

**Client:** Abbott

**Project:** Capability Building

**Document:** Storyboard

**Module**: TPP

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| **Version History** | | | | | | |
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Table of Contents

[Launch 4](#_Toc77271296)

[Module Objectives 4](#_Toc77271297)

[Why is a TPP important? 5](#_Toc77271298)

[**Chapter 1: Key stakeholder priorities to keep in mind when developing a TPP 6**](#_Toc77271299)

[Key Stakeholders 6](#_Toc77271300)

[What is a TPP? 8](#_Toc77271301)

[What is Value? 9](#_Toc77271302)

[TPP Elements 11](#_Toc77271303)

[Stakeholders Priorities 12](#_Toc77271304)

[Knowledge check 1 14](#_Toc77271305)

[Knowledge check - 2 14](#_Toc77271306)

[Knowledge check - 3 15](#_Toc77271307)

[Knowledge check - 4 16](#_Toc77271308)

[Knowledge check - 5 17](#_Toc77271309)

[**Chapter 2: Deep dive into key elements of a ‘Best Practice’ TPP 17**](#_Toc77271310)

[Deep dive into TPP Elements 18](#_Toc77271311)

[TPP Element - Indication 18](#_Toc77271312)

[TPP Element – Clinical Benefits 19](#_Toc77271313)

[TPP Elements: Clinical Benefits – An Example 20](#_Toc77271314)

[TPP Element – Relative Clinical Benefits 21](#_Toc77271315)

[TPP Elements: Relative Clinical Benefits – An analogy 22](#_Toc77271316)

[TPP Elements: Relative Clinical Benefits – Product Value 23](#_Toc77271317)

[TPP Elements: Relative Clinical Benefits – An Example 24](#_Toc77271318)

[TPP Element – Target Patient Population 25](#_Toc77271319)

[TPP Elements: Target Patient Population – An Example 26](#_Toc77271320)

[TPP Elements: Target Patient Population - Best Practice TPP Vs. Poor TPP 27](#_Toc77271321)

[TPP Elements – Fulfillment Channel 29](#_Toc77271322)

[TPP Elements –Dosing and Administration 30](#_Toc77271323)

[TPP Elements – Packaging & Storage 31](#_Toc77271324)

[TPP Elements: Fulfillment, Dosing and Administration, Packaging & Storage – An Example 32](#_Toc77271325)

[TPP Elements: Fulfillment, Dosing and Administration, Packaging & Storage – Best Practice TPP Vs. Poor TPP 34](#_Toc77271326)

[TPP Element – Funding Archetype 34](#_Toc77271327)

[TPP Element: Funding Archetype – An Example 35](#_Toc77271328)

[Knowledge check - 6 36](#_Toc77271329)

[**Chapter 3: Commercial and Cost Implications When We Fail to Develop a Robust TPP 38**](#_Toc77271330)

[Case Study 38](#_Toc77271331)

[Why is a TPP important? 41](#_Toc77271332)

[Quiz Introduction 43](#_Toc77271333)

[Question 1 43](#_Toc77271334)

[Question 2 45](#_Toc77271335)

[Question 3 45](#_Toc77271336)

[Question 4 46](#_Toc77271337)

[Question 5 47](#_Toc77271338)

[Question 6 47](#_Toc77271339)

[Question 7 48](#_Toc77271340)

[Question 8 49](#_Toc77271341)

[Glossary 51](#_Toc77271342)

[**Thank You** 51](#_Toc77271343)

