Interview with Guido Rasi, General Director, AIFA

21.09.2009

Tags: AIFA

When you were appointed General Director of the Agenzia Italiana del Farmaco (AIFA) in 2007, the dedicated Investigation Commission highlighted the need for an in-depth reorganization of the Agency in order to create a more cohesive and transparent structure- which implied significant changes in the main six macro-areas and the intermediate responsibility levels. At which stage is AIFA in achieving its transformation and what are the main guidelines of such a re-shuffling process?

Upon my arrival, I found a two-speeds AIFA- with peaks of excellence but also many failures. Therefore, the first task was to enhance internal and external awareness of the priorities and objectives to be met, as well as to implement a change of mentality regarding the approach to the authorization procedures. Compared to the past, radical changes have occured since then. The regulatory area has been completely redesigned, through the unification of the two former offices, as well as the rational and efficient allocation of responsibilities that are not follwing anymore the traditional division berween domestic and European procedures, but between pre- and post marketing. Moreover,specific task forces haven been created as to deal as best as possible with specific issues, such as those involving radiopharmaceuticals or equivalent drugs. Of course, this is only the beginning. Now that the organigram’s enlargment to 450 units has been approved, and will will enable to catch up on the other European agencies’ headcount, AIFA will also have the potential to align in terms of regulatory efficiency. The inclusion of new resources will be phased over three years, since the high level of proficiency needed will require a training period. The first perceptible changes in AIFA’s structure will consist of a new attribution of responsabilities that will

enable to recover quality, speed up and streamline all processes.

As one of the current challenges mainly mentioned by the industry is the excessive length of new drugs registration processes, which is an obstacle to market penetration; how does AIFA now works in maintaining its efficiency in assessing the quality of drugs, whilst reducing registration delays?

So far, the main obstacle to industrial investments in Italy has been a strong lack of certainty- not only in terms of drug's registration timeframes but also regarding the conduction of the adequate inspections for the productive sector. Both these areas are involved in quality audits and enhancing there efficiency will achieve a double result: to better ensure drug's quality and safety on one hand, while at the same time supporting the industry and attracting invetsment in the country.For this reason, such fields that have been suffering until now, will be the first to benefit from the integration of new staff resources. Indeed, improving the efficiency of regulatory inspections will enable to provide the companies with precise timelines to plan their activities, as well as to issue in in brief deleys the Commercialization Certificates allowing exports and thus providing an important contribution to industry's development. Beyond these initiatives, AIFA will also foster the implementation of the Accordi di Progarmma aiming at promoting research and development investments in Italy, and will work towards the establishment of specific Agreements with biotech companies. Indeed, while the traditional pharmaceutical pipelines are drying up, Italy' booming biotech segment offers about 150 products in very advanced development stages. Therefore, AIFA can bring a consistent legal and organizational contribution to this sector- and will endeavor to do so.

How does the highly decentralized nature of the Italian territory, with 21 regions which seem to correspond to "21 different healthcare systems" in the words of many interviewees, hampers AIFA's drug registration processes, and how do you assess the level of cohesion and cooperation between AIFA and the Local Health Authorities?

The Agenzia Italiana del Farmaco is warrant of the Italian pharmaceutical system's unity. This statement implies that all drugs approved in class A (ie to be borne by the National Health Service) and in class H (ie for hospital use) are included in the Essential Levels of Assistance (LEA) and as such, must be guaranteed to all citizens regardless the region in which they reside. For this reason, I consider the limitation of access to medicines included in the LEA –that has been implmenetd by some autonomous regions- as a grave mistake, creating inequalities related to the places of residence, and affecting the right of citizens to have an equal access to healthcare. All attempts made so far by the regions to avoid AIFA's decisisons were due to their mismanagement of expenditure, especially regarding the hospitals' budget, which brought them to implement

inappropriate and often innefective corrective actions. But regions do have an interest in relying on of AIFA an interface, and should understand that each of AIFA’s negociations is the conclusion of a long, careful and rigorous assessment process conducted in accordance with European guidelines and following the best professional standards. It is therefore irrelevant for regions to try and replicate some of AIFA’s tools and assessment bodies; as these processes are very unlikely to have better outcomes once they are multiplied by twenty-one. Thus, I personally hope that the Agency’s role will become increasingly crucial thanks to the Regions’ support and involvment in the Management Board and Commissions. However, the representative role of regional components shall be enhanced in order to develop a unique approach fitting the needs of all Italian citizens, and ensuring them equality in terms of Health. While the Government keeps strengthening its cost-containing approach to healthcare spending, ongoing negotiations are aimed at favouring the registration and use of generics,

which still have a low penetration in the local market. What is AIFA’s contribution in reference to the promotion of generic drugs in Italy?

