POLICY BOARD AGENDA

Health & OTC products division is a new division regulating the alternative medicines and health products. Fee for the enlistment of the manufacturer, importers and products have been defined by the Policy Board.

The activities for which the fee has not been defined OR approved are submitted as under along with the proposed fee structure and justifications;

S.No.	Activity	Proposed fee in PKR	Justification
1	Contract manufacturing per product	10000	Rule 3(g)
2	Transfer of Contract manufacturing per product	10000	Rule 3(g)
3	GMP/Free sale certificate	5000	Rule 9(1)
4	Certificate of pharmaceutical products(COPP) on WHO format	5000	Rule 9(1)
5	Change of Brand Name	2000	To avoid similarity/identical brand names.
6	Approval Labelling material all type	2000	For standardization of prescribing information or patient information leaflets or change in specifications
7	Approval of additional Principal for importer	10000	Enlistment of additional principal manufacturer
8	Transfer of Product from one importer to other importer or import to local manufacturing	2000	Change of importer or change from import to local manufacturing.
9	Transfer of Product from one manufacturer to another manufacturer	2000	Change of manufacturer
10	Change in formulation/excipients	2000	Change in formula
11	Miscellaneous application on plain paper not defined in the rules e.g. application for N.O.C for clearance from port.	2000	Application of any type not mentioned here

Enlistment of new Manufacturing facility (Rule 3) Procedure for Enlistment

S. No	Activity	Proposed fee in PKR
1	Approval site inspection	5000
2	Approval of Layout Plan	5000
3	Approval of additional (new) section	5000
4	Approval of qualified person	5000

Abdul Sattar Sohrani

Deputy Drugs Controller

Health & OTC Division

Distribution to

1. Director Legal DRAP.
2. Director Admin DRAP
3. Director Budget/Pricing DRAP
4. Director Evaluations & Registration DRAP.
5. Director Legal DRAP.
6. Director Medical Devices DRAP
7. Director Biological DRAP.
8. Director Pharmacy Services DRAP
9. Director M.I.S DRAP
10. Director Licensing DRAP.
11. Director QA & LABS DRAP
12. Director Health & OTC DRAP
13. PS to CEO DRAP