Collaboration between public sector researchers and the pharmaceutical industry in pharmacoepidemiological research.

A position paper by the Danish Pharmacoepidemiological Society (DSFE) and the Danish Association of the Pharmaceutical Industry (Lif)

Background

Denmark has a unique position in pharmacoepidemiological research, partly owing to the acclaimed Danish health data registries. These registries constitute a resource that is often used in collaborations between public sector researchers and the pharmaceutical industry. This position paper by the Danish Pharmacoepidemiological Society (DSFE) and the Danish Association of the Pharmaceutical Industry (Lif) originates from the realization that the best results predicate good collaboration based on a common understanding.

Accordingly, our ambition is to highlight the existing, well-functioning collaborations between public sector researchers and the pharmaceutical industry whilst also supporting closer collaboration in the future.

Aim

In this joint paper, DSFE and Lif wishes to describe the two associations' approach to the use of health data from Danish registries and set out the principles for collaboration between public sector researchers and the pharmaceutical industry for pharmacoepidemiological studies.

About the Danish Pharmacoepidemiological Society (DFSE)
DSFE is a scientific society that aims to promote the development of pharmacoepidemiology as a research discipline in Denmark and thus contribute to appropriate usage of drugs.

About the Danish Association of the Pharmaceutical Industry (Lif)
Lif is the industry association for research-based pharmaceutical companies in Denmark. Lif represents 33 Danish and international pharmaceutical companies.

Position

DSFE and Lif find that is it important that health data from Danish registries is actively used to benefit patients and the community. This can be achieved both by using the registries to support efficiency, quality, and safety in the national health service's treatment of patients, and via research that contributes to effective and safe use of drugs. The rights of citizens with respect to health data and not least the rules of the Health Act and Data Protection Act on disclosure, insight and consent, must be respected. Further, DSFE and Lif find that it is important that clear guidelines on access to and use of health data exist.

Dealing with health data predicates solid professional competencies. Accessing and using health data should be based on assurance of the requisite professional quality. This applies to both public and

private parties. If companies do not themselves have adequate competencies, collaborating with public sector researchers is a good way to ensure the necessary quality of the work.

A good public/private partnership provides for safe and confidence-building use of health data in research. The associations have found that we currently have good, safe public/private collaborations on non-intervention studies with high quality research. Such studies may be initiated by the authorities or on the initiative of companies and they most often involve the use of Danish health data.

DSFE and Lif agree with the established principles for public/private collaboration in the field of pharmacoepidemiological research. These are set out in European legislation on Good Pharmacovigilance Practice (GVP) Module VIII, and in two key guidelines: Good Pharmacoepidemiological Practice (GPP) issued by the International Society of Pharmacoepidemiology (ICPE) and the Code of Conduct issued by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Reference is also made to the Joint Declaration on clinical drug trials and non-intervention trials, by the Danish Association of the Pharmaceutical Industry (Lif), the Organisation of Danish Medical Societies (LVS) and the Danish Medical Association.

Further to these guidelines, DSFE and Lif wish to specifically emphasise the following four principles that should also in future act as the basis for collaboration between private companies and public sector researchers:

- **Contractual basis**
  Projects are subject to the above-identified guidelines, i.e. before they start, projects are to include a contract, protocol, analysis plan and publication plan
- **Publication of scientific results**
  As described for example in GPP, contracts must: (i) explicitly address the right for the scientific results achieved to be used in further research and teaching and (ii) ensure that researchers are fully entitled to publish their findings (with companies however having the opportunity to comment).
- **Relevant competencies**
  Both parties in a project must have the knowledge and necessary skills in processing data and an understanding of registry research and public/private collaboration. Public sector researchers should thus ensure they have a basic understanding of the frameworks within which the industry operates, and companies should have an understanding of the conditions for public sector researchers and a basic awareness of pharmacoepidemiological methods. Both parties must also be aware of the special rules that apply to this type of collaboration, including the ethical aspects.
- **Involvement of third party coordinating bodies**
  In projects involving parties with limited experience in this type of collaboration, also in cases in which companies do not themselves have the requisite pharmacoepidemiological competencies, the two associations urge the involvement of a third party as a coordinating body (an Academic Research Organisation (ARO) or a Contract Research Organization (CRO)), to act as a link between company and public researcher.

Conclusion

The associations' ambition is for this position paper to support existing collaborations between public sector researchers and the pharmaceutical industry and to stimulate greater collaboration in the future. Lif and DFSE recommend that such collaborations comply with applicable guidelines.

About pharmacoepidemiological research

Pharmacoepidemiological research employs observational studies of drug usage patterns and studies of unintended and intentional effects of medicinal treatment. Pharmacoepidemiological studies are therefore key to our understanding of how medicinal products are used after marketing and the risks associated with treatment with drugs.

It therefore relates to so-called non-intervention studies, i.e. monitoring and documenting the use of drugs in normal practice.