**Patient Information Leaflets (PILs) Assessment Report Template**

**<Product Name (INN and brand name)>**

**< Active Ingredient >**

**<Applicant Name>**

**<Dossier Reference Number>**

|  |  |
| --- | --- |
| **Lead Assessor** |  |
| **Other Assessors** |  |
| **Rapporteur** |  |
| **PIL assessment started on** |  |
| **Date of report** |  |

# **General information**

1. The Patient Information Leaflet (PIL) is in English or local language

Yes  No

1. The PIL is prepared in conformity with the Summary of Product Characteristics (SmPC)

Yes  No

1. The PIL is prepared in a patient friendly manner

Yes  No

1. The information in the PIL does not contradict with the national therapeutic guidelines

☐ Yes ☐ No ☐ Not Applicable

**Remark** Click or tap here to enter text.

# **Comment on the PIL**

*Please enter your comments on the below major sections of the PIL.*

|  |  |
| --- | --- |
| **Section of the PIL** | **Comments** |
| Product description |  |
| Product contents |  |
| Clinical pharmacology |  |
| Indications and usage |  |
| Dosage |  |
| Adverse effects |  |
| Use in pregnancy |  |
| Drug interactions |  |
| Contraindications |  |
| Warning and precautions |  |
| Overdose |  |
| Contents of the pack |  |
| Storage conditions |  |
| Drug abuse and dependence, if applicable |  |

# **Recommendations**

Click or tap here to enter text.