European Commission

Study on the Legal Aspects of Supplementary Protection Certificates in the EU

Annex IV: Fact Finding Methodology

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The fact finding for this Study is based on a combined quantitative and qualitative approach. This allows for comparability of the responses and the inclusion of a large number of stakeholders on the one hand while providing sufficient flexibility and time to discuss certain issues in more depth with stakeholder experts.

1 STAKEHOLDER QUESTIONNAIRE

The Study uses an online based stakeholder questionnaire prepared together with the Institut für Demoskopie Allensbach ("Allensbach") and delivered to the stakeholders by Allensbach (Annex III). Compared to other studies there is one hurdle in conducting a stakeholder survey with respect to SPCs. Stakeholders to the matter of SPCs are not only SPC holders or SPC applicants, which are usually originator companies, but also their generic competitors, insurance companies as payers for medical services, research institutions, industrial and professional associations, legal and patent attorneys as well as consumer interest groups as representatives of the patients who require adequate and affordable medicinal products. However, there is no compiled list of the relevant stakeholders. Therefore, one possible approach would be to prepare a general consultation and request stakeholders through publicly available sources such as newspapers or blogs to participate in the survey. Such an approach cannot be controlled for validity since anyone interested can participate once or even multiple times.

Therefore, together with Allensbach, we decided to compile a list of stakeholders based on information available to us. We obtained contact details from various industry associations regarding their members. To exclude multiple participation and therefore to allow for quality control, only one representative of each stakeholder entity was included in the stakeholder list. Regarding the holders of SPCs we were able to partially rely on the registers. However, due to the market structure, particularly larger company groups do not use one legal entity to apply for an SPC but quite often different entities within one company group are used. For the purpose of the Study, however, each company group could only be considered as one stakeholder entity to prevent an overweight of larger companies in the responses. Therefore, we had to review the lists of SPC holders and SPC applicants and ensure that no company group was included twice. Furthermore, we relied on the list of marketing authorisations. Here again, the issue arose that for various reasons, the holder of a marketing authorisation and the SPC applicant or SPC holder are rarely the same legal entity. In most cases company groups use different subsidiaries for these purposes. Therefore, again, we had to compare the lists and ensure that no stakeholder was included twice.

For the other stakeholders no compiled list exists that could be used as a starting point. Particularly there is no complete list of generic companies active in the European Union. We contacted industrial associations representing generic companies to obtain lists of their members. Furthermore, we asked the associations to inform their members about the Study, and to contact us regarding participation in the survey. Two additional issues emerged regarding generic companies. Based on our discussions with interest groups and individual stakeholders, we obtained the information that a large number of generic companies are SMEs with only limited personnel with sufficient knowledge on patent law and SPCs. These smaller companies often rely on outside advice from law firms and do not have substantial in-house knowledge on the issue. In addition, many renowned generic brands or entities (e.g. Teva Pharmaceuti-

cal Industries with Cephalop, Ratiopharm, 1a-Pharma, Actavis etc.) are part of one company structure. Irrespective of our own classification these company groups have the policy that only one company responds on behalf of the company group. This reduces the number of potential participants significantly. Furthermore, in cases where generic companies are part of an originator company group (e.g. Novartis with Sandoz and Hexal) only the main company (usually the originator) was willing to participate in the questionnaire. This again reduced the number of large stakeholders.

The compiled list of potential stakeholders included more then 700 companies. To ensure a high participation rate of the relatively small number of potential stakeholders, we contacted each stakeholder directly by email or phone, requested a contact person with an address, phone number and email address. We also informed them that the invitation to participate in the survey together with an individualized code for participation will be send only to this individual person. Compiling the final list of 332 stakeholders has been conducted by a team of five researchers and research assistants over a period of five months.

Stakeholders	Positive Answers	Contacted (not interested OR no answer)	Contacted + Positive Ans.
Originator Companies	102	312	414
Generic Companies	42	24	66
Industry Associations	52	31	83
Professional Associations	12	4	16
Other Associations	12	4	16
Universities	14	39	53
Law Firms	98		98
Insurance Companies		33	33
	332	447	779

