Pricing and Reimbursement 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.

- In the absence of all mandatory documentation, the application process cannot commence. 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 https://healthservice.hse.ie/staff/information-healthcare-workers/pcrs/corporate-pharmaceutical-unit/.
- **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 email to CPU@hse.ie:**
- **Please note submission of hard copy documents is not required.**

HSE Documentation Requirements

1	**Company Cover Letter**	Type of application: 1) General Medical Service and Community Drug Schemes 2) Hospital or 3) High Tech Arrangement
2	**Price Application Form**	Each strength of the pharmaceutical product being applied for must be accompanied with **individual** and complete Price Application Form(s) (link shown above) **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 **in advance** of an application, please note invoices cannot be issued retrospectively. • 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	**Product Marketing Authorisation(MA)/Licence**	Issued by either : Health Products Regulatory Authority (HPRA) or European Medicines Agency (EMA).

6	**Summary of Products Characteristics (SPC)**	Summary of Products Characteristics (SPC) for each product is required for all applications.
7	**Rapid Review Template**	Where applicable the Rapid Review template is available from **www.ncpe.ie** 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 also required to be sent to CPU at CPU@hse.ie **Note: The NCPE requires confirmation from the CPU to commence Rapid Reviews.**
8	**Artwork (coloured outer packaging)**	Artwork (coloured outer packaging) with EU/PA number.
9	**Patient Information Leaflet (PIL)**	Patient Information Leaflet (PIL) for each product is required for all applications.
10	**Copy of DPR label**	Relates to Dual Pack Registered (DPR) product applications.

PCRS Bank Details for Application Fee Payment

Account Name:	HSE Primary Care Reimbursement Service (PCRS)		
Bank Name and Address	Danske Bank, 3 Harbourmaster Place, IFSC, Dublin 1.		
Account Number:	10007145	**Sort Code:**	95-15-99
IBAN:	IE82DABA95159910007145		
IBAN BIC:	DABAIE2D		

The HSE Corporate Pharmaceutical Unit (CPU) will only consider applications complete and valid when all of the above documentation and the required fee is submitted.

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. Marketing Authorisation/Licence (MA or HPRA) ☐
3. Summary of Products Characteristics (SPC) ☐
4. Artwork (coloured outer packaging) ☐
5. Patient Information Leaflet (PIL) ☐
6. Application Fee ☐
7. Cover Letter ☐
8. Rapid Review (where applicable) ☐

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

Please note that the HSE reserves the right to request further supporting documentation.