

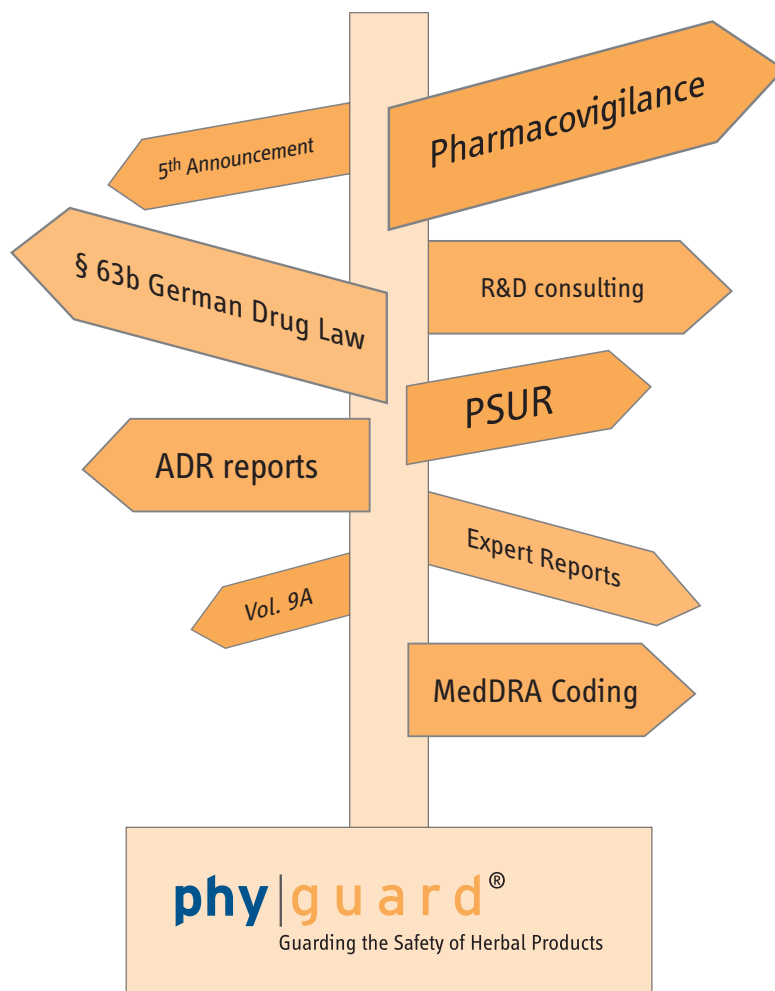
Safety and Security for Herbal Products

phy | **guard**®
Guarding the Safety of Herbal Products

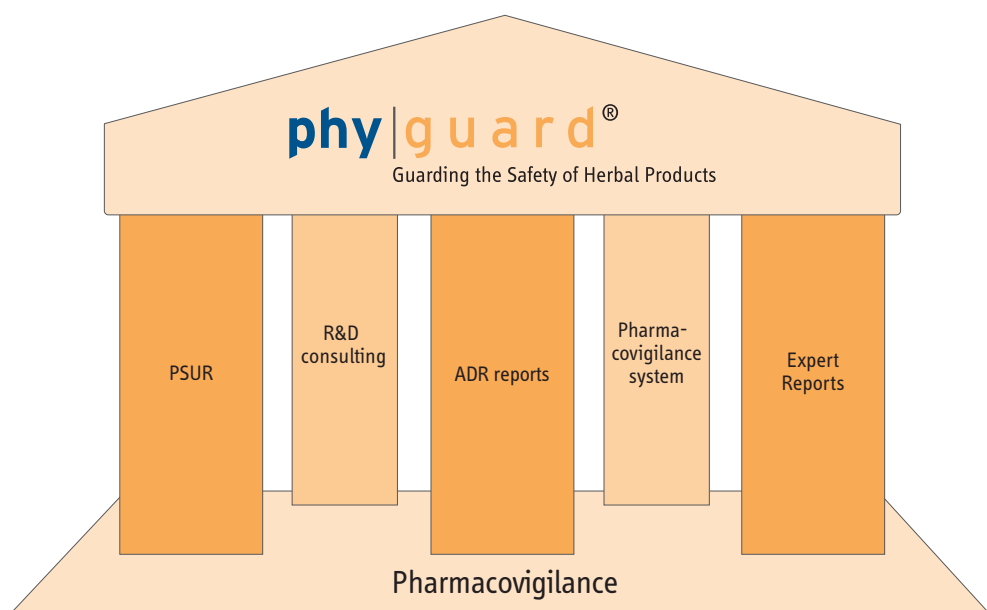
Guarding the Safety of Herbal Products

In its capacity as an accredited laboratory, PhytoLab has been providing professional services relating to the analysis, development and registration/marketing authorisation of herbal medicinal products (HMPs) since the company was founded in 1993. Everything we do is oriented to the safety and security of our customers' products and we have bundled all of our pharmacovigilance activities under the **phyguard®** brand name. More than 400 businesses in the pharmaceutical and food industries trust in the experience and professional competence of PhytoLab, one of Europe's leading service providers.

phyguard® offers you a customised service spectrum for all aspects of pharmacovigilance and product safety. Close contacts established with associations and authorities ensure continuously up-to-date handling in accordance with current statutory requirements.



Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO 2002). HMPs are also required to comply with the European regulations concerning continuous monitoring, which aim to achieve a situation in which products undergo continuous benefit/risk assessment. Regular bibliographic research, sifting through international literature searching for case reports, MedDRA encoding of adverse events, sound scientific evaluations, electronic reporting of serious adverse drug reactions (ADRs) to national authorities and the EMEA, and Periodic Safety Update Reports (PSURs) constitute the key factors for compliance with these requirements. PSURs for HMPs as well as for homeopathic and anthroposophic preparations exclusively prepared for the German Medicines Manufacturers Association (BAH) by PhytoLab; the company was successfully audited within the framework of this project in July 2007. Particular attention is drawn to the fact that our **phyguard[®]** activities also include foodstuffs.



PSUR

The Periodic Safety Update Report (PSUR) plays a central role in pharmacovigilance. Based on bibliographic preclinical, clinical and toxicological data, meta-analyses and reviews, we analyse all of the available data within the framework of the benefit/risk assessment of your herbal medicinal products. If you wish, we can incorporate your own, product-specific data and provide you with the finished PSUR, ready for submission to the national or international authorities.

