# Annexe I : Déclaration de distribution parallèle d’une spécialité pharmaceutique à usage humain

**Article R. 5121-136-1 du Code de la santé publique**

**Entreprise assurant la distribution parallèle de spécialité pharmaceutique en France :**

**Nom ou dénomination sociale :**

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**Spécialité pharmaceutique faisant l’objet de la distribution parallèle :**

**Le nom, le dosage et la forme pharmaceutique :**

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| **Procédé de modification du conditionnement (reconditionnement ou changement d’étui)** |  | | |
| **Nom ou dénomination sociale et adresse**  **de l'établissement autorisé chargé d'effectuer la modification du conditionnement et autorisé au titre de l’article 40 de la directive 2001/83/CE instituant un Code communautaire relatif aux médicaments à usage humain** |  |  |  |
| **Le cas échéant,**  **nom ou dénomination sociale et adresse**  **du dépositaire au sens du 4° de l'article R. 5124-2 du Code de la santé publique, chargé du stockage** |  |  |  |

**Réservé à l’ANSM** :

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| Date de réception du dossier : |  |  |  |  |  |  |  | N° d’enregistrement : |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | Signature du demandeur : |

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| Date de la déclaration de distribution parallèle : |  |  |  |  |  |  |  |  |  |  |  | Signature du demandeur : |

**Informations et pièces accompagnant le formulaire**

* Une copie de l'autorisation d'ouverture de l’établissement pharmaceutique de l’entreprise assurant la distribution parallèle en France ;
* Une copie de l'autorisation d'ouverture de l'établissement pharmaceutique chargé d'effectuer la modification du conditionnement et autorisé au titre de l'article 40 de la directive 2001/83/CE instituant un Code communautaire relatif aux médicaments à usage humain ;
* Le projet de conditionnement de la spécialité pharmaceutique telle qu'elle sera commercialisée en France ;

# Annexe II : Proposition de modèle de tableau de suivi des lots des spécialités distribuées parallèlement en France

**(Articles R. Article R. 5121-136-2 alinéa 1 du Code de la santé publique)**

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| **Nom de la spécialité** | **Dosage** | **Code CIP** | **Etat membre de provenance** | **Numéro de lot** | **Date de péremption du lot** | **Date de la déclaration de conformité du lot de reconditionnement** | **Quantités importées** | **Etablissements pharmaceutiques destinataires en France** |