

Interview with Sergio Sparacio, Director, ADF

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Intermediate distribution plays a crucial role in establishing bridges between industrial production and final delivery to patients- and in Italy, this function is executed with highly contained costs and commercial margins amongst the lowest in Europe, yet adapting to the ever changing environment. How is the current structure of Italian distribution channels enabling such a performance?

The core role of intermediate distribution is to ensure the right conservation, distribution and delivery of drugs in a capillary way throughout the territory. In Italy, each warehouse has two main daily peaks of activity; the first in the early afternoon, and the second at night, in addition to two intermediate emergency deliveries. Visiting a warehouse during one of these rush hours can give a clear idea of the amount of work required to achieve such goals. For instance, looking at the first shift, each distribution company receives the orders of hundreds of thousands of pharmacies by 12:30 pm and is ready to deliver to every single one in little less than two hours. During this timeframe, the goods go through four main steps -arrival, storage, preparation and expedition- before being finally delivered in sealed containers to the pharmacists' hands. In practice, this process requires a highly organized logistic- that has almost reached perfection in Italy, due to two main success factors. Firstly, most distributors have been able to elaborate long-term strategies and continuous investment plans. And in addition, they can rely on high-tech equipment, such as semi-automatic machines able to guide the workers in the warehouses' product zone and indicate them in which box has to be placed each product in order to correctly reach its final destination. All this work is aiming at ensuring patients with the possibility to find the products they need at

anytime in any Italian pharmacy, yet reducing as much as possible the pharmacists' constraints in terms of stock management, since their warehouses are managed by the wholesalers themselves. Without such intermediation, each pharmacist would have to deal directly with thousands of suppliers and could not dedicate enough time to his institutional role, which is to address the patients' needs. This crucial task is ensured in Italy by various types of distribution companies, both multinationals and private or pharmacists' societies, as in most other European countries. But the country's main peculiarity is related to the nominative diffusion of pharmacies – whereas chain of pharmacies can be found abroad, Italy is one of the country requiring the pharmacist to be the full owner and titular of its commercial activity. This restriction could soon change, and we are currently expecting the sentence of the European Court on this issue.

As you have been at the head of ADF for 20 years, what would you say are the main challenges to be faced by Italian distributors?

When I took the reins of ADF in 1988, the distribution segment was strongly lacking recognition in Italy. Its role was not even recognized by Law, and the only existing legal reference was the Art.181 bis of the 1934 Sanitary Law, stating that any warehouse managing pharmaceutical distribution shall have a technical director. Therefore ADF was created in order to enhance the wholesalers' recognition in the pharmaceutical chain. It has been possible thanks to the support of excellent experts, such as Prof. Marcello Marchetti from Roma University, as well as the precious role of the European Directives as a point of reference. Legal recognition was eventually obtained by the Decree 538 of 1992, which represented a small revolution as it identified intermediate distribution as an essential element of the pharmaceutical channels. But beyond this first progress, the second goal was to become accepted as a real interlocutor for the institutional world. In this regard, adapting to the Italian decentralized healthcare system required an organizational effort, and ADF now has referents in each region, in order to deal directly with all the stakeholders. Now that a good level of recognition has been obtained, both in theory and in practice, Italian distributors are facing the same challenges as most pharmaceutical operators on a global scale. In today's healthcare world, the main issue is to clearly define what is meant by Welfare State, and to which extent can cost containment policies ensure both long-term financial sustainability and a wide and capillary sanitary coverage. In Italy, the government established a ceiling for healthcare spending, of which only 14% can be dedicated to drugs for the year 2009. In addition, other measures aiming at containing drugs prices and enhance the generics' penetration strongly limit the industry's growth potential. Looking at the margins' regulations for distribution companies, the Financial Law of 1997 set that 26,7% of the margins of a drug sale shall be kept by the pharmacist, leaving 6,65% to the wholesaler, and the rest to the industry (taking into account that a 10% VAT

applies to pharmaceutical products in the country). In the case of generics products, these margins used to be higher thanks to the possibility to offer additional discounts to the original price. But a new legal framework might be put in place very soon stating that pharmacist and wholesaler shall not concede discounts over 8%, therefore limiting their combined margin to a maximum of 41,33%. But despite these challenges, the Italian intermediate distribution really manages to fulfil its social function, by ensuring the efficiency of distribution channels not only in a quick and secure way, but also following cost-rationalization patterns.

This is why each Italian pharmacy can be reached, regardless of the economic considerations. In a context where some pharmaceutical companies tend to focus on easily accessible regions, neglecting the more isolated ones for clear logistics and economics reasons, how can the distribution segment help ensuring equal access to medicines?

