

CUATRECASAS, GONÇALVES PEREIRA

**Portugal - Medicinal Products Act – A new framework on Pharmacovigilance and Promotion of medicinal products**

On February 2013, the Portuguese Medicinal Products Act was amended by Decree-law 20/2013, of February 14 that introduced important changes to the legal regime of promotion of medicinal products and to the pharmacovigilance system.

According to the new rules on promotion, it is now mandatory for pharmaceutical companies to communicate to Infarmed (the Portuguese Authority of Medicines and Health Products) any kind of sponsorship or subsidy granted to an association or any other entity representative of a particular group of patients, a company, association or a scientific society. This reporting obligation also applies with respect to any kind of sponsorship or grants received by health care professionals from pharmaceutical companies.

This new regulation immediately raised queries on whether or not, an insignificant subsidy or gift (for instance a pen granted by a pharmaceutical company to a physician) should be reported to Infarmed, as there was no minimum value prescribed in the Law. These queries were clarified by an order of the Health Ministry dated March 20, establishing that the minimum amount that triggers the above mentioned reporting obligation is EUR 25.



Regarding the pharmacovigilance system, this amendment to the Medicinal Products Act approved by Decree-law 20/2013 implemented Directive 2010/84/UE, of December 15. The new regulation aims to recast the national pharmacovigilance system and provides new requirements to ensure a better traceability and monitoring of the risks related to the use of medicinal products in the European Union. The pharmaceutical companies' duties to report adverse reactions that have occurred in EU and in third countries are strengthened.

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**Ireland - Competition Law**

The Companies (Amendment) 2012 inserted into the Competition Act 2002 (as amended) a new section 14B provision which applies to an Agreement entered into by the Competition Authority with an undertaking following a competition investigation under the Act.

Such an investigation could require an undertaking to do or refrain from doing such things as are specified in an Agreement in exchange for the Competition Authority agreeing not to bring court proceedings against it.

What is significant about this provision is that it strengthens significantly the Authority's enforcement powers by allowing it to apply to the High Court in Ireland to have the Agreement made an order of court. A breach of the commitments provided in the Agreement would constitute contempt of court.

Under the new law the Competition Authority can agree not to bring court proceedings under the Act in relation to any matter to which that investigation related, or any findings resulting from that investigation. However, this does not preclude any private enforcement that might be initiated subsequent to the Competition Authority's investigation.



Eames Solicitors advised on the first "section 14B agreement" in Ireland to have been made an order of court by the High Court on 18 December 2012.

All Irish Competition and Procurement law queries should be directed to Adrian Smyth at Eames at +353 18725155 or a.smyth@eames.ie.



**Changes To Slovak Tax Legislation**

As part of the effort to increase state revenues and fight tax fraud, important legislative changes have come into effect in Slovakia.

**1. End of flat tax rate**

As of 1 January 2013, Slovakia does not have a flat rate tax for companies (legal persons) and individuals anymore. Tax rate for companies increased from 19% to 23%. With regards to individuals, two tax rates exist and these will be applied in the following way:

- Individuals earning per year less or equal to the amount of 176,8 times the subsistence level (currently EUR 34,401.74) will pay 19% tax; and
- Individuals earning per year more than the amount of 176,8 times the subsistence level will pay:
  - 19% tax on to the amount of up to 176,8 times the subsistence level
  - 25% tax on the amount above the amount of 176,8 times the subsistence level.

**2. VAT guarantee**

In certain cases defined by law the VAT payer, as recipient of services or purchaser of goods, guarantees the amount of VAT that was stated on invoice but which the supplier did not remit to the state.

For example, if a supplier stated in the list of potentially risky VAT payers published by the Financial Directorate supplies goods or provides services but does not remit the respective VAT to the state, the tax authority might request the VAT from the recipient.



**Streamlining the Australian trade mark opposition process: Raising the Bar reforms**

The Intellectual Property Laws Amendment (Raising the Bar) Act 2012 reforms that commence on 15 April 2013 will introduce substantive changes to Australian trade mark opposition process and procedure. The reforms will impact strongly on the way trade mark oppositions are presently managed, and will also likely affect the tactics and pace of any commercial negotiations or co-existence discussions.

In short, the burden to identify relevant grounds of opposition and to substantiate an opposition case has been brought sharply forward, a positive requirement to indicate whether an opposition will be defended has been imposed, the periods within which to oppose and file evidence have been condensed, and rights to extensions of time to oppose and to suspend proceedings for commercial negotiations curtailed. The Australian Registrar of Trade Marks will also have greater powers to case-manage oppositions.

Importantly, an opponent will only have **2 months** (as opposed to the previous 3 months) from advertising of acceptance of a trade mark application in the *Australian Official Journal of Trade Marks* to file a notice of intention to oppose.

Both a table showing the significant changes introduced by the Raising the Bar statutory reforms and a flowchart summarising the new trade mark opposition process can be accessed by visiting the CBP Publications page.

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