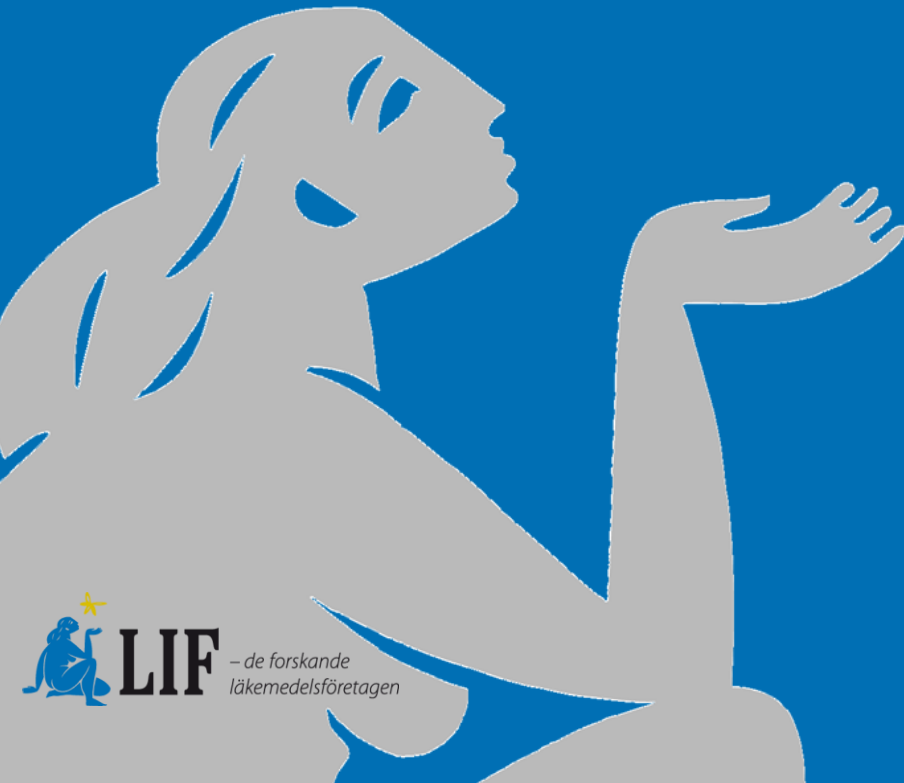




## Self-regulation system in Sweden for the pharmaceutical industry

Pär Tellner  
Compliance Officer  
Director Veterinary Medicine  
**LIF**



# Ethical rules for the pharmaceutical industry

- Chapter I: Rules governing drug information
- Chapter II: Agreements on collaboration (healthcare personnel)
- Chapter III: Ethical rules for co-operation between companies and interest organisations
- Chapter IV: Rules for non-interventional studies

In addition there are IGM and Information Practices Committee (NBL) statutes and Ethical rules for Interaction between Companies and Veterinary care personnel.

# LIF definitions of terms and values as called for by the EFPIA and IFPMA Codes of Practice

<p><b>Hospitality</b></p> <p>EFPIA art 9.05</p> <p>IFPMA art 7.5.2</p>	<p>The value of a lunch should not exceed <b>250 SEK</b> (incl. VAT) per person.</p> <p>The value of a dinner should not exceed 600 SEK (incl. VAT) per person.</p> <p>For hospitality abroad, local rules take precedence. In the absence of local rules or guidance the Swedish levels apply.</p> <p>No limits expressed on hotel accommodation.</p>
<p><b>Venues</b></p> <p>EFPIA art 9.01 and 9.06</p> <p>IFPMA art 7.5.1</p>	<p>Companies should avoid using venues that are known for leisure activities, or in other ways are viewed as exclusive, e.g. winter sport resorts, motoring events or golf tournaments. The same applies for cities during or in conjunction with major international events.</p> <p>Companies should not contribute financially to the arrangement of or the participation of professionals at such venues.</p>
<p><b>Promotional aids and reminder items</b></p> <p>EFPIA art 10.02</p> <p>IFPMA art 7.6.3</p>	<p>Value should not exceed 100 SEK (incl VAT).</p>
<p><b>Items of medical utility</b></p> <p>IFPMA art 7.6.4</p>	<p>Value should not exceed 600 SEK (incl VAT), unless given to libraries of hospitals, clinics or primary care units employing more than one prescriber.</p>

