PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

# MEDICAL INFORMATION SERVICES

## ONE-STOP SHOP FOR MEDICAL INFORMATION INCLUDING ADVERSE EVENT AND PRODUCT QUALITY COMPLAINT MANAGEMENT

Marketing Authorization Holders are legally required to have a dedicated **medical information service** in place for their marketed medicinal products (Article 98 of Directive 2001/83/EC indicates that "the marketing authorization holder shall establish, within his undertaking, a scientific service in charge of information about the medicinal products which he places on the market").

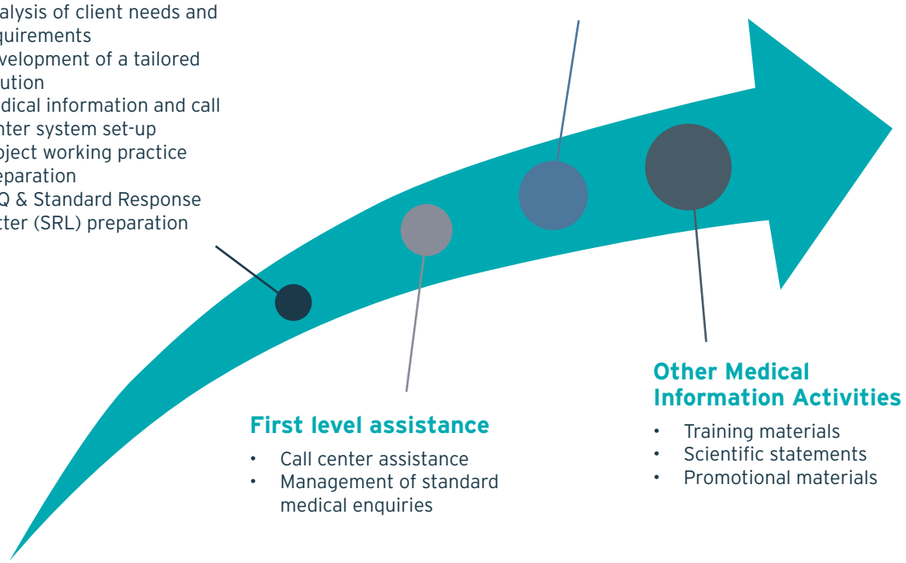
The legislation also reinforces the importance of regulating the quality of the information made available to patients and healthcare professionals, as well as setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products (Article 88a of Directive 2004/27/EC amending Directive 2001/83/EC).

**PharmaLex** can help clients to consolidate their local presence worldwide through a dedicated network of Medical Information Experts, speaking more than 40 languages and with extensive industry expertise. We are committed to developing Medical Information departments to become the leading source of **high-quality, balanced and constructive information**.

## EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

### Project set up

- Analysis of client needs and requirements
- Development of a tailored solution
- Medical information and call center system set-up
- Project working practice preparation
- FAQ & Standard Response Letter (SRL) preparation



### First level assistance

- Call center assistance
- Management of standard medical enquiries

### Second level assistance

- Management of non-standard medical enquiries
- FAQ / SRL maintenance

### Other Medical Information Activities

- Training materials
- Scientific statements
- Promotional materials


## PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

### Medical Information Services

- Service managed by Medical Information experts with long-term experience in different therapeutic areas
- Provision of Medical Information Officers with native language skills for all EU countries
- Provision and set up of a fully compliant Medical Information database
- Preparation and maintenance of Frequently Asked Questions (FAQ) and Standard Response Letters (SRL)
- Provision of a full FIRST line multi-lingual call centre support for medical information enquiry management
- Provision of SECOND line support by an in house medical team (Health Care Professionals and Safety Physicians)
- Compliance with local/global legislation and client procedures and requirements
- Management of product complaints, adverse events, device incidents and non-medical enquiries
- Promotional material review handling
- Review of training materials
- Scientific statements consistent with product labelling and regulatory guidance

