

**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*

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

|  |  |
| --- | --- |
| **Technology description** | **Confidential Information****Tick (√) where applicable** |
| Technology/product name |  |  |
| Generic name/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? |  |  |

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| --- | --- |
| **Stage of development, availability, and 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? |  |  |

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| --- | --- |
| **Current alternatives** | **Confidential Information****Tick (√) where applicable** |
| What are 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*) |  |  |

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| **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. |  |  |
| Are 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? |  |  |

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| **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. |  |  |

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| --- | --- |
| **Research Evidence** | **Confidential Information****Tick (√) where applicable** |
| Published clinical trials.*Please list references, and 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
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| * 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 |

Please email/fax this Proforma to:

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