

## THE FEDERAL AND STATE PORTAL FOR PHARMACEUTICAL INFORMATION

### Drug information – centralised and transparent

**PharmNet.Bund is intended to establish an integrated drug information system allowing users to access the official data available within the Federation relating to approved medicinal products in Germany.**

At present, authorisation data, medical information and data concerning clinical trials of medicinal products in Germany are stored in various locations in different configurations and in a variety of formats. This does not make sense. Redundancy and intrasparency of the data management result in unnecessarily lengthy retrieval times with delays to research, data exchange and data administration.

The purpose of the PharmNet.Bund internet portal is to provide a central platform to afford patients, doctors and pharmacists the means to undertake reliable research. Furthermore, the PharmNet.Bund internet portal allows public authorities to efficiently make changes, and enables the pharmaceutical industry an easy facility for the submission of documentation, e.g. in the authorisation procedure.

This will result in significantly leaner communication structures within the health care sector, also leading to a reduction in the economic costs – not only for administration and industry, but also for partners in the health care system. The foundation stone will be thereby put in place for the urgently necessary exchange of drug information on a European level.

The respective user groups will be granted commensurate access permissions and insight into data, by appropriate standards of security. The drug information, prior to its release, will be evaluated by scientific and regulatory experts.

PharmNet.Bund is a co-operative project of the German regulatory authorities – Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), the Paul Ehrlich Institute (PEI) and the Federal Office for Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL) – together with the Robert Koch Institute (RKI) and the German Institute of Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information, DIMDI). The project is implemented in close co-operation with the competent State authorities for drug supervision, which are represented by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, ZLG).



[www.pharmnet.bund.de](http://www.pharmnet.bund.de)

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#### Project Management

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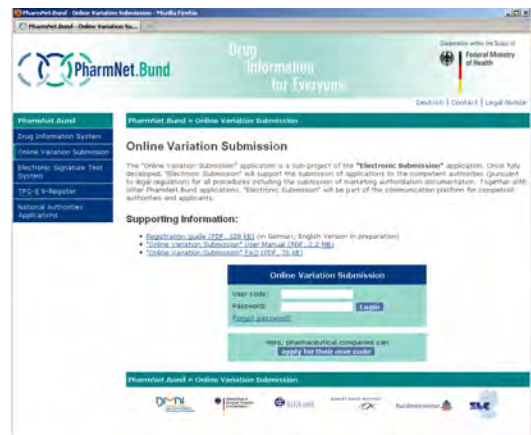
Note: Use of the PharmNet name is made possible through the friendly approval of Cerner Deutschland GmbH that – as a provider for health-care information technology solutions – offers software solutions for pharmaceutical management in hospital pharmacies under this trade-mark. DIMDI and Cerner Deutschland GmbH are not involved in a business relationship.

## The planned PharmNet.Bund Applications

### Online Variation Submission application

This application from the *Electronic Submissions* area will, in its final expansion phase, serve to allow applications for amendments to licensing dossiers and to product information for licensed medicinal products licensed through national or decentralised European procedures.

The *Online Variation Submission* application currently includes the online recording of national change notices and changes to the procedure for mutual recognition and the decentralised procedure of BfArM. The Online Variation Submission application is already in actual operation.



### Clinical Trials (CT)

This application contains national data on clinical trials with medicinal products. The routine operation started in May 2007. Access is currently restricted to competent authorities of the Federal Government and the Laender. The database is continuously adapted to users' requirements. Furthermore, complexity and content are advanced pursuant to the development of EudraCT, the European database of clinical trials, (e.g. paediatrics regulation).

### Register: GMP, TFG Section 9 and Tissues section 8f

- **GMP:** This Register will contain data on the **Good Manufacturing Practice**, i.e. manufacturing and importation authorisations, GMP certificates as well as non-compliance notifications issued by German competent authorities and on verification of relay to the corresponding EMA database. Those data will be transferred to the European EudraGMP database. The first release of the GMP register is the application for online data entry of manufacturing and importation authorisations and was launched in June 2008. The continuous data transfer to EudraGMP is in testing.
- **TFG-§ 9:** This register is based on the German Transfusion law Section 9 and started in December 2008. It is a publicly accessible register of human blood stem cell establishments specifying the activities for which they have been authorised and containing their contact details.
- **Tissues (TPG § 8f):** This register is based on the German Transplantation law section 8f and will be a new register open for public analogue to the register TFG-§9. It will contain information about identification and availability of institutions working on human tissues.

### AMIce

The new information system will assimilate the data from the licensing authorities' current drug information system (AMIS) (AMIS – public section, AMIS – medical service and AMIS for the Bundesländer) and supplement this with further data from the PharmNet.Bund pool. This will create a unified national data pool, which will also facilitate the data exchange with European databases like EudraPharm of the European Medicines (Evaluation) Agency EMA. AMIS is already accessible without a licence (user contract) via PharmNet.Bund: The search and the output of some data, such as name of drug, Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) or Public Assessment Reports (PAR) are free. PAR are evaluation reports which have to be released according to law. Based on information from the registration procedure they describe the quality, efficacy and safety of a drug.