|  |  |  |  |  |  |
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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Launch | | **Page Number** | | **00** |
| **Template Type** | Splash Animation | | **Duration** | | **5 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| Welcome to the module, “Best Practices in Target Product Profile Development – A Market Access Perspective”.  Select Start to begin. | | **Best Practices in Target Product Profile Development – A Market Access Perspective**  **Duration: 45** minutes  *Select* ***START*** *to begin.* | | * Play a short splash animation and display the OST overlaying the background image. * Enable the START button when the VO completes.   medical stethoscope , syringe and vaccine drug and pills, health care costs or medical insurance ,medical purchasing concept with graph  ID: 541312222 | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Module Objectives | | **Page Number** | | **01** |
| **Template Type** | Text And Image animation | | **Duration** | | **45 seconds** |
| **Screen Visuals: NA** | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| By the end of this module, you will have learned about: | | **Elements of a ‘Best Practice’ TPP**  By the end of this module, you will have learned about: | | * Present the OST in sync with the VO. | |
| Key stakeholder priorities to keep in mind when developing a target product profile – which we will refer to from now on as a “TPP”, | | * Key stakeholder priorities to keep in mind when developing a target product profile, TPP | | * Display OST along with this image:   Medication Profession Occupation Team Smiling Concept  Stock ID: 374324860 | |
| Deep dive into key elements of a ‘Best Practice’ TPP, and | | * Key elements of a ‘Best Practice’ TPP | | * Display OST along with this image:   Benchmarking and market leader concept. Manager (businessman, coach, leadership) draw graph with three lines, one of them represent the best company in competition.  Stock ID: 389578876 | |
| What the commercial and cost implications are when we fail to do develop a robust TPP. | | * Commercial and cost implications when we fail to develop a robust TPP | | * Display OST along with this image:   Depressed businessman lost his business. Destroyed businessman. Concept of business loss, bankruptcy and crisis.  Stock ID: 1694602114 | |
| **-** | | *Select* ***NEXT*** *to continue.* | | * Display the user instruction and enable the next button when the VO completes | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Why is a TPP important? | | **Page Number** | | **02** |
| **Template Type** | Text and image Animation | | **Duration** | | **30 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| Why is it important to have a robust target product profile, TPP? The TPP is the foundation for | | A robust TPP is important because it helps in defining the: | | * Play VO * Use below image in the background:     Please refer the slide 6 from ppt given below for editable image. | |
| defining the medical marketing communications, | | Medical / Marketing communications | | Show OST along with this icon:  Stock ID: 613339448 | |
| it directly feeds into the forecast opportunity, | | Forecast & investment decisions | | Show OST along with this icon:  Stock ID: 1199245750 | |
| and it helps us define our go-to-market strategy. | | Go-to-market strategy | | Show OST along with this icon:  Stock ID: 622923110 | |
| In other words, the TPP is the foundation for all commercial and investment decisions for the product. | | **TPP is the foundation for all commercial and investment decisions for the product** | | Display the OST pointing to the base of the house. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Chapter 1: Key stakeholder priorities to keep in mind when developing a TPP | | **Page Number** | | **03** |
| **Template Type** | Text and image Animation | | **Duration** | | **5 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| So, let’s start with Chapter – 1: Key stakeholder priorities to keep in mind when developing a commercially oriented TPP | | Chapter – 1: Key stakeholder priorities to keep in mind when developing a TPP | | * This is a topic separator page. * Play VO * Use below image along with the chapter name:   Medication Profession Occupation Team Smiling Concept   * Stock ID: 374324860 | |
| **-** | | *Select* ***NEXT*** *to continue.* | | * Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Key Stakeholders | | **Page Number** | | **04** |
| **Template Type** | Click to reveal interactivity | | **Duration** | | **120 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| In other Propel7+ Market Access modules, you learned there are many stakeholders to be aware of and take into consideration when it comes to the operational aspects of market access, pricing and reimbursement.  Have a look at the key stakeholders that we need to consider. | | Here are the stakeholders to consider when dealing with operational aspects of:   * Market Access * Pricing * Reimbursement | | * Present the tabs in the below format: | |
| Select each tab to learn more. | | *Select each* ***tab*** *to learn more.* | | * Display the UI. | |
| - | | **Tab 1 - Regulatory Bodies** | |  | |
| Regulatory bodies. Regulatory bodies, i.e., FDA, EMA, NMPA, MFDS or SFDA or government health authorities. They set standards for safety and efficacy and appropriate risk benefit trade-offs. | | * Regulatory approval (e.g., FDA, EMA, NMPA, MFDS, SFDA) * Government Health Authorities * Ministers of Health or Finance | | Show OST along with this icon:    Stock ID: 560285125 | |
| - | | **Tab 2 - HTA & Price Setting Bodies** | |  | |
| Health Technology Assessment and price setting bodies. HTA and price setting bodies like AIFA in Italy, HIRA in South Korea or NHIA in Taiwan. | | Price setting bodies:   * AIFA (Italy) * HIRA (South Korea) * NHIA (Taiwan) * G-BA (Germany) | | Show OST along with this icon:    Stock ID: 1195681351 | |
| Such bodies do in-depth, objective analyses of new products, generally comparing the product’s clinical, safety, humanistic, financial, and public health benefits vs. a rationally selected comparator. These bodies generally publish public reports and provide their detailed assessments to insurers, reimbursement bodies, and other “at risk” payers in a health care system. | | These bodies:   * Do in-depth, objective analyses of new products. * Compare the product’s clinical safety, humanistic, financial, and public health benefits vs. a rationally selected comparator. * Publish public reports. * Provide detailed assessments to insurers, reimbursement bodies, and other “at risk” payers. | | Fade in OST in sync with the VO. | |
| - | | **Tab 3 – Insurers / “At Risk” Payers** | |  | |
| Insurers or entities that buy products with the intent of re-selling onto patients determine the clinical value of new products, or in other words, value for money. | | Insurers / “At Risk Payers”:   * Determine the clinical value of new products | | Show OST along with this icon:    Stock ID: 367728188 | |
| When no incremental value vs. alternatives is demonstrated, this stakeholder may be able to erect financial or other barriers that result in manufacturers having a more difficult time getting their products to the consumer population. | | * May be able to erect financial or other barriers, when no incremental value vs. alternatives is demonstrated. | | Fade in OST as the second bullet. | |
| This happens as a result of granting or not granting access to something called a formulary, which is essentially a list of drugs that may be subsidized for patients or procured by a hospital or pharmacy, which can ultimately effect whether a product is available on pharmacy shelf for dispensing to the patient. Depending on the market, without buy-in from this stakeholder group, a new product introduction may have a hard time achieving optimal success. | | Depending on the market, without buy-in from this stakeholder group, a new product introduction may have a hard time achieving optimal success. | | Fade in OST at the end of the bullets. | |
| - | | **Tab 4 –Providers / Entities** | |  | |
| Providers or entities, i.e., hospitals and out-patient practices, etc., are the next important stakeholder group. | | The Provider or Entities have following stakeholders:   * P&T committee * Pharmacy directors * Practice managers * Therapeutic department heads * Chief of Nursing | | Show OST along with this icon:    Stock ID: 1397201111 | |
| As providers of healthcare, they are subject to meeting certain KPIs and to provide health care as efficiently as possible. This stakeholder group evaluates products typically in a rational way and by committee, as missing a KPI can have dire financial and human resource consequences for the entity. | | Function of the stakeholders include:   * Meeting certain KPIs and providing health care as efficiently as possible. * Evaluating products in a rational way and by committee. | | Fade in OST in sync with the VO. | |
| - | | **Tab 5 – Health Care Practitioners** | |  | |
| Lastly, we have healthcare practitioners or HCPs. HCPs are the individual doctors, nurses, and pharmacists ultimately delivering care and administering or dispensing medications to patients. | | HCPs include:   * Key opinion leaders (*academic affiliation*) * Practicing HCPs   **Function of the HCPs are the following:**   * Delivering care and administering or dispensing medications to patients | | Show OST along with this icon:    Stock ID: 697523377 | |
| They are often limited to prescribing budgets and are tracked closely to ensure rational use of medicines as defined by local authorities. | | HCPs are:   * Limited to prescribing budgets. * Tracked closely to ensure rational use of medicines as defined by local authorities. | | Fade in OST in sync with the VO. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | What is a TPP? | | **Page Number** | | **05** |
| **Template Type** | Text and image animation | | **Duration** | | **105 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| 1. To start, let us review what a TPP or target product profile is. 2. The WHO defines a TPP as a description of a product that “outlines the desired 'profile' or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics”. 3. In other words, it is a summary of a pharmaceutical or biopharmaceutical product. | | “A target product profile (TPP) outlines the desired 'profile' or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics.” | | * Play the VO1. * Show the below image at one side and display OST in sync with the VO2.   Logo, company name  Description automatically generated  Stock ID: 1658523400   * Play the VO3. | |
| 1. We use TPPs as a foundation for the development of a business case i.e. 2. to describe the value of the product to the healthcare system and customers the product should help, and therefore the value to our organization. 3. As such, it is critical that a TPP contains the key elements which help us gain insights to all the parameters that make up the commercial potential of the product. 4. For example, how does this product stack up against competition i.e. current standard of care at the expected launch date? 5. What is the size of the population in which this product most likely will be used? 6. What level of access and reimbursement will this product achieve? | | TPPs is used as a foundation for the development of a business case.    TPP:   * Describes the value of the product to the customers * Contains the key elements which helps gain insights to all the parameters   Some of the parameters are:   * How does this product stack up against competition? * What is the size of the population in which this product most likely will be used? * What level of access and reimbursement will this product achieve? | | * Fade out the elements on the previous screen. * Play VO 4 with the below image on the screen: * Use below image in the background:      * As the VO5 plays, fade away the previous elements and show the below image along with OST “TPP… parameters”:   Stock ID: 1712679982   * Then, move the OST of VO5 to one side of the screen. * The product image and the OST, “Some of...” will come on the other side of the screen in sync with VO6. * As VO 7, 8 and 9 plays, show arrows originating from the bottle image and pointing to each OST bullet consecutively. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | What is Value? | | **Page Number** | | **06** |
| **Template Type** | Text and image Animation | | **Duration** | | **105 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| A good TPP will describe a future product in terms that allow key stakeholders to determine the value of the product and ultimately how much it should be worth. | | A good TPP will describe a future product in terms that:   * Allow key stakeholder to determine its value and price. | | On one side of the screen, show the OST and its bullet in sync with VO. | |
| In most markets, these stakeholders eventually influence and / or determine a product’s price, the population that will have covered or financially subsidized access to the product, and how much – if anything – of the product’s costs will be covered for the patient. | | In most markets, stakeholders eventually determine:   * The product’s price * The population that will have covered access to the product – if at all * The product’s cost to patients | | As VO begins, on the other side display the below icon:  Stock ID: 596464301 | |
| A good TPP should describe product benefits – be they public health, financial, humanistic or clinical benefits – all in terms relative to appropriate alternatives. | | Describes product benefits in terms relative to appropriate alternatives in sectors like:   * Public Health * Finance * Humanism * Clinical | | * Fade out the above text on stakeholders. * Fade in OST as second bullet for “A good TPP describes” | |