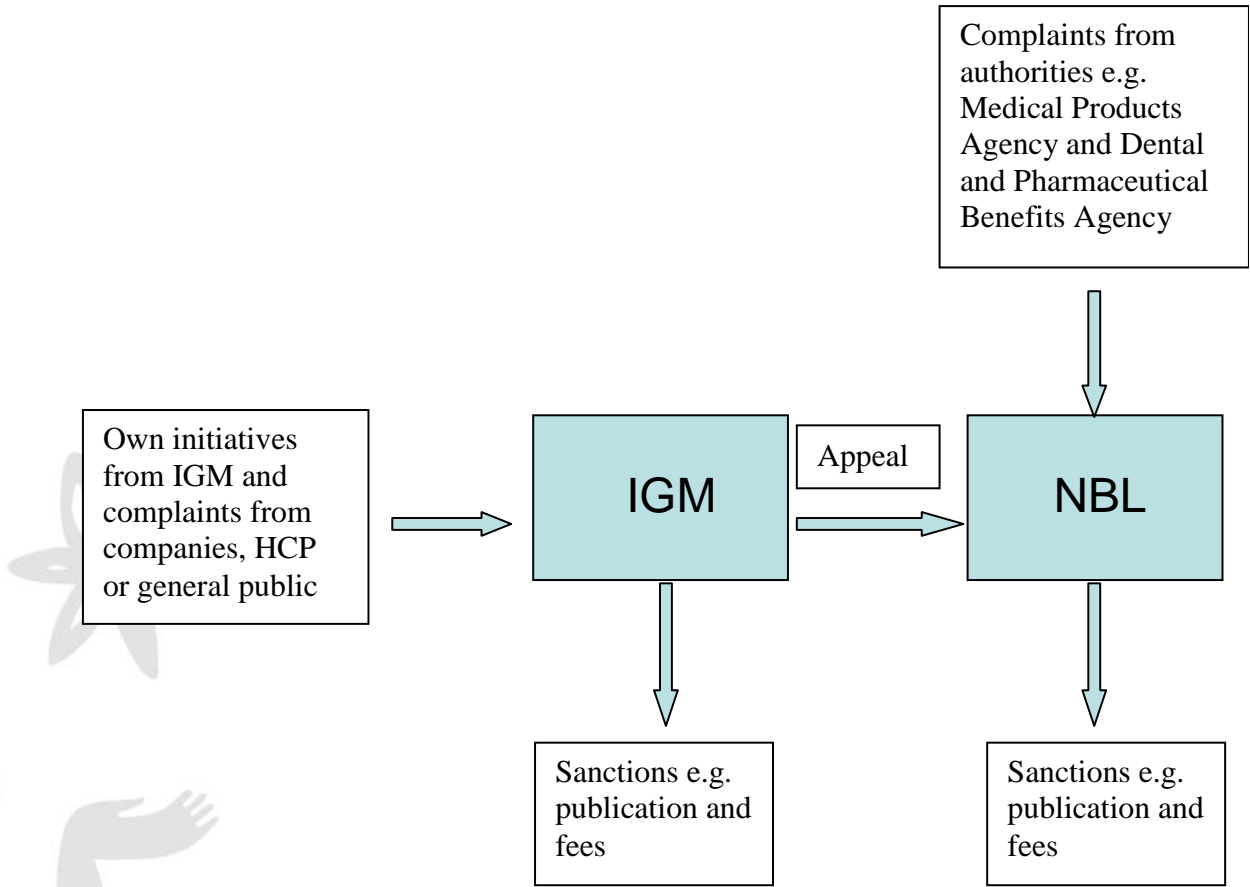
# Ethical rules for the pharmaceutical industry

- LIF and IML members must comply with the rules and ethical agreements. From Oct 1 2009 FGL members also comply with the rules. Members of Svensk Egenvård also comply with chapter 1, Rules governing drug information.

