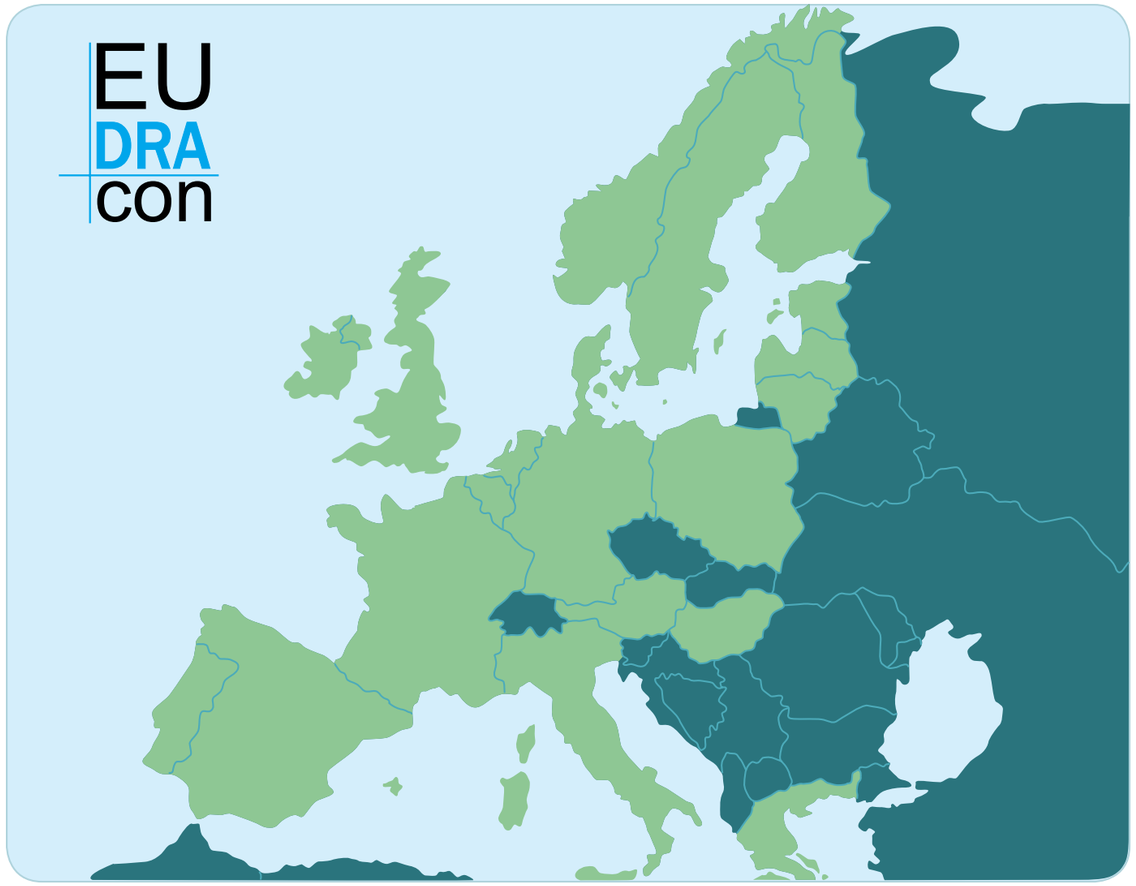

EuDRAcon members list

Currently the following members, in alphabetical order of country, belong to the EuDRAcon network.

Country	Member	Contact
Austria	Lionpharm GmbH	www.lionpharm.com
Belgium	Farmaconsult	www.farmaconsult.be
Denmark	Jacobsen Pharma AS	www.jacobsenpharma.dk
Estonia	CentralPharma Communications Oü	www.centralpharma.ee
Finland	DRA Consulting Oy	www.dra.fi
France	Medipha Santé	www.medipha-sante.fr
Germany	Lionpharm GmbH	www.lionpharm.com
Greece	Pharos Ltd.	www.pharosgr.gr
Hungary	Pro-Pharma '93 Ltd.	www.propharma.hu
Italy	Di Renzo Regulatory Affairs	www.direnzo.biz
Ireland	Wainwright Associates Limited	www.wainwrightassociates.co.uk
Latvia	CentralPharma Communications SIA	www.centralpharma.lv
Lithuania	CentralPharma Communications UAB	www.centralpharma.lt
Luxembourg	Farmaconsult	www.farmaconsult.be
Netherlands	Baggerman Farma Consult BV	www.bfc.nl
Poland	APC Instytut	www.apcinstytut.pl
Norway	Mericon	www.mericon.no
Portugal	PharSolution	www.pharsolution.com
Spain	R.C.A. Pharma	www.rcapharma.com
Sweden	Scandinavian Regulatory Services AB	www.srs.se
UK	Wainwright Associates Limited	www.wainwrightassociates.co.uk

EuDRAcon is a young developing network pursuing to fill the vacancies for those EU member states not yet included in the list.
Check the EuDRAcon website for the last details of membership.