| Take for example the definitions of value in Germany and France: value is described in terms of “additional benefit over a comparator” or “comparative efficacy and safety”. | | **Definition for Value**  **G-BA (Germany)**  “Additional benefit claimed over the appropriate comparator”  **TC (France)**  “Comparative efficacy and safety data with regards to available treatments (reference medicinal product or better treatment modalities” | | * Retain the above text on one side. * On the other side, as the VO begins, show the below image with Germany and France highlighted.   world map   * Display the above in sync with VO 1 and the corresponding OST. * Germany and France will display as the VO2 is played. * Then, by the end of VO2 fade out the OST and retain the world map with Germany and France highlighted. | |
| You might be asking yourself why we mention two European HTA bodies here.  Well, the simple answer is, most EPD markets refer formally or informally to the outcomes of HTA bodies in EU markets.  Therefore, the value claims of our TPPs should be evidenced as though we were submitting our dossier for price setting and coverage in an EU market.  In the next few sections, we will learn more about how our stakeholder think about value and what this means for us when we develop a TPP. | | Why did we mention two European HTA bodies?   * Most EPD markets refer formally or informally to the outcomes of HTA bodies. * The value claims of TPPs must be evidenced as if submitting the dossier for price setting and coverage. | | * Screen will show the world image and the OST at one side of the screen as it loads. * Display OST4 in sync with VO3. * Show OST bullets in sync with VO 4 and 5 respectively. * Play VO6. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | TPP Elements | | **Page Number** | | **07** |
| **Template Type** | Click to Reveal interactivity | | **Duration** | | **165 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| The contents of a TPP can vary depending on the type of product or therapeutic area. However, there are eight key elements which should always be included in a commercially oriented TPP.  1. **Indication**. It determines the possible patient population and is defined as the indicated patient population as per the regulatory label.  2. **Clinical benefits**. These should be described in terms of efficacy on patient relevant endpoints as well as safety in the indicated population. Clinical benefits when supported with evidence serves as the basis for our value claims.  3. **Relative clinical benefits**. It differentiates our value claims vs. competitors, and, if we are targeting sub-populations, shows how benefit differs or is the same across sub-populations.  4. **Target patient population**. It defines our strategic positioning in the treatment algorithm and describes the sub-populations within our label that we wish to target from a commercial standpoint.  5. **Fulfillment channel**. This describes something referred to as “the site of care”, or in more simple terms, where a product dispensing transaction occurs, i.e., in a hospital, in an out-patient practice or in a retail pharmacy.  6. **Dosing and administration**. This shows the amount of the drug that is needed to elicit a therapeutic response as well as the frequency with which that dose should be taken to maintain the response. This section should also describe any preparation steps that are needed to prepare the drug for consumption, for example, reconstitution for injections, or the insertion of a capsule into an inhaler device if the product is meant to be inhaled; and  7. **Packaging and Storage**. This outlines practical considerations from a provider and HCP standpoint but also from a “payer” perspective in that it will describe how much of the drug is in a unit, which, when coupled with dosing and administration, helps stakeholders understand such things as wastage; Finally,  8. **Funding archetype**. Defines what segment or segments we are targeting, and what the expected access and reimbursement status should be. | | The contents of a TPP vary depending on the type of product or therapeutic area. Here are the eight key elements of TPP.  *Select each* ***tab*** *to learn more.*  **TPP Elements**  Tab 1: Indication   * Determines the possible patient population. * Is defined as the indicated patient population as per the regulatory label.   Tab 2: Clinical Benefits   * Is described in terms of efficacy on patient relevant endpoints as well as safety in the indicated population. * Serves as the basis for value claims, when supported with evidence.   Tab 3: Relative Clinical Benefits   * Differentiates our value claims vs. competitors. * Shows how benefit differs or is the same across sub-populations.   Tab 4: Target Patient Population   * Defines the strategic positioning in the treatment algorithm. * Describes the targeted sub-populations within the label.   Tab 5: Fulfillment Channel   * Describes “the site of care”   Tab 6: Dosing & Administration   * Shows the amount of the drug that is needed to elicit a therapeutic response and the frequency of the drug needed to maintain the response. * Describes preparation steps that are needed to prepare the drug for consumption. * Explains reconstitution for injections. * Describes the insertion of a capsule into an inhaler device if the product is meant to be inhaled.   Tab 7: Packaging & Storage   * Outlines practical considerations from a provider and HCP standpoint and the “payer” perspective. * Describes how much of the drug is in a unit, which, when coupled with dosing and administration, helps stakeholders understand such things as wastage.   Tab 8: Funding Archetype   * Defines what segment or segments are targeted. * Defines the expected access and reimbursement status | | * Display the lead OST in sync with the lead VO. * Display the OST 1 to 8 in the below format:   Vector circle element for infographic. Template for cycle diagram, graph, presentation and round chart. Business concept with 8 options, parts, steps or processes. Abstract background.  Stock ID: 389968696   * Please reuse the icons suggested for each element in Chapter 3 of this storyboard. * As each tab is selected, present the OST in sync with the corresponding VO. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Stakeholders Priorities | | | **Page Number** | **08** |
| **Template Type** | Click to reveal | | | **Duration** | **120 seconds** |
| **Screen Visuals: NA** | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| 1. Each of our key stakeholders focuses on different elements of the TPP. 2. Regulatory bodies tend to focus on the labelled indication and the clinical evidence of the product to determine that it is safe and efficacious within this indication. 3. HTA and price setting bodies and insurers use the label indication to track appropriate use of a product in a defined sub-set of the population where benefit is deemed to be the greatest. 4. Insurers also focus on the fulfillment channel / site of care, meaning they want to understand if the product should be administered by an HCP, for example, an intramuscular injection, or if a patient can self-administer, for example, taking a drug orally without the presences of an HCP. The reason for this is that different fulfillment channels can impact which budget the cost of the product will be paid from, assuming the cost of the drug is partially or fully covered for the patient. 5. Providers and HCPs are both focused on clinical benefits vs. standard of care, but also dosing, administration, packaging and storage i.e., what is the wastage per vial, does it require cold storage etc.? 6. Providers and HCPs also consider the funding of the product i.e., to what extent is the product reimbursed and does the patient need to fund parts of the cost itself? Insurers too focus on the funding route, as it determines what share of the product cost they will cover. | | Each of our key stakeholders focuses on different elements of the TPP. | | * Display OST1 (red highlights) in sync with VO1 as per below image.      * Allow the learner to select below icons as per below VO and reveal contents of OST:  |  |  |  | | --- | --- | --- | | **Icon** | **VO** | **OST highlights** | | ID: 560285125 | VO2 | Yellow | | ID: 1195681351 | VO3 | Green | | ID: 367728188 | VO4 | Purple | | ID: 1397201111 | VO5 | Black | | ID: 697523377 | VO6 | Maroon | | |
| **-** | | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Knowledge check 1 | | **Page Number** | | **09** |
| **Template Type** | Text and image Animation | | **Duration** | | **30 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Question**  Identify if the following statement is True or False.  Regulatory bodies assess the economic value of products.  *Select the correct option and then select* ***Submit****.*   * True * False | | * Use this image for KCs:   question mark hanging concept,  3D illustration 1340443982   * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
|  | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite! | | * Display a popup when the learner selects an option. | |
|  | | **Feedback Pop-up**  They assess risk – benefit profile.  In many markets there is a strong division between regulatory bodies that grant marketing authorization and other bodies that assess the value of a product and determine if the product should be reimbursed or how much the product can cost the payer – whether that payer is an individual, an insurance company or a national coverage body. Simply because a product can be approved from a regulatory perspective does not mean it will be commercially viable. | | Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Knowledge check - 2 | | **Page Number** | | **10** |
| **Template Type** | Text and image Animation | | **Duration** | | **30 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Question**  Which of these is not an HTA body (more than one answer may be possible)?  *Select the correct option and then select* ***Submit****.*   * AIFA * FIFA * HIRA * TLV | | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
|  | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite! | | * Display a popup when the learner selects an option. | |
|  | | **Feedback Pop-up**  Answer: FIFA - FIFA is an international federation of football clubs. It has nothing to do with Health Technology assessment. If you selected “TLV”, try Googling “TLV HTA” – you will see that it is a body from Sweden. | | Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Knowledge check - 3 | | **Page Number** | | **11** |
| **Template Type** | Text and image Animation | | **Duration** | | **30 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Question**  Identify if the following statement is True or False.  Not enough information – Insurers and “At Risk Payers” define value in the context of alternatives.  *Select the correct option and then select* ***Submit****.*   * True * False | | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
|  | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite! | | * Display a popup when the learner selects an option. | |
|  | | **Feedback Pop-up:**  True – it would be irrational to simply pay $100 for a product without considering whether the alternatives that cost $5 can accomplish similar outcomes. Comparisons and assessment of value for money always occur – even in instances when there are literally no therapeutic options remaining. These stakeholders must balance granting the population access to healthcare against the real financial constraints that they operate within. | | Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Knowledge check - 4 | | **Page Number** | | **12** |
| **Template Type** | Text and image Animation | | **Duration** | | **30 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Question**  Identify if the following statement is True or False.  It is very common at a hospital (i.e. provider or entity) for the head of a department to decide on his/her own to add a product to the hospital formulary, making it available for prescription and purchase.  *Select the correct option and then select* ***Submit****.*   * True * False | | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
|  | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite! | | * Display a popup when the learner selects an option.   Show feedback as OST on the pop-up. | |
|  | | **Feedback Pop-up:** Because providers / entities such as a hospital are frequently managed like a business, decisions regarding what to add to formulary are done by committee. Most hospitals have health- and/or financial efficiency-related KPIs. If these KPIs are missed, there can be severe financial penalties imposed on the operating entity. | | Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Knowledge check - 5 | | **Page Number** | | **13** |
| **Template Type** | Text and image Animation | | **Duration** | | **30 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Question**  **True or False**  Almost all health care practitioners have no constraints on what they can prescribe.  *Select the correct option and then select* ***Submit****.*   * False * True | | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
|  | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite! | | * Display a popup when the learner selects an option. | |
|  | | **Feedback Pop – up**  In many markets, prescribing physicians’ prescribing behavior is monitored closely. Physicians can be constrained by an individual prescribing budget, a quote of some sort – for example, the percentage of all prescriptions written for a pure generic vs. a brand, or even whether use of a medication is medically necessary – something called rational use f medicine. If a coverage body performs a retrospective analysis of medicines prescribed and identifies that use of a medicine was not medically necessary, the individual HCP could face repercussions. | | Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Chapter 2: Deep dive into key elements of a ‘Best Practice’ TPP | | **Page Number** | | **14** |
