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Generics and Back Margins: Why Is the Assessment Unchanged since 2013?

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During the launch of its pharmaceutical sector inquiry in November 2017, the French Competition Authority (FCA) expressed interest in the discounts granted by generics firms to pharmacies.¹ The FCA quoted the decision issued following the previous sector inquiry carried out in 2013, which “had revealed that pharmacies benefit from substantial discounts on those [generic] drugs, which are nevertheless very rarely redistributed to the final consumer and to the public health insurance scheme.” According to the annual report on social security published by the Court of Auditors in 2017, these discounts amounted to 1.1 billion euros in 2015.² The public consultations carried out in the context of the FCA’s 2013 decision³ had, however, resulted in greater transparency of the discounts granted to pharmacies that must now be declared every year by generics firms to the Economic Committee for Medicinal Products (Comité économique des produits de santé, hereafter “CEPS”). Since 2014, the discounts granted by generics firms can reach a legal maximum of 40% of the before-tax manufacturer price for generics, as opposed to 17% prior to the decision.

The Court of Auditors’ report severely criticizes the efficiency of these measures and highlights the lack of use of the collected data, as well as the opacity of the discount mechanism for generics. The report reveals that, beyond the discounts granted specifically for certain drugs, generics firms can play with the payments made to pharmacies for the promotion of their non-reimbursable and parapharmacy products. These financial incentives, which may, for instance, take the shape of commercial cooperation contracts, are only granted if the pharmacy also agrees to purchase non-reimbursable or parapharmaceutical products from the same generics firm. Given that discounts and rebates are not capped for these products, generics firms are able to provide financial incentives that are not specific to generics and that are not subject to the 40% cap on the manufacturer’s before-tax price. In practice, these are back margins⁴ indirectly linked to generics since they are only granted under the condition that pharmacies purchase non-reimbursable or parapharmaceutical products from the same supplier. Therefore, it is impossible to dissociate those financial benefits from the purchase of generics.

Despite the substantial discounts from which pharmacies can benefit, the FCA mentioned “the excessive pricing of some generic drugs” in its 2013 opinion. In the absence of pass-on of these discounts to consumers, the pharmacies appear to be the beneficiaries of the regulation on generics prices and of the practices observed in this market. The French General Inspectorate of Social Affairs observed in a report published in 2012 that “the margin on generic drugs is, in percentage terms, double the margin of the branded drug.”⁵ More recently, the 2017 report issued by the Court of Auditors has shown that, if pharmacies benefited in 2015 from a remuneration of two billion euros beyond the regulated remuneration, more than half of it came from discounts granted by generics firms.⁶

As explained by the Court of Auditors, the incentivising measures regarding the distribution of generics are meant to give pharmacists a key role in the diffusion of generics. Yet a note published by the General Directorate of the Treasury in June 2017 explains that “if those measures aimed at pharmacies have contributed to the growth of consumption of generics, they also come at a high price since they redistribute to professionals part of the potential gain coming from the substitution with generics.”⁷ The cost of this redistribution was estimated to be equal to 1.75 billion euros in 2013, which is half of the savings triggered by the substitution of branded drugs with generics, according to the General Directorate of the Treasury. These observations have led the Court of Auditors to conclude on “the considerable cost of distribution of generics.”

While there seems to be a consensus about the high cost of generics distribution—both for social security because of the financial incentives provided to substitute branded drugs with generics,⁸ and for the generics firms that give substantial discounts to pharmacies—the economic mechanism behind this finding has not been discussed. Yet there are some similarities with the effects of the Galland Law in the retail market between 1997 and 2004. The Galland Law excluded from the price floor the financial benefits obtained by the distributors in exchange for commercial cooperation services. Therefore, given the legislative framework in place in the retail sector at the time, which did not allow for competition based on invoice prices, distributors were competing on the basis of the back margins negotiated with suppliers. Each supplier was incentivised to grant more back margins than its competitors. This did not, however, benefit consumers because back margins were not passed on to retail prices by distributors.

In the case of generics, the mechanisms differ from those in retail markets since both selling prices and pharmacies’ margins (excluding discounts and rebates) are regulated. Nevertheless, generics firms still have an incentive to give higher discounts than their generics competitors. Indeed, pharmacies only choose a limited number of generics suppliers. As such, generics companies compete to be selected by pharmacies and competition is based on the discounts given to pharmacies.