EuDRAcon - how to contact

EuDRAcon can be contacted in a number of ways:

- Contact the website www.eudracon.com for more details of the network or its members
- Contact the current chairman, to be found on the website, to discuss potential projects and the potential involvement of the EuDRAcon network
- Contact any of the members in the countries relevant to your project

EUROPEAN KNOWLEDGE AND NATIONAL EXPERTISE IN REGULATORY AFFAIRS








EuDRAcon-an introduction

EuDRAcon is a pan-European network of regulatory affairs consultancy companies dealing with drugs, medical devices, cosmetics and food supplements. The network was established in 2007 and the majority of the members share a long history of cooperation in various international regulatory projects. From the member list it will be clear that the network covers most of the member states of the European Union plus Norway.

The members of EuDRAcon are all independent companies with strong local roots and sound knowledge of their national regulatory systems and procedures. All members have a well-established track record, some of them dating back to the late eighties.

EuDRAcon's mission

It is EuDRAcon's strong belief that European regulatory projects are best served by providers with an excellent European exposure and knowledge, while maintaining their primary national focus and expertise.

EuDRAcon's solid European network

EuDRAcon has a solid structure under rotating chairmanship. Six-monthly meetings are held to optimise the cooperation between members, to define codes of conduct and to identify and discuss emerging regulatory issues of interest to clients, as well as constantly expand the range of services it can offer clients. By doing so, EuDRAcon provides its clients, both from inside the EU as well as from non-EU countries, with easy access to this combined expertise without the need to look for separate contacts in the various European countries.

From the network only those companies will be involved as needed for clients specific projects, be it only one member for a purely national procedure; two for a small-scale Mutual Recognition Procedure or the complete spectrum for a full scale Centralised or Decentralised Procedure. Additionally, full scale assistance can be given regarding CE marking of medical devices.

This gives clients' full flexibility to tailor their European regulatory projects according to specific requirements and to adapt such projects to whatever European marketing strategy best fits their products.

EuDRAcon's strong national exposure

European regulatory projects need a strong national exposure in the various member states, in particular during the last national phase of the submission. All EuDRAcon members have a long history of cooperating with the national regulatory authorities and have solid contacts in these authorities. This enables the smooth and quick resolution of any issues that might occur during any of the European registration procedures.

Naturally, each of the EuDRAcon members operates within its local network which may cover related areas of interest for that particular member state. Some member states require pharmaceutical companies' to apply or to omit specific distribution models in their country, needless to say that detailed knowledge of such additional requirements is paramount for your access to that country.

Such national exposure is certainly of interest for the country which you might want to choose as the reference mem ber state in your European procedure. The coordination of such a project requires a project leader, fully acquainted with the local peculiarities, which is why all projects with EuDRAcon are led by its member companies principals with high personal involvement. Such an engagement may be hard to find from multinational full service providers.

EuDRAcon's comprehensive regulatory services

EuDRAcon is able to provide sound strategic advice during early product development in planning for an eventual regulatory approval. Naturally, leadership can be provided in preparing the necessary documentation for submission and in handling the day-to-day communications with the authorities during the assessment phase of the procedure, both at the national and European level.

Even in the situation where a regulatory submission has been refused, EuDRAcon would be pleased to advise on a suitable strategy for overcoming the refusal and provide leadership in preparing for and presenting an appeal to the appropriate regulatory authority.

EuDRAcon can also help with the regulatory life cycle maintenance including variations and renewals, as well as with relevant post-approval activities, such as distribution model design, pricing & reimbursement, pharmacovigilance, promotional review and approval.

EuDRAcon has specialists experienced in many product types and therapeutic areas. These include medicines (both human and veterinary), medical devices, food supplements, herbals and cosmetics. All the relevant scientific disciplines are covered by consultants within EuDRAcon, such that advice can be provided on technical as well as regulatory matters.

Full list of services

- Appeals and referrals
- Assessment of scientific data
- CE marking of medical devices
- Centralised, Decentralised and Mutual Recognition procedures
- Clinical development
- Clinical trial authorisations
- Compiling/writing of dossiers
- Demarcation of drugs, medical devices, cosmetics and foods eCTD compilation and publishing
- GCP and GMP audits
- Leaflet user testing
- Liaison with regulatory authorities
- Licensing
- Medical writing
- Orphan designation
- Pharmaceutical development
- Pharmacovigilance
- Pre-clinical development
- Pricing and reimbursement
- Promotional material review
- Renewals
- Scientific advice applications
- Strategic regulatory planning
- Translations
- Variations
- Writing of summaries and expert reports