| **Template Type** | Text and image Animation | | **Duration** | | **5 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| Chapter – 2: Deep-dive into key elements of a ‘Best Practice’ TPP | | Chapter – 2: Deep-dive into key elements of a ‘Best Practice’ TPP | | * This is a topic separator page. * Play VO * Use below icon along with the chapter name:   Benchmarking and market leader concept. Manager (businessman, coach, leadership) draw graph with three lines, one of them represent the best company in competition.   * Stock ID: 389578876 | |
| **-** | | *Select* ***NEXT*** *to continue.* | | * Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Deep dive into TPP Elements | | **Page Number** | | **15** |
| **Template Type** | Static | | **Duration** | | **10 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| Now, let’s deep dive into each of the key elements of a TPP and show a few examples of what a ‘good’ vs. ‘poor’ TPP looks like. | | - | | * Play VO and replicate the screen used on Page 07. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Element - Indication | | **Page Number** | **16** |
| **Template Type** | Click to reveal | | **Duration** | **45 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
|  | | The first element of TPP is Indication.  Why  What | * Use this image if space permits:   Diversity People Group Team Union Concept 393603379   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the UI and OST1 along with below icon as the screen loads.   Stock ID: 167168900 | |
| Select each tab to learn more. | | *Select each* ***tab*** *to learn more.* | Display UI.  Show 2 tabs below: | |
| - | | **Tab 1 - Why** |  | |
| The indication is critical to include as it determines the potential target population for our product. | | Determines the potential target population for our product | On clicking tab 1 > display the OST and play the VO. | |
| **-** | | **Tab 2 - What** |  | |
| The indication should state the regulatory labelled indication as it will likely be formulated by regulatory approval bodies e.g. the FDA or EMA. | | The regulatory label as formulated by the regulatory approval body e.g. EMA, FDA etc. | On clicking tab 2 > display the OST and play the VO. | |
| The indication usually reads “[Product X] is indicated for the treatment of patients with [disease] who have / have not [any patient criteria that has to be fulfilled]. | | Indication usually reads –  *[Product X] is indicated for the treatment of patients with [disease] who have / have not [any patient criteria that has to be fulfilled]* | Display OST below the above text. | |
| Having a clear position on the target indication will help with developing a forecast population potential. | | A clear target position will help with developing a forecast population potential. | Display OST below the above text. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Element – Clinical Benefits | | **Page Number** | **17** |
| **Template Type** | Click to reveal | | **Duration** | **75 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| The next critical element of any TPP are the clinical benefits of the product. | | **Clinical Benefits** | * Use this image if space permits:   Major choice. Shot of a beautiful cheerful female customer choosing between two products at the beauty store female holding two bottles consumer shopper buyer choosing choice industry concept 553522045   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the lead OST1 and UI along with below icon as the screen loads.   Stock ID: 1229634457 | |
| Select each icon to learn more. | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | **Tab 1 - Why** | - | |
| Clinical benefit is the foundation of a product’s utility in treatment and serves as the basis for our value claims. | | Validates our value claims with robust data | On clicking tab 1 > display the OST and play the VO. | |
| Understanding our clinical benefit is also the foundation for determining product differentiation and positioning vs. competition. | | Supports product differentiation | Display OST below the above text. | |
| Validating our claims with data supports our overall marketing strategy and increases the healthcare system’s confidence in the product. | | Increases healthcare system’s confidence in the product | Display OST below the above text. | |
| **-** | | **Tab 2 - What** | - | |
| The product’s clinical benefits should be represented with clinical data from the clinical trial program, registration trial or other credible source such as real-world evidence data or literature review. | | Represents clinical data from clinical trial programs, registration trials or other credible sources. | * On clicking tab 2 > display the OST and play the VO. | |
| It should include both details on the clinical efficacy and safety of the product and state statistical significance of the data, i.e., p-value and HR, when relevant and possible. Statistically significant data alone may not be enough; magnitude of effect relative to alternatives is especially important if the product is subject to an HTA assessment. | | Includes details on clinical efficacy and safety of the product and statistical significance of the data. | Display OST below the above text. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Clinical Benefits – An Example | | **Page Number** | **18** |
| **Template Type** | Click to reveal | | **Duration** | **120 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| Let’s review an example of a best practice TPP clinical benefits vs. what a poor TPP looks like. | | Example of a best practice TPP vs. a poor TPP  *Select each* ***image*** *to learn more.* | * Display the lead OST in sync with the VO and display both images on the screen with titles as Best | |
| A best practice TPP includes a summary of the product efficacy and safety profile including data statistical significance. It is also important to note that today, most HTA bodies do not accept placebo as a control arm in the clinical trial. HTA bodies are increasingly expecting to see a product up against the current standard of care in a head-to-head trial to grant the new product access, reimbursement and a price premium. Also, when we include a minimally acceptable threshold for clinical benefit in our TPPs, it may help us determine early if we should cease further development if it is clear from early data that the threshold cannot be met. | | Image 1 title: **Best Practice TPP**  Control arm should ideally be the current standard of care. | * Practice TPP and Sub-optimal TPP, as the screen loads. * For title 1, display the below image without the highlights and callout:   A picture containing table  Description automatically generated | |
| Let’s look at an example of a sub-optimal TPP. It does not include clinical efficacy and safety data. Without the clinical benefits of the product, we cannot support our value claims with data. The clinical profile of the product is also crucial when the product is reviewed by our key stakeholders, including regulatory and HTA bodies, insurers, providers and HCPs. For example, providing the clinical data of the product in the marketing to HCPs helps substantiate our messaging and can be the tipping factor when an HCP decides to switch from one product to another or complement current treatment by adding something new that may increase the cost of treatment to the system, the patient or both. | | Image 2 title: **Sub-optimal TPP**  A sub-optimal TPP does not include clinical efficacy and safety data of the product. | * For title 2, display the below. * image without the strikeout and callout:   Graphical user interface  Description automatically generated with medium confidence   * Then, display the UI. * Once the user selects title 1 image, play the VO for **Best Practice TPP** and show the dotted highlights and OST in a callout. * Once the user selects title 2 image, play the VO for **Sub-optimal TPP** and show the OST in a callout. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Element – Relative Clinical Benefits | | **Page Number** | **19** |
| **Template Type** | Click to reveal | | **Duration** | **45 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| Besides the clinical benefits of our product, the TPP should ideally also include relative clinical benefits of our product vs. standard of care. | | **Relative Clinical Benefits** | * Use this image if space permits:   Pharmacy and healthcare. Close up of young female hands holding opened pill bottle and two soft-shelled capsules taking medicine for flu, influenza, painkiller, vitamin complex, oral contraceptives 1849643242   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the lead OST along with below icon as the screen loads.   ID: 1195681351 | |
| Select each tab to learn more. | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | **Tab 1 - Why** | - | |
| Understanding our clinical benefits vs the standard of care is critical for determining product value and placement of the product in the treatment pathway. | | Supports understanding of product placement in treatment pathway | On clicking tab 1 > display the OST and play the VO. | |
| Serves as a basis for assessing the product value | Display OST below the above text. | |
| **-** | | **Tab 2 - What** | - | |
| Standard of care products should be represented with clinical data including efficacy and safety i.e. similar to what we show for our product. | | Represents standard of care products with clinical data including efficacy and safety | On clicking tab 2 > display the OST and play the VO. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Relative Clinical Benefits – An analogy | | **Page Number** | **20** |
| **Template Type** | Text and image animation. | | **Duration** | **60 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| 1. Relative clinical benefits can be understood as oranges vs orange juice. 2. Both products contain the same thing – orange juice. 3. However, calories per mg is higher in the juice vs the actual oranges, the formulation (whole fruit vs juice) and administration (eating vs. drinking), storage needs (basic storage needs for whole oranges, refrigerated storage for orange juice) and the experience when consuming them are very different. 4. This analogy is also true for pharma or biopharmaceutical products that are seemingly similar i.e., being indicated for the same disease. Yet there are often relative benefits and drawbacks if you compare the products that helps us define our strategic positioning and value proposition. | | 1. **Similarity:** The content of both products is the same – oranges. 2. **Difference:**  * Calories per mg is higher in the juice. * Formulation (whole fruit vs juice) * Administration (eating vs. drinking) * Storage needs (no storage needs for whole oranges) * Refrigeration instructions * Consumption experience  1. Similarly, pharma or biopharmaceutical products that being indicated for the same disease, often have relative benefits and drawbacks when the products that helps us define our strategic positioning are compared with value proposition. | * This will be text and image animation. * Play VO1 and display below images: * A picture containing cup, food, orange, beverage    Description automatically generated * As the VO2 begins, move the images to the top of the screen to make space for OST. * Display OST 1 in sync. * Then display OST 2 and the bullets in sync with VO 3. * Retain the previous OST and Fade in OST 3 in sync with VO 4. * Display OST 3 in bold. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Relative Clinical Benefits – Product Value | | **Page Number** | **21** |
| **Template Type** | Text and image animation. | | **Duration** | **105 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| 1. The relative clinical benefit is critical when determining the product value. 2. A product can add value i.e., and justify a higher price than current standard of care in two ways. 3. A higher price can be justified if the product off-set healthcare system costs. For example, a new formulation of an IV product as an oral pill reduces healthcare costs as the patient can take the medication at home vs. sitting several hours in an infusion chair. 4. The other justification of a higher price is by adding clinical value as defined by public health metrics. For example, by reducing mortality. | | Relative clinical benefit is critical when determining the product value.  *<<OST to be added in the animation>>*   1. **Product Cost** 2. SOC 3. New Product 4. Price increase justified by healthcare system **cost-offsets** 5. Price increase justified by **adding value** e.g., reducing mortality | * Please animate below image in sync with the VO. * A picture containing diagram    Description automatically generated * Please animate as per below outlines: * Red – VO1 * Yellow – VO2 * Blue – VO3 * Pink – VO4 * Display OST 1 in sync with VO1. | |
| But are products always as good as they claim? Prescrire, a nonprofit, published aggregated ratings of new products and indications over the past 10 years. In contrast to what we may think, most new products are perceived to be ‘nothing new’ or ‘not acceptable’ by HTA bodies. Only a fraction of new products are considered to be a real advance or to be offering an advantage over current standard of care. This is mainly due to new products inability to demonstrate value vs the current standard of care in head-to-head clinical trials. | | *-* | * Fade out the elements on the previous screen. * This will be static image. * Play the VO in syn with the below image:   Chart, pie chart  Description automatically generated | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Relative Clinical Benefits – An Example | | **Page Number** | **22** |
