Introduction

There is no doubt that thanks to the large-scale availability of pacemakers and cardioverter-defibrillators, the life expectancy and quality of life of numerous patients has much improved. Pacemakers are used since a long time, they have proven their value, and they have become big business for the industry, scientists, and cardiologists. Although technical innovation has resulted in safer and more effective pacemakers, thereby reducing the number of adverse effects and improving patient compliance, it has also created three areas of potential conflicts of interest:

1. Innovation may still have to prove its value for the patient. Extensive clinical testing and patient follow-up studies are then required, for which recognized end-points within the framework of evidence-based medicine are needed.

2. As pacemakers are widely used, innovation may yield enormous financial rewards to the industry and cardiologists. This could interfere with safety priorities, the patient-doctor relation, and the cardiologists' independence of the industry.

3. As pacemakers and cardioverter-defibrillators are potentially life-saving devices, cardiologists may adopt a liberal policy in terms of the indication for use. This might lead to technical and budgetary disputes on what should be considered an appropriate indication.

Medico-Legal Responsibilities of the Cardiologist

A doctor's duty is characterized by his responsibility for medico-technical patient care within the constraints of the medical standards. These medical
standards can be imposed by legislation or by a hospital, a medical profession, or an individual doctor. So, medical standards are laid down in laws or regulatory directives and are present as unwritten medical practice codes based on bioethical and moral principles.

The purpose of this study is to provide information on the legal regulations that are important to those dealing with decision-making on pacemaker application and patient safety. It particularly focuses on the regulations and pre- and postimplant responsibilities of the cardiologist and the industry.

When we review the contents of these regulations, we will note that the regulations on the preimplant responsibilities are meant to ensure that the implant is safe and effective before it is used in patients, while those on the postimplant responsibilities underline the importance of consumer protection and civil litigation. (As criminal behaviour is hardly ever exposed, criminal litigation is rare).

Taking as our basic assumption that the use of a medical device presupposes the presence of a legitimate indication (medical diagnosis or treatment), it is important to recognize that the cardiologist can be put in a position where he has to act as his patient’s representative (e.g. when selecting a device or when dealing with the industry). His relation with the patient becomes even more complex when he has entered the patient in a clinical study. This forces the cardiologist not only to provide patient care but also to pursue scientific progress while remaining loyal to the sponsor. Whatever the circumstances may be, a cardiologist should, of course, always reserve his primary loyalty for his patient. Although one has to admit that there has not been much arguing about this yet, the proper sequence when serving various interests cannot be reiterated often enough.

For health administrators, this can be different, because the occasion may arise that the interest of an individual patient should become secondary to the interest of the general public. Interestingly enough, the industry, which likes to boast that its top priority is patient welfare whatever the circumstances may be, feels usually obliged to pursue a thriving business, the reasons for which are obvious.

Therefore, for the patient, the cardiologist is the first to rely on for effective and safe medical treatment. Second, via the cardiologist or hospital, the patient is exposed to subsets of rulings on product quality and safety, which are the aspects a manufacturer likes to emphasize most. Third, the framework of rules on standardization, certification, and product liability, which applies to most industrial and economic activities, provides an outer legal shell.