REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

Patient Information Listing (PIL) Review Checklist

PRODUCT NAME:…….

SECTION	Information required (please comment below, if requirements not fully met)	YES	NO
1.	**WHAT <PRODUCT NAME, STRENGTH, DOSAGE FORM> IS AND WHAT IT IS USED FOR** *The indication of the product and the population or age group that the formulation is applicable to should be stated. The pharmacological class, active ingredient(s), dosage form and mechanism of action of the product should also be stated in simple, easy to understand words.*		
Comment			
2.	**BEFORE YOU <TAKE> <USE> {PRODUCT NAME}** **Important information about some of the ingredients of {product name}** *[For those excipients included in the guideline on "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use"*, note that statements do not need to be reviewed by quality assessors as the final wording will be decided at the WHOPAR stage. The applicant can be reminded of this process.]* [*See European Commission (EC) guideline: (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf)]		
Comment			

3.	HOW TO TAKE <PRODUCT NAME> *Information on how to take the product should be provided e.g. whether tablets should be swallowed whole with water, if crushing is permitted or whether tablet should be taken with or without food.* **How much to take** *The dosage and frequency of dosing of the product based on body weight should be provided for adults, adolescents, children and infants if applicable should be provided.* *If the product is contraindicated in a particular age group, this should be stated under this section.* **If you take more <Product Name, strength, dosage form> than you should** *The likely effect of taking an overdose of the product should be stated*		

4.	**POSSIBLE SIDE EFFECTS** *<Like all medicines, <Product Name, strength, dosage form> can cause side effects, but not everybody gets them>* 4.1 Common Side Effects *Common side effects should be stated (affecting 1in 10 people)* 4.2 Uncommon Side Effects *Uncommon side effects should be stated (affecting 1 in 100 people)* 4.3 Rare Side Effects *Rare side effects should be stated (affecting 1 in 1000 people)* 4.4 Very Rare Side Effects *Very Rare side effects should be stated (affecting 1 in 10, 000 people)* 4.5 If You Get Side Effects <*Tell your healthcare provider if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet>* 4.6 Other Possible Side Effects *If there are any other possible side effects especially those that can results from combinations with other medications, it should be stated here.*		
COMMENT			

5.	**HOW STORE (PRODUCT NAME)** *Keep out of the reach and sight of children.* *<Do not store above ºC>, <Store in the original <container><carton>* *Do not use {product name} after the expiry date which is stated on the <label> <carton> <bottle>* *<...> <after {abbreviation used for expiry date}.> <The expiry date refers to the last day of that month.>* *Do not use {product name, strength, dosage forms} if you notice {description of the visible signs of deterioration}.>* *<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>* *[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]* *[Please refer to "Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution" (CPMP/QWP/159/96/corr).]* *<Read the package leaflet before use>.*		
Comment			
6	**FURTHER INFORMATION** **6.1 What the product contains;** *The active substance(s) is (are)…* *The other ingredient(s) is (are)...* *[List all excipients except solvents removed during processing.]* *[Grades/standards should not be indicated.]* *[The ingredients of mixtures (colourants, inks, capsule shells) should be listed. Flavour ingredients do not need to be listed. Only the solids of the printing ink should be included, usually shellac and black iron oxide.]*		

	6.2 What {product name, strength, dosage form} looks like and contents of the pack *[All pack sizes for this pharmaceutical form and strength should be detailed here; if appropriate indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.]* ***6.3* Supplier and Manufacturer** {Name and Address} < {Tel}> < {Fax}> < {E-Mail}>		
Comment			

Comments on deficiencies **with reference to table above and specific sections of the PIL**

Additional data requested (to be communicated to the applicant)