| **Template Type** | Click to reveal interactivity | | **Duration** | **60 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| Let’s review an example of a best practice TPP relative clinical benefits vs. what a poor TPP looks like.  [best practice TPP]  A best practice TPP include a summary of the product efficacy and safety profile including data statistical significance as well as a summary of the clinical benefits of the competitors i.e., current standard of care.  [Sub-optimal TPP]  Let’s look at an example of a sub-optimal TPP. It includes only a short summary statement of the ‘competitive analysis’ but does not actually determine what the current standard of care is, and how our product compares. Even in areas where there is currently now approved treatment, there is almost always an established best practice and clinical guidelines. | | Let’s review an example of a best practice TPP vs. a poor TPP.  *Select each* ***image*** *to learn more.*  Image 1 title: **Best Practice TPP**   * Includes a summary of the product efficacy and safety profile. * Summarizes the clinical benefits of the competitors.   Image 2 title: **Sub-optimal TPP**   * Includes only a short summary statement of the ‘competitive analysis’ but does not determine the current standard of care, and how our product compares. * Establishes best practice and clinical guidelines even in areas where approved treatment.   *<<OST from the image 2>>*   * A sub-optimal TPP does not include a comparison of the product vs standard of care | * Display the lead OST in sync with the VO and display both images on the screen with titles as Best Practice TPP and Sub-optimal TPP, as the screen loads. * For title 1, display the below image without the highlights:   Diagram  Description automatically generated   * For title 2, display the below image without the highlights:   Graphical user interface, text, application, email  Description automatically generated   * Then, display the UI. * Once the user selects image 1, play the VO for **Best Practice TPP** and show the dotted highlights and OST in a callout. * Once the user selects image 2, play the VO for **Sub-optimal TPP** and show the highlights and title OST and image OST in 2 different callouts. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Element – Target Patient Population | | **Page Number** | **23** |
| **Template Type** | Click to reveal interactivity | | **Duration** | **75 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | Target patient population  is a sub-set of the population implied by the labeled indication | * Use this image if space permits:   Patients In Doctors Waiting Room 284499956   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the lead OST along with below icon as the screen loads.   Stock ID: 648461866 | |
| Select each tab to learn more. | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | **Tab 1 - Why** | - | |
| The target patient population may or may not consist of all patient segments covered under the labeled indication. It is commonly a sub-set of the population implied by the labeled indication. Simply having a product with an indication in its label does not necessarily mean that the product will get access to the whole of that population. Therefore, a best practice TPP should also include a target patient population. The target patient population defines the strategic positioning of the product. | | Defines the strategic positioning of the product | On clicking tab 1 > display the OST and play the VO. | |
| **-** | | **Tab 2 - What** | - | |
| It is either the population that we wish target from a strategic and commercial standpoint. That could, for example, be a sub-population where we believe to have a competitive advantage. Or, it could be the sub-population where we think we think our product will be utilized i.e. where we will be able to get access, achieve our price ambitions, obtain public reimbursement or gain market share. | | Patient sub-populations we wish to target in our commercial strategy or in which populations our product likely will be utilized | On clicking tab 2 > display the OST and play the VO. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Target Patient Population – An Example | | **Page Number** | **24** |
| **Template Type** | Click to reveal interactivity | | **Duration** | **75 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| 1. To show you an example, think of the label as the entire potential patient population eligible for our product based on the labeled indication, and the target population as a sub-set of this population. 2. The value of the product may be different in the labeled population vs a sub-set of the label. That means, if we seek reimbursement for the labeled population, we might be able to achieve a price of X, while if we seek reimbursement only in a sub-set of the population where the product benefits are greater, we might be able to obtain a price of 2X.   [Rinviq example]   1. For example, IQWiG in Germany assigned ‘'minor added benefit' for AbbVie's Rinvoq in some psoriatic arthritis patients, 'no added benefit' in ankylosing spondylitis’ in an assessment in Q2 2021. In other words, they only found the product valuable in a sub-set of the label population, not the entire labelled population. | | 1. **Population based on the label indication** 2. *<< Rinvoq logo>>* 3. Target patient population 4. psoriatic arthritis = minor added benefit 5. ankylosing spondylitis = no added benefit | * Fade out the elements on the previous screen. * This will be text and image animation. * Display OST1 as a sub-title in sync with VO1. * Animate the below elements as they appear in VO1 and VO2.   Diagram  Description automatically generated   * Add more elements to the animation in sync with VO3.   Diagram  Description automatically generated   * Use below icon in in above animation in different colors to depict different sets of population:   Stock ID: 648461866   * Add all elements to the animation as they appear in the VO. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Target Patient Population - Best Practice TPP Vs. Poor TPP | | **Page Number** | **25** |
| **Template Type** | Click to reveal interactivity | | **Duration** | **60 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| [Best Practice TPP]  A best practice TPP includes a statement about which part or parts of the labeled patient population the product will be used in. It will also indicate clearly how the product will be used in relation to other therapies the patient may be treated with. For example, it would indicate if the treatment were meant to replace or complement alternative treatments that the patient is on. In other words, in which patients do we expect our product to be utilized given how our product will be revived by our stakeholders including regulatory and HTA bodies, insurers, providers and HCPs?  [Sub-optimal TPP]  Let’s look at an example of a sub-optimal TPP. The sub-optimal TPP includes an element of the product USP or unique selling proposition. However, it does not specify in which patients we will gain access, reimbursement or where our product will be placed in the treatment pathway relative to the current standard of care. Not including a target patient population can result in an overly optimistic forecast from both a volume and price opportunity perspective. | | **Target Patient Population – Best Practice TPP Vs. Sub-Optimal TPP**  *Select each* ***image*** *to learn more.*  *<<Callout OST to be displayed on image 1 selection>>*  Labeled Population  *<<Callout OST to be displayed on image 1 selection>>*  Subset of the labeled population, i.e., the target population where we expect the clinical benefit to be the most meaningful.  Image 1 title: **Best Practice TPP**   * “Product X is expected to be used as an *alternative* to Product Y in patients with chronic migraine **who tried and failed prior pharmacological treatments**”   *<<Callout OST to be displayed on image 2 selection>>*  A best practice TPP includes a statement of what the expected target patient population.  Image 2 title: **Sub-optimal TPP**   * A sub-optimal TPP doesn’t determine what our target patient population will be | * Display the lead OST in sync with the VO and display both images on the screen with titles as Best Practice TPP and Sub-optimal TPP, as the screen loads. * For title 1, display the below image without the highlights:   Graphical user interface, text, application  Description automatically generated  Fade in the call out for labeled “Labeled Population”   * For title 2, display the below image without the highlights:   Graphical user interface  Description automatically generated   * Then, display the UI. * Once the user selects image 1, play the VO for **Best Practice TPP** and show the callout OST in a callout. * Once the user selects image 2, play the VO for **Sub-optimal TPP** and show the highlights and OST in a callout. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | TPP Elements – Fulfillment Channel | | | **Page Number** | **26** |
| **Template Type** | Click to reveal | | | **Duration** | **90 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| A TPP should also include the expected fulfillment channel. | | | TPP also includes the expected Fulfillment channel. | * Use this image if space permits:   attractive asian woman nurse and doctor working with smiling and freshness together to takecare ill old senior patient in hospital 1151118797   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the lead OST in sync with the VO as the screen loads.   Icon  Description automatically generated [Stock](https://www.shutterstock.com/vectors) ID: 1095746831 | |
| Select each tab to learn more. | | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | | **Tab 1 - Why** | - | |
| The fulfillment channel defines the route to market. The fulfillment channel determines the expected delivery channel of the product i.e., will the prescription be dispensed to and administered by an HCP in a hospital, which is typical for patients who are admitted to hospital for over-night stays, or will it be filled by an HCP but in an outpatient setting, which is common for infused products, or will it be filled by the patient through a specialty or retail pharmacy directly? Often, a product can be filled through a combination of these channels, however it is critical to understand through what route the product comes to market. | | | * Defines route to market * Determines the expected delivery channel of the product | On clicking tab 1 > display the OST and play the VO. | |
| **-** | | | **Tab 2 - What** | - | |
| The fulfillment channel or site of care can put the provider or HCP at a financial risk if administered in a hospital our outpatient setting since they often need to acquire the product before they get reimbursed by the insurer or paid by the patient. Sometimes, the site of care is restricted by the HTA and price setting body or insurer. | | | Site of care / filling of prescription | On clicking tab 2 > display the OST and play the VO. | |
| **-** | | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | TPP Elements –Dosing and Administration | | | **Page Number** | **27** |
| **Template Type** | Click to reveal | | | **Duration** | **120 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| - | | | **Dosing And Administration** **in TPP** | * Use this image if space permits:   White calculator and pills on a blue background as a symbol of paid (expensive) medicine 1357016903   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the OST along with below icon as the screen loads.   A black and white drawing of a hand holding a card  Description automatically generated with low confidence  [Stock](https://www.shutterstock.com/vectors) ID: 588251810 | |
| Select each tab to learn more. | | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | | **Tab 1 - Why** | - | |
| Dosing and administration demonstrate practical and budget impact considerations from both the HTA and price setting and insurer perspective, but also from a provider and HCP point of view. | | | Demonstrates practical and budget impact considerations | On clicking tab 1 > display the OST and play the VO. | |
| **-** | | | **Tab 2 - What** | - | |
| When we look at a product dosing and administration, | | | Dose specifications and instructions | On clicking tab 2 > display the OST and play the VO. | |
| it is critical to understand how the product is dosed and how it compares to current standard of care to get a | | | How is the product dosed?  How it compares to current standard of care? | This will be a build up screen.  Fade in the two question OST. | |
| true understanding of the product cost differentials. | | | True understanding of the product cost differentials | Build up the OST below the questions | |
| For example, two products can have similar price per mg/kg, but one product might be a 10 mg dose / three time per week while the other product is a 20 mg/ dose two times per week. The dosing will then have a large impact on the product price. If both products cost $10 per mg, then one product has a weekly cost of $300 while the other $400. Over the course of a year, assuming it is a chronic treatment with 100% compliance, this adds up to a $5,200 difference in costs. Just imagine if the population indicated for such treatments is large – that could result in a very large incremental budget impact just for 1 dose fewer per week.  Dosing regimens as well as *duration on treatment are both important to understand*. | | | For Example:   |  |  |  | | --- | --- | --- | |  | Product A | Product B | | Price | similar price per mg/kg | | | Dose | 10 mg dose / three time per week | 20 mg/ dose two times per week | | Cost, $10 per mg | weekly cost of $300 | weekly cost of $400 | | Course of a year | adds up to a $5,200 difference in costs | | | Result of such doses | Large incremental budget impact just for 1 dose fewer per week in terms of dosing regimens and duration of treatment. | | | Build up the table in sync with the VO. | |