R&D consulting

The launch of a new product begins with the idea behind it. We support you through every phase of its realisation, including extract development, coordination of preclinical and clinical trials and/or genotoxicity studies. This service applies to medicinal products, food and food supplements (Health Claims Directive). We're with you every step of the way – from the idea through to the finished product.

ADR reports

Regulated by the 5th Announcement of the German Health Authority BfArM relating to the Notification of Adverse Drug Reactions and Drug Abuse, marketing authorisation holders are under obligation to conduct regular research on adverse drug reactions, perform scientific assessments and report them to the responsible authority/authorities electronically. The case reports must also appear as line listings in the PSUR. PhytoLab can perform all of the work relating to this on your behalf.

Pharmacovigilance system

Implemented in German legislation by the 14th Amendment to the German Drug Law (AMG), an application for marketing authorisation must be accompanied by a detailed description of the pharmacovigilance system and the risk management system, where applicable. The way in which our procedures are presented in work instructions and flowcharts enables them to be integrated into the description of your systems.

Expert Reports (pre-clinical and clinical)

We prepare the expert reports required by law for you in the CTD format and for the traditional registration process as well. We draw up draft texts for summaries of product characteristics and package leaflets and provide support for readability user testing at your request. Our medical science experts also draw up customised opinions for special situations (e.g. processing notices of defects).

According to § 63b of the German Drug Law (AMG), the holder of a marketing authorisation is required to submit regular, updated reports on the safety of the pertinent drug (Periodic Safety Update Report [PSUR]) to the responsible authority (cf. § 63b sub-

sections 5 and 7 AMG). We research professionally in Medline and Toxline – and other databases if you wish – on your behalf and prepare literature-based PSURs, including product-specific data as an option.

We also provide a flowchart on request, which gives an overview of the procedures and sequences that are permanently defined in our internal SOPs for integration into the description of your pharmacovigilance system.

