20 AGOSTO 2021

Gabriella Muscolo
ANTITRUST
muscolo@franzosi.com

Pharmaceutical markets and antitrust: selected issues on *compliance* and *private enforcement*

Antitrust *compliance* programmes: Italy, a virtuous model.

The predisposition of antitrust law to evolve according to changing market developments, combined with the creation of innovative theories of harm by the National Competition Authorities ("NCAs"), makes it sometimes complex for companies to carry out an **ex ante analysis of the legality of their conduct**.

This complexity is further exacerbated by a number of phenomena in which the **pandemic** crisis has acted as an **accelerator**: the growth of the *digital and data-driven economy involving* all markets, including that of pharmaceuticals, the blurring of boundaries between different regulatory sectors (e.g. *antitrust*, *privacy*, *data regulation*, *consumer protection*), the competition between *ex post* enforcement of competition rules and *ex ante* regulation of gatekeeper platforms.

The debate on *compliance* programmes has focused, both in Italy and abroad, on whether companies should be rewarded for adopting them. The question is whether the *ex ante* definition of a reward mechanism is a complement to deterrence in the dissemination of **competition culture** or an incentive to commit antitrust violations.

In this scenario, the Italian experience is characterized by the fact that the **Italian Competition Authority** ("AGCM" or "Authority") clearly favours the importance of *compliance* programmes: among the mitigating circumstances contained in the "***Guidelines on the application of the criteria for quantifying administrative fines imposed by the AGCM***" is also included the adoption of and *compliance* with "*a* ***specific compliance programme***, *adequate and in line with European and national best practices*".[1]

The mere adoption of a *compliance* programme, however, **does not** in itself determine the application of the attenuating circumstance, since strict requirements of timeliness and effectiveness of the programmes themselves are prescribed, in order to avoid so-called "***cosmetic compliance***".

In order to encourage the widespread dissemination of programmes, in 2018 the AGCM published the ***Antitrust Compliance Guidelines*** on the essential elements that must characterise programmes[2], which intervened on two aspects in particular: the "*minimum*" content of a *compliance* programme and the conditions for obtaining a reduction of the penalty.

With regard to the first profile, the AGCM requires that *compliance* programmes be designed and implemented in line with the size and market position of the company, as well as the

[1] AGCM, resolution No. 25152 of 22 October 2014, *Guidelines on the modalities of application of the criteria for quantifying administrative fines imposed by the Authority in application of Article 15(1) of Law No. 287/90*, 2014, par.23. Available at this link

[2] AGCM, case No. 27356 of 25 September 2018. Available at this link

characteristics of the market in which they operate (so-called "***mapping antitrust***")[3]. In fact, recognition of the business risk in the programme is considered a "*key element in the assessment of its adequacy for the purposes of recognising the mitigating factor*".[4]

Once the adequacy of the programme has been ascertained, the *Guidelines* provide for a basic distinction between programmes adopted prior to the commencement of the investigation procedure and those adopted thereafter, with obvious repercussions on the possible **penalty benefit**, which varies between **5%** and **15%** of the penalty to be imposed.[5]

The Italian model of implementing antitrust *compliance* is a virtuous one, which has aroused much interest and debate in international[6] and institutional fora.[7]

As a result of the above-mentioned AGCM policy, there has been a **gradual increase in the implementation of the programmes by companies**.[8] Despite their importance in the European and global markets, companies in the **pharmaceutical sector** in Italy are still in the initial stages of moving towards ***compliance* programmes**, due to internal entrepreneurial dynamics, which differ according to their different business models.

However, it is appropriate and urgent to address the issue of *compliance* programmes for pharmaceutical companies, while taking into account all the specificities of this market, of which Italy is an industrial leader.

EU Directive 104/2014 ("Directive")[9] was adopted by the European legislator with the aim of encouraging antitrust **damages actions before courts** in Europe by harmonising the rules, including in continental law jurisdictions where competition enforcement was mainly entrusted to the intervention of NCAs.[10]

---

[3] The structure of the supply chain, the degree of transparency of commercial conditions, the presence of entry barriers and the relations with competitors, suppliers and customers are some of the criteria that must guide the assessment of the company in the analysis of the antitrust risks that the programme aims to prevent

[4] Guidelines, para. 10

[5] From 2015 until April 2020, there were 24 antitrust and abuse of dominance proceedings in which requests for reduction of the penalty for adoption of a compliance programme were examined by the AGCM, compared to a total of 51 proceedings concluded with the imposition of penalties in the same period (excluding those of mere redetermination of the penalty or review of commitments)

