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Medical Information

Medical information

Marketing Authorisation Holders must make arrangements for the provision of a medical information service and maintain a system for managing advertising materials for their medicinal products.

Medical information

The provision of accurate and up-to-date information on medicinal products for which a company holds marketing authorisations is an important contributor to ensure their safe and effective use. Marketing Authorisation Holders must therefore make arrangements for the provision of a medical information service for their medicinal products. As defined by Article 98 of Directive 2001/83/EC, Marketing Authorisation Holders must also maintain a system for managing advertising materials, including their provision to the authorities as requested.

Without the provision of a contact for the above “Scientific Services” Marketing Authorisation applications in the EU will not be validated.

Medical information enquiries

We are able to work with you to set up a medical information enquiry service which is tailored for your company and products. This can range from the provision of advice on setting up an in-house medical information function, to standalone operation of a medical information service on your behalf. Our experienced team can take calls directly and provide appropriate answers utilising a variety of sources.

Enquiries can be received via a dedicated medical information e-mail address, via telephone to our medical information department, via fax or letter. Alternatively we can receive forwarded enquiries from your own initial contact points.

All enquiries are documented and tracked appropriately including allocation of an enquiry-specific code to facilitate tracking, according to written Standard Operating Procedures.

Adverse drug reaction reports

Medical information enquiries can often be a source of adverse drug reaction reports or other safety-related reports. It is important therefore that a medical information function has appropriate links with your company’s pharmacovigilance department and that your medical information personnel are trained in basic pharmacovigilance requirements to facilitate identification of adverse event reports and their transfer to the pharmacovigilance department. Our medical information and pharmacovigilance teams are part of the same department and all personnel are experienced in the provision of both medical information and pharmacovigilance services. Interaction between these two functions is important and is greatly facilitated for those clients for whom we provide both services types.

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One of our strengths is the ability to provide a tailor-made service which best suits your particular business and operating model.

A flexible model

For any of the services mentioned one of our strengths is the ability to provide a tailor-made service which best suits your particular business and operating model. Standard Operating Procedures which are required to document appropriate quality management can be prepared specifically to capture the chosen model. In summary we will work with you to construct the most appropriate model, making use of your in-house product expertise and supplemented by our knowledge and experience of requirements for medical information and scientific services.

Management of advertising materials

The Scientific Services referred to in Article 98 of Directive 2001/83/EC require that a sample of all advertising materials together with information as to who the material is aimed at and how the material is disseminated should be maintained. In addition Marketing Authorisation Holders should ensure that the material conforms to the requirements and that sales staff are appropriately trained.

The team can provide the following services:

- Evaluation of materials and proposed promotional activities for compliance with EU legislation (e.g. Directive 2001/83/EC) and guidance (e.g. the EFPIA Code of Practice)
- Confirmation of compliance of promotional items and proposed activities with national regulations, guidelines and codes of practice throughout the EU
- Establishment of fully functional outsourced promotional compliance solutions backed up by an appropriate quality system for clients with limited EU infrastructure
- Training in the rules, principles and procedures for promotional compliance

Whilst the above focuses on EU requirements, we can provide a similar service for other jurisdictions via our network of local advisors in over 70 countries.

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

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