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.

I. Summary-Overview

PROJECT NAME	(NAME)
1. *Project Description*	*Summary description of the product*
2. *Project Category*	*Is the project an additional indication for an existing drug or a new project?*
3. *Strategic Fit and Value*	*How well does this drug/biologic fit with the core expertise and capabilities of the User/client?*
4. *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*
5. *User/Client's competitive position*	*Does the User/Client have a competitive advantage?*
6. *Company's IP position*	*Brief summary of the IP position regarding this drug*
7. *Rationale for success*	*Brief summary as to why the developing team believes that this product would be successful*
8. *Factors for success*	*Brief statement as to the User/Client's core competencies and market conditions that would drive a successful outcome*
9. *Key risk factors*	*Brief statement identifying possible risks*
10. *Consequences for not pursuing the project*	*What would happen if this project is not pursued?*
11. *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**

II. 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*
2. *Target Indication(s)*	*Define target indication(s). Evaluate each indication separately (TPPs)*
3. *Competitive Experience Other molecules on the marked against the same disease*	*Examine approved claims of competitors (efficacy and safety)*
4. *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*
5. *Scenarios*	*Elaborate on minimal and optimal profiles*

III. 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*

IV.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*