[6] Concurrences, *Antitrust Compliance Awards*, available at this link

[7] J. Almunia, Businesseurope & US Chamber of Commerce, *Competition conference - Compliance and Competition policy*, Brussels, 25 October 2010. Available at this link
International Competition Network, 12th annual meeting, *Antitrust compliance*, 24-26 October 2013, Warsaw

[8] *Confindustria Antitrust Compliance Guidelines*, available at this link

[9] Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union, available at this link

[10] The continental law context is marked by clear differences from the British *common law* system, which provides for a more favorable regime for *private plaintiffs*, *in* terms, in particular, of access to evidence (discovery)

The Directive introduces a so-called **"two-*pillar*" system**, favouring **private enforcement** of antitrust law without compromising **public enforcement**, and providing for coordination mechanisms between the Courts and the NCAs.[11]

The Directive has been **implemented** in all Member States, including Italy, by **Legislative Decree No. 3 of 19 January 2017**[12]**,** and in recent years private litigation actions, both follow-on and stand-alone, have increased also before the Italian specialised sections, with the consequent formation of case law on the subject.[13]

Two provisions of the directive and of the implementing decree, namely **Articles 9 and 17.3** respectively, have given rise to lively debate. The first provides for the **binding effect of the decision of the NCAs – and thus, in Italy, of the AGCM – on the national courts in the part relating to the positive finding of the antitrust infringement in follow-on actions**.[14] The decisions of the NCAs of other Member States, on the other hand, constitute only *prima facie* evidence of the infringement.

The second regulation, which instead introduces the case where the **Italian Competition Authority assists the Judge in the quantification of the damage**, is one of the phases of the antitrust trial in which the information asymmetry of the parties is more evident in the access to the proof of the *quantum* of the prejudice suffered.[15] This is a form of *amicus curiae*

---

[11] With regard to the principle of coordination, it should be recalled that it was already provided for in the provisions of Articles 15 and 16 of Regulation 1/2003, respectively entitled "*Cooperation with national courts*" and "*Uniform application of Community competition law*"

[12] Available at this link

[13] The Decree made the specialised sections of only three Italian courts competent to settle disputes: the Court of Milan, the Court of Rome and the Court of Naples. Although there are no capillary monitoring tools available on *anti-trust litigation*, as it is not possible to know how many actions are filed in national courts, we would like to point out the *database* of the Milan courts *Italian Case-Law on Private Antitrust Enforcement*, accessible at this link

[14] Directive 2014/104/EU, *supra* note 9

Article 9 - *Effect of national decisions*

1. Member States shall ensure that an infringement of competition law established by a final decision of an NCA or a review court is deemed to be finally established for the purposes of an action for damages brought before their courts under Article 101 or 102 TFEU or under their national competition law.
2. Member States shall ensure that a final decision within the meaning of paragraph 1 taken in another Member State may, in accordance with their national law, be presented before their courts at least as prima facie evidence that an infringement of competition law has occurred and may, where appropriate, be assessed together with other evidence submitted by the parties.
3. This Article shall be without prejudice to the rights and obligations of national courts set out in Article 267. TFUE.

As mentioned at note 11, Regulation 1/2003 on the implementation of the competition rules laid down in Articles 101 and 102 TFEU by the European Commission and NCAs already regulated, in Article 16.1, the coordination between *public enforcement*, in particular by the European Commission, and *private enforcement*, by national courts (available at this link).

[15] Directive 2014/104/EU, *supra* note 9

Art. 17.3 - *Quantification of damages*

(...)

3. Member States shall ensure that, in proceedings relating to an action for damages, an NCA may, at the request of a national court, provide assistance to the court with regard to the quantitative determination of the damage if the NCA considers such assistance appropriate.

intervention that has already been introduced into Italian law by a European Union source, entrusted to the discretion of the requesting Court and the intervening Authority, which has the judge as its interlocutor and to whom it provides indications on the econometric models of liquidation of damages. This institution is therefore quite different from the one which exists in our system, where technical advice is provided by the Office, and the role of the Authority is also different from that of a judge-appointed adviser.[16]

Both of the above-mentioned rules can be read as **mechanisms of cooperation between the Courts and the NCAs**, with the multiple purpose of **promoting private litigation** by facilitating the parties' access to proof of the anti-competitive wrongdoing and the amount of damage caused, and of ensuring the **uniform application of EU competition law**.

Private antitrust enforcement is a challenge that all market players have to face: companies in the pharmaceutical sector must also be ready to act and defend themselves in court, with full awareness of the **specificities of the competition process**.

G. Muscolo, *Il ruolo del giudice nel governare l'acquisizione delle prove*, Concorrenza e mercato, 2014

[16] G. Muscolo, P. Caprile, *La quantificazione del danno nel processo antitrust*, in Lorenzo F. Pace, Dizionario Sistematico del Diritto della Concorrenza, 2020