When patients and consumers join forces

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From the perspective of the EMA, it was clear from the beginning that patients and consumers, two groups who do not approach medicines in the same manner, had to be brought together to the same table to have an open discussion.

The working group with patient organisations brought with it some challenges but it is clear that this is one of the key elements for success and we can proudly say that we would not have achieved what we have today if we had not put them both together – complementing each other.

Juan Garcia Burgos (EMA)

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Contribution by Ilaria Passarani

What is the difference between a patient and a consumer?

The word patient comes from the Latin "patiens," from "patior," which means to suffer i.e. to bear the consequences of the diseases and the external interventions of healthcare professionals. The idea of a passive patient that will do what he or she is told until recovery has however become obsolete especially for chronic disease patients who are very well informed and want to play an active role in the management of their diseases.

The term consumer is often associated with the idea of the market and/or consumption but also the image of a consumer constantly ingesting pills doesn't correspond to the concept of the healthcare consumer, at least in Europe. Consumers are simply the users of health products and services.

According to EU legislation[1] a consumer is a natural person, who is acting outside the scope of an economic or professional activity while the Directive[2] on the application of patients' rights in cross-border healthcare defines patient as a natural person who seeks to receive or receives healthcare in a Member State.

According to the Framework of interaction between the European Medicines Agency and patients and consumers and their organisations, patients' organisations are defined as not-for-profit organisations that are patient-focused, general umbrella organisations (e.g. representing either European disease-

[1] Article 2 of the original doorstep selling directive (85/577/EEC) and Article 2 (2) of the distance contracts directive (97/7/ EC); Article 2 (b) of the unfair terms directive (93/13/EEC); Article 1 (2) a) of the consumer sales directive (99/44/EC); Article 2 (e) of the electronic commerce directive (2000/31/EC); Article 2 e) of the price indication directive (98/6/EC); Article 2 (1) f) of the new timeshare directive (2008/122/EC); Article 2 (D) of the distance marketing of consumer fi nancial services directive (2002/65/EC); Article 2 (a) of the unfair commercial practices directive (2005/29); Article 4 (11) of the new payment services directive (2007/64/EC); Article 2 (4) of the package travel directive (90/314/EEC); Article 3 (a) of the original consumer credit directive and Article 3 (a) of the new consumer credit directive (2008/48/EC), Regulation (EC) No. 593/2008 of the European Parliament and Council of 17 June 2008 on the law applicable to contractual relations (Rome I). – OJ L 177, 4.7.2008

[2] (Article 3 of Directive 2011/24/EU)

specific organisations and/or national umbrella organisations) and European disease-specific organisations representing national organisations or individual patients on acute and/or chronic diseases.

Consumers' organisations are defined as not-for-profit organisations that defend and promote the general interests of European consumers - citizens as purchasers or users of goods and services.

No matter the definition, the interests of all European citizens need to be at the core of all health policy and regulatory decisions - including those related to pharmaceuticals - and therefore of the work of EMA. It is the role of patients and consumers organizations to ensure that the health of citizens comes before any other consideration (political, economic). It is also important to note that those affected by EMA decisions are not only patients/consumers who need a medicine but also the children, parents, partners and other carers who often administer the medicine or seek information about it or have to take difficult decisions between alternative treatments on behalf of their loved ones.

What are the priorities and interest/importance in working with EMA?

Our main priority is ensuring that consumers have timely access to safe, innovative and affordable medicines. Another important priority is to guarantee that consumers are provided with high-quality and independent information about medicines to make informed choices. We also want to ensure consumers trust in the work of regulators and ultimately on the medicines on the market. Working with EMA is vital to reach these goals and our contribution to all EMA activities is guided by these key objectives. For example, we highly value the involvement in the EMA quality review of documents as it is for us and for our members an opportunity to make concrete contributions in the improvement of the information that consumers receive about medicines, in package leaflets and other EMA communication directed to the general public (e.g. EPAR summaries, Q&A). We also considered it very important to have been involved and consulted in the definition of the symbol to identify medicines under additional monitoring (black triangle), in the preparation of the EMA clinical trials transparency policy and in the policy of conflict of interest. This gave us the opportunity to share our views on how to improve transparency and safety of medicines and on how to guarantee that the Agency remains a reliable and trusted regulatory authority.

