

HELM AG.



"When choosing a partner for a transdermal development, experience, professionalism, and trust are key. Amarin has brought that along with deep expertise into our business relationship, exceeding all our expectations and leading to a long-lasting partnership."

Dr. Christian Zechel, Head Portfolio Development Pharma, Helm AG.

- Multifunctional distribution company specializing in Chemicals (feedstocks and derivatives), Crop Protection, Active Pharmaceutical Ingredients and Pharmaceuticals & Fertilizers.
- Presence in +30 countries.
- +1600 employees
- + EUR 5 billion in external revenues

The opportunity

Since their foundation in Hamburg in 1900, HELM has concentrated and developed a business model focused on commercialization, being today one of the world's major independent chemicals marketing enterprises. It is due to this that they do not own development capabilities for their Pharmaceutical Business Unit, but instead, are constantly seeking for high quality pharmaceutical products that can offer a significant added value to their portfolio. On the other side of the ocean, Amarin Technologies, was a growing and promising R&D company making its way into the international market, obtaining international patent that protected its developments, but counting with limited financial resources to expand globally. However, their professionalism, expertise, company values and determination allowed them to reach an agreement with HELM for a transdermal development project, where both companies would benefit: Helm would be able to expand its portfolio of niche products in Pharma with non-traditional pharmaceutical forms and Amarin would validate its technology and capabilities with products of its development being commercialized in international markets.

The development success: Fentanyl

In early 2004, HELM & Amarin Technologies signed an agreement for the development of a generic transdermal patch of Fentanyl (a synthetic opioid narcotic used in medicine for its analgesic and

anesthetic effects). The R&D work was led by Amarin Technologies. The company carried out the pharmaceutical development and the readiness of the production processes, as well as all the necessary stability studies, the initial clinical studies and the collection of the pharmaceutical information to face an investigational medicinal product dossier.

After verification of the proof of concept, HELM funded and led the clinical program required to ask for the marketing authorization. After successful results, Amarin was in charge of the preparation of the dossier to be presented to the European Authorities, with the support of the regulatory area and expertise of HELM's team, who had a greater knowledge of European regulations.

Two years later in 2006, the final product was submitted for registration and approved for commercialization in early 2007.

The generic product was conceived as a bilayer transdermal patch with the capability to exert a controlled drug release, assuring that the dose delivered is not only metered by the skin of patient but also by action of the delivery device. This concept deserved the grant of US and EU patents which protect the composition.

One of the major highlights of this project was the construction of a patch manufacturing plant in Argentina required to supply the product to international markets. During the development process, the plant was built in record time, followed by a scaling up of the manufacturing process and it was inspected and approved in August 2006 by the German authority. To this day, Amarin owns the only transdermal patch factory in Latin America.

Amarin Technologies supplied over 6 million patches between 2007 and 2013. After this period and due to the growing demand of the Fentanyl patch in Europe, the production was transferred to two European manufacturers.

The result

The development project was a major success for both companies. To date, close to 40 million patches have been sold in more than 10 countries, such as Germany, Argentina, Austria, Chile, Colombia, Spain, France, Greece, Hungary, Italy, Portugal, South Africa, Korea and Taiwan. The project overall generated a cumulative turnover of more than € 170 million and the product continues to have a prominent place in Helm AG's sales.

The project in numbers

- 40 million patches sold
- Reached over 10 countries
- € 170 million turnover up to date