AGENZIA ITALIANA DEL FARMACO

Ufficio Autorizzazione all'Immissione in Commercio

Presentazione delle traduzioni di RCP, FI ed Etichette - Riferimenti e Link correlati

- *CMDh/255/2012 Best Practice Guide on the submission of high quality national translations* https://www.hma.eu/human-medicines/cmdh/procedural-guidance/general-info.html

- *Notice to Applicants Volume 2 Guideline on the readability of the label and package leaflet of medicinal product for human use* https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en#volume-2c---regulatory-guideline

- *EMA/25090/2002 Compilation of QRD decisions on stylistic matters in product information* https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-reference-documents-guidelines

- *EMA/57325/2011 Compilation of QRD decisions on use of terms* https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product information/product-information-reference-documents-guidelines

- *EMA/62470/2007 QRD convention to be followed for the EMA-QRD templates* https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-reference-documents-guidelines

- *CMDh/258/2012 "Blue – Box" requirements* https://www.hma.eu/human-medicines/cmdh/procedural-guidance/application-for-ma.html

- Comunicato AIFA *Richiesta di eliminazione delle parti coperte da brevetto dai testi degli stampati - Modalità operative* https://www.aifa.gov.it/-/richiesta-di-eliminazione-delle-parti-coperte-da-brevetto-dai-testi-degli-stampati-modalita-operative

- *CMDh/201/2005 "CMDh annotated QRD template for MR/DC procedures* https://www.hma.eu/human-medicines/cmdh/templates/qrd.html

- *MedDRA Best Practice and Documents* https://www.meddra.org/how-to-use/support-documentation/english

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- *QRD Appendix I Statements for use in Section 4.6 "Fertility, pregnancy and lactation" of SmPC* https://www.ema.europa.eu/documents/template-form/qrd-appendix-i-statements-use-section-46-pregnancy-lactation-summary-product-characteristics-cover_en.docx

- *QRD Appendix II Medical Dictionary for Regulatory Activities terminology to be used in Section 4.8 "Undesirable effects" of SmPC"* https://www.ema.europa.eu/documents/template-form/qrd-appendix-ii-medical-dictionary-regulatory-activities-terminology-be-used-section-48-undesirable_en-0.docx.

- *QRD Appendix V Adverse-drug-reaction reporting details* https://www.ema.europa.eu/documents/template-form/qrd-appendix-v-adverse-drug-reaction-reporting-details_en.docx

- *EMA/CHMP/302620/2017 Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'* (SANTE-2017-11668) https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human

- *EDQM List of Standard Terms pharmaceutical dose forms, routes of administration and containers* https://standardterms.edqm.eu/

- *QRD Appendix III- Appendix III to the QRD templates for human medicinal products* https://www.ema.europa.eu/documents/template-form/qrd-appendix-iii-quality-review-documents-templates-human-medicinal-products-cover-page_en.doc

- *QRD Appendix IV- Terms and abbreviations for batch number and expiry date to be used on the labelling of human medicinal products* https://www.ema.europa.eu/documents/regulatory-procedural-guideline/qrd-appendix-iv-terms-abbreviations-batch-number-expiry-date-be-used-labelling-human-medicinal_en.pdf

- *Tables of non-standard abbreviations* https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/tables-non-standard-abbreviations-be-used-summary-product-characteristics_en.pdf

- *EMA/CHMP/287710/2014 Guideline on the acceptability of names for human medicinal products processed through the centralised procedure* https://www.ema.europa.eu/en/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure#current-version-section

- *EMA/707229/2009 QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SPC, and in the name section of labelling and PL)* https://www.ema.europa.eu/documents/regulatory-procedural-guideline/quality-review-documents-recommendations-expression-strength-name-centrally-authorised-human_en.pdf

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