

EUPATI Workshop, Berlin, 20 July 2016

Case Study – Swissmedic's cooperation with patient and consumer organisations



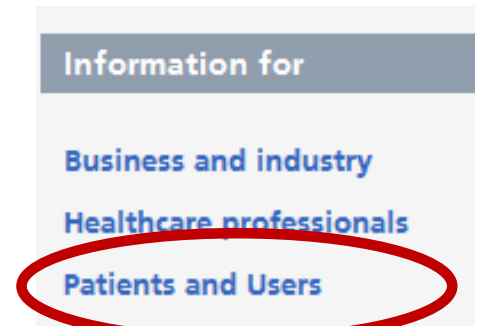
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From where we started ...

Re-alignment of cooperation with Patient and Consumer Organisations

As of January 2014

- Active provision of information targeted to patient/consumer needs via dedicated entry point on Swissmedic Homepage
- **Involvement of patient/consumer organization representatives in pre-defined work areas of Swissmedic**



Involvement as important point

Swissmedic Management Board approved the re-alignment concept with the involvement component upon the following pre-requisites:

- Step by step approach
- Pre-defined work areas and activities
- As a pilot to test and not product related
- Similar to EMA approach but adapted to Swissmedic's capacities
 - ☞ no “re-inventing the wheel”

Swissmedic Working Group with Patient and Consumer Organisations

1. Step

Pilot for 2 years

Establishment of a Swissmedic working group with patient and consumer organizations

2. Step

Evaluation of results/outcome after two years

Nominations to newly established Working Group

- All patient and consumer organisations with whom Swissmedic had worked in the past were contacted directly
- Nomination request form published on Swissmedic Internet side
- Criteria for participation according to EMA criteria

Lessons learned:

More “promotion” right from the beginning?

Initial membership

- 14 patient organisations and 2 consumer organisations
- Patient organisations: both small ones focusing on specific therapeutic areas and umbrella organisations

Quite heterogeneous group, some “relevant” Swiss patient organisations missing

Transparency

Mandate, Rules of Procedure, Agenda and Meeting Minutes are published on Swissmedic website (German and French language)

<https://www.swissmedic.ch/00129/index.html?lang=de>

+ Collaboration with patient and consumer organisations

Lesson learned:
Absolutely crucial for acceptance and success

What has been done so far ...

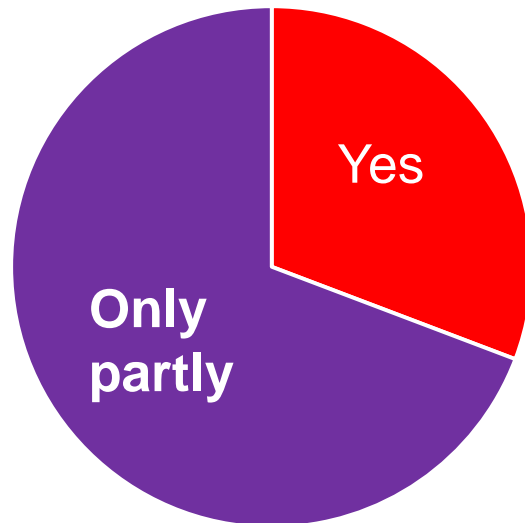
What has been done so far?

- Kick-off meeting on 2nd May 2014:
 - Discussion of Mandate and Rules of Procedure
 - Regulatory training on topics of mutual interest
- 2nd to 6th Meeting :
 - Continuation with Regulatory focus themes
 - EUPATI & EUPATI National Liaison Team CH
 - Start with involvement projects
- 7th & 8th Meeting December 2015 / February 2016:
 - Preparation for end of pilot phase (May 2016)
 - Development of survey

Where we are now ...

Evaluation of survey results

- 9th Meeting on 26 April 2016:
 - First presentation of results of the survey and discussion how to proceed with the working group



■ Ja ■ Nein ■ Teilweise

Have the objectives as laid out in the mandate and rules of procedures been met?

Evaluation of survey results

Lessons learned:

- Pilot phase of just two years too ambitious?
- Group needs time to establish good working relations and to build confidence (even more so in case of heterogeneous group)
- Not enough focus on involvement or not well communicated what pilot wanted to test (step by step approach, pre-defined work areas)?

Where we might go ...

- Extension of pilot for a further two years?
- If yes: focus on involvement during this time based on strategic working plan
- If yes: re-publish possibility to join working group via nomination request

To be further discussed at next meeting of the working group on
30 August 2016

Conclusion

- Cooperation has to be tailored to the specific situation / needs of the stakeholder group
- Time and financial constraints by patient and consumer organisations have to be taken into account
- Different level of knowledge about regulatory processes among working group members
 - ☞ Training (regulatory focus theme) extremely important
- Involvement at Swissmedic has just started
 - ☞ still some way to go ... but ...

**“What is not started today
Is never finished tomorrow.”**

Johann Wolfgang von Goethe



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