Parallel import and pacemakers: who pays the ferryman?

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Fifty years after its introduction in clinical cardiology, artificial pacing for patients with bradyarrhythmias has made a huge leap forward.¹ The development from bulky, simple fixed-rate pacemakers to small, complex, multi-programmable devices paralleled the vast technological achievements of the second half of the 20th century. In the late 1990s hope emerged even for patients with severe heart failure, with the introduction of biventricular pacing which resulted in an additional class I indication according to the recent guideline of the European Society of Cardiology.² Consequently, the number of implantations has steadily increased, resulting in more than 10,000 implantations (both first implants and replacements) in the Netherlands in 2007.³ Despite the well-documented cost-effectiveness of pacemaker therapy, accumulating healthcare costs have raised issues on the financial burden associated with pacemaker implantation. Many industrial products are available at substantially different prices within the 27 member states of the European Union. These price disparities are the base for commercial companies focussing on medical devices, facilitating import in 'cheap' countries and distributing these devices in 'expensive' countries. Recently, these companies have also explored the Netherlands for this parallel import of pacemakers and pacemaker leads. Although competition for many products between manufacturers should certainly be encouraged, things may be different as far as pacemakers are concerned. A number of important considerations in this respect are discussed below.

1. When pacemakers from parallel import are assembled, labelled and provided with a manual in the local language by the hospital, according to Dutch law the hospital is regarded as the manu-

facturer. In contrast to pharmacological products, there are no formal regulations for the labelling and the manual for medical devices. This implies that the hospital is responsible for this product and that consequently the hospital is also responsible for any claims in case of malfunctioning, e.g. recall procedures. Hospitals should be aware of the enormous costs involved in case of malfunctioning or defective devices.

2. Both the hospital using parallel imported pacemakers and the company facilitating parallel imports are obliged to develop a post-marketing surveillance system. In addition, both parties have legal obligations for medical supplies to maintain and guarantee the quality of the product involved. Hospitals should check if medical supplies are not sold after the expiry date and whether supplies are adequately stored. Obviously, storing conditions may be hard to monitor when parallel imported pacemakers are imported from remote regions, such as East European countries.
3. The typical pacemaker manufacturer spends about 20 to 30% of their annual budget on research and development of new products. Studies have demonstrated that parallel imports reduce manufacturers revenues by about 8%.⁴ Declining profits resulting from parallel imports will inevitably have a major impact on the search for innovation which is a cornerstone of the high level of treatment of patients with bradyarrhythmias.
4. Technical support during device implantation and dedicated support in 'troubleshooting' of contemporary complex devices during follow-up are offered by all device manufacturers. This close cooperation with cardiologists involved in pacemaker therapy is based on long-lasting experience and is crucial for optimal patient care. Pacemaker manufacturers will be less likely to continue their support when parallel import companies supply pacemakers to the same hospitals. In addition, pacemaker manufacturers offer continuing education and training and provide specific facilities that are not incorporated in the practical, hospital-based training of cardiologists and allied professionals.

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5. Since 2006, the Dutch healthcare system has changed by coupling a specific diagnosis with a subsequent individual patient treatment (DBC = diagnose behandel combinatie or diagnosis treatment combination) for which a fixed fee is calculated. Lowering the price of a pacemaker will inevitably result in a lower fixed price, although the workload for the implanting physician will remain the same.

The current practice in the European Union regulating parallel trading is based on Article 28 of the EU Treaty which prohibits all measures that could restrict the free movement of goods between member countries.⁵ A free market and competition for many products and services among the members of the European Union is one of the cornerstones of the Union and should be encouraged. However, a pacemaker constitutes a highly complex product which is often lifesaving throughout its considerable lifespan. During this period only close collaboration of qualified physicians and dedicated, highly trained, allied professionals can guarantee an optimal treatment for patients undergoing pacemaker therapy. A careful consideration to allow or prohibit parallel import of complex devices such as pacemakers is obligatory to maintain the high level of healthcare

in the Netherlands. Of notice, Article 30 of the EU Treaty allows member states to prohibit or limit imports to protect human life and public health.⁵

Any changes in this established practice will bare a serious risk of impairing the optimal care of these patients. The proposed strategy mimics the ferryman who gets paid for only one way and leaves his customer at the wrong side of the creek. At the end of the day no one has won anything and everyone has lost a little. ■

References

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