BONDOC & ASOCIAŢII in alliance with WHITE & CASE

Pharma LawConvention
Bucharest, Romania

Lucian Bondoc

April 3, 2014

Patients' access to medicines – Certain considerations on the status and trends regarding pricing and shortage (a legal perspective)

- Low prices help affordability/price access – on the other hand, they increase the risk of significant exports and, therefore, of shortage (reduce physical access)
- In EU, the principles of free movement of goods/common market, combined with the different national pricing regimes for RX products (with significant price variations) have facilitated for decades parallel trade
- The economic crisis has stimulated the phenomenon, but is also showing the limits of the exercise
- Public authorities are stretched between budget constraints (lower prices) and image considerations in connection with shortages; variable competence, populist temptations and sometimes illegitimate interests do not help
- Towards a new balance

Parallel trade - competition case law evolution

- Successful litigation campaign in the European Court in the 1970s. Trademarks and patents were held not to be lawful obstacles. Parallel traders won the right to repackage the products they had bought so as to conform to that of the country of resale. They even won, later on, the right to change the trademark when repackaging

- Almost 40 years later, the wind is changing - case-law increasingly recognizes that practice is different from original expectations – containment measures are legitimate

- Cases such as Syfait, Sot Lelos, GSK & co:
  - Restriction of parallel trade is not a *per se* abuse
  - A dominant company is entitled to protect its own commercial interests
  - Orders that are out of the ordinary can be refused

- In Romania, the Roche decision (2013) – along the GSK case lines

- The European Commission is under pressure to nuance its position

- As usual, reality seems ahead of the law

Regulatory pressure to avoid shortages (1)

- Directive no. 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use
  - Point 18. Public service obligation: The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question

- Romanian Healthcare Law no. 95/2006 (before amendment in February 2014)
  - Article 695. [..] Point 17. Public service obligation: The obligation of wholesalers to permanently ensure an adequate range of drugs in order to meet the needs of a determined geographical area

- Not really enforced in many countries for years – but things start to change (from modifications to public services obligations to export bans and others)

Regulatory pressure to avoid shortages (2)

- Directive no. 2001/83/EC
  - Art. 81: [..] The holder of a marketing authorization for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State in question are covered.
  - The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.

- Romanian Healthcare Law no. 95/2006 (before amendment in February 2014)
  - Article 792 (2) Market authorization holders for a drug and wholesale distributors of that drug actually placed on the market in Romania shall ensure, within the limits of their responsibilities, adequate and continuous stocks of that drug to pharmacies and persons authorized to supply drugs in such a way that the needs of Romanian patients are covered. [Para (3) closely mirrors the second paragraph above of art. 81.]

Regulatory pressure - certain issues regarding Romania's case (1)

- Export ban regarding certain products

- Very "interesting" changes to the Romanian Healthcare Law no. 95/2006 in February 2014, such as:
  - The minimum number of wholesalers rule
  - Expansion of the definition of public service obligation,

  in connection with market authorization holders/representatives

- Public authorities seem to have underestimated the possible effects of the changes and their complexity

- HTA, cost-volumes, discounted or free "sales" …

Regulatory pressure - certain issues regarding Romania's case (2)

Public Service obligation- main relevant provisions of Directive No. 2001/83/EC

- Article 1. – […]
- Point 18. Public service obligation:
- The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question

Public service obligation – Main relevant provisions from Law no. 95/2006, after its amendment through GEO no. 2/2014

- Article 695. – […]
- Point 17. Public service obligation:
- The obligation of marketing authorization holders/representatives of marketing authorization holders and of wholesalers to permanently ensure an adequate range of drugs in order to meet the needs of a determined geographical area and to supply within the entire respective area the requested quantities in the shortest time possible after receiving the order
- Art. 836. - (1) The following acts are contraventions and are sanctioned, as follows:
- *[newly inserted in the law]* m¹) by a fine between RON 50,000 and RON 100,000 and a temporary suspension of the authorization for up to 6 months, in case of failure to comply with the obligations provided under Article 695 point 17, and Article 792 (2), as well as with the obligations established according to art. 792 (2¹).

What`s next?

- Public authorities seem to try to contradict regularly any reasonable answer
- If to try one, the economic situation and demographics will likely continue to increase tensions between the various interests/forces referred to above
- Case-law expected to confirm the trends in recent years at EU level; EU Commission strongly pressured to nuance its position
- Recent experience shows that Romanian authorities are not in lack of all sorts of “interesting” ideas
- Suing/challenging public authorities – no longer a tabu; law modifications such as those in February are likely to push towards changes to business models and some litigation looks just a matter of time
- There is a shift – but in more tension and lack of transparency/predictability than it could/should be

Questions?

Lucian Bondoc
Managing Partner

Bondoc si Asociatii SCA
in alliance with White & Case LLP
34 Londra Street, Bucharest, Romania
E-mail lbondoc@Bondoc-asociatii.ro
Tel. +40 31 224 84 00
Fax +40 31 224 84 01