A common feature with the Galland Law is the absence of passing-on of pharmacy discounts to consumers, though this is not a legal restriction as with the Galland Law. Yet the data communicated to the CEPS on the discounts given by generics firms to pharmacies could, in principle, allow the CEPS to negotiate lower prices. The sharing of such information with the CEPS increases transparency in the market and provides further information about the “true” prices paid by pharmacies. In order to lead to a price renegotiation based on the observed discount levels, these discounts must, however, be linked to a specific drug. This task is more complex when it comes to bundled discounts. Indeed, the economic literature shows that there exists no methodology allowing bundled discounts to be allocated to each product of the bundle. Regardless of the methodology

used, it is necessarily arbitrary, particularly in the presence of common costs. As explained above, the discounts granted by generics firms are only granted to the extent that pharmacies purchase both generics and non-reimbursable or parapharmaceutical products from the same supplier. Therefore, these are by definition bundled discounts. In this context, the CEPS can hardly exploit the available data to negotiate lower generics prices.

The second common feature with the Galland Law is the central role of back margins in the generics market, highlighted above, in the negotiations between generics firms and pharmacies. In the same way that the net price was not considered a strategic variable in the negotiation between suppliers and distributors under the Galland Law, the manufacturer's price is not taken into account by pharmacies when they choose one generic supplier over another. Indeed, since 1999, the margin (excluding discounts and rebates) earned by pharmacies on the sales of generics is based on the before-tax manufacturer price of the branded drug, in order to encourage the substitution of branded drugs with generics. Therefore, pharmacies cannot increase their margins when negotiating the purchase price of the generic because it does not have any impact on profit. In this context, the discounts and financial incentives granted by the generics firms to pharmacies constitute selection criteria of generics suppliers since they have a direct impact on the pharmacies' margins, unlike the manufacturer's price.

Therefore, one may identify the reasons why the FCA is still interested, despite the recent measures, in the pass-on of the discounts obtained by pharmacies on the purchase of generics to consumers and health insurers:

1. Discounts and financial incentives represent key elements of the negotiation between generics firms and pharmacies.
2. Because discounts are bundled with non-reimbursable and parapharmaceutical products, it is, in practice, impossible to allocate the discounts to each product in a non-arbitrary way.

As a result, the observations made by the FCA and the Court of Auditors over the last few years may be explained by the current regulatory framework that makes the recently-adopted measures (i.e., the increase in the maximum discount rate on generic drugs and the transparency obligation on the levels of discounts offered) ineffective in lowering the distribution cost of generics. As such, it is necessary to deeply reform the mechanisms of pharmacies' remuneration regarding generics so that consumers and the public health insurance scheme can benefit from the pharmacies' bargaining power.

Notes

- ¹ Décision n° 17-SOA-01 du 20 novembre 2017 relative à une saisine d'office pour avis portant sur les secteurs du médicament et de la biologie médicale, Autorité de la concurrence.
- ² Rapport sur l'application des lois de financement de la sécurité sociale, Cour des comptes, septembre 2017, chapter IX.
- ³ Avis n° 13-A-24 du 19 décembre 2013 relatif au fonctionnement de la concurrence dans le secteur de la distribution du médicament à usage humain en ville, Autorité de la concurrence.
- ⁴ Back margins have been defined in the context of the Galland Law (1997–2004) that regulated the relationships between suppliers and retailers in France. They are rebates granted on a yearly basis by suppliers to retailers and often justified by the provision of promotional services by retailers. These rebates have been identified separately from other types of rebates, which are part of the “front margin,” as they could not legally be included into the computation of the price floor.
- ⁵ Evaluation de la politique française des médicaments génériques, Inspection générale des affaires sociales, septembre 2012.
- ⁶ Regulated remuneration must be understood as the remuneration defined by the legal framework.
- ⁷ Quelle politique pour poursuivre la diffusion des médicaments génériques ?, Trésor-Eco Lettre n°199, juin 2017.
- ⁸ The regulated margin earned by pharmacies with generics is based on the margin earned with the equivalent branded drug to incentivize pharmacies to substitute branded drugs with generics.

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