| Æ | APPLICATION FORM FOR ADMISSION<br>OF A MEDICINE TO THE<br>"HIGH-TECH" ARRANGEMENTS<br>OCTOBER 2021 |
|---|--|
|   |  |

| Ι |      | of |         |
|---|------|----|---------|
|   | Name |    | Company |

hereby apply to have the following product admitted to the scheme for the dispensing of High-Tech medicines.

| NEW PRODUCT (Name, form & strength) | PACK SIZE | PROPOSED DATE OF<br>INTRODUCTION |
|-------------------------------------|-----------|----------------------------------|
|                                     |           |                                  |
|                                     |           |                                  |
|                                     |           |                                  |
|                                     |           |                                  |
|                                     |           |                                  |
|                                     |           |                                  |

Signed:

MANAGING DIRECTOR / GENERAL MANAGER

Print Signature: \_\_\_\_\_

Please submit a copy of this Application Form to the Corporate Pharmaceutical Unit HSE Primary Care Reimbursement Service Exit 5 M50 North Road Dublin 11 D11 XKF3 at least <u>3 months</u> before the proposed date of introduction



## PRICE APPLICATION FORM AGREEMENT ON THE SUPPLY TERMS, CONDITIONS & PRICES OF MEDICINES SUPPLIED TO THE HEALTH SERVICES EXECUTIVE OCTOBER 2021

| 1. | Company Name:         |
|----|-----------------------|
| 2. | Company Address:      |
| 3. | Contact Name:         |
| 4. | Telephone No:         |
| 5. | Fax No:               |
| 6. | Email Address:        |
| 7. | Date of Notification: |

## Central Bank of Ireland Euro Exchange Rates on Date of Notification:

| € | = | : | Danish Krone (DKK)     |  |
|---|---|---|------------------------|--|
| € | = | : | Swedish Krona (SEK)    |  |
| € | = | : | Pound Sterling (STG £) |  |

| I hereby certify that the notified Irish Price(s) to Wholesaler, to take effect from | / | / 20 |  |
|--|---|------|--|
| comply with the above Agreement of October 2021.                                     |   |      |  |

Signed:

## MANAGING DIRECTOR / GENERAL MANAGER

Print Signature: \_\_\_\_\_

Completion and submission of this form to the HSE means acceptance by the applicant of all the terms and conditions as set out in IPHA/HSE Agreement which came into effect on the <u> $1^{st}$  October 2021</u>.

 THIS FORM ALONG WITH A COPY OF THE MARKETING AUTHORISATION SHOULD BE SENT TO:

 Corporate Pharmaceutical Unit, HSE Primary Care Reimbursement Service, Exit 5 M50, North Road, Finglas,

 Dublin 11. D11 XKF3. Tel No: 353-1-8915725 / Fax No: 353-1-8915757 / E-mail: CPU@hse.ie

| Type of Application  |   |                                  |         |   |   |
|--|---|----------------------------------|---------|---|---|
| GMS  |   | □ High Tech □                    |         | Hospital                                  |   |
| <b>Regulatory Pathway</b>  |   |                                  |         |   |   |
| New Chemical Entity (Small molecule)   Generic   Generic   Other: (please specify)   New Chemical Entity (Biologic)   Biosimilar |   |                                  |         |   |   |
| Product Name:<br>(Name, Form & Strength)   |   |                                  |         | ATC Code                                  |   |
|  |   |                                  |         |   |   |
| PACK SIZE  |   | PROPOSED DATE OF<br>INTRODUCTION |         | NEW IRISH PRICE TO<br>WHOLESALER €        |   |
|  |   |                                  |         |   |   |
| Current EU Prices to wholesa<br>Euro at the exchange rate on t   |   |                                  | ce stat | es, converted where appropriate, t        | 0 |
| Austria  |   | Belgium                          |         | Denmark - DKK                             |   |
| €  | Α | € B                              |         | €   | С |
| Finland  |   | France                           |         | Germany                                   |   |
| €  | D | € E                              |         | €   | F |
| Greece   |   | Italy                            |         | Luxembourg                                | 1 |
| €  | G | € Н                              |         | €   | I |
| Netherlands  |   | Portugal                         |         | Spain                                     |   |
| €  | J | €                                | К       | €   | L |
| Sweden - SEK   |   | UK - GBP                         |         | Average of<br>A+B+C+D+E+F+G+H+I+J+K+L+M+N |   |
| €  | М | €                                | N       | €   | 0 |

| 1. O is the average basket price of A to N                                     |
|--|
| 2. The New Irish Price to Wholesaler must be less than or equal to O           |
| 3. Price to Wholesaler = Price to Pharmacist less wholesale margin.            |
| 4. If product is not available in the list of 14 Basket Countries specify N/A. |
| 5. If pack size is not identical, use equivalent pack price and specify E.P.P. |
| 6. Provide Danish, Swedish and Sterling PTW and Euro conversions               |
|  |

The following documents must be enclosed with this Price Application Form (in softcopy and hardcopy format):

Company Cover Letter □ 2) Application Fee □
 Licence (EU and/or HPRA) □ 6) SPC □

3) Patient Information Leaflet 
4)

4) Product Artwork  $\Box$ 

 $\Box$  7) Rapid Review (if appropriate)  $\Box$