Table 1.1: The type and responsiveness of the stakeholders

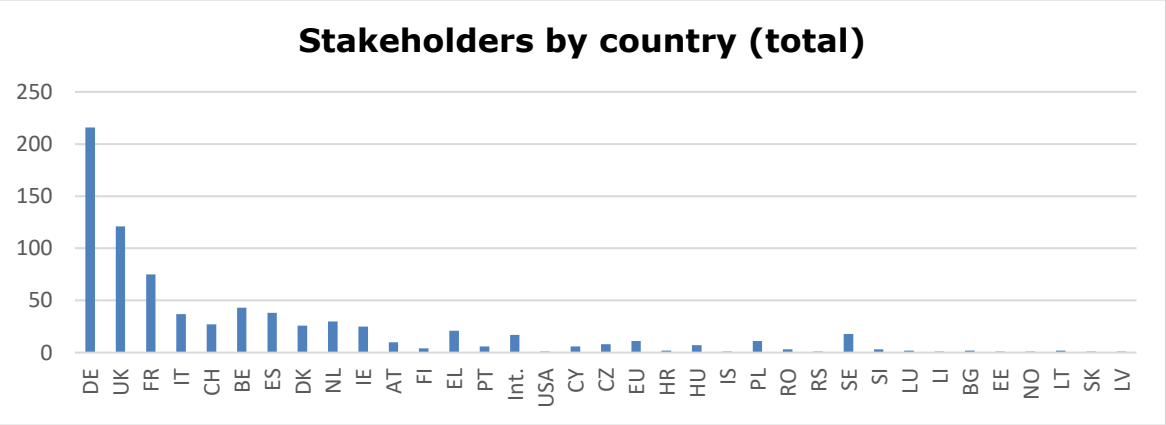

Table 1.2: Stakeholders by country

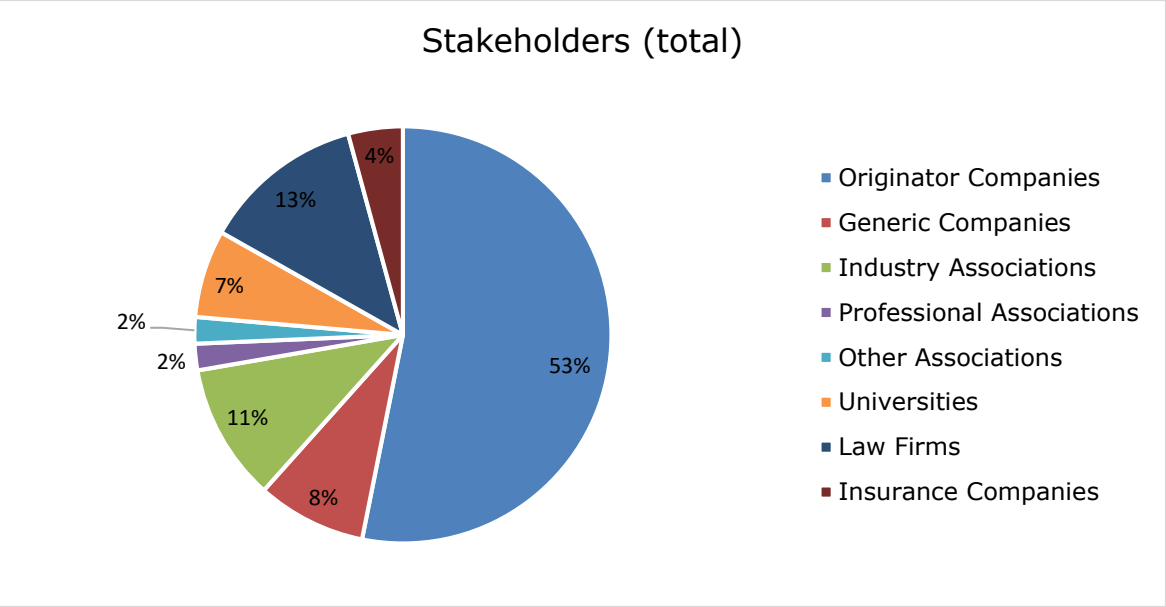

Table 1.3: The Stakeholders (total)

From the 332 stakeholders who initially expressed their interest in taking part in the survey, 203 completed it, of which 89 were companies in the pharmaceutical or agrochemical sector (representing 43.84% of the total of participating stakeholders), 63 law/patent attorneys firms (31.03%), 46 associations (22.66%) and 5 universities/research institutions (2.46%). Between all the aforementioned stakeholders, 99 were representatives of originator companies and 46 of generic companies.

The companies (89 stakeholders in total) comprised 51 originators and 31 generics. Between the companies, 14 were small, 20 medium size and 53 large enterprises. Regarding the position hold by the person who answered the questionnaire on behalf of each company, 19 were owners, directors or members of the board; and 53 held managerial or non-managerial positions.

- From the law/patent attorneys firms (63 stakeholders in total) 30 (47.62%) represented originator companies; 6 (9.52%) generic companies; and 42.86% both. In addition, 46.03% represented right holders; 3.17% competitors of right holders; 49.21% both; and 1.59% did not respond.
- Divided by sector of activity, 33 (71.74%) of the associations represented the industry (of which 84.85% represented the pharmaceutical industry and 15.15% the agrochemical industry); 9 (19.57%) represented professional associations; and 8.70% represented the rest of associations. Divided by size: 36.96% of the associations had below 50 members; 13.04% from 50 to 99 members; 15.22% from 100 to 299; and 34.78% had 300 members or more. Between all the associations (46 in total), 18 were representatives of originator companies and 9 of generic companies.
- From all the industry associations (33 in total) 84.85% represented pharmaceutical companies and 15.15% agrochemical companies.
- From the industry associations who represented pharmaceutical companies (28 in total); 18 (64.29%) represented originator companies; 9 (32.14%) generic companies; and 3.57% did not respond.

