



Market Access in Eastern European Countries

CAPABILITY STATEMENT:

Medical development infrastructure management and clinical services and market access projects in Eastern Europe, Africa, Middle East and Central Asia

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HEAP Research BV: Focus on Eastern Europe Countries

Economic power is shifting from traditional health care markets in Europe and North-America to upcoming markets in Developing Countries and Eastern Europe. Health care and pharmaceutical industries and providers realize that in the decade to come, the battle for the health care consumer will be fought in developing countries rather than in traditional markets in Europe and North-America.

HEAP Research BV anticipates on these developments by offering medical services development and market access and health restructuring systems and investments opportunities in markets in Eastern Europe, Africa, Middle East and central Asia. We have invested more than 20 years in setting up a network of in-market experts in health and pharmaceutical care, which - together with our team of technical experts in health and economics - can offer you a thorough service in medical services and market access of health care in developing countries and Eastern Europe.

Background and services of the company

In 1994, HEAP Research BV was founded as a limited liability company according to Dutch law. Main Objective of the company: To provide market access capability to manufacturers of pharmaceuticals and medical devices and technical consultation services to mainly the public and private sector to further the development of health care systems within the European Community, Eastern Europe and Developing Countries.

The company provides market access and project investment opportunities for small and medium sized pharmaceutical and medical technology manufacturers and private and public health care providers in growth markets. HEAP Research BV has developed an extensive set of market access and business advisory and project acquisition, development and management services for clients in the pharmaceutical and medical technology industries as well as healthcare policy and delivery organisations and investments in the health care sector

HEAP Research BV is a specialised consultancy in market access and development and marketing of pharmaceuticals and medical devices. Over the last decade, HEAP Research BV has invested extensively in establishing a network of market access specialists, especially in central and eastern Europe and Developing Countries.



Picture: Lining up early morning at a public hospital in Sumatra (2009, EU)

Types of projects by HEAP Research BV

We are active in three different fields:

Medical services development management and investment projects: public and private health care

Increasingly, HEAP Research BV has developing medical services and in addition to a technical and managerial role, the company is assuming the role of investor in health care infrastructure projects. In particular, HEAP Research BV has developed a concept to establish clinics for persons with chronic disabilities in Eastern Europe and Developing Countries. With support from the Netherlands' PSI programme, HEAP Research BV has now established four rehabilitation clinics (Armenia, Georgia, Egypt, Morocco) and the concept is to be rolled out in more markets in the near future.

Health care restructuring: public and private sector

On a global scale, countries are involved in structural healthcare reform. Typical reforms involve the introduction of primary healthcare, the setting up of systems of equitable healthcare financing and the improvement of standards of healthcare delivery. Since 1994 HEAP Research BV has been involved in many

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institutional healthcare reform projects supported by international organisations such as the European Union, the World Bank and national Governments. HEAP Research has developed particular project strength in setting up and managing hospital facilities in niche sectors of a health care system such as rehabilitation services for the chronically ill and mental health. In mental health HEAP Research has also contributed to the development of health policies and strategies on a national and regional level in many countries in the South Eastern European and Caucasus region.

In Georgia, HEAP Research has been active in the field of hospital sourcing and management since 2011. With its partner Medison Ltd, the company set up a clinic for cardio rehabilitation in Tbilisi. The clinic was officially opened in June 2016 and is tailoring to a wide range of patients with cardiovascular problems.

Market access: private sector

Once pharmaceutical products and medical devices are entering clinical stage III, manufacturers need to start thinking about appropriate pricing and reimbursement of their products. HEAP Research BV offers a one stop shop solution for all issues related to pricing and reimbursement from early scoping studies on price identification to successfully finalise negotiations with reimbursement authorities



Picture: Comparative study of clinical practice in EU and Russian Federation (2012, EU)



Picture: Construction of a pharmaceutical production plant in Bulgaria (2006, PSOM)

Track record of HEAP Research BV

Market access of pharmaceuticals and medical devices manufacturers

Clients of HEAP Research BV the past five years have included (list not exhaustive): Alkalabo, Allergan, Ammirall, Amgen, Axogen, Biolitec, BMS, Celltech, Celution, Covidien, Cytosol, Eisai, Genzyme, Grünenthal, GSK, Inspire, Ipsen, Knopp, Linde, Norgine, MSD, Pharmamar, Pharmaxis, Pfizer, Raptor, Sanofi, Shire, Sigma Tau, Solvay, Stallergenes, Tigenics, Takeda, UCB.

Clinical areas of experience have involved: acromegaly, ADHD, allergy, Amyotrophic Lateral Sclerosis (ALS), breast cancer correction, bronchiectasis, cartilage defects, chronic hand eczema, chronic pain, cystic fibrosis, cystinosis, depression, diabetes, DVT, endocrine carcinoma, epilepsy, Enzyme Replacement Therapy (ERT), HIV/AIDS, heart disease and ischemic attacks, hypertension, Irritable Bowel Syndrome (IBS), epilepsy, macular oedema, malaria, medical cannabis, medical devices, oncology, pain management, Parkinson's disease, reflux, respiratory immunotherapy, rheumatoid arthritis, status epilepticus, squamous cell carcinoma, testosterone, steroids, ventilation services and stem cells.

Market opportunities for the public and the private sector

Development of funding proposals for investments supported by institutional organisations such as AgentschapNL (former EVD), FMO, IFC and EBRD for approximately 25 private and public sector clients. Recent

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projects include: Mother and Child Health Care in Macedonia (ORIO) and the set up of rehabilitation facilities for patients with chronic disabilities in Armenia, Egypt and the Sudan (PSI).



Picture: October 2011: Opening by the NL Ambassador and the Armenian Minister of Labour of the "JV Artmed-HEAP" rehabilitation hospital in Yerevan, Armenia (PSI)



Picture: June 2016: Official opening of the Cardio Rehabilitation Centre in Tbilisi, Georgia of the "JV Georgian-Dutch Rehabilitation Centre"

Opportunities for international healthcare reform projects

Over the past ten years about 45 projects in health care reform in Albania, Armenia, Chile, Czech Republic, Egypt, Estonia, Hungary, Georgia, Indonesia, Kazakhstan, Kenya, Lao PDR, Latvia, Lesotho, Lithuania, Macedonia, Malawi, Moldova, Morocco, North Cyprus, Poland, Russian Federation, Romania, Slovakia, South Africa, Serbia, Sudan, Surinam, Tanzania, Thailand, Turkey, Ukraine, Vietnam and Zambia on primary health care, health financing and insurance, pharmaceutical policy, mother and child health care, sexual health, reform of the blood sector, vaccines, hospital management, occupational health, mental health, health policy development on behalf of European Union, Netherlands Government, World Bank, ADB and WHO. Recent work has involved a large reform project of the blood sector in Kazakhstan (World Bank) and a comparative study of clinical practice guidelines in the EU and the Russian Federation (EU).



Picture: Pharmaceutical supply in a regional hospital in Sumatra, Indonesia (2009, EU)

Dr Frans van AnDEL
Chairman of the Board

March 2017