

**PHARMACEUTICAL INFORMATION PROFORMA**

Instruction notes:

1. This form is intended to be used for pharmaceutical only.
2. For other medical technologies, please use form PTK-Bor-14 (Medical Technologies Information Proforma).
3. Please fill in the form as complete as possible.

|  |  |  |  |
| --- | --- | --- | --- |
| **Company Detail** | | **Contact Person Detail** | |
| **Date:** |  | **Name:** |  |
| **Company name:** |  | **Position in company:** |  |
| **Address:** |  | **Email:** |  |
| **Telephone:** |  |

|  |  |  |
| --- | --- | --- |
| **Technology description** | | **Confidential Information**  **Tick (√) where applicable** |
| Technology/product name |  |  |
| Generic/ active pharmaceutical ingredient name |  |  |
| Patient group/indication including stage of disease and targeted patient-sub-groups (e.g.: advanced or metastatic disease in women with HER-2 positive breast cancer) |  |  |
| Place in the treatment pathway (e.g.: first or second line) |  |  |
| Brief description of the technology |  |  |
| Is it a new drug? |  |  |
| Intended use of technology (e.g.: prevention, treatment) |  |  |
| Route of administration (e.g.: oral or intravenous) |  |  |
| Treatment schedule &/or combination (e.g.: once a day, 28 days cycle) |  |  |
| Is the new technology planned to be additional to current therapy or used as a substitute? |  |  |
| Is the technology already available for a different patient group? |  |  |
| Who are the commercial developers &/or distributors? |  |  |
| **Stage of development, availability, licensing and launch plans** | | **Confidential Information**  **Tick (√) where applicable** |
| Does the technology have the marketing authorization in a different patient group/s |  |  |
| When do you anticipate submitting a local marketing authorization application? |  |  |
| Is your product a designated orphan drug in any countries? Please state |  |  |
| Is your product available, licensed or launched in other countries? If not, do you have any marketing plans in other countries? |  |  |
| **Current alternatives** | | **Confidential Information**  **Tick (√) where applicable** |
| What is the current treatment or management options for the patient group? |  |  |
| What advantages does the new technology have over current options? (e.g.: fewer adverse effects, shorter length of stay etc) |  |  |
| **Costs** | | **Confidential Information**  **Tick (√) where applicable** |
| What is the cost per treatment or per unit of administration &/or estimated cost over a specific time period. |  |  |
| Is the additional cost related to your product? (e.g.: days in hospital, monitoring tests) |  |  |
| What is the cost of current treatment or other management options for this patient? |  |  |
| **Clinical need, burden of disease** | | **Confidential Information**  **Tick (√) where applicable** |
| What is the burden of disease in Malaysia? (e.g.: morbidity, service use & quality of life) |  |  |
| Estimated potential uptake of the technology amongst the relevant patient group or healthcare professionals. |  |  |
| **Research Evidence** | | **Confidential Information**  **Tick (√) where applicable** |
| **Published clinical trials**  Please list references, attach copies of relevant publications and abstracts from publications or conferences that are not readily available on the internet. | | |
| * trial number/name |  |  |
| * location |  |  |
| * trial funders, sponsors |  |  |
| * study design |  |  |
| * inclusion and exclusion criteria |  |  |
| * treatment arms |  |  |
| * length of follow up |  |  |
| * primary and secondary endpoints |  |  |
| * numbers of patients in trial |  |  |
| * start date |  |  |
| * date of full patient accrual |  |  |
| * date of interim analysis |  |  |
| * date of final analysis or publication |  |  |
| * results |  |  |
| **Unpublished completed clinical trials**  Please give details of the following, &/or attach copies of protocols, press releases and abstracts | | |
| * trial number/name |  |  |
| * location |  |  |
| * trial funders, sponsors |  |  |
| * study design |  |  |
| * inclusion and exclusion criteria |  |  |
| * treatment arms |  |  |
| * length of follow up |  |  |
| * primary and secondary endpoints |  |  |
| * numbers of patients in trial |  |  |
| * start date |  |  |
| * date of full patient accrual |  |  |
| * date of interim analysis |  |  |
| * date of final analysis or publication |  |  |
| * results |  |  |
| **Ongoing clinical trials**  Please give details of the following attaching copies of protocols, press releases and abstracts. | | |
| * trial number/name |  |  |
| * location |  |  |
| * trial funders, sponsors |  |  |
| * study design |  |  |
| * inclusion and exclusion criteria |  |  |
| * treatment arms |  |  |
| * length of follow up |  |  |
| * primary and secondary endpoints |  |  |
| * planned patients number |  |  |
| * start date |  |  |
| * anticipated date of full patient accrual |  |  |
| * date of interim analysis |  |  |
| * expected date of final analysis or publication |  |  |
| * expected results |  |  |

**What is the potential or intended impact of the technology (speculative)?**

Please tick at the relevant boxes.

|  |  |  |
| --- | --- | --- |
| **Patients** | | |
| Reduced morbidity | Reduced mortality or increased survival | Improved quality of life for patients or carers |
| Other, please specify: | | |
| **Services** | | |
| Increased use e.g. length of stay, out-patient visits | Service re-organization required | Staff or training needs |
| Decreased use e.g. shorter length of stay, reduced referrals | Services – other, please specify: | |
| **Costs** | | |
| Increased unit cost compared to alternative | Increased – more patients coming for treatment | Increased – capital investment needed |
| New costs, please specify: | Savings, please specify: | Other, please specify: |