NEWS LEXTTER

November 2009

LIFE SCIENCES

RECENT LEGISLATION IN LIFE SCIENCES

In Portugal, since at least 1997, we had a multitude of legislative provisions on medical devices. These provisions have been amended and supplemented over the years leading to a certain difficulty in achieving a comprehensive reading of all applicable legislation.

Decree-Law no. 145/2009 of 17 June seeks to bring together all the legal provisions relating to medical devices, including active implantable medical devices, in a single piece of legislation, at the same time revoking a great deal of the existing legislation. The rules governing the research, manufacture, sale, commissioning, monitoring and advertising of medical devices and their respective accessories also apply to:

- medical devices manufactured using tissues of animal origin;
- Portugal's National Medical Device Monitoring System (*Sistema Nacional de Vigilância de Dispositivos Médicos*);
- clinical research into medical devices;

but do not apply to *in vitro* diagnostic medical devices, which still warrant separate regulations (although some crossover provisions of this law do apply to such devices, such as those involving monitoring, manufacturing, wholesale distribution, advertising, confidentiality and control).

This law also aims to clarify a number of issues which are not exclusively technical, such as the software supplied by device manufacturers to be used specifically for diagnostic or therapeutic purposes and which is required for the medical device to work properly (Art. 3 t). This article treats the software as a medical device- and issues involving patient health and safety during the use of devices, such as procedures involving clinical research, measures to reinforce transparency, control, risk management, monitoring and advertising.

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A LAW FOR ALL MEDICAL DEVICES

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The possibility of centralising clinical research data in a **European database** (still awaiting legislation), with the appropriate confidentiality rules, is also envisaged.

Although it does not enter into force until 21 March 2010, an obligation has already been imposed on those responsible for manufacture, assembly, packaging, execution, renewal, remodelling, changing the type of, labelling or sterilising medical devices destined for sale to the public, export or wholesale distribution. Such establishments in operation on this date must now begin the process of notification of their activities to the competent authority *(Infarmed – Autoridade Nacional do Medicamento e Produtos de Saúde IP)* within 180 days (that is, before 17 September 2010), failing which the establishment will be closed down (Art. 70).

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Amendment of the System for the Parallel Import of Medicinal Products

Decree-Law no. 182/2009 was published on 7 August, revising the Portuguese system for the parallel import of medicines established in the so-called "Medicines Statute" passed by Decree-Law no. 176/2006 of 30 August.

The purpose of this amendment is essentially to simplify the established procedure for the parallel import of medicines, that is, the mechanism by which, upon verification of certain requirements, a medicine with a valid marketing authorisation, either in its member state of origin or in Portugal, may be imported and sold in Portugal without the need to request a new authorisation for the Portuguese market.

From a consumer interest standpoint, the advantages of a flexible mechanism for authorising the parallel import of medicines are indisputable. The mechanism encourages market competition and allows medicines to be distributed outside the distribution network of manufacturers and suppliers already established in Portugal, so such a mechanism may provide easier and more cost-effective access to medicines.

This change to the law is based on the proposition that the procedure for obtaining parallel import authorisation for a medicine from INFARMED, in compliance with the principles set out by the European Commission in its 2003 Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, should be proportionally simpler than the procedure for obtaining a new marketing authorisation. By making this change, the law seeks to alter the status quo in which, although the parallel import mechanism has been enacted into law, it has so far failed to achieve any practical application as it does not provide any benefits for medicine distributors.

Under the new rules, to authorise parallel importing, the medicinal product in question must have a valid market authorisation in Portugal, and the medicinal product subject to this market authorisation must have the same quantitative and qualitative composition in active substances, the same pharmaceutical form, the same therapeutic indications, and can only use different (or varying amounts of) excipients without therapeutic impact.

To simplify the procedure, it is presumed that the above requirements are met, together with the requirement that the parallel import authorisation does not pose a risk to public health when the medicinal product previously subject to market authorisation in Portugal and the parallel import medicinal product have a common origin (i.e. manufactured by companies with contractual ties or belonging to the same company group). In such cases, INFARMED is responsible for taking all necessary measures to determine whether a given medicinal product, although similar to another previously authorised for the Portuguese market, poses a risk to public health.

However, when a common origin does not exist, applicants for parallel import authorisation are responsible for furnishing INFARMED with a statement attesting that the medicinal product to be imported does not pose a risk to public health, and has no adverse effects on the medicinal product's efficacy and safety if varying quantities of excipients exist. Since INFARMED can still require applicants to submit additional documentation (which may be in the possession of the market authorisation holder, and thus unavailable) to analyse a statement's validity, the current system is not a dramatic departure from the previous one, and may still unjustifiably burden applicants for parallel imports.

To simplify and expedite the procedure, prior notification to the market authorisation holder in the medicinal product's member state of origin is no longer required as under EU law such notification is neither justified nor required. However, notification to the market authorisation holder in Portugal is still required. INFARMED is now responsible for this notification which is to be made within INFARMED's time limit for assessment but, the notification causes an extension to the established time limit until the submission of a response by the interested party, or after the 10 days established for the submission of this response.