**25+ YEARS**
OF INDUSTRY EXPERIENCE

**9/10**
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

**200+**
EXPERIENCED AND CERTIFIED LOCAL REPRESENTATIVES SUPPORTING OUR GLOBAL COVERAGE

**40+ NATIONALITIES**
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS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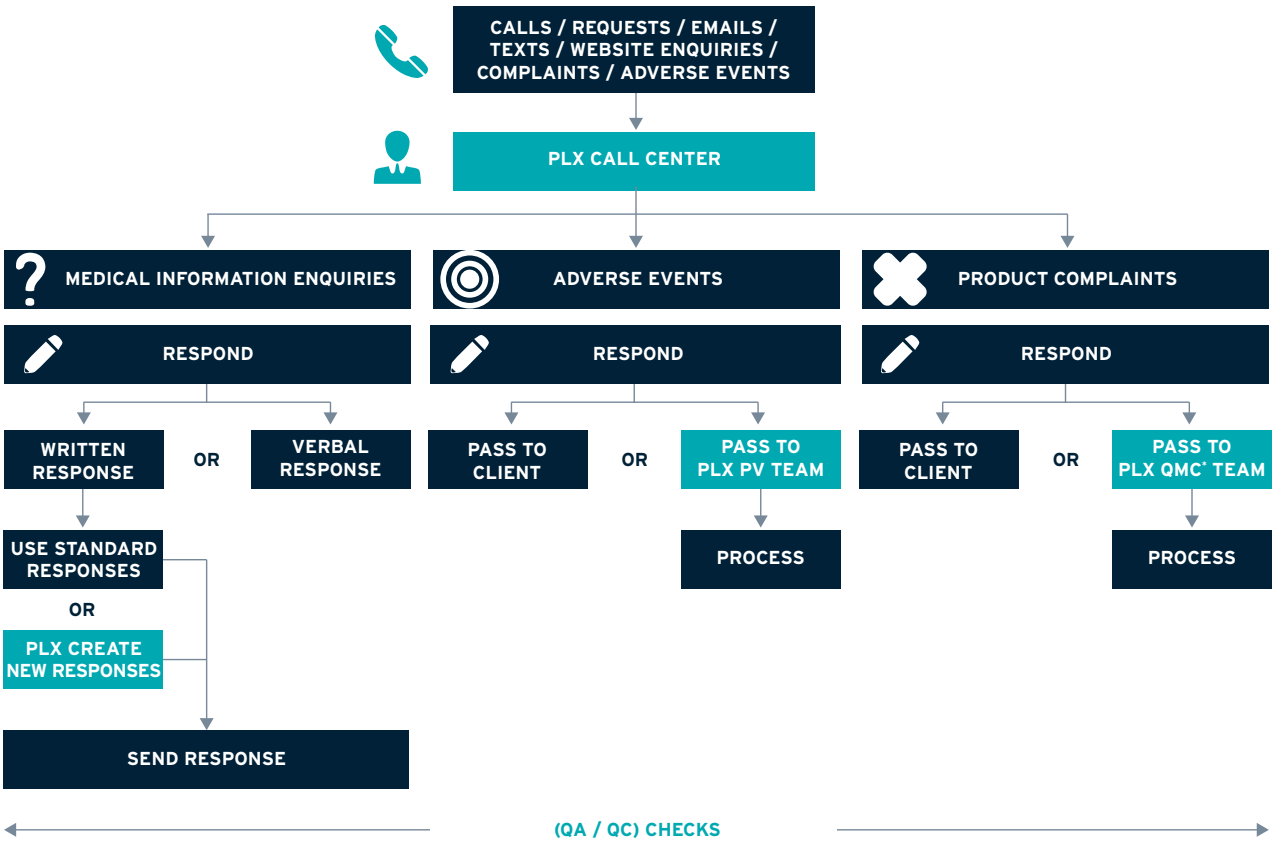
## OUR PROCESS:




## DELIVERING SUCCESS WITH CONFIDENCE

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

The PharmaLex Group now has over **1000** employees, with **33** offices in **21** countries and more than **600** satisfied clients worldwide.

Stay **one step ahead** of essentials requirements needed by health agencies. Our knowledge accelerates your business sucess...

**Knowledge. Accelerated.**

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

## CONTACT US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