Guidelines for Reimbursement Applications to the HSE

This document provides guidance on the HSE/CPU documentation requirements when making an application for the reimbursement of Pharmaceutical products under the GMS and Community Drug Scheme/ Hospital/ High-Tech Arrangement.

The efficiency of processing an application submitted to the HSE is dependent on the format and quality of the data submitted by companies.

Price Application forms and closing dates for receipt of applications are accessible from **www.hse.ie**

Link to Price Application Forms:
http://www.hse.ie/eng/about/Who/cpu/priceapplicationforms.html

The HSE must be in receipt of the application fee in full in order to progress the price application (see Point 4 below).

Completed applications to be sent via e mail to **CPU@hse.ie** and followed by one hard copy to:

Corporate Pharmaceutical Unit
Primary Care Reimbursement Service
Exit 5 M50
North Road
Finglas
Dublin 11
D11 XKF3

HSE Documentation Requirements

1	**Company Cover Letter**	Type of application: 1) General Medical Service and Community Drug Scheme 2) Hospital or 3) High Tech Arrangement
2	**Price Application Form**	Each strength of the pharmaceutical product being applied for must be accompanied **with a separate** and completed Price Application Form (links shown above and below) signed by the Manager/Director of the company.
3	**Application Fee Payment**	• Electronic Funds Transfer (EFT) directly to the PCRS. • Confirmation of payment (EFT Screenshot) to be sent to **CPU@hse.ie** naming product, i.e. App Fee "PRODUCT NAME". • **The HSE must be in receipt of relevant fee in order to progress application.**
4	**Application Fee Rates**	• New Chemical Entity **€5,000.00** • New Generic medicinal product **€500.00** • New Parallel Import Medicinal product **€500.00** • New strength or line extension of an existing reimbursed product **€500.00** • Name change to an existing reimbursed product **€100.00** *(**Note:** Application fees are based on an 'individual drug substance' i.e. having the same 5th level ATC, one fee will apply for all strengths and formulations in a submission at any one time point).* **For payment details please contact** CPU@hse.ie

5	**Copy of Product Licence**	Issued by either : Health Products Regulatory Authority(HPRA) or European Medicines Agency (EMA)
6	**Summary of the Products Characteristics (SPC)**	Part 1 and 2 of the SPC is required for all applications. In the case of Parallel Import/Distributed/or Dual Pack Registered Applications only Part 2 is required.
7	**Rapid Review Template**	Available from **www.ncpe.ie** in the case of an application for a New Chemical Entity. A copy of the completed Rapid Review Template should also be forwarded to **info@ncpe.ie** *Note: The NCPE acquires confirmation from the CPU to commence Rapid Reviews*
8	**Copy of the Product Packaging and Label Artwork**	Applicants must submit a copy of the product outer packaging and label artwork in colour via email and post.
9	**Patient Information Leaflet (PIL)**	A copy of the PIL to be submitted along with the artwork (above).
10	**Copy of DPR label**	Relates to Dual Pack Registered (DPR) product applications.

Applications will only be deemed complete by the HSE Corporate Pharmaceutical Unit when accompanied by all of the above documentation and fee requirements.

Link to Price Application Forms:
http://www.hse.ie/eng/about/Who/cpu/priceapplicationforms.html

The above guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

Document Check List

1. Price Application Form ☐
2. Licence (EU or HPRA) ☐
3. Summary of Products Characteristics ☐
4. Artwork (outer packaging) ☐
5. Patient Information Leaflet ☐
6. Application Fee ☐
7. Cover Letter ☐
8. Rapid Review (new chemical entities only) ☐