

Arbeiten aus dem Paul-Ehrlich-Institut
11th International Paul-Ehrlich-Seminar, Bad Homburg 2005
Verlag Chmielorz

Summary of the Response to the Questionnaire Marketing Authorization of Allergen Products in Europe sent to National Regulatory Agencies

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The aim of sending out a questionnaire to regulatory agencies in Europe was to obtain an overview on licensed products and procedures. Not all national regulatory agencies responded to the questionnaire; ten agencies from Denmark, Czech Republic, Finland, France, Ireland, Italy, the Netherlands, Sweden, Switzerland, and Germany sent in their questionnaire. The groups involved in the regulatory work on allergen products tend to be small. On average three individuals are involved. However, often no expert or group of experts are responsible for all parts of the evaluation process and panels of up to ten experts may be involved to deal with matters of e.g. quality, and efficacy. Most frequently the experts have backgrounds in medicine (6/22), pharmacology (6/22), chemistry (4/22), biology (4/22), toxicology (1/22), and law (1/22).

The type of marketing authorizations granted are mostly specific (8/10) for a particular form of therapy or use (e.g. SPT, SIT, SLIT); other types of marketing authorizations e.g. for bulk preparations are rare (2/10). The allergen products licensed are mostly non-adsorbed, not modified extracts (7/10), adsorbed, not modified extracts (7/10), extract mixtures (7/10), adsorbed, chemically modified extracts (4/10), and non-adsorbed, modified extracts (1/10). Since we were interested in the topic of if and how named-patient products should be regulated we asked for the percentage of licensed products in relation to named-patient products. Most agencies (4/10) estimated that 75 – 100% of allergen products on their national market are NPPs, 5/10 did not give the percentage of NPPs, or answered that NPPs are either prepared from licensed bulk material or the agency has no legal role in use of NPPs. One agency estimated that 25-50% of the national market for allergen products is covered by NPPs. In the authorization process the concept of “Allergen Families” (CPMP/BWP/243/96) is almost used by all (7/9) regulatory agencies. Major problems and obstacles seen by the agencies during the licensing process of allergen products are (1) lack of allergen standardization (2x), (2) quality of clinical trials (2x), and (3) insufficient resources.

Four/10, 3/10, 2/10, and 1/10 have no, one, two, and three manufacturers of allergen extracts in their countries, respectively. Products of up to seven different manufacturers are sold per country, three agencies reported that four companies sell products nationally. The number of manufacturers that sell licensed products range from zero to seven, three agencies reported no licensed products.

Discussion

Kroon: I want to add that the European Allergen Manufacturers Group has eleven members, but apparently there are only ten recognized by the authorities?

Reese: No, we only got responses from ten members.

Vieths: But I think that this might also result from the fact that not all eleven manufacturers sell their products in our countries.

Kristensen: On one of your first slides you showed relation between Named-Patient Products and licensed products and their percentages. Could you please explain a little more what is behind this, how is this to be understood?

Reese: The question we asked was what is the ratio of licensed and non-licensed products. So, apparently, in some cases you have only licensed products on the market. At least that was the way it was stated by the agencies, which was kind of surprising.

Vieths: But we asked the different agencies just to give a rough estimate. I think we have to go ahead, but I would like to stress what Gerald Reese already mentioned. If an agency is represented here that did not receive our questionnaire, we would be happy to send it again to complete the data.