

Safety Observer

Clinical Safety & Pharmacovigilance Intelligence Review

-- Subscription Agreement --

Article 1 - Description of Services

Through “Safety Observer”, SUNNIKAN Consulting and PV Focus are providing a service of periodic screening of relevant Clinical Safety and Pharmacovigilance information available on various websites. The purpose of this service is to capture and communicate information relevant to the management of Pharmacovigilance Systems, and to make it available to our clients through web links to the source of information. Our aim is to provide significant time savings to our clients by sparing them the screening of sources and the locating of the relevant information.

“Safety Observer” is the result of the periodic monitoring of a number of websites including, without limitation:

- ICH
- CIOMS
- WHO
- EMA
- European Commission
- FDA
- MHRA
- Afssaps

In accordance with applicable laws, information published under Copyright may be referred to but the content will not be reported in “Safety Observer”.

Admittedly, the choice of the sources is influenced by language, and this review is limited to information published in either French or English. “Safety Observer” is the result of a systematic screening of information with an international impact (e.g. ICH, CIOMS, WHO), an impact on the whole of Europe (e.g. EMEA, EC), or national impact for the USA, the UK or France.

This review does not include a systematic screening of information with a national impact for other countries than those mentioned above (e.g. Germany, Spain, Italy, Canada, Australia, etc.). Such information will however be also included in case we become aware of relevant announcements through the monitoring of our sources.

Article 2 – Content of “Safety Observer”

Section 1 “Regulatory Update” includes those news items related to regulations and guidelines. This includes the implementation of new standards and initiatives that are deemed to have an impact on applicable standards.

Section 2 “Safety Update” includes all updates regarding the safety profile of drugs on the market, as issued by the main authorities including EMA and FDA, MHRA and Afssaps.

Section 3 “Quality Assurance, Inspections and Audits” brings information on any new material related to Regulatory Authorities Inspections, internal auditing, and more generally to Quality Assurance, as relevant to Clinical Safety and Pharmacovigilance.

Section 4 “Drug Safety and Business Risk” brings information on the impact safety issues can have on companies due to legal action.

Section 5 “Other relevant Information and Resources” includes additional news items of relevance to the management of Pharmacovigilance Systems. This includes relevant meeting minutes, the publication of Dear Doctor Letters, Safety Newsletters and more.

Section 6 “Time to Register” provides a list of training/conferences related to Clinical Safety and Pharmacovigilance planned in the 3 months following the date of issue of “Safety Observer”.

Article 3 – Delivery of “Safety Observer”

“Safety Observer” will be delivered by e-mail in Adobe PDF format at the frequency of 11 issues a year. This includes a double issue for the months of July/August.

Every effort will be made to deliver “Safety Observer” before the 10th of the month following the period covered.

Article 4 – Price and Payment

This service is proposed for the following annual fee depending on the option selected:

Option A - Electronic version sent to one email address for the personal use of one individual: € 800

Option B - Unlimited electronic distribution to members of the same organization at the same site: € 2000

Option C - Unlimited electronic distribution within an organization of the same name at any number of sites: € 4000

Those fees will be invoiced by SUNNIKAN Consulting to the client at the time of subscription.

Note: “Safety Observer” will be delivered to one e-mail address only. In the event that options B or C are selected, internal distribution is the responsibility of the client.

Article 5 – Liability

Although great care is taken in compiling the content of “Safety Observer”, SUNNIKAN Consulting and PV Focus are not responsible or in any way liable for the currency of the information, for any errors, omissions or inaccuracies, or for any consequence arising therefrom. SUNNIKAN Consulting and PV Focus do not make, and specifically disclaim any warranties, express, implied, statutory or otherwise with respect to the services rendered through “Safety Observer”. In no event shall SUNNIKAN Consulting and PV Focus be liable for consequential, incidental, special, punitive or indirect damages.

Article 6 – Intellectual Property

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Article 7 – Applicable law and settlement of disputes

This Contract will be governed by and construed in accordance with the applicable French and European laws, without reference to conflict of law principals. Any suit arising out of or relating to this Agreement must be brought and tried only in France.

Article 8 – Agreement

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For queries or further information, please write to: info@safetyobserver.com