In order to comply with regulatory requirements, *company name* needs to obtain the following information before being able to process your request for drug supply in the Medical Need Program with *product name* in *the indication*.

**May we kindly request you to fax the next pages accurately completed and signed to ………………………………………………………………………..**

**FAX …………………………………………………………………………………….**

Physician Declaration Form

In order to comply with the Medical Need Program with *Product name* in the *indication,* the undersigned physician declares that

* He/she is personally responsible for the use of a medicinal product that is authorised in Belgium for which:

1. the sought indication has been obtained but the product is not yet

commercially available in Belgium, or

1. a demand to obtain the sought indication is in process, or
2. clinical trials are ongoing in the sought indication and/or results are

relevant for the scope of the Medical Need Program .

Except for the first category here above, he/she takes into consideration the risk for the patient to use *Product name* in the scope of this Medical need program and considers that the benefit for the patient overweigh the risks.

* + The disease for which the medicinal product is requested is a chronic disease or severely affects patient’s health or is life-threatening and cannot be satisfactorily treated by a medicinal product currently marketed, approved and reimbursed for the treatment of the sought indication.

The requesting physician should include a description of the disease.

*Description of the disease*:

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* + He/she will inform the patient of all aspects of the Medical Need Program in a clear and complete manner and will obtain informed consent from the patient, at the latest before the start of the treatment with *Product name* received according to the modalities of the Medical Need Program.

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| --- |
| Physician’s signature: ……………………………………… Date: …... / ……. / 20……  **Physician’s Name ...................................................................................................**  **Address ...................................................................................................**  **...................................................................................................**  **Telephone ...................................................................................................**  **Fax ...................................................................................................**  **E-mail (mandatory) ....................................................................................................**  **Email contact person (if applicable)...........................................................................** |