References of principal services provided by PharMillennium Consulting d.o.o.

The following is a list of relevant major pharmaceutical sector assignments and services provided to customers:

Project	Main contractor	Start/finish date	Euro Amount	Recipient
1. Drug regulatory seminars Location: Serbia, Montenegro	PharMillennium	Dec 1999, Dec 2000, June 2001	Approx 15,000 for each seminar - total 45,000	All Serbian and several regional pharmaceutical producers and regional MoHs
Project description: Training seminars "PharmLex 2001, Medicines - WHO, EU & National regulation" provided to all Serbian pharmaceutical producers, wholesalers, pharmacies, University and laboratory institutions on EU, WHO and national drug regulatory requirements. Two-day intensive lecturing type presentations presenting advances in international harmonization, covering regulations and guidelines for medicinal products for human and veterinary use, medicinal devices, OTC, biological, biotechnology products, etc. Concept includes open sessions and round tables for participants. Seminar sponsored by the Ministry of Health of Republic of Serbia and organized with support of Belgrade WHO office. Experts of PharMillennium Consulting d.o.o presented majority of presentations; PharmLex Monte 2001 was organized for the Ministry of Health and Ministry of Agriculture, Forestry and Waters as presentation of novel Republic pharmaceutical regulation.				
2. Ongoing regulatory support to Serbian pharmaceutical industry Location: Serbia	PharMillennium	1998 – ongoing	Private clients	Hemofarm Concern & Zorka Pharma pharmaceutical producers
Project description: Regulatory support for product registration in CEEC and EU member states for 2 Serbian manufacturers including advising to documentation (Part II) development, Pharmaceutical Expert Reports writing (25 products), stability testing studies consulting and leading, analytical development & validation, GMP issues and training, etc. Contracted consulting and advising company for research and development in the scope of quality control and stability testing of pharmaceuticals for Zorka Pharma (Sabac, FRY) pharmaceutical and chemical manufacturer. Assignment covers the development and conduction of stability testing studies for 10 medicinal products. The on-going study also covers planning, tender issuing and qualification of all required equipment, staff organization and training, analytical methods development, establishing of shelf-life specifications, preparation of stability testing protocols, scheduling and supervising of studies, statistical analysis and final report writing, as well as establishing of expiration dates for all products under study. Consulting and advising for the applications in CTD format (Module 2 and 3 compiling, reformatting of SFA to CTD files, etc) including preparation of Quality Overall Summaries.				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
3. Pharmaceutical sector restructuring Republic Montenegro Location: Montenegro	PharMillennium (Sub-contract Lemis, Vienna)	September 2000 - 2004	600,000 (projected) 100,000 (contracted)	Ministries of Health and Agriculture, Republic Montenegro
Project description: Strategic planning and contracted activities on the reorganization of the pharmaceutical sector of the Republic Montenegro covering projecting and reorganization of the pharmaceutical regulatory framework, preparing draft regulations and establishing the Republic's regulatory framework in the scope of medicinal products, food and controlled (toxic, narcotic, abuse) substances including veterinary medicinal products, reorganization and restructuring of the Ministry of Health and establishing of Pharmaceutical Sector, restructuring and reorganization of the Ministry for Agriculture and establishing of Department for veterinary medicines, assessment of the present resources and projecting of the national control laboratory for the quality control of medicines of the Republic Montenegro, as well as projecting and establishing of the Republic Agency for medicines, food and controlled substances; The second phase covers establishing and development of pharmaceutical computerized information systems including networking of Ministries (Health and Agriculture), Agency, NCL, wholesalers, importers and pharmacies. (PHMC experts are authors of the Project, PHMC subcontracted by Lemis, Vienna as investor for project realization as leading company)				
4. Ongoing expert advise & consulting on importation and manufacture of medicines Location: Montenegro	PharMillennium	Jan. 2001 – December 2001	30,000	Ministries of Health and Agriculture, Republic Montenegro
Project description: Continual expert advise and consulting activities for the Ministry of Health and Ministry of Agriculture of Republic Montenegro covering the scope of requirements for the importation, QA/QC and distribution of imported medicines for human and veterinary use, as well as advising on and participation in GMP requirements conformity assessment procedures for local manufacturing sites;				
5. Translations and expert advise & consulting on GMP inspection Location: FRY	PharMillennium	May 2000 - September 2000	0,000	Ministry of Health, Federal Republic of Yugoslavia
Project description: Leading of the ad-hoc working party, nominated by the Federal Ministry for Health, in translation of EU, PIC, PIC-S and WHO documents, preparation of national GMP regulation, GMP Annexes and GMP inspection guidelines;				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
6. Translations and editing of current Ph. Eur. monographs Location: FRY	PharMillennium	May 2000 – September 2000	3,000	Federal Institute for Public Health FRY, Faculty of Pharmacy
