Mapping of innovative treatments and devices in EFCCA member countries

Interim report

February 2017

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United We Stand

1. Introduction of the project

National health systems and access to various treatments tend to be unequal in different EFCCA member countries, in particular when dealing with new/innovative treatments and devices. In some EFCCA member countries, there are no national registers of IBD patients available that would assist in obtaining information about IBD patients. This project aims at reducing health inequalities in Europe by carrying out a thorough mapping of all innovative treatments and devices (biologics, biosimilars, apheresis, nutrition etc.) available in EFCCA member countries. Seven national IBD associations (Finland, France, New Zealand, Poland, Serbia, Slovenia, Spain) participated in the pilot phase in October-December 2016 to test an online survey developed by EFCCA.

The pilot phase will be continued by a second phase in 2017 where more national associations will be involved. The final product will be a general overview of the situation in various EFCCA member countries, including the level of involvement of different payers and the role of national health authorities. The outcomes of the project will support the exchange of knowledge and experience among EFCCA members, promote a better understanding of European healthcare systems, improve the mobility of people with IBD in European countries and facilitate access to treatment in other countries.

2. Pilot phase

National associations from Finland, France, New Zealand, Poland, Serbia, Slovenia and Spain volunteered to participate in the pilot phase, which was carried out in October-December 2016. The aim of the pilot phase was to test the online survey and help fine tune the project and shape the following phases. The volunteers were asked to fill out the survey online and give feedback about it to EFCCA. In most participating countries, the survey was filled by the patient association in

cooperation with gastroenterologists.

Technical issues

The pilot phase showed that the online survey, carried out using the Limesurvey software, mostly functioned well. There was very little feedback from the participants concerning the technical aspects of the survey; the biggest technical issue was that all required questions on one page must be answered before moving on to the next page. Not being able to move between the pages made it difficult to have several people working on the survey simultaneously. Such a change, however, was considered problematic within the software. Therefore, the participant in question was given the survey as a pdf to use as a "road map" of what to expect on the next pages. There was also a suggestion that the respondent should be able to save the survey as a pdf when they submit their answers, so they can keep record of their own responses; this was considered a good idea and saving own answers was enabled.

Contents issues

In addition to the technical issues, there were some issues from within the EFCCA working group in regards to the contents and wording of the survey, listed below:

- To avoid confusion, should the word 'resident' or 'citizen' (or perhaps simply 'patient') be used when asking about the country's health insurance?
- Should the number or percentage of patients receiving a given treatment be asked – what is more descriptive, and more importantly, what data is available for the respondents? If information is not available, the number should be estimated to the best of knowledge. (However, as respondents had no data available in most cases, this point is not that relevant.)
- As there were discrepancies in terms of EMA information and the responses in terms of approvals of certain medications, the survey should more clearly differentiate between approval of the drug (by both EMA and the national

medicine agencies) and its actual market availability.

Furthermore, the question arose whether patient associations should be responsible for the responses as e.g. gastroenterologist might have better access to answers, and whether responses should be cross-checked by the EFCCA working group. However, as a patient organization EFCCA's primary partners in the project are patient associations, their involvement and role in providing information and giving country context is important and their answers should be taken as such, without additional checks. The respondents should, however, be encouraged to check with responsible authorities in their own country before submitting their answers.

3. Steps to take in preparation for the next phase

Before the next phase, the open contents issues mentioned above will be solved by the EFCCA working group. After optimizing the survey, other EFCCA member countries will be invited to participate. Further steps can be seen in the schedule below.

In the next phase, a pdf of the survey will be sent to the participants in advance so that respondents can prepare, get the information they need etc. Respondents will also be encouraged to cross-check information with the national authorities in their country (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp). When the second phase is running, the EFCCA working group will start preparing the design of the final product.

Time	Action	Participants	
Summer	Identifying pilot countries	EFCCA working group	✓

2016	Developing the work sheet		
September 2016	Launching the pilot phase	EFCCA working group Pilot countries	✓
February 2017	Interim report	EFCCA working group	✓
February 2017	Optimizing the survey based on pilot phase	EFCCA working group	
March 2017	Launching the second phase with more countries	EFCCA working group EFCCA member countries	
Summer 2017	Closing the second phase	EFCCA working group EFCCA member countries	
Late 2017	Analysing the outcomes, generating the final product	EFCCA working group	
Early 2018	Final report and development of recommendations	EFCCA working group	
2018	Event at European Parliament?	EFCCA	

4. Outcomes of the pilot phase

The availability and source of a precise number of IBD patients varied greatly in the pilot countries. In Finland, for example, a number (45 000) is provided by the Social Insurance Institute based on the amount of patients receiving coverage for medication based on IBD diagnosis, whereas Serbia, for example, has a register of patients, but the data is incomplete and the number (7000-8000) is estimated by the gastroenterologists dealing with IBD. All participating countries had a universal state insurance / public health service with a possible additional private insurance.