| Whether the treatment is chronic, in other words “on-going”, episodic, meaning short courses of treatment with a break, repeated multiple times throughout a year, or single event like what you might expect in an emergent situation, can have an impact on the total annual cost, which is important for any paying stakeholder. | | | Annual Cost will impact the paying stakeholder in all the following cases:   * On-going * Episodic * Repeated multiple times in a year * Emergency situations | Fade in the table and display this OST | |
| **-** | | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | TPP Elements – Packaging & Storage | | | **Page Number** | **28** |
| **Template Type** | Click to reveal | | | **Duration** | **75 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Packaging and Storage** **in TPP** | | * Use this image if space permits:   12 10 2018  Modena - automatic pick and place robot for pharmacy warehouse applications. Robot Pharma Dispenser 1205284159   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the lead OST and UI along with below icon as the screen loads.   Icon  Description automatically generated [Stock](https://www.shutterstock.com/vectors) ID: 1834666102 | |
| Select each tab to learn more. | | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | | **Tab 1 - Why** | - | |
| Packaging and storage is especially important to providers and HCPs. As mentioned previously, providers are often at risk when they acquire and pharmaceutical products and not knowing when or if they will get reimbursed. Therefore, storage needs, and shelf life is critical. | | | Demonstrates practical and budget impact considerations | On clicking tab 1 > display the OST and play the VO. | |
| **-** | | | **Tab 2 - What** | - | |
| The packaging is also important, especially for liquid formulations with a per kg dosing as it can create waste product. For example, if an HCP opens a vial of 100 mg and only uses 70mg for a patient, the HCP usually need to discard the remaining 30 mg. The ‘waste’ is usually counted as a ‘loss’ from the provider as well as insurers point of view, and this should be explicitly considered when developing a TPP. | | | Packaging details and storage needs and shelf-life | On clicking tab 2 > display the OST and play the VO. | |
| **-** | | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | TPP Elements: Fulfillment, Dosing and Administration, Packaging & Storage – An Example | | | **Page Number** | **29** |
| **Template Type** | Animation | | | **Duration** | **90 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| 1. Fulfillment channel, dosing and administration and packaging are critical factors of a TPP, and it is important to have a good understanding of the impact of a different fulfillment channel, administration or packaging on the product commercial potential.   [5-FU vs Xeloda]   1. An example is the cytostatic 5-FU used to treat different tumors. The 5-FU was the most extensively used infused agent in the treatment of advanced colorectal cancer for more than 40 years. 2. When capecitabine (Xeloda) launched, an oral fluoropyrimidine carbamate designed to generate 5-FU preferentially in tumor tissue, it received favorable HTA assessments in several markets not due to its superior efficacy, but because the HTA body saw that patients and the healthcare system could avoid the cost of infusions. 3. Roche, the manufacturer behind Xeloda, likely expected a great uptake by their new product given the oral formulation of Xeloda vs. the infused treatment option. 4. However, in this case, many patients still preferred the infused treatment as it made them feel cared for and it enabled them to get time with an oncology nurse and their doctor while at the infusion center or hospital. | | 1. Fulfillment channel, dosing and administration and packaging are critical factors of a TPP.   *<<OST to be displayed below 5-FU image>>*   * Patients preferred the infused treatment. * Patients got time with an oncology nurse and their doctor.   *<<OST to be displayed below Xeloda image>>*   * Healthcare system could avoid the cost of infusions. * Manufacturer expected a great uptake given the oral formulation. | | * Fade out the elements on the previous screen. * This will be text and image animation. * Display the lead OST in sync with lead VO. * Then, display elements on the screen in sync with the VO. * Display elements roughly in the below format:   A picture containing graphical user interface  Description automatically generated   * Display Xeloda OST in sync with VO 3 and 4. * Display 5-FU OST in sync with VO 5. | |
| **-** | | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Elements: Fulfillment, Dosing and Administration, Packaging & Storage – Best Practice TPP Vs. Poor TPP | | **Page Number** | **30** |
| **Template Type** | Click to reveal | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| [best practice TPP]  A best practice TPP includes all three aspects of the expected delivery channel, dosing considerations and packaging and storage needs of the product.  [Sub-optimal TPP]  Let’s look at an example of a sub-optimal TPP. The sub-optimal TPP does include dosing, formulation, packaging and storage needs, but it does not cover the expected delivery channel which is fundamental for the product’s overall access strategy. | | Let’s review an example of a best practice TPP vs. a poor TPP.  *Select each* ***image*** *to learn more.*  Tab 1: **Best Practice TPP**  A best practice TPP includes all three aspects of the expected delivery channel, dosing considerations and packaging and storage needs.  Tab 2: **Sub-optimal TPP**  An example of a sub-optimal TPP includes *target channel* and *dosing* and *storage details*, however, does not cover the expected delivery channel. | * Display the lead OST in sync with the VO and display both images on the screen with titles as Best Practice TPP and Sub-optimal TPP, as the screen loads. * For title 1, display the below image:   Graphical user interface  Description automatically generated with low confidence   * For title 2, display the below image without the highlights and callout:   Graphical user interface, application  Description automatically generated   * Then, display the UI. * Once the user selects title 1 image, play the VO for **Best Practice TPP** and show the OST in a callout. * Once the user selects title 2 image, play the VO for **Sub-optimal TPP** and show the dotted highlights and OST in a callout. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | TPP Element – Funding Archetype | | | **Page Number** | **31** |
| **Template Type** | Click to reveal | | | **Duration** | **78 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| The final TPP element is Funding Archetype. | | | The final TPP element is Funding Archetype. | * Use this image if space permits:   Medicine and money. Vials of antibiotics, white anti-virus tablets, and a medical syringe with a needle. The financing of medicine and the profits of pharmaceutical companies.    1706157142   * Use the below format to present the elements on the screen.     Stock ID: 401428744   * Display the lead OST and UI along with below icon as the screen loads and play lead VO.   Stock ID: 562491391 | |
| Select each tab to learn more. | | | *Select each* ***tab*** *to learn more.* | * Display UI. * Show 2 tabs below: | |
| - | | | **Tab 1 - Why** | - | |
| The funding archetype defines our access and reimbursement expectations. | | | Defines our access and reimbursement potential | On clicking tab 1 > display the OST and play the VO. | |
| **-** | | | **Tab 2 - What** | - | |
|  | | | Expected target markets | On clicking tab 2 > display the OST and play the VO. | |
| It includes the target markets for the product and the expected funding archetype in each of these markets. The funding route can be either of or a combination of full or partial public reimbursement or private coverage, or a cash product i.e., that patients need to pay for the product out of pocket. | | | Respective funding route i.e. full/partial public reimbursement, full/partial private coverage, cash-market | Display the OST and play the VO. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | TPP Element: Funding Archetype – An Example | | **Page Number** | **32** |
| **Template Type** | Click to reveal | | **Duration** | **60 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| [best practice TPP]  A best practice TPP includes the target markets and the expected funding archetype within those markets, for example, “Partial public reimbursement in target markets with supplemental private coverage for most part”. The TPP can also include any risks associated with the funding archetype, i.e., that if public reimbursement is not secured, affordability become a major barrier to access, ultimately impacting volume.  [Sub-optimal TPP]  Let’s look at an example of a sub-optimal TPP. This example does include the target markets, but it does not cover the expected funding archetype. Not including funding archetype makes it difficult to develop a business case of the product as well as identify any risks associated securing funding for the product. While EPD might be commercially successful with some products in some markets without reimbursement, in several of our key markets, reimbursement is becoming more of the norm than the exception, and patients will think twice before they pay the entire cost of a product out of pocket when alternatives are partially to full covered. | | **Funding Archetype example of a Best Practice TPP Vs. a poor TPP**  *Select each* ***image*** *to learn more.*  Tab 1: **Best Practice TPP**  A best practice TPP includes the target markets and the expected funding archetype within those markets.  Tab 2: **Sub-Optimal TPP**  An example of a sub-optimal TPP includes target markets, however, does not cover the expected funding archetype | * Display the lead OST in sync with the VO and display both images on the screen with titles as Best Practice TPP and Sub-optimal TPP, as the screen loads. * For title 1, display the below image:   Diagram  Description automatically generated   * For title 2, display the below image without the highlights and callout:   Graphical user interface, application  Description automatically generated   * Then, display the UI. * Once the user selects title 1 image, play the VO for **Best Practice TPP** and show the OST in a callout. * Once the user selects title 2 image, play the VO for **Sub-optimal TPP** and show the dotted highlights and OST in a callout. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Knowledge check - 6 | | **Page Number** | | **33** |
| **Template Type** | Drag and Drop Interactivity | | **Duration** | | **60 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
|  | | **Question**  Identify the correct Why’s and What’s for the given TPP elements.  *Drag and drop the correct option and then select* ***Submit****.*  **Column 1: TPP elements**   |  | | --- | | Indication | | Clinical Benefits | | Relative Clinical  Benefits | | Target Patient Population | | Fulfillment | | Dosing and Administration | | Packaging & Storage | | Funding Archetype |   **Column 2: Why**   |  | | --- | | **Why (draggable)** | | Determines the potential target population for our product | | Validates our value claims with robust data | | Serves as a basis for assessing the product value | | Defines the strategic positioning of the product | | Defines route to market | | Demonstrates practical and budget impact considerations | | Demonstrates practical and budget impact considerations | | Defines our access and reimbursement potential | | | * Display the question, its drag and drop column options and the UI. * These columns are answered in current format. Make sure you shuffle them during development. * Add a Submit button. | |
|  | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite! | | * Display a popup when the learner selects an option. | |
|  | | **Correct Feedback:**   |  |  | | --- | --- | | **TPP element** | **Why** | | Indication | Determines the potential target population for our product | | Clinical Benefits | Validates our value claims with robust data | | Relative Clinical  Benefits | Serves as a basis for assessing the product value | | Target Patient Population | Defines the strategic positioning of the product | | Fulfillment | Defines route to market | | Dosing and Administration | Demonstrates practical and budget impact considerations | | Packaging & Storage | Demonstrates practical and budget impact considerations | | Funding Archetype | Defines our access and reimbursement potential | | | Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Chapter 3: Commercial and Cost Implications When We Fail to Develop a Robust TPP | | **Page Number** | | **34** |
| **Template Type** | Text and image Animation | | **Duration** | | **5 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| Chapter – 3: Commercial and cost implications when we fail to do develop a robust TPP | | Chapter – 3: Commercial and cost implications when we fail to develop a robust TPP | | * Show this page as a topic separator. * Use this image:   Depressed businessman lost his business. Destroyed businessman. Concept of business loss, bankruptcy and crisis.  Stock ID: 1694602114   * Pause on this screen for few seconds and auto transition to the next screen. | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Case Study | | **Page Number** | **35** |
| **Template Type** | Interactive (Carousel) | | **Duration** | **195 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | - | * Show the following as a 2-panel carousel. * The content for the first panel should be visible from the beginning. | |
| - | | - | **Panel 1** | |
