Commission Decisions related to medicinal products - Language waiver for Commission Decisions addressed to [name of legal entity/natural person]

We, [name], as the legal representative of the [company / companies/individual] mentioned below, hereby declare, in the context of Commission Decisions related to marketing authorisations for medicinal products or orphan designations, that the European Commission may notify to us pursuant to Article 297 of the Treaty on the Functioning of the European Union in English any such Commission Decision it may take. We waive all rights to receive such documents in any other language.

This request is valid for all Commission Decisions concerning marketing authorisations or applications for medicinal products or orphan designations of the following [company/companies/individual]:

|  |  |
| --- | --- |
| Name of company / individual | Official address, as recorded in European Commission decision(s)/application dossier  |
|  |  |

…

The waiver is valid for a period of 3 years from the date of notification, and will be automatically renewed for periods of 3 years unless the [company/companies/individual] decides to withdraw the waiver. The withdrawal of the waiver will take effect at the end of the three years period or three months after it has been notified, whatever is earlier.

Print name and signature: Date: