SCIENCE PHARMA

More than consulting

Support services for

REGULATORY AFFAIRS

RICH EXPERIENCE

TRANSPARENCY IN ACTION

CREATIVITY IN SOLUTION SEARCH

INTERDISCIPLINARY TEAM

www.sciencepharma.com

ABOUT US

SciencePharma (SPh) is a dynamically developing Polish private company offering specialized **consulting services** for the **pharmaceutical sector**. We are a leader among consulting companies operating in Poland and abroad since **2004**. For several years, we have been successfully implementing national and international projects (**EU, non EU**).

OUR STRENGTHS

REASON 01

knowledge of legal requirements, guidelines, procedures and expectations of registration agencies regarding the scope and quality of registration documentation,

REASON 02

multidisciplinary, highly qualified team of experts in various specializations - pharmacists, chemists, biologists, lawyers...

REASON 03

holistic and interdisciplinary approach to projects,

REASON 04

flexibility of services and **tailor-made solutions,**

WHY US?

WHAT WE DO ?

For almost 20 years, we have been supporting clients from Poland and abroad in the field of **registration of medicinal products**, **pharmacovigilance**, **GxP audits**, **clinical** and **non-clinical trials**, and the implementation of **research and development projects**.

We also specialize in the **import of medicinal products**, having in our team experts on **GMP requirements** and **qualified persons (QP)**. We also offer a full range of services in the field of the **quality** of medicinal products, including assistance in **technology transfers**, **validation of manufacturing processes** or implementation of the **GMP system**.

We provide support throughout the whole **product life cycle**, of development research to commercialization.

OUR SERVICES

1	2	3	4
Product development	Clinical trials	Quality	GxP Audits

5	6	7	
Regulatory Affairs	Pharmacovigilance	QP Services/ importer	Read more

REGULATORY AFFAIRS

SciencePharma offers multidisciplinary services covering all aspects of regulatory affairs, including pre-authorisation stage of a **medicinal product** (**human/veterinary**). We also have all the conditions to support your company in the field of regulations regarding **medical devices**, **cosmetics** and **dietary supplements**. We also assist in placing **ATMP products** on the market.

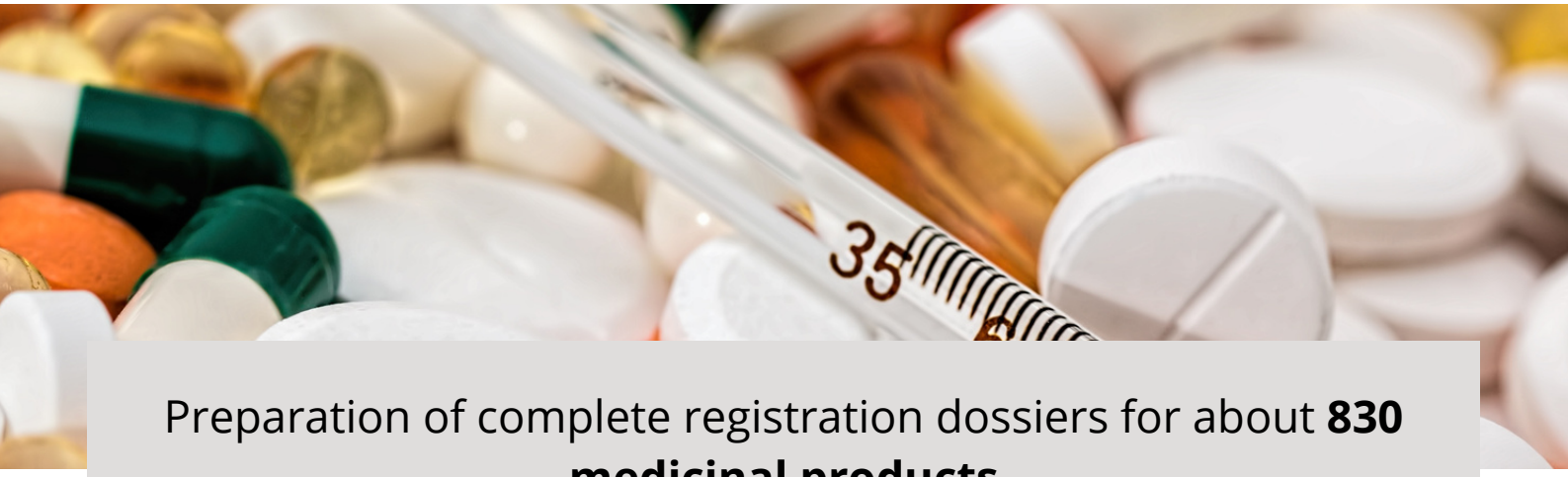
OUR EXPERIENCE

Over **320** successful registration processes in **national procedure.**

Over **170** registration processes in **European procedures** (MRP, DCP).

Over **200** scientific opinions/advices concerning the scope of requirements for the registration dossier.

Preparation of more than **330 ASMF** assessments in view of their registration readiness.



Preparation of complete registration dossiers for about **830 medicinal products**

ABOUT 20

for original medicinal products.

OVER 550

for generic medicinal products.

OVER 50

for herbal medicinal products.

ABOUT 40

for hybrid medicinal products.

ABOUT 120

for well-established use medicines.

OVER 8

for biological medicinal products.

OVER 5

for biotechnological medicinal products.

OVER 15

for ATMPs and Medical Cannabis.

SCOPE OF ACTIVITY

THE MAIN TASKS OF REGULATORY AFFAIRS DEPARTMENT INCLUDE:

1. Pre-authorisation procedures support
2. Handling the registration process
3. Post-authorisation procedures support
4. Regulatory outsourcing
5. Pharmaceutical law consulting

1. Pre-authorisation procedures support

SCOPE OF PRE-AUTHORISATION SERVICES INCLUDES:

- **Regulatory strategy** preparation indicating the optimal registration path, registration category, costs and the chances of the project success.
- Assessment of documentation readiness for the registration procedure – so-called '**dossier Gap analysis**'.
- Planning, organization and active participation in **Scientific Advice** and pre-submission meetings.
- **Product Information** management covering both: **Readability test** & **Bridging report**, **Product Information Preparation** & **Verification** (including mock-ups) & **Translation** and **Educational materials verification**.
- **Preparation of registration dossier** (modules 1-5) for the national and European procedures in CTD/eCTD/NeeS format encompassing starting from **Application Form Preparation**, through **Quality Overall Summary (QOS)** & **Module 3** preparation ending with preparation of **non-clinical** & **clinical** part of dossier...

...AND MUCH MORE!

2. Handling the registration process

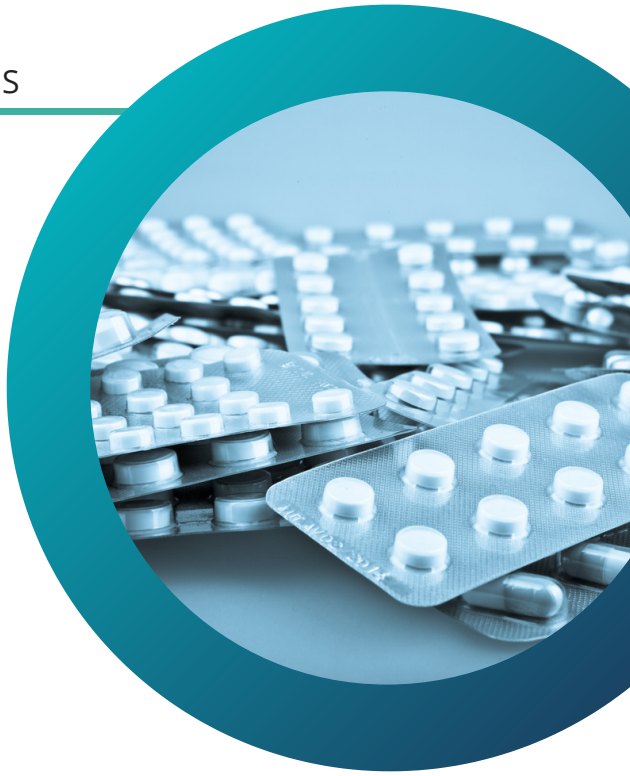
We have taken part in hundreds of marketing authorisation processes covering all types of procedures: **purely national, European including decentralised**, mutual recognition and repeat use procedures (**DCP/MRP/RUP**) and centralised (**CP**).

We had the pleasure of cooperating with different **EU Competent Authorities (CA)** such as AGES (AT), BfArM (DE), FAMHP (BE), BDA (BG), AIFA (IT), MoH (CY), SUKL (CZ, SK), OGYEI (HU), MMA (MT), INFARMED (PT), AEMPS (ES), URPL (PL) & others. In regards to non-EU CA, we have cooperated with CA such as MHRA (UK), Health Canada (Canada) or Swissmedic (CH).

SCOPE THE REGISTRATION SERVICES INCLUDES:

- **eCTD compilation** and dossier submission to CA.
- Active monitoring of national and European registration procedures.
- Full support during communication with national competent authorities and with EMA.
- **Preparation of responses to the deficiency letters.**
- Coordination of registration procedures as "**Central Coordinator**" or as "**Local Point**" in mutual recognition and decentralised procedures.
- Preparation of **Product Information**, including PI translation.

3. Post-authorisation procedures support



Obtaining **Marketing Authorisation (MA)** is undoubtedly a milestone, but it is worth remembering that post-authorisation aspects are an important stage in the product life cycle, and they need to be supervised properly.

SciencePharma offers a wide range of post-authorisation services helping to keep MA in proper condition.

SCOPE OF POST-AUTHORISATION SERVICES INCLUDES:

- **Product lifecycle management** covering **all types of variations management, line extension application, sunset clause exemption, annual fees, renewals** and **withdrawals applications**
- **OTC switches** comprehensive support – we have experience in Rx to OTC switches performed in different EU countries, by different EU CA.
- **MAH transfers** application and support, not only in Poland but also in different EU countries.
- **Promotional materials review.**
- **Medical information** service...

...AND MUCH MORE!

4. Regulatory outsourcing

Regulatory outsourcing in the case of SciencePharma is a broad concept that covers many activities that our experts perform for our clients in the field of Regulatory Affairs. For many years, our Regulatory Outsourcing has been used by many pharmaceutical companies with a diversified portfolio.

SCOPE OF THE REGULATORY OUTSOURCING SERVICES INCLUDES:

- **Full regulatory service** and **consultations** concerning actual normative regulations referring to registration, renewal, variations and notifications of medicinal products.
- Interactions with the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, other governmental or regulatory authorities in connection with any product.
- **Marketing Authorization application (MAA) submissions.**
- **Life-cycle management:** post-approval submissions (eg. variations, notifications, line-extensions, renewals), keeping track of annual fees, sunset clause exemption submissions.
- **Regulatory dossier compilation** (eCTD), publishing and dispatch.
- **Updates** and **translations of product information** (PI) in Polish and English.
- **Translation** of deficiency letters, MA and any other official documents into English.
- **Review of the product mockups** for compliance with PL and EU legislation.

5. Pharmaceutical law consulting

Pharmaceutical law consulting in the case of SciencePharma is a broad concept that covers many activities that our experts perform for our clients in the field of Pharmaceutical law.

SCOPE OF PHARMACEUTICAL LAW CONSULTING SERVICES INCLUDES:

- Medicinal product (human and veterinary), ATMPs, medical devices, cosmetics, food supplements **consultations regarding authorisation/notification**.

- **Support in meeting** the local requirements in Poland but also in other EU countries (e.g. Bollini label in Italy, support in finding MAH exploitant in France) and non-EU registration agencies, such as Canada or Switzerland.

- **Consultations on various types of imports**: import from third countries, parallel import, targeted import, compassionate use, hospital exemption and other non-standard methods of introducing a medicinal product to the EU market.

- **Consultation and assistance in legalization process of documents** (e.g. GMP certificates, MIA or CPPs) in different embassies, such as the embassy of Iraq and others located in Poland.

- **Assistance in the preparation of various types of legal contracts**, including technical contracts required for MAH transfers or quality/distribution contracts...

...AND MUCH MORE!

REGULATORY SERVICES LIBRARY

Preparation of **Scientific advice**

Preparation of **Regulatory strategy** (Regulatory roadmap)

Pharmaceutical **law consulting**

Conduct of **Package Leaflet Readability Test**

Dossier preparation (**Module 3)**

Preparation of **clinical part** of registration dossier

Preparation of **Environmental Risk Assessment**

Dossier Gap analysis

Preparation & translation of **Product Information**

Preparation of **Bridging Report**

Preparation of **Educational materials** (with RMM)

Preparation of **QOS**

Preparation of **non-clinical part** of registration dossier

...READ MORE!

- **Product Information** & **mockups verification**
- Preparation of **Application form**
- **eCTD compilation**
- Responses to **Deficiency Letter**
- **OTC switch**
- **Product lifecycle management**
- Preparation of **Line extensions**
- Preparation of **Sunset clause exemption**
- Preparation of **Renewal**
- Preparation of **Annual fees**
- **Transfer of MA**
- Preparation of **Withdrawals**
- **Promotional materials** review
- Preparation of **Medical Information**

If you have **any questions** related to Regulatory Affairs services, do not hesitate to **contact us.**

SCIENCE PHARMA

CONTACT US

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District Court for the Capital City of Warsaw in Warsaw, XIII Commercial Division of the National Court Register
KRS: 0000957621, VAT EU: PL 113-26-79-319, share capital in the amount of PLN 50,000
SciencePharma sp. z o.o. has status of a large entrepreneur within the meaning of art. 4 point 6) of the Act of March 8, 2013 on counteracting excessive delays in commercial transactions.