EU product information and translation

The product information (summary of product characteristics/SmPC, labelling and package information leaflet/PIL) provides the essential information for the physician, pharmacist, and patient to ensure the proper use of medicines. The PI needs prior approval by the competent authority as part of the MAA and needs to be kept up to date on an on-going basis. PhaRA can support companies as of the initial development of the target label, draft/update the PI compliant with European and national requirements, handle QRD conversions, provide high-quality translations in all BENELUX languages, and organise translations for the other EU languages. We can also coordinate art work and readability testing, and can be instrumental for compliance checks and proofreading.
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