	US $ 200