SERVICE SHEET

WAINWRIGHT associates
Regulatory Affairs

Product literature and user testing

Our experienced consultants write product leaflets using clear and simple English to ensure successful communication with patients.

Product literature and user testing

Good quality product literature is key to successful communication with patients and for regulatory approval. Attention to detail is particularly important in writing the Summaries of Product Characteristics (SPCs), Package Leaflets and labelling.

We can advise on the regulatory requirements for both content and format under EU legislation, as well as write or review the relevant texts. The creation of the final artwork is also offered, including versions for blind or partially sighted people.

Package leaflets must be written in simple, clear English and, throughout Europe, the leaflets must be user tested to ensure their intelligibility. Wainwright Associates provides a full user testing service with test reports suitable for submission.

Product and patient literature

We provide a writing service for SPCs, Package Leaflets, labelling and Patient Support Information. These documents can be written for you or your existing texts can be updated, either to reflect changes in the registered details or to improve the intelligibility and user-friendliness of the text.

We can assess clients' own regulatory product literature in depth, checking for:

- medical and scientific accuracy.
- compliance with the registered details.
- legal requirements.
- applicable guidelines.
- EU standard terms.

As part of SPC harmonisation, copies of SPCs approved in each EU member state can be reviewed for consistency, allowing a single, consolidated SPC to be proposed. We can also advise on the requirements for labels and leaflets under the Clinical Trial Directive.

This regulatory product literature is provided ready for inclusion in a Marketing Authorisation Application, as are texts with changes tracked, for ease of review by the client.

We are a team of scientists, medical translators, teachers of English and linguists able to provide product literature in all the languages of the European Union. Back-translations can be provided to check for authenticity, as can linguistic review of texts in any European language.

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EU legislation requires all package leaflets to submit a detailed readability report with their MAA.

User testing package leaflets

EU legislation means that all Package Leaflets for new products must be user tested for intelligibility and patient-friendliness. A test report has to be submitted in the Marketing Authorisation Application.

User testing a leaflet involves several steps.

- We design a protocol and questionnaire which focus on the most important safety factors in the leaflet.
- We have a large database of volunteers for testing. The volunteers are members of the public. We document their demographic details, so that a group who meet the relevant product indications can be chosen for each test.
- In the tests, only trained, experienced interviewers are used. They time and record volunteers' responses to each question, noting whether, how easily and how accurately the information is found. Each volunteer's understanding of his/her answers is also checked.
- Our user testing is normally done in English and, as required for Centralised, Decentralised and Mutual Recognition Procedures, test reports are written in English.
- In these test reports, the results are analysed statistically and may be used to propose improvements to the leaflet. The report is then sent to the client for review, before submission to the authorities. Our objective is to test a leaflet which passes after the required minimum of two rounds.

For multiple products, we can advise on a bridging strategy which avoids the need to test every leaflet.

Artwork creation

Colour mock-ups of leaflets and labels, meeting all relevant guidelines and suitable for submission to regulatory authorities, can be provided in all EU languages. This includes the creation of a 'worst case' example, usually a trilingual leaflet or label.

Small packs can sometimes be a problem; we can advise on the best way to meet the legal requirements.

Artwork creation includes the label 'blue box' required under the EU Centralised Procedure. The blue box contains the information specific to individual member states, such as legal status, pricing and reimbursement. Some countries also require barcodes or symbols and we can advise on the details required in each case. The Artwork is provided as PDF files suitable for electronic submission.

Throughout the EU there is a legal requirement to provide the product name in Braille on the pack and to have available a version of the leaflet suitable for partially sighted people, such as in large print or an audio tape. We can advise on both these issues as well as provide the Braille translation.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

www.wainwrightassociates.co.uk