In most participating countries health care is financed by employers, employees and/or the state together. Only in New Zealand the patient him/herself pays the insurance. While getting treatment, in Poland the patient pays nothing while insurance covers everything; in Serbia, Slovenia and Spain the patient pays a part while insurance covers rest. In France, the patient pays everything at the point of care and gets partially reimbursed later. In Finland, health care has an upper limit per calendar year, beyond which the patient does not have to continue paying fees.

Only Spain reported regional differences; there are 17 regional health services in Spain, and not all of them work in the same way to support the needs of patients and their families.

In Finland, France, Poland, Serbia, Slovenia and Spain the patient can choose their GP / specialist / point of care freely, whereas in New Zealand the GP / specialist / point of care is defined by the system based on e.g. where the patient lives. Access to IBD medication requires an official recognition of diagnosis in Finland (a marking on the health insurance card) and Poland (needs to be confirmed by a specialist).

Biologics

Humira (adalimumab) is approved to IBD patients in all pilot countries. It is administered at home. In New Zealand and Poland certain preconditions need to be met for the patient to have access to the drug. The drug is administered at home. Poland reported 453 adults and during hospitalization 22 children being treated by adalimumab; Serbia reported about 150 patients. Other countries had no data.

Remicade (infliximab) is approved to IBD patients in all pilot countries. In Poland, Serbia and Slovenia, certain preconditions need to be met for the patient to have access to the drug. In Poland about 700 Crohn's disease (150 children) and 285 ulcerative colitis patients have reveiced the drug in the past years, in 2016 practically only biosimilars were administered. In Serbia, about 200 patients are receiving the drug. Other countries had no data. In Finland, the drug is no longer used in adult patients. In all pilot countries, the drug is administered in hospitals. In many regions in Spain, only the biosimilar is available.

Simponi (golimumab) is approved to IBD patients in Finland, Serbia, Slovenia and Spain. In Finland, the drug is considered a good option for ulcerative colitis

patients. In Spain, it is available for ulcerative colitis but not Crohn's disease patients. In Serbia, the therapy is in the procurement process. In Serbia and Slovenia, certain preconditions need to be met for the patient to have access to the drug. The drug is administered at home (hospital in Serbia). No country had data about how many patients are receiving the treatment.

Cimzia (certolizumab) is approved to IBD patients only in Finland (but has no trading license).

Entyvio (vedolizumab) is approved to IBD patients in Finland (second line biological therapy for IBD patients mainly due to its cost and lower response rate for induction compared to infliximab), France, Slovenia (available for ulcerative colitis but not Crohn's disease patients) and Spain (available for Crohn's disease but not ulcerative colitis patients). It is administered in hospital. No country had data about how many patients are receiving the treatment.

Biosimilars

Inflectra (infliximab) is approved to IBD patients in Finland, France, Poland, Serbia (no patients, therapy in procurement process), Slovenia and Spain (not available in every hospital). It is administered in hospital. For Poland, see Remicade; other countries had no data about how many patients are receiving the treatment.

Remsima (infliximab) is approved to IBD patients in Finland (more common than Inflectra), France, Poland, Slovenia, Spain (not available in every hospital). It is administered in hospital. For Poland, see Remicade; other countries had no data about how many patients are receiving the treatment.

Devices / techniques

Otsuka Adacolumn is available for IBD patients in Finland (unusual, lack of good experiences), France (few gastroenterologists administer it due to its medical

complexity) and Spain (unusual due to costs). It is administered in hospital. No country had data about how many patients are receiving the treatment.

Patients' unmet needs

IBD patients' unmet needs and priorities in terms of access to new innovative therapies were defined by the participants as follows:

Finland: *New therapies are approaching clinics in the near future and for the first time it seems like clinics in Finland will be able to participate in these studies and provide new treatment options also for Finnish patients. So far, only in very few cases we have been able to treat patient with new upcoming drugs before these drugs have been provided with a trading license.*

France: *Access is of no problem. With so many new treatments now available, not all gastroenterologists have equal experience in prescribing them.*

New Zealand: *Geographical variation in access to specialist care and to allied health care (due to distance and population distribution). Some areas in NZ have low population and have few specialist services, or people need to travel longer distances to access these. Therapies managed by central government agency - Pharmac. Limits access and range of drugs therapies available, including for IBD.*

Poland: *Access is difficult for patients with CD and illusory for those of CU.*

Serbia: *A delay in the application of the latest therapeutic options because the long process of their approval by the Health Insurance.*

Slovenia: *IBD patients could access all new and innovative therapies if they are indicated but maybe with a little delay compared with more developed countries.*

Spain: *Nowadays, our regional governments have the priority of saving money. As a consequence, innovative therapies are remaining the last option. It doesn't matter how much they change our lives.*

5. The final outcomes

The final outcomes of the survey will most likely be presented three-dimensionally:

1) a fact sheet will be generated for each country's information,

2) a comparison sheet between the participating countries will be generated for each question, and

3) a report of the most important outcomes will be prepared.

The final outcomes can be used to display discrepancies to European policy makers and to stress the importance of equal access to treatment.