

DRAFT

**Report on the state of play
of the drug retail distribution reform in Italy**

22 April 2016

1. In brief: rationale of the reform

Consolidation in the pharmacy channel has been prevented so far by the existing legal restrictions to the ownership and the number of pharmacies.

Under the existing legislative framework **there cannot be any pharmacy chain**, since:

- a. **Ownership**: pharmacies can only be owned by individuals, partnerships and limited-liability cooperative companies. Partnerships, in particular, shall have the management of one or more pharmacies as their sole mission; their members shall be registered pharmacists. Also, partnerships and cooperative companies cannot own more than 4 pharmacies in the Province where they are legally based
- b. **Number**: there cannot be more than 1 pharmacy every 3,300 inhabitants.

However, **this state of affairs is likely to change soon, as a consequence of a legislative initiative taken by the Government** in early 2015 and still in the approval process. Under a legislative proposal (*Legge annuale per il mercato e la concorrenza - s.c. Competition Bill*) which is currently being examined by Parliament:

- **corporations would be allowed to own pharmacies**, provided that the management of pharmacies is their sole mission. Corporations' shareholders would **not** (of course) be bound to be registered pharmacists
- any restriction to the ownership of pharmacies by a single entity (either a partnership or a cooperative company or a corporation) would be removed: this means that **corporations would be allowed to own more than 4 pharmacies**
- the restriction to the number of pharmacies (no more than 1 every 3,300 inhabitants) would remain in place.

Overall, this reform is aimed at **allowing consolidation, through the creation of pharmacy chains, without undermining the profitability of pharmacies: in fact, the reform will leave the following pillars unquestioned:**

- existing limits to the number of pharmacies
- existing monopoly on the sale of drugs subject to medical prescription (both reimbursable and non-reimbursable) – *on this, see also below ("Political debate")*
- existing margins of profit on the sale of NHS-reimbursed medicines (in the form of a minimum share on the price, fixed by the law at roughly 28.5%).

Also, rules on the **acquisition, transfer and sale** of pharmacy licenses **are not going to change** as an effect of the reform, meaning that:

- **new licenses** will still be assigned basing on the results of public competitions launched at the regional level, in compliance with the "1 pharmacy every 3,300 inhabitants" rule. Public competitions are reserved to pharmacists who own the relevant University Degree and are already enrolled in the professional register. Competitions are based on qualifications and exams and do not require winning pharmacists to pay any fee to acquire new licenses.
- **existing licenses** will still be marketable only after 3 years from the original issuance.

2. Political debate

As mentioned, under the proposed reform pharmacies will retain the **monopoly on the sale of drugs subject to medical prescription**, while drugs which are not subject to

medical prescription can already be sold by s.c. parapharmacies and by large-scale organised distribution (supermarkets), at the presence of a registered pharmacist. In the original draft of the Bill, upon the initiative of the Ministry of Economic Development, parapharmacies and large-scale organised distribution would have been allowed to sell non-reimbursed drugs subject to medical prescription (s.c. “C-class” drugs).

The proposal created some jitters between the then-Minister of Economic Development, Federica Guidi, supporting it and the Health Minister, Beatrice Lorenzin, opposing the liberalisation, publicly stating it would be a threat to patients’ safety. The real reason of Lorenzin’s opposition (explicitly admitted on other occasions such as policy debates) was that she regarded the liberalisation of the sale of non-prescription drugs as a **threat to the profit margins of licensed pharmacies**, which she sees both as a fundamental pillar of the NHS and a source of income for healthcare professionals (i.e. registered pharmacists, part of the traditional constituency of her centre-right party).

In the end, **Lorenzin managed to have the proposed liberalisation withdrawn from the Government’s Bill**, most likely because her efforts to safeguard the profitability of pharmacies were consistent with the more general goal of making the ownership of pharmacies attractive for foreign investors willing to establish chains.

In spite of some other attempts to liberalise the sale of C-class drugs during the parliamentary process, it is a fair assumption that such a measure will not be approved: recently, even the Chair of the Senate Health Committee, Emilia De Biasi (from Renzi’s Democratic party, traditionally in favour of this measure), declared that “*in view of big capitals entering the market as an effect of this Bill*”, the priority for the Government should not be to allow the sale of C-class drugs outside licensed pharmacies, but rather to allow parapharmacies to acquire a license as pharmacies: this would imply (*de facto* if not *de jure*, even though De Biasi was not explicit) restoring a **full monopoly** of licensed pharmacies on the sale of all kind of drugs, including those not subject to medical prescription.