- Breaches can be sanctioned

- Fees up to 500 000 SEK
- Publication of all cases at [www.lif.se](http://www.lif.se)
- Corrective advertisement
- Temporary suspension





*IGM – Pharmaceutical Industry’s Information Examiner*  
*NBL – Information Practices Committee*  
*HCP – Healthcare Professional*



# IGM

- The self-regulation system in the form av NBL started already 1969. IGM was added 1973.
- IGM is a qualified physician. He is appointed by the Board of LIF. He works 60 % from his home for LIF.
- All companies must send statutory copies of all drug information and invitations to meetings to IGM. From these 4 000 – 5 000 objects he takes out samples for control.
- IGM handles appr 100 cases per year of which 60 % are taken up on IGM's own initiative.
- IGM can also at the request of a company provide non-binding advance statement on measures not yet implemented.

# NBL

- NBL consists of 6 company representatives (at least 2 represent OTC companies), 3 rep's for public interests e. g. patient organisations, 2 rep's for medical expertise and 1 chairman, who is a justice of the Supreme Court .
- NBL also have 8 alternates, who are company rep's (at least 2 represent OTC companies, 1 represent veterinary companies, 1 represent generic companies and 1 represent natural products companies. 2 alternates repr public interests, 1 alternative repr medical expertise and 1 alternate is deputy chairman and a justice at the Supreme Court.
- NBL also have 2 secretaries, who are lawyers. These are now employed by a law firm, which is secretariat to NBL.
- NBL issues also advisory statements.
- LIF appoints the members, alternates and secretaries of NBL.



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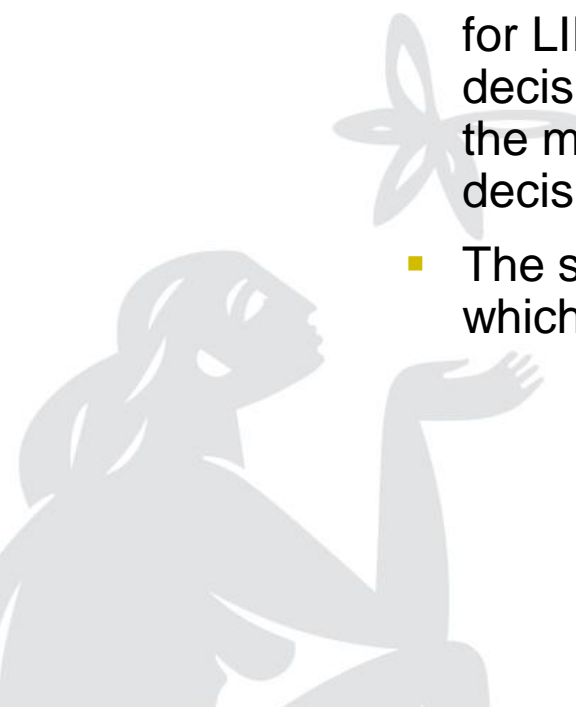
# Swedish Compliance Officer

- Should work proactively towards the member companies (training and advice)
- Contact person for IFPMA Code Compliance Network
- Quality control of Co-operation databases
- Decides if a venue (location) for arrangement is acceptable or not



# Pär's personal view on the Swedish self-regulation system

- IGM works very efficiently and makes quick decisions, usually within 1 month. Important role in monitoring the market.
- IGM/NBL has a good reputation for high quality decisions. The decisions of IGM and NBL are independent, e. g. not possible for LIF-members, -Board or -Secretariat to influence the decisions. The Medical Products Agency therefore uses NBL for the majority of their complaints. All companies accept the decisions of NBL and pay the sanction fees.
- The system is financed by the relatively high sanction fees, which are paid to LIF.



# Pär's personal view on the Swedish self-regulation system

- Preventive role of LIF CO is appreciated by companies. As CO cannot issue sanction fees, some companies prefer to contact CO with questions instead of IGM.
- For further info on the self-regulation system, including a summary in English, and a database on all IGM/NBL cases please see [www.lif.se](http://www.lif.se)