| As you have learned, a robust TPP is critical in the development of a business case for a new product, but what happens when we fail to develop a robust TPP?  Let’s review a recent case study from ABBOTT. | | A robust TPP is critical in the development of a business case for a new product.  What happens when we fail to develop a robust TPP? | * Show OST along with this image on one side of the screen:   Close up of vaccine vial dose injection, flu shot for immunization with needle and syringe for medical background, copy space, medicine and drug concept 1256725060 | |
| Abbot was developing a pain medication to be launched in EPD markets. | | Abbott’s Severe Pain Medication | * Fade out the above text and retain the image. * The following content will be presented in this format.   Infographic template with hexagons with main idea and 5 steps or options, workflow, process chart, vector eps10 illustration   * Show OST as the central content. | |
| Compared to the standard of care products in this category, the new product was to be delivered in a pre-filled syringe, which makes getting the dose correct simple vs. using a vial and syringe. | | Features of the new product:   * Delivered in a pre-filled intra-muscular syringe. * Reduced administration and need for manual measurement of the dose. | * Show this set of OST on one side of the flowchart. | |
| The TPP contained a lot of details on the physical attributes of the product but lacked details on the fulfillment channel. The commercial assumptions including the product’s volume and price forecast were based on the assumption that “pre-filled syringe” equates to self-administered, but in many markets, intra-muscular injections would need to be administered by an HCP, making use of the retail pharmacy channel impractical. | | TPP of the product:   * Included details on its physical attributes. * Lacked details on the route of administration and fulfillment channel. * Mentioned incorrect commercial assumptions | * Show this set of OST on the other side of the flowchart. | |
| Because patients are rarely in a position to administer intramuscular injections at home without having previously been trained, this type of product was more suited for administration by an HCP in a hospital or clinic setting. This was a big oversight in the TPP which resulted in several market access problems. | | **Commercial assumption** → Intra-muscular pain medication was going to be filled in a retail pharmacy.  **Reality** → Patients are rarely in a position to administer intramuscular injections at home. This type of product can only be prescribed at a hospital and administered by a health care professional. | Fade in OST at the bottom of the screen. | |
|  | | *Select the forward arrow to move to the next panel.* | Show UI | |
| - | | - | **Panel 2** | |
| The disconnect between the product fulfillment channel (hospital) vs the forecast assumptions (retail pharmacy) resulted in several market access related issues for the product. | | **Outcome**  The disconnect between the product fulfillment channel vs the forecast assumptions resulted in several market access related issues for the product. | Fade in OST at the top of the screen. | |
| It significantly overstated volume forecasts since a retail channel has greater reach vs. hospital administered products. | | **Overstated volume forecast**  Overstated the volume forecasts significantly since a retail channel has greater reach vs. hospital administered products | Show OST along with this icon:  Bar graph with downward trend | |
| It resulted in a slower time to market estimate. In most EPD markets, hospital administered drugs require the product to be listed on a hospital’s formulary, and the listings happen one hospital at a time. This slows down time to market. | | **Slower time to market**  Resulted in a slower time to market estimate as hospital administered drugs required the product to be listed at each hospital | Show OST along with this icon:  Turtle | |
| A lower price potential. Hospital administered products are often subject to price controls as well as additional pricing constraints. In this case, the price estimate in the business case assumed that the product would not be subject to price control, which was a mistake. This resulted in a downward revision to the price assumption vs. the initial business case, which ultimately made the case margin dilutive. Besides consequences for market access and pricing, selling an intramuscular syringe to patients directly might have caused real pharmacovigilance challenges. | | **Lower price**  Resulted in a lower price vs. product launched in a retail pharmacy channel as Hospital administered products are subject to price controls through the listing process. | Show OST along with this icon:  Tag | |
|  | | *Select the forward arrow to move to the next panel.* | Show UI | |
| - | | - | **Panel 3** | |
| In the end, this product did not make it to market. This all resulted in financial expenses over two years and the development of prototypes that could have been avoided. | | **Impact**  Resulted in:   * Financial expenses * Unnecessary development of prototype | Show OST along with this icon:  Interest rate reduction or percent down thin line icon.  Vector illustration eps 10 1516473386 | |
| This case study shows you the importance of developing a robust and comprehensive TPP. If you do not, you might miss key elements which will have downstream impact on the product’s commercial potential. | | **Learning**  A robust and comprehensive TPP should be developed. If not, missing key elements will have downstream impact on the product’s commercial potential | Show OST along with this icon:  Light Bulb line icon vector,  isolated on white background. Idea sign, solution, thinking  concept. Lighting Electric lamp. Electricity, shine. Trendy Flat style for graphic design, Web site, UI. EPS 416374336 | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Why is a TPP important? | | **Page Number** | **36** |
| **Template Type** | Text and image animation | | **Duration** | **45 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| So, do we need a robust TPP? Yes, we do! | | Is a robust TPP necessary? | * Play VO | |
| It is the foundation for defining the medical marketing communications, | | Medical / Marketing Communications | Show OST along with this icon:  Stock ID: 613339448 | |
| it directly feeds into the forecast and | | Forecast | Show OST along with this icon:  Stock ID: 1199245750 | |
| it helps us define our go-to-market strategy. | | Go-to-market Strategy | Show OST along with this icon:  Stock ID: 622923110 | |
| In other words, the TPP is the foundation for all commercial and investment decisions for the product. If we do not have a crystal clear TPP, it is probably not going to be a good investment and we should be focusing our time and investment elsewhere. | | **TPP is the foundation for all commercial and investment decisions for the product** | Display the OST pointing to the base of the house. | |
| **-** | | *Select* ***NEXT*** *to continue.* | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | | |
| **Page Title** | Quiz Introduction | | **Page Number** | | **37** |
| **Template Type** | Text and image Animation | | **Duration** | | **5 seconds** |
| **Screen Visuals:** NA | | | | | |
| **VO** | | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| Now, let’s see test what you have learned in this module by conducting a short quiz. | | Let’s see what you have learned in this module with a short quiz. | | * Play VO * Fade in OST along with this image:Multi ethnic colleagues mates work together using pc. African mentor explain application help to interns at group meeting. Coaching, teamwork concept. Horizontal photo banner for website header design   1746359519 | |
| **-** | | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 1 | | **Page Number** | **38** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 1**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  Price is a critical element of a TPP.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:** Although price is an important forecast assumption, it is almost never an input into a TPP. The achievable price is an *outcome* of the value of the product as described in a TPP. The critical elements of a TPP help the reader come to a clear understanding of the relativevalue of the product, which can then be quantified in terms of a price. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 2 | | **Page Number** | **39** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 2**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  The target patient population is the same as the labelled patient population.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:** The value of a product may be very different across the various sub-populations that can exist within the labeled population. Depending on the commercial strategy, it may be more sensible to target a subset of the labeled population so as to achieve a smoother route to reimbursement at target price. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 3 | | **Page Number** | **40** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 3**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  A product’s mode of administration can impact the site of care and therefore the channel.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:** If patients cannot ingest a product at home alone without help from an HCP, it is necessary in many markets to physically acquire the product at a healthcare facility instead of a retail pharmacy. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 4 | | **Page Number** | **41** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 4**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  Regulatory bodies grant marketing approval only if a product demonstrates a relative clinical benefit vs. an active comparator.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:**  Regulatory bodies grant approval for anything that fits their definitions for “safe and effective”, which is a fundamentally different hurdle than “valuable”. There is a common misperception that simply because a product is “approved” that market access at a desired price automatically happens. It does not, and if we forget this, we are not setting ourselves up for success. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 5 | | **Page Number** | **42** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 5**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  EPD market HTA bodies’ product assessment criteria are vastly different from those of EU markets.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:**  Although many EPD markets are considered developing, several have robust HTA bodies, and many have robust processes that rely on input from competent assessment bodies or organizations for determining a product’s value to the healthcare system. This input can inform the markets’ starting point for price and access negotiations where concrete rules for price setting and coverage do not exist. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 6 | | **Page Number** | **43** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 6**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  Combining 2 loose components into a single fixed-dose combination necessarily improves clinical benefits.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:**  The idea that lessening pill burden will necessarily result in better compliance is only that – an idea. Until it can be proven in a trial that pits the 2 loose components against the fixed-dose combination, no rational healthcare system will allow for premium pricing, and many will exclude such a product from reimbursement. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 7 | | **Page Number** | **44** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 7**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  A different product packaging would (generally) grant a price premium as a result of the HTA assessment.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:** Unless the difference in packaging can impact clinical outcomes or reduce wastage and is *proven* to do so, a change in packaging is not going to be allowed premium pricing in markets with price controls. | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | Best Practices in Target Product Profile Development – A Market Access Perspective | | | |
| **Page Title** | Question 8 | | **Page Number** | **45** |
| **Template Type** | MCSS | | **Duration** | **30 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | | **On Screen Text (OST)** | **Visuals and Notes to Developers** | |
| - | | **Question 8**  Identify if the following statement is True or False.  *Select the correct option and then select* ***Submit****.*  A clinical or safety benefit can be credibly demonstrated even if the data are generated outside of a Ph III trial or even if there is no active comparator.   * True * False | * Display the question, its options and the UI. * The option marked in green is the correct answer. * Add a Submit button. | |
| - | | **Feedback:**  **Correct answer:** That’s right!  **Incorrect answer**: Not quite!  **Common feedback:**  Although the “gold standard” for proving value is in a randomized-controlled Ph III trial, sometimes the benefit is so obvious that it need not be demonstrated. Or sometimes the benefit that would be seen in a trial is so contrived because of the controlled environment that payer bodies will actually want to see evidence from a real-world setting before they believe that the benefit demonstrated in a controlled setting will be observed in real life. We should always seek early payer input, however, before finalizing a development plan that relies on anything other than the gold standard approach. Talk to your Market Access team – they can help provide you guidance! | * Display a popup when the learner selects an option. * Show feedback as OST on the pop-up. | |