3. The reform in detail

Ownership structure: Status quo	Proposed reform (Competition Bill)
<ul style="list-style-type: none"> • The Italian law limits the number of pharmacies to 1 every 3.300 inhabitants. • Private NHS pharmacies can be owned in partnership (<i>società di persone</i>). • Partnerships shall have the management of one or more pharmacies as their sole mission. • Partnership members shall not be active in the production and/or intermediation of drugs. They shall not be active as sales representatives as well. 	<ul style="list-style-type: none"> • the restriction on the number of pharmacies remains unchanged. • Pharmacies can be owned in partnership, as well as by corporations (<i>società di capitali</i>). • This measure remains unchanged and will also apply to corporations. • Like before, members of a partnership (<i>società di persone</i>)/shareholders of a corporation (<i>società di capitali</i>) shall not be active in the production of drugs and/or in the business of sales representatives of drugs; also, they shall not be active as medical

<ul style="list-style-type: none"> Partnership members shall be licensed pharmacists. The managing director of a pharmacy shall be one of the partnership members. Partnerships cannot own more than 4 pharmacies in the Province where they are legally based. 	<p>doctors. However they will not be restricted from acting in the intermediation of drugs any longer.</p> <p><i>The wording of the revised provision <u>appears</u> not to prevent members of a partnership/shareholders of a corporation which runs a chain of pharmacies from being also active in the wholesale distribution of pharmaceuticals.</i></p> <ul style="list-style-type: none"> Partnership members and/or corporations shareholders are not bound to be licensed pharmacists any longer. The managing director of a pharmacy shall be a registered pharmacist. Partnerships/Corporations can own more than 4 pharmacies (no limit is foreseen in the current version of the Bill).
<p>Monopoly on the sale of drugs subject to medical prescription</p>	<p>NO REFORM AT ALL</p>
<ul style="list-style-type: none"> OTC products, as well as all other medicines that are not subject to medical prescriptions, can be sold by parapharmacies and by dedicated stores within large distribution centres, provided that they are sold at the presence and under the responsibility of one or more registered pharmacists. 	<ul style="list-style-type: none"> Unchanged: the efforts put by the Ministry of the Economic Development to liberalise the sale of non-reimbursed medicines subject to medical prescription were thwarted by the Ministry of Health.

4. Procedure and timing

Introduced in Parliament in April 2015 upon the Government's initiative, the Competition Bill was approved by the Lower House in October 2015 and is now being considered by the Senate's relevant Committee (Industry). The process has recently slowed down as an effect of the resignation of the Minister of Economic Development Guidi; it will be resumed as soon as a new Minister takes charge. The Senate will adopt Amendments to the version passed by the Lower House, therefore **a second reading by the Lower House will be required**. However, the second round will allow a narrow maneuvering room for further amending the text, and the **Law may be expected to be finally approved by the end of 2016**.

5. Amendments still under discussion

The examination of the Bill at the Committee level in the Senate (currently going on) is probably the last stage of the parliamentary process where Amendments have a fair chance of being adopted.

Under an Amendment tabled (with minor wording differences) by Senators from different political groups, **limits to the number of pharmacies that partnerships/corporations are allowed to own would be introduced, in order to prevent them from exploiting dominant positions.** Limits would be set both in absolute terms (e.g. max. 100 pharmacies in a given Municipality) and as a percentage of the total number of pharmacies (in a given Municipality, in a given Region and across the country).

This attempt at modifying the Bill reflects the interests of incumbent pharmacy owners, but it is also a way to reconcile the promotion of ownership consolidation with the safeguard of competition in the drug retail distribution market.

Another amendment signed by Senators from both the majority coalition and opposition groups requires corporations and partnerships owning a pharmacy to **pay 2% of the annual turnover resulting from the sale of non-reimbursed medicines to the National Welfare Fund of Pharmacists (ENPAF).** This would only apply to the cases where the majority of partnership members / corporations shareholders are not registered pharmacists.

6. Conclusions – likeliness of the adoption of the reform

We can draw the following conclusions from the picture we described in this report:

- a. It is **100% sure that the s.c. Competition Bill will be passed** by the Parliament, since this is a Government's Bill
- b. The **timing of its adoption remains speculative**, particularly in light of the current stalemate originated from the resignation of Minister Guidi (actually, the Competition Bill is intended to be an annual piece of legislation, so theoretically it should have been adopted by the end of 2015!). The timing crucially depends on how soon a new Minister of Economic Development is appointed; our judgement is that **the parliamentary process should be over before the end of the year**
- c. We assume that **the reform of the ownership structure of pharmacies will be passed** with no major changes compared to the version we have analysed in this report, because this is part of the Government's Agenda: this means that **corporations will be allowed to own pharmacies and to establish chains**
- d. An important detail that **could** still change is **how many pharmacies corporations are allowed to own**: no limit is foreseen at the moment, but this could pave the way to dominant positions. As mentioned above, Amendments have been tabled introducing thresholds for the ownership of pharmacies and it is plausible that the Senate's Committee will examine this issue very closely.