- From the professional associations (9 in total) 22.22% represented a particular industry and 77.78% represented the legal sector.
- 82 of the companies who participated in the survey (92.13%) declared to be active in the field of SPCs. Of those 82 companies; 91.46% were active in the field of pharmaceutical products for humans; 15.85% in veterinary products and 8.54% in the area of plants protection. In addition, of the same 82 companies 62.20% described themselves as being originators and 37.80% generic.
- 40% of the universities/research institutions were involved in research and development activities in fields for which SPC protection is available and 60% were inactive in such fields.
- Most of the participating stakeholders had a high territorial scope regarding their activities, i.e. from the 203 participating stakeholders, 70 affirmed to undertake their activities in 10 or more EU member states, and only 15 affirmed to have a low/medium territorial scope regarding their activities (undertaking their activities only in 1-9 EU member states).
- The companies were geographically located mainly in EU member states (64 companies, representing 71.91%); 48 (53.93%) were located in the Eurozone; 6 (6.74%) in new EU member states (since 2004) and 28.09% outside the EU. Per country: 2.25% were located in Austria; 3.37% in Belgium; 1.12% in Czech Republic; 3.37% in Denmark; 7.87% in France; 16.85% in Germany; 3.37% in Greece; 2.25% in Hungary; 1.12% in Ireland; 5.62% in Italy; 2.25% in Poland; 1.12% in Portugal; 1.12% in Slovenia; 11.24% in Spain; 8.99% in the UK; and 28.09% in non-European countries.
- 84.78% of the associations were geographically located in EU member states; 63.04% in the Eurozone; 8.70% in new EU member states (since 2004) and 15.22% outside the EU. Per country: 2.17% of the associations were located in Austria; 15.22% in Belgium; 2.17% in Croatia; 2.17% in Czech Republic; 2.17% in Denmark; 2.17% in Finland; 8.70% in France; 13.04% in Germany; 6.52% in Greece; 2.17% in Hungary; 4.35% in Italy; 2.17% in Poland; 2.17% in Portugal; 8.70% in Spain; 2.17% in Sweden; 8.70% in the UK; and 15.22% in non-European countries.
- The law/patent attorneys firms was comprised by 33.33% global or international firms; 30.16% regional (active in more than one country); 33.33% national (office(s) in only one country); 1.59% local; and 1.59% did not respond.

2 QUALITATIVE INTERVIEWS

To supplement the quantitative survey, we conducted qualitative interviews with selected stakeholders. The stakeholders were selected based on presumed experience in the field of SPCs and availability for the interview. Most interviews were conducted by a team of two researchers with at least one researcher being trained and experienced in conducting qualitative interviews. The participants received a list of questions prior to the interview which was used as a guideline for the actual interview but which was not exhaustive. All interviews were conducted on an anonymous basis. The interviews lasted between 60 and 120 minutes based on availability and knowledge of the stakeholders. Seventeen stakeholders had been contacted regarding an interview. Fifteen interviews have been completed. The stakeholders included six originator companies, four generic companies, two industry associations including one representing generic companies and one representing originator companies, and one professional lawyers' association. The companies included companies from the pharmaceutical and the plant protection sector. The participants to the interviews came from Germany, the United Kingdom, France, Switzerland and Hungary. Some of the companies were local companies and some part of international company groups.

Furthermore, we conducted more informal interviews with three judges and five lawyers specialised in the field of SPCs.

3 STAKEHOLDER WORKSHOP

To have the opportunity to discuss pressing issues regarding SPCs at an early stage of the study, we organized a two-day-workshop together with the German Patents and Trademark Office in Munich. Stakeholders including professional and industry associations, law firms and companies were invited for the first day of the workshop (20 March 2017) and total number of 190 individual participants signed up for the workshop. In some cases several individual represented one stakeholder. The presentations and discussions were recorded with the consent of the participants for the purpose of this Study. On a second day (21 March 2017), we invited representatives from the SPC granting authorities (NPOs) for a discussion on pressing issues and possible legislative changes to the SPC regulations. 80 individual participants signed up for the workshop and as on the first day, the discussion was recorded with the consent of the participants.

4 STAKEHOLDER SEMINAR

The responses to the Allensbach Survey provided in the text boxes and submitted to us directly by various stakeholders made it clear that stakeholders had the strong desire to discuss some matters regarding the SPC regime in more detail. To respond to this wish, we conducted a seminar with a limited number of stakeholdes on 11 September 2017. In the course of the seminar we discussed selected topics with the invited stakeholder representatives that have been see as most important by the stakeholders. Furthermore, the stakeholders received the opportunity to submit written statements before and after the seminar. The participants of the seminar included representatives of originator and generic companies as well as representatives of industry associations.

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