Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organisational, ethical and compliance issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making (WHO, 2017).

New health Technology and New therapeutic practices “include all but not limited to new emerging devices, medical, surgical procedures and therapeutic practices”. The main goal of HTA is to provide decision makers with evidence based information on all policy alternative. Taking into consideration all the clinical (safety, efficacy, effectiveness), economical and societal outcome of healthcare policy.

Kindly, fill in all the requested information given below. This is a mandatory step in order to proceed further. Failure to provide information will result in a delay in the processing of the applicant request. Please give us adequate time for the review process. In case further information is required, the provider will be contacted

|  |  |  |
| --- | --- | --- |
| **A. General Information:** | | |
| **Requester Name** | **English:** | |
| **Arabic:** | |
| **Requester Position** | **English:** | |
| **Arabic:** | |
| **Company Name** | **English:** | |
| **Arabic:** | |
| **Company Address:** | | |
| **Contact Number:** | | **Email:** |
| **Pharmacovigilance Focal Point Name for Medical device reporting\*:** | | |
| **Contact Number:** | | **Email:** |
| **Type of Request:**  Evaluation of a new health technology.  Evaluation of a new therapeutic practices. | | |

\* Medical Device Reporting

Manufacturers, importers, agents, distributors or any other person who is responsible for placing the device on the market are required to report to DOH Pharmacovigilance Program ([PVE@doh.gov.ae](mailto:PVE@doh.gov.ae)) when they learn that any of their devices may have caused or contributed to death or serious injury. They must also report to the DOH pharmacovigilance program when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

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| **B. Brief Description of the Technology/therapy** | |
| 1. **Name of proposed Technology/therapy:** 2. **Version or Model Number:** 3. **Manufacturer Name:** 4. **Country of origin:** 5. **Technology Type:**   Device System/Software/AI/App Technique/Procedure Diagnostic Test Product/Kit Others (specify): ……………….   1. **Technology Category:**   Diagnostic Therapeutic Others (specify): ……   1. **Technology speciality:** | |
| 1. **Description of Technology/Therapy (Briefly describe it and how it works):** 2. **Technology website/link:** | |
| 1. **Category for requested proposed Technology/therapy:** | |
|  | Proven new technology – Clinical safety and effectiveness have been demonstrated, but not been used in Abu Dhabi. |
|  | Innovative/Experimental new technology |
|  | New Therapies, Medical Treatments |
| 1. **Is the technology/therapy Approved from International Bodies?** If Yes, please state the name of the Organization.   MoHaP (UAE)  Others (specify): ……………. | |
| 1. **What are the best practices adopted in the use of this service?** | |
| 1. **Where there any clinical trial conducted? Where? How long? And what stage is it at? Has it been published and where?** | |
| 1. **What is the clinical need or the gap that the current practice does not address while the technology being assessed does? Kindly elaborate.** | |

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| **C. Access and Targeted Population:** |
| 1. **Targeted Population:** 2. **What are the most important clinical characteristics of the patients that technology/therapy will serve?** 3. **What is the estimated number of patients for every indication that might use this technology/therapy in Abu Dhabi?** *The estimated cost for the same number studied somewhere else* |

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| **D. Quality and Impact of the Technology/therapy:** |
| 1. **The Impact of this Technology/therapy on Current Practices will be:**   Minor Change in Current Practice. *Please explain:*    **OR**  Significant change in current practice. *Please explain:* |
| 1. **What opportunity or challenge is the technology/therapy trying to address?** |
| 1. **Describe the expected health benefits/improvements in patient outcome compared to current practice** (KPI’s) |
| 1. **What are the Risks associated to this Technology/therapy?**   Risks are the same as the current practices.  Risks are Different than current practices. *Please Describe:*  Risk is Unknown (Safety Has not been Determined). |
| 1. **Are there known or potential contraindications, product warnings, or risks to:**   Patients  Yes  No Health care practitioners  Yes  No  If yes to either of the mentioned above, kindly elaborate: |

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| **E. Cost of the Technology/therapy:** |
| 1. **What is the financial impact of introducing this technology/therapy?**   Financial impact ..outcomes ..mention details such as CEA, QALYS,,etc |
| 1. **What is the estimated contractual price for the requested technology/therapy?**   Is there any signed agreement with others for future application …explain |
| 1. **How did you calculate the proposed price? Please provide the breakdown in details?** |
| 1. **Will additional training or certification be required to operate the technology/therapy ?**  Yes  No   Or Ongoing CME, or other Local and international certification after approval..how /where |

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| **F. Additional comments:** |
| **Kindly elaborate on any additional information that could be of an added benefit.**  Details of reference, economic evaluation…etc    ***Thank you for your time. You will be approached shortly by provider relations department for further guidance.*** |

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| **G. Information Security Compliance and Data Privacy:** |

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| --- | --- | --- | --- |
| **No** | **Action** | **Y N N/A** | **Remarks** |
|  | **The technology/therapy involves health data** |  |  |
|  | **Health data transferred/made available and/or hosted outside UAE** |  |  |
|  | **Secure data exchange channels defined & agreed for health data exchange** |  |  |
|  | **NDA signed with data recipients as needed/applicable** |  |  |
|  | **Data retention period defined & agreed** |  |  |
|  | **The technology/therapy involves parties from outside UAE** |  |  |
|  | **Utilization of Cloud Infrastructure and Services from outside UAE** |  |  |
|  | **Technological dependency on vendors/parties from outside UAE, for the purpose of operations/support** |  |  |
|  | **Technology compliance with** [**DOH Standard on the Internet of Medical Things**](https://www.doh.gov.ae/en/resources/standards#:~:text=DOH%20Standard%20on%20the%20Internet%20of%20Medical%20Things) **[IoMT]** |  |  |
|  | **Technology and initiative compliance with** [**DOH Standard on Patient Healthcare Data Privacy Standard**](https://www.doh.gov.ae/en/resources/standards#:~:text=DOH%20Standard%20on%20Patient%20Healthcare%20Data%20Privacy) |  |  |

* 1. **Compliance Requirements**

1. It is not permitted to store, develop, or transfer data and health information outside UAE that is related to health services provided within the country (Reference: Federal Law No. (2) For the year 2019 On the Use of Information and Communications Technology (ICT) in Healthcare)
2. Information Exchange
   1. All information exchanged shall be classified, tagged and controlled, as per the requirements of the classification. Please refer ABU DHABI HEALTHCARE INFORMATION AND CYBER SECURITY STANDARD (ADHICS) for more details about Information Classification.
   2. All information exchanged shall be in a pre-defined structure agreed by both parties, which provides the minimum information required for the specific purpose.
   3. All information exchange shall only be through approved channels agreed by both parties, in compliance with requirements of the classification.
3. Administration
   1. All receiving parties shall sign separate NDAs for ensuring maintenance of confidentiality of all information handled.
   2. There shall be binding agreements with parties for ensuring maintenance of confidentiality of all information handled.
4. Further sharing of information
   1. Any, and all requirements to share the information further with any third parties at any circumstances shall be only after obtaining written consent from the Discloser party and DOH.
   2. Any information shared further shall be only after the assurance that the information be classified, tagged and controlled, as per the requirements of the classification.
   3. No third party shall share the information further under any circumstances.
5. Incident Management
   1. Any, and all compromises and breaches shall be informed to the DoH immediately along with the impact analysis and consequences