What is the added-value of the PCWP for the patients and consumer organisations?

The patients and consumers working party gave us the opportunity to have direct contact with the Agency as well as with health groups and patients organisations. It is a useful forum to gather information about key developments in the work of the Agency and on pharmaceuticals in general. The meetings of the PCWP are also a good opportunity to exchange views and ideas both with regulators and other NGOs on issues of common interest. Moreover via the PCWP we had the chance to take part to very interesting trainings on various topics such as communication and pharmacovigilance. In our role as an umbrella organisation we also use the PCWP as a platform to get our national members closer to EMA by sharing with them the information received in the PCWP meetings, as well as consultation documents and invitations to EMA workshops and conferences where seats are often allocated to PCWP members.

What do you feel is the added value that the patients and consumer organisations bring to the PCWP and EMA?

Patients and consumers organisations bring the voice of those affected by EMA decisions to the Agency. At the level of PCWP, patients and consumers organisations play an advocacy role and provide input on general issues and discussions while through their members involved in the committees and in the scientific advisory groups they provide real-life experiences of those who need to use medicines. Patients and consumers organisations give EMA what policy-making scholars define as "input" and "output" legitimacy. Input legitimacy because they contribute to improve the quality of EMA decisions by providing additional evaluation elements to EMA experts. Output legitimacy, because their involvement in itself increases EMA's transparency and accountability.

How did the combination of consumers with patients in the working group function in the beginning?

At the beginning the interaction between patients and consumers organisations was a bit tense and also confrontational on some sensitive issues such as the role of the pharmaceutical industry in the provision of information to patients, in the context of the debate of the legislative proposal on information to patients between 2008 and 2010 which was then withdrawn by the European Commission. The tension was mostly linked to the lack of knowledge of the respective work and background of the two stakeholder groups and it has significantly improved over the years. It was a learning exercise and we learned to work together. We also well understood that our perspectives are complementary to each other: patients' organisations' focus and contribution is mostly from the perspective of chronically ill patients who have needs and experiences – including level of information, risk perception etc. - very different from a consumer who needs once in his/her life a medicine for an headache or for a surgery or a parent who has to decide whether or not to vaccinate his/her child.

Contribution by Christoph Thalheim

It is only 12 years ago, that no common voice for the 150 million patients with chronic diseases existed in the EU. If you ask consumer rights protection groups in Europe, patient advocacy has always been and still is part of their task portfolio.

And this exactly is the crux – how efficiently can you defend the rights and interests of patients with a chronic disease, if your work is focused on all kinds of consumer goods?

On the other hand, disease specific patient advocacy groups were working for people with a chronic successfully for 30 or more years on national and also on European level, just the common voice of them was missing.

However after having worked together, I can only say thank you to my dear colleagues on the consumer side, for having convinced fully an all-time sceptic that consumer protection does not find its limits in low consumption washing machines or the best insurance policy.

For healthcare in general and for our involvement at EMA specifically it is not an "either them – or us", but the way forward is cooperation through our individual input for the benefit of both the chronically ill and the once in a while healthcare consumer.

***Extra reading*:**

- Annual report 2015: European Medicines Agency's interaction with patients, consumers, healthcare professionals and their organisations - http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2016/06/WC500209168.pdf

- Juan Garcia Burgos and Isabelle Moulon (2014) Patient Contribution to Medicines Regulation: the EMA approach. Pharmazeutische medizin 1-2014 of the German Society for Pharmaceutical Medicine (Deutsche Gesellschaft für Pharmazeutische Medizin) Vol. 16 (1), OEMUS Media AG, Leipzig, February 2014, p. 4-8.

- Isabelle Moulon and Nikos Dedes (2010) The Patients' and Consumers' Working Party at the European Medicines Agency – A model of interaction between Patients, Consumers, and Medicines Regulatory Authorities. J. Ambulatory Care Manage. 33 (3): 190-197 PMID: 20539145 DOI: 10.1097/JAC.0b013e3181e59322