**CHECK LIST FOR APPLICATION FOR PRICE INCREASE UNDER HARDSHIP CATEGORY AS PARA 9 OF DRUG PRICING POLICY-2018.**

The following documents/information under the provisions of Drug Pricing Policy-2018 are required:

1. Original fee Challan as per DRAP notification.
2. Application on the prescribed form for respective category of drug available on the official website of DRAP.
3. Copy of invoice of all active and in-active raw materials and certified by concerned Assistant Director (Import & Export), DRAP attested in original in case of imported raw materials; for locally manufacturing drugs.
4. Copy of Import invoice certified from concerned Assistant Director (Import) of DRAP, for imported finished drug.
5. Copy of bills of entries / GD of all imported raw materials of respective invoice.
6. Copy of evidence in respect of payment of Freight / custom duty / income tax paid at import stage / insurance / bank charges/ clearing charges / civil aviation charges or other import levies, if any
7. Copy of invoice of purchase of unit cost of bottle, vial, ampoule, or Strip etc , unit cartons, foils, inserts, labels, outer cartons, etc to justify costs of your product’s packaging materials.
8. Copy of master formulation to justify per batch quantity consumed for each API and in-active materials.
9. Evidence/Justification for conversion factor for those raw materials which need %age activity calculation.
10. In case of Originator Brand, reference prices as per Drug Pricing Policy-2018. Verification of retail price provided directly to the Division of Costing & Pricing, Drug Regulatory Authority of Pakistan by the verifying agency.
11. Copy of registration letter along with renewal letter.
12. Copy of subsequent price increase letters (if any granted).
13. Copy of valid CRF certificate.
14. Copy of valid D.M.L.
15. Copy of valid GMP certificate.