Project description: Translation of certain parts of General Methods and monographs of current Ph. Eur. and preparation of certain monographs for new edition of national (Yug.) Pharmacopoeia, led by the Federal Institute for Public Health of FRY;				
7. Translations and presentations of EU veterinary directives and regulation Location: FRY	PharMillennium	Sept. 2000 - October 2000	3,000	Yugoslav Veterinary Medicines Association
Project description: Translation and presentations of EU directives for veterinary medicinal products, VICH guidelines and EU GMP Annexes for the veterinary medicinal products for the Yugoslavian Veterinary Association including participation to organization and realization of SLUV 2000, veterinary medicines symposium;				
8. SEE regional pharmaceutical co-operation initiative Location: SEE countries	PharMillennium (co-operation proposed to WHO, EU, EU Phare BiH, Nordic Council, etc.)	December 2000 - 2004	Project funding under development (CARDS)	Pharmaceutical manufacturers and regulatory bodies of SEE countries
Project description: Promotion of regional idea on December 2000, Belgrade PharmLex 2001 seminar, participation to proposal, organization and realization of presentations of the first SEE Pharmaceutical Manufacturers Conference, held by EU Phare BiH in Sarajevo, April 2001, promoting the idea for the establishment of regional free pharmaceutical market and regional pharmaceutical forum for co-operation of SEE drug regulatory bodies and pharmaceutical industry in the scope of pharmaceutical regulation harmonization; Participation to organization and realization of the first Drug regulatory bodies Meeting, held by EU, WHO and Phare BiH in Sarajevo, October 2001 (participation of DRA representatives from Slovenia, Croatia, Montenegro, RS, Brcko and BiH, Serbia (FRY), FYR Macedonia, Hungary, Romania and Bulgaria).				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
9. Department for pharmaceuticals in the Ministry of Health and Veterinary Department in the Ministry of Agriculture of Republic Montenegro – establishment, training, coordination and computerization Location: Montenegro	PharMillennium (Sub-contracts Lemis, Vienna & IQ Net, Belgrade)	September 2001 – March 2002 Extended to September 2002 Extended to January 2003	50,000 + 5,000 + 25,000	Ministry of Health and Ministry of Agriculture, Republic Montenegro
Project description: Activities on the organization of new, specialized departments as organizational units of the Ministry of Health and the Ministry of Agriculture Republic Montenegro, responsible for human and veterinary pharmaceuticals covering implementation of regulation, education and training of staff, developing of software applications for these departments, projecting and installation of computer networks as well as the applications, training of staff for use of databases and applications, expert advice on-site during six months upon establishment of departments including implementation of Good Regulatory Practice, projecting, organization, software installation and staff training of the proposed National Pharmacovigilance Center in the Ministry of Health. (PHMC experts are authors of the Project and software applications and databases, PHMC subcontracted by Lemis, Vienna as investor for project realization as leading company, IQ Net is software-developing company subcontracted by PHMC). The assignment is extension to the Montenegro MoH restructuring project listed above as the point 3.				
10. GMP auditing and consulting issues and Plant Master Files preparation for local pharmaceutical industry Location: Serbia, Montenegro	PharMillennium	September 2001 January 2002	Private clients	HabitPharm a.d. Podgorica & Zorka Pharma, Sabac pharmaceutical producers
Project description: Assignment covered conduction of internal, contracted GMP audits of these two companies according to PIC/S recommendations, reports writing, training of employees for the preparation of EU-type Plant (Site) Master File(s) and the development as well as the compiling of the appropriate Master Files for contracted facility locations in written and electronic formats. The on-going activities cover continual expert advice services for the maintenance of prepared documentation.				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
11. GMP consulting and Validation Master Plan preparation for local pharmaceutical industry Location: Serbia	PharMillennium	February 2002 - March 2002	Private client	Zorka Pharma, Sabac pharmaceutical manufacturer
Project description: GMP consulting activities in the scope of strategic operation approach to establishing of the company's validation policy. Training of staff within company's Main Validation Team. Collecting of documents and preparation of the major Validation Master Plan for the whole company Zorka Pharma				
12. GMP/Validation consulting and validation Master Plans & protocols preparation for local pharmaceutical industry Location: Serbia	PharMillennium	Feb. 2002 - February 2003	Private client	Zorka Pharma, Sabac pharmaceutical manufacturer
Project description: GMP/Validation consulting activities in the scope of implementation of the established company's validation policy. Training of staff within company's Validation Teams. Collecting of documents and preparation of the Validation Master Plans for the six facilities and five supporting services within the company Zorka Pharma. Preparation of the appropriate Validation protocols proposed by the VMPs, as well as the other validation documentation, including SOPs. Consulting and expert advice as support to the conduction of validation activities according the protocols.				
