Survey on patient organizations' involvement in the national medicines agencies processes (May 2017)

In the framework of the **XI European Patients' Rights Day** dedicate to "European & National Medicines Regulatory Systems: challenges for an equitable, timely and suitable access to innovation" Active Citizenship Network realized a mini survey among their partners in the different EU Countries about the involvement of patients' associations in the decision making process within the national medicine agencies.
We received answers from from 20 EU Countries[1] (from patients and civic associations, in Latvia a former member of a patients association) and also from Israel. We will analyze only the EU ones.

The first question was, thus, about the official involvement of patient organizations: **"Are patient representatives / associations in your country officially involved in the decision making process within the national medicine agency?"**
10 out 20 Countries (The Netherlands, Cyprus, Slovenia, Spain, Germany, France, UK, Slovakia, Croatia, Belgium) answered "yes" there is an official involvement.

Questions for Countries with the official involvement in the National Medicine Agencies:

Then we ask to them "**What are the criteria to become an officially involved association?"** we received very different answers: from "be a recognized registered patient association" (Netherlands) to "be just political association" (Croatia). In France there is a specific approval/accreditation procedure and in UK the association has to be registered as stakeholder. More of the others respondents answered, in different ways, that "the size of the organisation is important" and "to be an umbrella organization representing several patients organization" is a criteria taken in consideration. Also to be visible and well recognized by the public.

So we asked to them "**What issues will be discussed and open for advice by patient representatives/associations?".** In the most of Countries (Netherlands, Cyprus, Slovenia, Germany, Slovakia) the associations answered that there are no restrictions (except pricing in Netherlands). France specified some examples like "adverse events, clinical trial, process of information with patients organization and public, drug approval, HTA"; in UK "the patient perspective on new medicines"; quite the same in Spain: "reports about the cost-benefit of new drugs". Croatia cited patients 'Rights and obligations and the Belgian association "rare diseases, chronic diseases, literacy, patient's empowerment".

At the question if the **patient representatives/associations are entitled to add topics to be discussed within that advisory board,** quite all the associations answered yes only UK and Slovakia answered NO.

[1] **The Netherlands** (Fibromialgie En Samenleving FES), **Finland** (Suomen Kipu ry), **Bulgaria**(Patient's Organizations With You and National Patients' Alliance "Health for you"), **Cyprus** (Member of the central committee of POSPF), **Latvia** (National Health Service), **Greece** (Hellenic Cancer Federation), **Slovenia** (Kultlab Celje Association), **Malta** (Malta Health Network), **Spain** (Fundación MÁS QUE IDEAS), **Denmark** (Lyle), **Austria** (Lower Austrian Patient and Nursing Advocacy), **Germany** (Leukämiehilfe Rhein-Main E.V.), **France** (Association Française Des Hémophiles), **Czech Republic** (Diagnoza leukemie), **UK** (Neil Betteridge Associates), **Slovakia** (Society of Consumer Protection), **Croatia** (Hrvatska Udruga Za Promicanje Prava Pacijenata), **Romania** (Romanian National Alliance for Rare Diseases), **Poland** (Institute of Patient' Rights and Health Education), **Belgium**(LUSS-Ligue des usagers des services de santé).

At the end of this first battery of questions we asked to these associations if **patient representatives/associations have a consultative or a deliberative role.** Only Slovenia answered deliberative. In the Netherlands the role is consultative however within the executive board there is a dedicated representative. In France there is no vote but decision by consensus**.** In all the others countries the role is consultative.

Going into the contents, we asked if the **access criteria to (innovative) medicines are discussed in this committee,** most of the respondents (The Netherlands, Cyprus, Slovenia, Germany, France, Croatia) said yes except UK and Belgium for which the answer is NO and Spain and Slovakia that answered "not sure".

For those that answered yes to the previous question we asked **if the role of patients representatives / associations has been influential in the access criteria for (innovative) medicines within their agencies** and all of them affirmed that yes it has been influential.

About another important topic "the prizes of medicines" we asked: **Is there an involvement of patient representatives/associations in the setting of prices for medicines by the dedicated public body (medicine agency, governments/special authorities etc..)?** The answer is NO for all the Countries! In France the association tell us that they strongly lobby to be part of the CEPS (the national body for fixing price) and at regional level they strongly try to be part of the process.

The reasons of the lack of involvement in the other Countries:

Going to the 10 Countries[2] where the answer to the first question (are patient representatives/associations in your country officially involved in the decision making process within the national medicine agency?) is NO, we asked to them "**what would be the reason of no for that in their understanding?".** The answers are very different, most of them told about a lack of cooperation between Institutions and Associations, the lack of law or a democratic structure, ignorance. Someone speaks about "not so strong or competently patients 'representatives". The Austrian association, in particular, affirmed that they "don't think that's useful to be involved in the decision making of the national medicine agency because the question of access to innovation refers more to the national public insurance system".

When we asked if **they would be willing to collaborate in initiatives which are aimed to involve patient representatives/associations in the work of your national medicines agency by means of an advisory board?** Most of them answered YES. (Except Austria, Latvia, Poland)

The role of patients' involvement:

As last question we asked: **"Do you think that, in general, the involvement of patient representatives / associations has an added value according to your understanding?"**

The answer is "Strongly" for 13 out of 20 Countries (The Netherlands , Finland, Cyprus, Greece, Malta, Spain, Bulgaria, Denmark, France, Czech Republic, Romania, Belgium). Poland, Croatia, Germany and UK said "A little". Latvia and Slovakia "Fairly. (Slovenia, Austria no answer).

To who answered "a Little" to the previous question we asked **what do they think would work to make the patient advisory board more effective** and the answers were the following:

Germany :Inviting the real patient advocates/representatives and not only the ceo's /administrative staff

UK: Voting rights

Croatia: better communication between government and organizations

Poland: Organize trainings for selected representatives of patient organizations in the HTA field.

[2] Finland, Bulgaria, Latvia, Greece, Denmark, Malta, Austria, Czech Republic, Romania, Poland.