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| **Module Title** | | Best Practices in Target Product Profile Development – A Market Access Perspective | | |
| **Page Title** | | Glossary | **Page Number** | **46** |
| **Template Type** | | Animation | **Duration** | **10 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| - | |  |  | | --- | --- | | **Abbreviation** |  | | AIFA | Agenzia Italiana del Farmaco (Italian HTA body) | | EMA | European Medicines Agency (EU) | | FDA | U.S. Food and Drug Administration | | G-BA | Gemeinsame Bundesausschuss (German HTA body) | | HIRA | South Korean HTA body | | HTA | Health Technology Assessment | | MFDS | Ministry of Food and Drug Safety (South Korea) | | NHIA | Taiwanese HTA body | | NMPA | National Medical Products Administration (China) | | P&T | Pharmacy & Therapeutics | | SFDA | Saudi Food and Drug Authority | | TC | Transparency Committee (French HTA body) | | TPP | Target Product Profile | | | If possible, show glossary as a button on the screen, next to the Help button. Else, show the glossary as a last page. | |
| **-** | *Select* ***NEXT*** *to continue.* | | Display the user instruction and enable the next button when the VO completes. | |

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| **Module Title** | | Quality Gate Audit Process | | |
| **Page Title** | | **Thank You** | **Page Number** | **47** |
| **Template Type** | | Animation | **Duration** | **5 seconds** |
| **Screen Visuals:** NA | | | | |
| **VO** | **On Screen Text (OST)** | | **Visuals and Notes to Developers** | |
| You have completed this module successfully. | **Thank You**  *Select* ***X*** *to exit.* | | * 'Thank you' would be displayed as stylized text along with Abbott logo. | |