

CHANGE HISTORY**GENERAL CONDITIONS OF SALE AND USE**

Section	Version dated 16-Sep-2024	Revised Version (dated 11-Dec-2024)
	<p>These reports (hereinafter “Reports”) are sold in the form of quarterly or annual subscriptions which can be taken out on the website www.safetyobserver.com (hereinafter the “Website”), and made available on a dedicated platform (hereinafter the "Platform").</p>	<p>These reports (hereinafter “Reports”) are sold in the form of annual subscriptions which can be taken out on the website www.safetyobserver.com (hereinafter the “Website”), and made available on a dedicated platform (hereinafter the "Platform").</p>
<p>2.1. Content of the Reports</p>	<p>The content of the Reports is the result of active monitoring of identified sources, publishing their content in English or French. The list of sources screened on a systematic basis by SAFETY OBSERVER includes without limitation:</p> <ul style="list-style-type: none"> – International sources: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Council for International Organizations of Medical Sciences (CIOMS), Pharmaceutical Inspection Co-operation Scheme (PIC/S). – European sources: European Medicines Agency (EMA), European Commission (EU), European Co-ordination Group for Mutual Recognition and Decentralised procedures – Human (CMDH). – National Authorities: US Food and Drug Administration (FDA), UK Medicines & Healthcare products Regulatory Agency (MHRA), Australian Therapeutic Goods Administration (TGA), Health Canada. – Other sources: Professional Associations, Service Providers and Law Firms. <p>The Reports produced by SAFETY OBSERVER may contain information from other sources and countries, but only when such information is identified through the monitoring of secondary sources, including News Agencies and Service Providers.</p>	<p>The content of the Reports is the result of the selection of relevant updates from identified sources, which are classified into two categories:</p> <ul style="list-style-type: none"> - “Core” sources: This designates the sources under systematic and active surveillance, including International sources (ICH, CIOMS, etc.), European sources (EMA, EU Commission, CMDh), and selected National Agencies (US FDA, MHRA, ANSM). Admittedly, the selection of the “Core” sources is influenced by language, as the current capabilities include the surveillance of updates published in English or French. - “Other” sources: This includes all other authorities. Although some are subject to systematic surveillance (e.g. Australian TGA, Health Canada, Swissmedic), some publications are identified through secondary sources (e.g. Service Providers, Law Firms, News Agencies, Social Media, etc.). Although these secondary sources may occasionally involve delays or varied reliability, they contribute valuable additional insights. <p>The Reports are produced following a standard template, which includes various sections. As presented on the website (see page “Plans”), the users can access all information presented in those sections included in their subscription plan.</p>

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2.2. Description of the Platform		Additional functionalities may become available over time. As presented on the website (see page “Plans”), the users can only access those functionalities included in their subscription plan.
3. Description of the Subscription Plans	<p>The Subscription Plans offered for sale are the following:</p> <ul style="list-style-type: none"> - 1 year Subscription Plan : 11 consecutive Reports, starting with the next release (includes a double issue for July/August) - 3 months Subscription Plan : 3 consecutive Reports, starting with the next release. <p>The price of each of these Subscription Plans varies according to the number of Users to whom the Client wishes to give access to the Reports.</p> <p>Each Subscription Plan gives access to the Reports and to the Platform’s functionalities, described in articles 2.1 and 2.2 above.</p>	<p>The Subscription Plans offered for sale are the following:</p> <ul style="list-style-type: none"> - The “Basic” Plan includes a single user account and access to content and functionalities is limited - The “Advanced” Plan includes multiple user accounts and provides access to all content and functionalities . The price of this Subscription Plan varies according to the number of Users included. <p>Both Subscription Plans cover a 1-year period, which includes 11 consecutive Reports, starting with the next release (includes a double issue for July/August).</p> <p>As presented on the website (see page “Plans”), users can access the platform functionalities and the sections of the reports included in their subscription (see also articles 2.1 and 2.2 above).</p>