Although the recently published Decree-Law reduces some requirements of a merely procedural nature, the time limit of 45 days for INFARMED's decision to authorise or reject (considered adequate by the European Commission itself in the Communication referred to above) remains in effect. The decision in question must be an express decision, thus leading to the conclusion that the legislator did not see fit to create an implied approval of the applicant's request where no notification of

INFARMED's decision is received within the established time period. In fact, the only consequence provided for in this event is the requirement to reimburse the applicant for twice the amount paid. There is no substantive effect on the applicant's request to obtain parallel import authorisation.

Even though the overwhelming majority of the provisions of the system for the parallel import of medicines have undergone changes, considering the apparent underlying objective of the legislation was to make the mechanism for obtaining authorisation for parallel imports easier and more streamlined, one can only conclude that the recent legislative movement was somewhat timid. Despite the relevance of the principle of ensuring a proper balance between procedural simplification and upholding quality and safety standards for introducing medicines on the market, it is beyond question that the innovations have no real substance and may not be enough to create the conditions required for a true parallel import market in Portugal.

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Draft Law on Living Wills

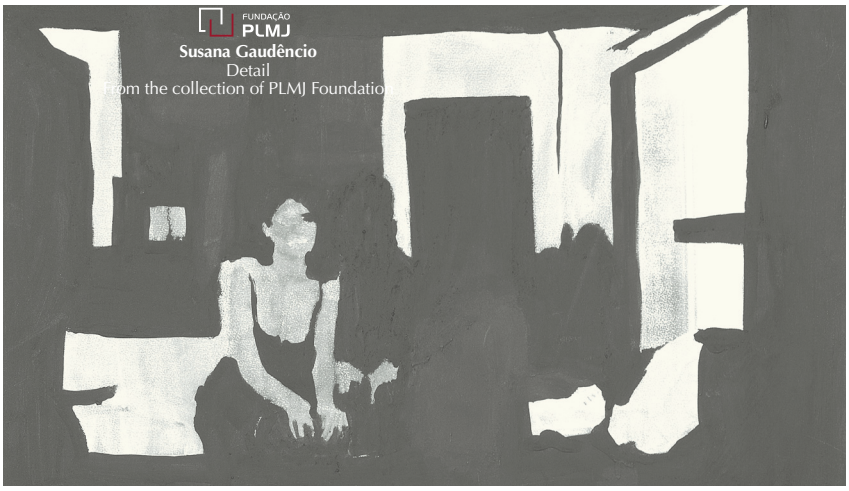
In a society which is increasingly interested in and open to discuss this issue, and following the example of neighboring countries, where living wills have already been subject to legislative intervention, the Socialist Party submitted the draft law n. 788/X, entitled "Patients' right to information and informed consent" for parliamentary debate, that took place on 28th May 2009.

The draft law was generally approved, with votes in favor from members of the PCP, opposition from members of the PSD, members of the CDS-PP and one socialist member, and the abstention by members of the BE. Despite this general approval, the PS decided to defer the final approval of the draft law after the next general election, due to the sensitive nature of the issue.

The draft law, in its current formulation, illustrates the strong concern for safeguarding the value of human dignity and the patients' right to self-determination, namely by allowing patients, trough a prior statement of their wishes, to pre-determinate treatments, procedures and medical care that they wish (or not) to have in the event of a future incapacity.

From a formal point of view, the prior statement of wishes must be made in writing and may be freely revoked at any time.

The declaration's enforceability will depend on an analysis of the various circumstances which allow the assessment of the author's degree of conviction in expressing his or her wishes.



These circumstances include whether the author had a proper understanding of his or her state of health and the nature of the disease, the degree of the doctor's participation in the provision of the information disclosed or the accuracy of the description of the treatment. It should be noted, however, that the doctor will not be bound by the patient's declaration if it is in breach of the law or public order or if it results in procedures that are inconsistent with the technical standards of the medical profession. The doctor may also refuse to be bound by the statement if the treatment is outdated in the light of advancements in medical care or if it becomes obvious that the patient would no longer stand by the statement. It is therefore essential that the patient's wishes have been formulated freely, thoughtfully and in an informed manner.

The draft law also grants patients the right not to be informed of their situation, except in cases where it poses health risks to third parties or to the public.

Furthermore, doctors are also granted the "therapeutic privilege" whereby, on the basis of a reasoned decision, they may withhold information from patients when the circumstances in question may endanger the patient's life or damage the patient's physical or mental health.

In the wake of solutions being embraced elsewhere, this law enables patients to designate a health care representative and delegate decision-making powers in the event of future incapacity.
The Portuguese Ethics Council for Life Sciences issued an opinion on this draft law, levying a number of criticisms, including more formal aspects such as conceptual and written inaccuracies, together with truly substantive aspects, believing that the issue was handled

The Ethics Council ultimately recommended that the section on the prior statement of wishes should be excluded from the law and dealt with in a future, more carefully drafted law.

somewhat lightly, in particular in relation to the complete omission of the role of families in this matter. The Ethics Council ultimately recommended that the section on the prior statement of wishes should be excluded from the law and dealt with in a future, more carefully drafted law.

The draft law was also opposed by a large section of the medical community due to concerns that the statement of future wishes could be made long before the patient becomes ill. This would mean there could be no true understanding of the medical, psychological and emotional issues that may arise.

In view of the comments received and the recognized need for broader public reflection, the government decided to shelve an in-depth debate on the draft law. Accordingly, and with the end of the current legislative period, the continuity of this or other draft laws on this issue remains in doubt.

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