Case Study:
Pharmaceutical Plant

Funded by the European Union's Obnova and Phare Programmes within the project:
EIA Capacity-Building in South Eastern Europe

THE REGIONAL ENVIRONMENTAL CENTER
for Central and Eastern Europe

About the REC

The Regional Environmental Center for Central and Eastern Europe (REC) is a non-partisan, non-advocacy, not-for-profit international organisation with a mission to assist in solving environmental problems in Central and Eastern Europe (CEE). The center fulfils this mission by promoting cooperation among non-governmental organisations, governments, businesses and other environmental stakeholders, and by supporting the free exchange of information and public participation in environmental decision-making.

The REC was established in 1990 by the United States, the European Commission and Hungary. Today, the REC is legally based on a charter signed by the governments of 28 countries and the European Commission, and on an international agreement with the government of Hungary. The REC has its head office in Szentendre, Hungary, and country offices and field offices in each of its 15 beneficiary countries which are: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, FYR Macedonia, Poland, Romania, Serbia and Montenegro, Slovakia and Slovenia.

Recent donors are the European Commission and the governments of Albania, Austria, Belgium, Bosnia and Herzegovina, Canada, Croatia, the Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Italy, Japan, Latvia, Lithuania, FYR Macedonia, the Netherlands, Norway, Poland, Serbia and Montenegro, Slovenia, Sweden, Switzerland, the United Kingdom, and the United States, as well as other inter-governmental and private institutions.

ISBN: 963 9424 307

Published by:
The Regional Environmental Center for Central and Eastern Europe
Ady Endre ut 9-11, 2000 Szentendre, Hungary
Tel: (36-26) 504-000, Fax: (36-26) 311-294, E-mail: info@rec.org, Website: <www.rec.org>

This and all REC publications are printed on recycled paper or paper produced
without the use of chlorine or chlorine-based chemicals

This publication has been produced with the assistance of the European Union.
The contents of this publication can in no way be taken to reflect the views of the European Union.

Pharmaceutical Plant

Introduction

The enterprise will produce a range of pharmaceutical products. The operation will comprise of three sites called "1", "2" and "3", all of which are located in the northwestern industrial zone of the city of Sofia. [In the following text, the sites are only referred to as 1, 2 and 3. Check anything with 1, 2 and 3 to see if it should be labelled A, B or C.]

Site 1: Production Facility and Supporting Infrastructure

General Description

Site 1 occupies an area of approximately 4.3 hectares. There will be 24 main buildings, which will include company offices, production and packaging facilities, laboratories, a vehicle maintenance yard and some welfare buildings. It will be located between two boulevards, about 600 metres to the north of one residential district and approximately 400 metres east of another residential district.

Adjacent to Site 1 are a number of industrial operations, including a medical apparatus plant, a rubber products plant and metal-sawing machinery plant.

Production Processes

The various production processes carried out at Site 1 are as follows:

- tablet production, which consists of a workshop where tablets are formed from bulk products with processes including grinding, mixing, filtration, drying, tablet pressing, separation and sorting lines and packing;
- phytochemical production processes involving the extraction of re-agents from biological materials. Proposed equipment comprises diffusion extractors, grinders, fast-evaporators, separation funnels, distillers and various drying-process equipment;
- production of 'Carsyl', a product of purified concentrate involving grinding, ethanol-extraction, settling and drying;
- organic synthesis of 'Atenolol' and 'Pyroxicam' products. Proposed equipment includes reactors, grinders, collectors, pumps, vacuum-evaporators, filter-presses, centrifuges and shelf-dryers;
- a 'Galenica' section at which herb extracts, ready syrup forms, tinctures and barium sulphate preparations will be made. The facility comprises fodder-shredders for grinding herbs, percolators for extraction, fast-evaporators for regeneration of the solvent and filter-presses; and
- additional 'Galenica' production areas for syrup production. Proposed equipment includes reactors for sugar solutions, filter-presses; homogenisers, melting cauldrons and transport pumps.

Site 2: Production Facility

Site 2 is located 1,000 metres north of Site 1, on a boulevard, about 200 metres to the southeast of an industrial district. The site will include 28 main buildings, or plants, on an area of about 13.4 hectares, which will include production facilities, most of the bulk storage facilities for feedstocks, oil and products, offices, laboratories and some welfare buildings. Immediately adjacent to the site's southern boundary, located outside the fence-line but within the enterprise's land, is a former dumpsite area where production wastes have been disposed of in the past.

The closest residential buildings to Site 2 are about 450 metres away. Apartment blocks in a residential district are approximately 650 metres away.

Two cosmetic production plants are located adjacent to Site 2, along with an electrical appliance production plant.

Production Processes

The various production processes carried out at Site 2 are as follows:

- antipyretics workshops, which will produce 'Pyrasolon' using reactors, settling tanks for waste-water-salt liquor and dryers;
- an ampoules workshop for the production of distilled water ('Stilmaz') and demineralised water ('Milipor').

Processes will include sterilisation, filling, sealing, inspection and packaging;

- insulin production through pig pancreas extraction using grinders, extraction reactors, a decanter centrifuge, separators and a rotation-vacuum evaporator;
- 'Pyramem', 'Tempidon' and 'Captopril' production using reactors, grinders, collectors, pumps, centrifuges, filter-presses and dryers;
- lyophilic bioproduct production using reactors, filtering systems, automated filling and washing lines; and
- a gamma sterilisation workshop, which will comprise an industrial stationary irradiator, gamma-ray source and processing line.

Site 3: Warehouses

Site 3 will be located about 1,500 metres northeast of Site 2 in a semi-rural area, which is approximately 800 metres from a residential district. The site will occupy an area of about 5.1 hectares and will have eight subdivided warehouses to be used for the storage of drummed and dry goods and packaging materials. There will be several relatively small tanks and a storage compound for salvaged reactor vessels.

Warehouses used for the bulk storage of oils and other related chemicals owned by three different companies are located next to Site 3.