Generic drugs shall be promoted. Their competitiveness respect branded drugs have to be enhanced, yet ensuring their compliance with the same high quality requirements. AIFA will strongly get involved in this process, by setting up careful qualitative evaluation processes and deploying new technologies. A new and vigorous policy for this sector -that so far has not be supported by any effective interventions- will be implemented in Italy. Its main targets will be to definitively overcome the Italian market’s structural delays, and to remove the barriers currently impeding the diffusion of equivalent drugs, through proper price valorizations. AIFA has already been working in this direction for several months, and already introduced a greater adequacy in generic’s price contractions by transferring to the NHS the resources arising from the additional discounts- anticipating the Decree soon to be published in this regard. In addition, AIFA is willing to enhance the GP’s discretionary action by launching a new demand-side generics policy aiming at promoting a strong role of medical prescribers, especially regarding therapies’ initiation. Last but not least, AIFA is commited to provide better information to patients and avoid clinical complications related to substitutability issues. This is why our teams are already at an advanced stage in elaborating an ‘Orange book’ listing all the generics substituable to originators, and that will surely help raising the value of eaquivalent drugs. It will be accessible online in a quick and easy way, allowing patients and healthcare professionals to have a rapid assessment of price differences. When communicating about a product and the risk involved the information should be 100% objective and should come from the AIFA instead of the pharmaceutical companies themselves- but on the other hand pharmaceutical companies can also play an important role in

raising awareness about diseases, and the importance of prevention.

Would a PPP between AIFA and the industry aimed at solving this issue be possible?

AIFA is in the process of deeply reviewing its communication strategy. Joint campaigns should be conducted on specific issues- conveying a few messages, yet very impactful and clear about issues related to health. As AIFA also aims at reinforcing Italy's role and recognition inside EMEA and other international and European institutions,

what will be the main guidelines of the agency's international relations?

Many things will changed compared to the past. Firstly, we are regulating and re-oranizing the participation of AIFA's employees and external experts to the EMEA, by objectives and priorities. In addition, we are working towards a better application of all the decisions made at the EU level in the Agency's strategic lines. Indeed, many Italian exterts are currently strongly involved an highly appreciated in EMEA but there is a dispersion of their activities due to a lack of coordination. This is why AIFA is trying to reorganize the participative rules and ensure the Agency's adequate representation in Europe. The final goal is to really enhance the Italian influence in final decisions, and therefore no longer have to implement decisions without having contributed to the related debate- as it has been the case in the past. Personally participating in all meetings of the EMEA's Management Board provides me with greater opportunities in this regards.Beyond European borders, AIFA also intends to strengthen its relationships with the FDA and other international drug agencies in order to facilitate the integration of the Italian highly innovative experience in an international context.

With this objective in mind, AIFA will take part in the DIA's next edition in June 2009 in San Diego, California. As the last months of 2008 were very busy, with the deep reorganization of the agency- which main actions and initiatives will be launched by the "new AIFA" in 2009?

AIFA's restructuration is still ongoing and likely to be completed in 2009. Looking at new initiatives, efforts will be directed at promoting prescriptions' appropriateness through cooperation with GPs; organizing the Health Technology Assessment (HTA) to promote territorial homogeneity; reorganizing independent research that has not been able to express its full potential yet; and enhancing the sector analysis structure in order to support regulatory decisions with both HTA and Farameconomics principles.Which message would you like to give to Italy's top-level pharmaceutical executives about the possible ways pharmaceutical companies and AIFA could collaborate towards a real common industrial policy, which would reinforce Italy's attractiveness for investors?AIFA and the Industry certainly have common goals in reallocating all the resources

derived from any form of cost-rationalization in the pharmaceutical sector- with particular attention to the integration of innovative medicines, the enhancement of investment and consequently, the support of paharmceutical employment in the country.

See more interviews