13. Ongoing regulatory support to Serbian pharmaceutical industry Location: Serbia	PharMillennium	March 2002 - 2005	Private client	Slaviamed, Beograd pharmaceutical manufacturer
Project description: Development of Quality (Part II) registration documentation, advising to development of Efficacy and Safety parts of registration documentation for human medicinal products, as well as the regulatory support for product registration in FRY, CEEC and EU member states for local Serbian manufacturer, including Pharmaceutical Expert Reports writing, stability testing studies consulting and leading, analytical development & validation, GMP issues and training for the documentation preparation according EU standard formats for application, etc.				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
14. Development of QA system, GMP auditing and consulting issues, Plant Master Files preparation for local pharmaceutical industry Location: Serbia	PharMillennium	April 2003 - 2005	Private client	Slaviamed, Beograd pharmaceutical producer
Project description: Assignment covered projecting and initial development of quality assurance/management system including reorganization and conduction of internal, contracted GMP audits of this company according to EU regulations and PIC/S recommendations, reports writing, training of employees for the implementation of QA, GMP systems, for the preparation of EU-type Plant (Site) Master File(s) and the development as well as the compiling of the appropriate Master Files for contracted facility locations in written and electronic formats. The on-going activities cover continual expert advice services for the maintenance of prepared documentation.				
15. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	May 2003 – December 2004	Private client	Lek d.d., Ljubljana, Slovenia pharmaceutical manufacturer
Project description: Development of registration files according requirements of local regulations in S&CG including Quality (Part II) registration documentation, advising to development of Efficacy and Safety parts of registration documentation for human medicinal products, as well as the regulatory support for product registration in S&CG, including organization and monitoring of local bioequivalence/bioavailability studies, clinical trials, etc. Complete Regulatory Affairs service for the foreign manufacturer				
16. Ongoing regulatory support to pharmaceutical industry Location: Serbia, Kosovo	PharMillennium	December 2003 – December 2005	Private client	Farmakos, Prizren, Kosovo, Serbia & Montenegro pharmaceutical manufacturer
Project description: Development of applications and registration files according requirements of local regulations in Kosovo and S&CG including Quality (Part II) registration documentation, advising to development of Efficacy and Safety parts of registration documentation for human medicinal products, as well as the regulatory support for product registration in Kosovo and S&CG, including organization and monitoring of local bioequivalence/bioavailability studies, clinical trials, etc. Regulatory Affairs service as for the foreign manufacturer				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
17. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	June 2004 – February 2005	Private client	Sanofi-Synthelabo, France pharmaceutical manufacturer
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medicinal products of the foreign manufacturer in Serbia. Development of applications for submission according requirements of local regulations in S&CG. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office.				
18. Construction, building and refurbishment of the central laboratory for laboratory medicine Location: Serbia	PharMillennium	August 2004 - ongoing	Private client	Hexalab Institute for laboratory medicine, Belgrade, Serbia
Project description: Expert consulting services, construction, projecting and monitoring of works covering building of the central laboratory for laboratory medicine. Power supply, communication networking, cabling of the information system, internal and external telecommunication system projecting and developing, safety issues, security system and video-monitoring system projecting and establishing, remote access management issues, staffing and educational issues covering staff, organization of the laboratory, samples handling and tracking, electronic patient records system developing, etc. Totally more of 2000 sqm of laboratory and administrative services space on 8 different locations within 100 km distance is covered by the project. Medical diagnostics disciplines covered – biochemistry, hematology, endocrinology, microbiology, virology, PCR, molecular biology, etc.				
19. Training courses Location: Bosnia	PharMillennium	February 2005, May 2005	Private client	Bosnalijek, BiH, Pharmaceutical Manufacturer
Project description: Training courses "PharmLex 2005, Medicines – EU CTD files" provided to all leading Bosnian manufacturer on EU, WHO and national drug regulatory requirements including training on compilation of CTD registration files. Three-day intensive lecturing type presentations presenting advances in international harmonization, covering regulations and guidelines for medicinal products for human use, OTC, biological, biotechnology products, etc. Two courses included pre-course and post-cours testing of the knowledge levels for 87 participants.				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
20. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	February 2005 – May 2006	Private client	Aventis - Sanofi, France pharmaceutical manufacturer
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medicinal products of the foreign manufacturer in Serbia. Development of applications for submission according requirements of local regulations in S&CG. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office.				
21. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	November 2005	Private client	Bosnalijek, BiH, Pharmaceutical Manufacturer
Project description: Regulatory support for product registration in CEEC and EU member states for Bosnian manufacturer including advising to documentation development, CTD Overviews and Summaries writing and compiling of the complete CTD registration dossier Consulting and advising for the applications in CTD format (Module 1, 2, 3, 4 and 5 compiling, reformatting of SFA to CTD files, etc). Complete dossier is covered including administrative, non-clinical, clinical and quality data files. Consulting services and team advising for the manufacturer's registration team.				
22. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	January 2006 - ongoing	Private client	Bosnalijek, BiH, Pharmaceutical Manufacturer
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medicinal products of the foreign manufacturer in Serbia. Development of applications for submission according requirements of local regulations in S&CG. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and the Ministry of Health				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
23. Training courses Location: Serbia	PharMillennium	March 2006	Private client	Actavis-Zdravlje AD, Leskovac, Serbia, Pharmaceutical Manufacturer
Project description: Training courses "PharmLex 2006, Medicines – EU CTD files" provided to manufacturer's staff and management on EU, WHO and national drug regulatory requirements including training on compilation of CTD registration files as well as the reformatting of SFA files to CTD format. Three-day intensive lecturing type presentations presenting advances in international harmonization, covering regulations and guidelines for medicinal products for human use, OTC, biological, biotechnology products, etc.				
24. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	February 2006 - May 2007	Private client	Omnifarm Pharmaceutical Distributor and Representative
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medical devices of the few foreign manufacturers in Serbia. Development of applications for submission according requirements of local regulations in Serbia. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and the Ministry of Health.				
25. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	January 2006 – ongoing	Private client	MedikUnion, Serbia, for ADMEDA Germany Pharmaceutical Representative
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medicinal products of the foreign manufacturer in Serbia. Development of applications for submission according requirements of local regulations in S&CG. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and the Ministry of Health				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
26. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	June 2006 – March 2007	Private client	Messer Tehnogas, Serbia medical gasses manufacturer
Project description: Expert consulting services, professional support, and pre-inspection activities aimed to prepare the customer for the manufacturing site inspection by the official GMP inspection from EU concerning production of Medical oxygen, liquid. Included are validation of production, validation of computerized production control system, validation of technology transfer, validation of analytical procedures and the laboratory of QC, etc. The customer is granted GMP certificate of compliance by the PICs EU inspection.				
27. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	September 2006 – October 2006.	Private client	Messer Tehnogas, Serbia medical oxygen (gasses) manufacturer
Project description: Regulatory support for the registration in Serbia of whole production line of Medical oxygen in liquid and gaseous form. Included are advising to documentation development, writing and compiling of the complete registration dossier Consulting and advising for the applications Complete dossier is covered including administrative, non-clinical, clinical and quality data files. Consulting services and team advising for the manufacturer's registration team.				
28. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	January 2006 - ongoing	Private client	Sandoz,(Lek) Pharmaceutical Manufacturer
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medicinal products of the foreign manufacturer in Serbia. Development of applications for submission according requirements of local regulations in Serbia. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and the Ministry of Health				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
29. Ongoing regulatory support to pharmaceutical distribution company Location: Serbia	PharMillennium	September 2006 – March 2007	Private client	Inpharm, Serbia distributor, representative
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the registration of medicinal products of some foreign manufacturers in Serbia. Development of applications for submission according requirements of local regulations in Serbia. Improving performances of regulatory affairs and communications between responsible offices of the customer and the local representative office. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and the Ministry of Health. Good Distribution Practice consulting and inspection, TQM system development and training of staff				
30. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	March 2007 – ongoing	Private client	Ni Medic and IN Med, Serbia Pharmaceutical Manufacturers
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the manufacture and registration of medicinal products of the local manufacturer in Serbia. Development of applications for submission according requirements of regulations in Serbia. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and the Ministry of Health Supporting and advising in relation to issues of the contract manufacturing and control. Development of Stability testing performances of the local manufacturer.				
31. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	September 2007 – ongoing	Private client	Messer Tehnogas, Serbia medical gasses manufacturer
Project description: Expert consulting services, professional support, and pre-inspection activities aimed to prepare the customer for the manufacturing site inspection by the official GMP inspection from EU concerning production of Medical Nitrous Oxide gas. Included are validation of production, validation of computerized production control system, validation of technology transfer, validation of analytical procedures and the laboratory of QC, etc. The customer is expected to be granted GMP certificate of compliance by the PICs EU inspection.				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
32. Ongoing regulatory support to pharmaceutical distribution company Location: Serbia	PharMillennium	April 2007 – October 2007	Private client	Jugoremedia, Serbia Pharmaceutical Manufacturer
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the manufacture and registration of medicinal products of the local manufacturer in Serbia and Republika Srpska. Development of applications for submission according requirements of regulations in Serbia. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and in Republika Srpska and the Ministry of Health Supporting and advising in relation to issues of the contract manufacturing and control. Development of Stability testing performances of the local manufacturer.				
33. Ongoing regulatory support to pharmaceutical industry Location: Serbia, Republika Srpska	PharMillennium	January 2007 – ongoing	Private client	Actavis Trading, Malta Pharmaceutical Manufacturer
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the manufacture and registration of medicinal products of the foreign manufacturer. Development of applications for submission according requirements of regulations in Serbia and Republika Srpska. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and in Republika Srpska and the Ministry of Health Supporting and advising in relation to issues of the contract manufacturing and control.				
34. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	February 2007 – January 2008	Private client	Actavis Trading, Malta Pharmaceutical Manufacturer
Project description: Post marketing (Phase IV) Clinical Study of some Gastrointestinal medicines in the primary health care in Serbia. 25 Domova zdravlja, 125 medical doctors, 21 specialists of gastroenterology and 1500 patients were included. Complete development of the study documentation (Protocol, Brochure, CRF, etc) , approvals by the Agency, monitoring , etc				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
35. Marketing investigations for pharmaceutical industry Location: Balkans	PharMillennium	April 2007 – ongoing	Private client	Actavis Trading, Malta Pharmaceutical Manufacturer
Project description: Expert consulting services, complete support for the marketing investigations, pharmaco-economic studies, postmarketing surveillance studies, development of the strategic marketing plans, etc.				
36. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	January 2007 – ongoing	Private client	Actavis Trading, Malta Pharmaceutical Manufacturer
Project description: Expert consulting services and development of Pharmacovigilance system in Serbia for the Representative office of the foreign manufacturer. Included is preparation of the first PSURs for the registration (in English), as well as the development of regular local PSURs according the local regulation				
37 Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	March 2007 – ongoing	Private client	Medikunion, Serbia Pharmaceutical distributor and representative of Fleet Co., Spain
Project description: Expert consulting services, translations, and compilations of original files, leaflets, and documents covering local regulatory requirements for the manufacture and registration of medicinal products of the foreign manufacturer. Development of applications for submission according requirements of regulations in Serbia and Republika Srpska. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and in Republika Srpska and the Ministry of Health Supporting and advising in relation to issues of the contract manufacturing and control.				

Project	Main contractor	Start/finish date	Euro Amount	Recipient
38. Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	April 2008 – ongoing	Private client	B.G.Pharm. d.o.o. Belgrade Pharmaceutical Manufacturer
Project description: Expert consulting services, developments, translations, and compilations of files, leaflets, and documents covering EU and local regulatory requirements for the manufacture and registration of medicinal products of the local manufacturer in Serbia and Republika Srpska. Development of applications for submission according requirements of regulations in Serbia. Complete consulting services for the regulatory affairs concerning responsibilities of the Agency for medicines and medical devices of Serbia and in Republika Srpska and the Ministry of Health Supporting and advising in relation to issues of the contract manufacturing and control. Development of Stability testing performances of the local manufacturer.				
39 Ongoing regulatory support to pharmaceutical industry Location: Serbia	PharMillennium	May 2008 – ongoing	Private client	B.G.Pharm. d.o.o. Belgrade Pharmaceutical Manufacturer
Project description: Expert consulting services, professional support, and pre-inspection activities aimed to prepare the customer for the manufacturing site inspection by the official GMP inspection from EU concerning production of medical products for the new manufacturing site in Sopot. Development and implementation of ISO series standards of the QA system including ecology standards. Certification of the implemented standards by the Serbian and EU authorized bodies. Included are validation of production, validation of computerized production control system, validation of technology, validation of analytical procedures and the laboratory of QC, etc. The customer is expected to be granted GMP certificate of compliance by the PICs EU inspection, as well as to fulfill requirements of the national GMP standard as set up by the Law, in force in 2009..				