

GREECE

Pharma product pricing now ignores patents

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The pricing of medicinal products has always been a hot issue in Greece, even more in recent years, when the government is under pressure to drastically reduce the spending on health care.

According to the provisions applicable up to recently, other than adjustment to the average of the three lowest reference prices in the EU, the price of an original medicinal product could be reduced only after the patent protecting the active pharmaceutical ingredient (API), contained therein, had expired.

According to these provisions, the lapse of the patent protecting the API of original pharmaceutical products would trigger a 50% drop in their price.

These criteria for applying such a price drop have now been changed in the context of legislation passed to apply a third economic adjustment programme agreed with the European Commission in August 2015.

Law 4336/15, published on August 14 2015 and voted to implement the structural reforms agreed with the European Commission and the IMF, provides that the expiry of patent protection will no longer be the relevant triggering point for a price drop of original pharmaceutical products. This is replaced by the expiry of regulatory data protection. Regulatory data protection prevents third parties from relying, for up to 11 years, on the innovator's proprietary data in order to obtain marketing authorisations and market follow-on generic products.

In practice this means that, according to the new provisions, the price of originator pharmaceutical products will be reduced much earlier than in the past.

Following the publication of law 4336/15, a ministerial decision was is-

sued, on September 11 2015, to implement its provisions. This decision has set an additional criterion for applying a price drop to original pharmaceutical products: entry of a generic product in the market.

According to the provisions of this ministerial decision, an original medicinal product will receive a 50% drop in its price provided that the product is no longer under regulatory data protection and as soon as the first follow-on generic product is launched in the Greek market.

Patent protection is therefore no longer a guarantee that the price of a medicinal product will not be reduced.

It now remains to be seen how and when these provisions will be applied in practice and what the impact on the pharmaceutical market will be.