As a consequence of the industry general tendency to bet on marketing rationales beyond social promotion, some laboratories are increasingly betting on direct sales to pharmacies. But in Italy, direct sales of ethical products do not overpass 5% of the total. They are more important in which concerns the generics sector, in which competition is mainly based on the products' physical presence in the points of sale, therefore encouraging some producers to concentrate their efforts on the pharmacies with the highest turnover. Indeed, there are more than 17 500 pharmacies in Italy, amongst which 5000 in rural areas or small villages. These rural pharmacies do not follow any commercial logic but are focused on their social mission: act as a terminal of the National Healthcare System. Therefore, a laboratory eager to incentivize direct sales would clearly leave them aside and work only in the wealthiest regions or highly populated areas. But in this context, the distribution segment serves all the pharmacies independently from their economic weight. Its purpose is indeed to promote the healthcare industry's social role, beyond the individual interest of pharmaceutical laboratories. Aside from capillarity, another pre-requisite of distribution processes is their reliability.

As counterfeit scandals are emerging in Europe, where does Italy stand in terms of drugs' traceability?

Italy surely has one of the most advanced security systems in Europe. Each drug confection has an official high security stamp with two codes, printed in both optical and clear reading: the AIC (Autorizzazione Immissione Commercio), which is the ministerial code for all the products in Italy, and then the serial code for each box.

These numbers follow each product from production to the industry warehouse, and then from the industry warehouse to the distributor, ensuring a full traceability and a minimal risk of fraud. Overall, how do you assess the levels of competition in the Italian distribution model?

Until now, the Italian model ensured sufficient level of competition. Indeed, margins are fixed by law, but intermediate distributors can usually concede discounts to pharmacies – as long as the cumulative margin of both the intermediate and final distribution remains 33,35%. So there is room for competition between wholesalers, mainly in offering discounts or payments facilities to pharmacies. This is crucial in context when pharmacies are suffering from extremely long reimbursement delays from the National Healthcare System, yet have to maintain an uninterrupted service. In this regard, wholesalers act as financial intermediates, by accepting to postpone the date when pharmacies payment shall be due, and therefore supporting themselves the costs of the reimbursement delays.

How would you describe the supporting framework put in place by the Italian Government and where is there further room for improvement in ADF's view?

The Government is surely keener on taking than giving, and the industry is going through times of uncertainties. ADF would like authorities to keep in mind the importance of intermediate distribution. The sector has demonstrated its ability to execute its task with the most contained cumulative costs in Europe, and therefore deserve both the recognition of its role within the pharmaceutical supply chain and the adequate financial margins. Indeed, the distributors' real margin in terms of closed balance all tax paid is very contained compared to their cumulative turnover- and surely no other sector can claim to execute a wide and complex range of services with such low margins. This is why ADF is constantly developing lobbying activities at the government level, as to enhance the distribution sector's recognition and efficiency. The association takes part in all the pharmaceutical round tables and consultations, and is involved in the elaboration of most law projects. For instance, we are currently collaborating with the Ministry of Health and Welfare to design a new law aiming at rationalizing the management of narcotics registrations. In the same way, I personally take part in the Ministerial group in charge of drugs traceability, ensuring ADF's constant involvement in this field. Authorities do appreciate this type of relations, which are far from a mere confrontation between regulators and operators of the system. Indeed, both parts are committed to work together towards the best solutions in the interest of citizens and the public health- which is the main goal of any democratic government. Aside from these long term actions at governmental level, the role of ADF as an association is also to support the distribution industry in its daily operations.

Which initiatives would you highlight as the most representative of the scope of work ADF is carrying in the country?

ADF mostly helps the industry through its institutional publication Il Quaderno della Distribuzione Farmaceutica. In addition, ADF Service Srl publishes ADF Informa, a daily news bulletin referencing all the prices variations, commercial dispositions and legal evolutions that could be useful to the associates as well as the industry. Other news bulletins are specialized in legal aspects or sanitary aspects. Last but not least, ADF is strongly involved in training activities. All the associates adopted ISO quality certifications in this regard, and their personnel is carefully following the very strict controls and screenings it implies.

Looking at the future, in a context of consolidation and pharmaceutical clusters, which strategies shall be put in place in order to further enhance the competitiveness of intermediate distribution?

The future of the pharmaceutical industry is full of shadows. Laboratories tend to melt together in order to create entities that will be strong enough to face the current challenges- such as the lack of new chemical entities able to generate blockbuster drugs, the prevalence of costly biotech products moving from mass distribution to a very selective hospital-orientated distribution, and the genericization of primary care. Distributors clearly have to take these evolutions into account, and therefore put an end to the former strategy based on low economic value. In this context, the best way to ensure the long-term sustainability of the distribution sector is to bet on the future of pharmacies as centres of socialisation and medical advice, much beyond their commercial function that can be executed by supermarkets.

As a final message to the readers of pharmaceutical executive, could you share you long-term vision for the Italian distribution and your ambitions for ADF in the coming years?

Before looking for new strategies, the healthcare sector has to understand what are its ambitions and its intangible values. It is all about choosing to build a society based on profit, consumption and competition, or a people-centred harmonized community. Indeed, citizens now need more than ever to be protected against the fears of pain and illness- which represent no less than the fear of death. The role of healthcare operators is to build an environment in which the economic, industrial and distributive systems can provide answers to these deep sentiments. According to ADF, health has to be the central element to protect individuals, and we will do our best for this objective to be achieved- through pharmacies able to provide a wide range of professional services, GPs that are friends and advisors much more than bureaucrats, and distributors able to adapt to these trends.

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