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Parallel Distribution and Certificates

Statistics on certificates of medicinal products 2013

The European Medicines Agency's certification scheme is based on WHO recommendations and supports the work of health authorities outside the European Union.

The European Medicines Agency certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing authorisation status of products either authorised by the European Commission through the centralised procedure or products for which a centralised application has been submitted to the Agency, and products pursuant to Art. 58 of Regulation 726/2004/EC.

The certificates also confirm the good manufacturing practice (GMP) compliance status of the manufacturing site(s) producing the medicinal product bulk pharmaceutical form.

The European Medicines Agency issues certificates within 10 working days (standard procedure) or within 2 working days (urgent procedure) following receipt of a valid application form.

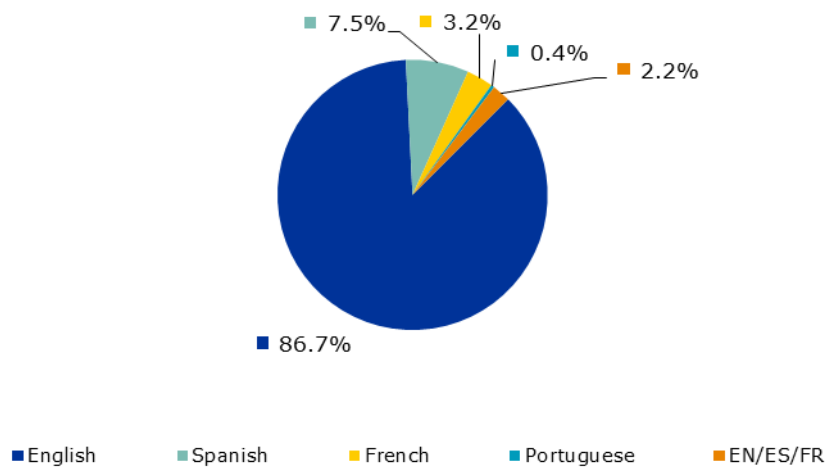
The following document provides an overview of the numbers of certificates issued by the Agency in 2013 with various tables and graphs showing their distribution by type of product, language and importing country.

- The total number of sets issued was 10 990 (see [table 1](#) for further details).
- The certificates of medicinal products can be issued in English (EN), Spanish (ES), French (FR), Portuguese (PT) or a combination of English, Spanish and French. Of all sets issued 86.7% were in English (see [graph 1](#)).
- The top three importing countries were Taiwan, Hong Kong and Israel (see [graph 2](#)).

Table 1: Types of products for which certificates were issued by the European Medicines Agency in 2013

Type of product	No of sets	% in total
Certificates of medicinal products for human use	10 990	96.4%
Certificates of medicinal products for veterinary use	242	2.1%
Certificates of medicinal products for Art.58 products	175	1.5%
TOTAL	11 407	100.0%

Graph 1: Distribution of languages for certificates issued by the European Medicines Agency in 2013



Graph 2: Distribution of the top ten importing countries for certificates issued by the European Medicines Agency in 2013

