

# Dr. Frits Lekkerkerker

## CURRICULUM VITAE

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### Personal details

Name	J.F.F Lekkerkerker
Education	Medical Doctor Specialisation in Internal Medicine

### Professional experience

#### Current position

- NDA Advisory Board member
- Chairman of MEC of MST Enschede the Netherlands (teaching hospital)
- Chairman NVMETC (Dutch umbrella organization of MECs)
- Member Board of “Galenus Price” Netherlands
- Member Steering Board for non-WOG ethical review
- Chairman Board of “Drogisterij College”
- Member of International Editorial Advisory Board GABI (Generics and Biosimilars initiative journal)

#### Previous positions

- 2012-2013: Chairman of Advisory Committee Dutch National Plan Orphan Diseases
- 2008-2012: Chairman of Dutch Steering Committee on Orphan Drugs
- 1991-2007: Chairman Dutch Medicines Evaluation Board
- 1974-2001: Member Dutch Medicines Evaluation Board
- < 2001: Specialist and later Co-ordinator (Head) in Internal Medicine/Endocrinology MST hospital, Head Haematology Laboratory/ Hospital De Stadsmaten, Enschede, Consultant Endocrinology/ University Hospital Groningen, all NL

### Area of Expertise

#### Regulatory

- More than 30 years in regulatory affairs and in decision making process
- More than 30 years in clinical medicine
- Detailed knowledge of the European approval system including European Medicines Agency (EMA), DCP and national procedures.

- CHMP Rapporteurship for more than 30 products
- Experience of Regulatory and scientific aspects incl. dossier assessment of a great variety of medicinal products
- In-depth knowledge of issues related to
  - Endocrine products, products in use for osteoporosis and diabetes
  - Similar biological medicinal products
- Experience in Medical Ethical Review

#### Medical Specialities

- Internal Medicine
- Endocrinology including osteoporosis
- Diabetes
- Clinical pharmacology
- Ultrasound

#### Major projects

- Chairman Dutch Medicines Evaluation Board
- Dutch Member of the CPMP/CHMP
- Core-Member of the CHMP WP on Biosimilar Medicinal Products
- Co-chairman and later member of the CPMP/EMA working group with patient organisations
- CHMP Rapporteur/Co-Rapporteur for diabetic products, blood products, vaccines and other products in the centralised procedure and in many referrals of national authorised products to the CHMP.

#### Associations

- Royal Dutch Society of Medicine
- Dutch society of internal medicine (NIV)
- Dutch society of endocrinology
- Dutch society of clinical pharmacology
- Drug Information Association

#### Publications

Publications and conference presentations on all aspects of Regulatory affairs and especially those related to osteoporosis, similar biological medicinal product and bioequivalence.

The complete list can be provided upon request.