**Annex 1: Target Product Profile (TPP) – Example for a new Pharma Product \***

**A target product profile (TPP) outlines the desired characteristics of a new drug or other medical intervention (e.g diagnostic tool). TPPs describe intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics. TPP can guide product research and development (R&D):**

* **In industry, in-house target product profiles (TPPs) are used as planning tools that guide development towards desired characteristics.**
* **In the regulatory context, TPPs are considered as tools to frame development in relation to submission of product dossiers**

**Below you can find a set of questions that will guide you when creating a TPP.  An example TPP can be found** [**here**](https://www.ninds.nih.gov/Funding/Apply-Funding/Application-Support-Library/CREATE-Bio-Example-Target-Product-Profile-TPP)**.**

1. Summary-Overview

|  |  |
| --- | --- |
| PROJECT NAME | (NAME) |
| 1. *Project Description* | *Summary description of the product* |
| 1. *Project Category* | *Is the project an additional indication for an existing drug or a new project?* |
| 1. *Strategic Fit and Value* | *How well does this drug/biologic fit with the core expertise and capabilities of the User/client?* |
| 1. *Value to Patients* | *What is the specific value of this drug/biologic to patients? Does it offer therapeutic, safety or ease of use advantages over existing or upcoming drugs/biologics* |
| 1. *User/Client’s competitive position* | *Does the User/Client have a competitive advantage?* |
| 1. *Company’s IP position* | *Brief summary of the IP position regarding this drug* |
| 1. *Rationale for success* | *Brief summary as to why the developing team believes that this product would be successful* |
| 1. *Factors for success* | *Brief statement as to the User/Client’s core competencies and market conditions that would drive a successful outcome* |
| 1. *Key risk factors* | *Brief statement identifying possible risks* |
| 1. *Consequences for not pursuing the project* | *What would happen if this project is not pursued?* |
| 1. *Possible alternatives to this project* | *Are there any alternatives to this project?* |

Note: The Parameters for evaluation may be changed or extended, depending on the nature of the project/product regarding e.g.:

* Product design and formulation
* Purity
* Contaminants
* Storage Conditions
* Shelf Life
* Any delivery system associated with the drug
* Projected dates of submissions, regulatory approval and launch
* Cost of goods, pricing, market size
* Target, optimistic, and minimal conditions may be set for these elements as well

\* Adapted from BayClinical R&D Services

1. Additional information

|  |  |
| --- | --- |
| PROJECT NAME | (NAME) |
| 1. *Non-clinical Properties* | *Define properties of the drug in non-clinical development, e.g.*   * *Pharmacokinetics* * *Toxicology*   *Efficacy in animal models* |
| 1. *Target Indication(s)* | *Define target indication(s). Evaluate each indication separately (TPPs)* |
| 1. *Competitive Experience*   *Other molecules on the marked against the same disease* | *Examine approved claims of competitors (efficacy and safety)* |
| 1. *Competitive Environment*   *Awareness of competition that may influence patenting of your drugs* | *Examine the competitive environment for compounds currently in development and likely to be approved in the near future* |
| 1. *Scenarios* | *Elaborate on minimal and optimal profiles* |

1. Efficacy Evaluation for the Primary Indication

|  |  |  |  |
| --- | --- | --- | --- |
|  | Minimum Scenario | Target Scenario | Optimistic Scenario |
| *Primary Clinical Outcome 1* | *Equal to Target* | *The primary endpoint of the pivotal study or studies* | *It is possible that secondary endpoints may result in additional claims* |
| *Primary Clinical Outcome 2* | *Equal to Target*  *(If essential for regulatory success)* | *Provide entries if more than one primary endpoint* | *Better than or equal to Target* |
| *Target Patient Population* | *Equal to or smaller than Target*  *(If successful in a more limited population)* | *Target*  *(Describe target population)* | *Larger than or equal to Target* |
| *Route of Administration* | *Equal to or worse than Target*  *(If the least desirable tested route is successful)* | *Target*  *(Describe target route of administration)* | *Better than or equal to Target*  *(if more than one route is tested)* |
| *Target Regimen* | *> Higher dosing and more frequent administration than target may still be acceptable* | *Target*  *(Describe target regimen)* | *> Lower doses and/or less frequent administration may provide advantages* |

1. Safety Evaluation for the Primary Indication

|  |  |  |  |
| --- | --- | --- | --- |
|  | Minimum Scenario | Target Scenario | Optimistic Scenario |
| *Non-clinical Safety* | *Equal to Target*  *(Less than Target would be acceptable if risk/benefit ratio is favourable)* | *Laboratory or other findings similar to those observed for the same class or similar classes of compounds that have been approved* |  |
| *Clinical Safety* | *Equal to Target*  *(Less than Target would be acceptable if risk/benefit ratio is favourable)* | *Target safety is usually equivalent to the known safety of the same class or similar classes of compounds that have been approved* | *Better than Target if fewer and less severe AE profile*  *Or else:*  *Equal to Target* |
| *Drug Interactions* | *Equal to Target*  *(Less than Target acceptability criteria should be explained)* | *Interactions similar to those observed for the same class or similar classes of compounds that have been approved* | *Better than Target if fewer and less severe interactions*  *Or else*  *Equal to Target* |
| *Precautions* | *Equal to Target*  *(Less than Target acceptability criteria should be explained)* | *Precautions similar to those observed for the same class or similar classes of compounds that have been approved* | *Better than Target if no or fewer precautions*  *Or else:*  *Equal to Target* |
| *Contraindications* | *Equal to Target*  *(Less than Target acceptability criteria should be explained)* | *Contraindications similar to those observed for the same class or similar classes of compounds that have been approved* | *Better than Target if no or fewer contraindications*  *Or else*  *Equal to Target* |