Reimbursement of P&R Applications

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/eng/about/who/cpu

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 are 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**	• CPU require proof that the application fee has been paid, i.e. the Bank Payment details as processed by your bank or a bank payment acknowledgement as proof of payment of application fee payments. • Confirmation of the Bank payment is to be sent to **CPU@hse.ie** naming product, i.e. App Fee "PRODUCT NAME". • If you require an Invoice, please contact CPU@hse.ie. • Please note the Invoice Term is strictly 30 Days from Date of Invoice • The HSE must be in receipt of the relevant fee in order to progress the application •
4	**Application Fee Rates**	• New Chemical Entity **€5,000.00** • New strength or line extension of an existing reimbursed product - **€500.00** • Biosimilar product **€500.00** • New Generic Medicinal product **€500.00** • New Parallel Import Medicinal 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)*
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**	The Rapid Review template is available from **www.ncpe.ie** in the case of an application for a New Chemical Entity. Please contact the NCPE at ncpe@stjames.ie for their secure share-file link to submit a copy of the completed Rapid Review dossier. A copy is required to be sent to CPU at CPU@hse.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.
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 application fee requirements.

You will find Price Application Forms at www.hse.ie/eng/about/who/cpu

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 (coloured outer packaging) ☐
5. Patient Information Leaflet ☐
6. Application Fee ☐
7. Cover Letter ☐
8. Rapid Review (new chemical entities only) ☐

Please submit documents to CPU@hse.ie.
For large documents please use the Cryptshare Web Interface – https://sfe.sspcrs.ie