The Impact of Measures Taken by the Federal Institute for Drugs and Medical Devices (BfArM) Regarding the Naming of Medicinal Products from 2010 to 2013

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List of Abbreviations

AkdÄ	Arzneimittelkommission der deutschen Ärzteschaft
AMG	*Arzneimittelgesetz* (translation: Drug Law)
AMIS	*Arzneimittelinformationssystem* (translation: medicinal product information system)
AMTS	*Arzneimitteltherapiesicherheit* (translation: drug therapie safety)
Art.	Article
BfArM	*Bundesinstitute für Arzneimittel und Medizinprodukte* (translation: Federal Institute for Medicinal Products and Medical Devises)
BGA	former German Health Authority
BVerwG	*Bundesverwaltungsgericht* (translation: federal administrative court
CA	Competent Authority
cf.	from Latin: confer, "compare"
DCP	decentralised procedure
D.f.	Decision from
Dir. 2001/83/EC	Directive (EC) 2001/83/EC, as amended
ed.	editor
HWG	*Heilmittelwerbegesetz* (translation: German law on the advertising of medicinal products, the so called)
loc. cit.	from Latin: loco citado, “in the place cited”
MAH	marketing authorisation holder
m.n.	marginal note
MRP	mutual recognition procedure
OVG	*Oberverwaltungsgericht* (translation: higher administrative court)
OLG	*Oberlandesgericht* (translation: higher regional court)
OTC	over the counter

PEI	Paul-Ehrlich-Institute
PL	package leaflet
QRD	The European Medicines Agency's Working Group on Quality Review of Documents
SmPC	Summary of product characteristics
UWG	*Gesetz gegen den unlauteren Wettbewerb* (translation: law against unfair competition)
VG	*Verwaltungsgericht* (translation: administrative court)

1. Introduction

1.1. Drug therapy safety regarding the naming of medicinal products and connection to the reorganisation of German administrative practice

The name of a medicinal product is an integral part of its marketing authorisation, since every person actually handling the medicinal product, regardless whether they are a health-care professional, patient or third person, will associate the name with a specific medicinal product. This association will lead to further connections, which will not only focus on the function of the medicinal product, but also on its reliability, its handling and other defining attributes. Consequently, the unique name of a medicinal product will not only influence its market value but also its usage safety, since the name of a medicinal product could lead to either more safety, by contributing to the medicinal product's identification, or to misuse and confusion of medicinal products. For this reason the name of a medicinal product can be seen as part of drug therapy safety, in German it is called "*Arzneimitteltherapiesicherheit*" (AMTS).

The naming issue, next to other issues, was also a focus of the action plans to improve drug therapy safety, which was initiated by the German Ministry of Public Health in 2007[1]. As a first step of the initial action plan from 2008-2009, measurement 24 and 25, the public had been called on to report medicinal products which looked or sounded like other medicinal products – also referred to as "Sound- and Look-Alikes". 400 medicinal products had been identified.[2] Afterwards, with measure 32 of action plan AMTS 2010/2012, the identified cases had been discussed and classified in the "Sound- and Look-Alike workshop" in 2010 and a forum of industry in 2011 with representatives of pharmaceutical industry[3]. Finally, changes to a few cases, most likely to lead to high safety hazard, was suggested.

In parallel to the AMTS Sound- and Look-Alike workshop the decision was made to work out a new guidance document regarding the naming issue. According to action plan AMTS 2013/2015, the results of the workshops mentioned above also were considered in the development of the new guidance document[4]. In the following years both a new guidance document was published, and the administrative practice in regard to the naming of medicinal products was changed. The Federal Institute for Medicinal Products and Medical Devises, in German, "*Bundesinstitut für Arzneimittel und Medizinprodukte*" (further on referred to as "BfArM"), was one of the key players in the German reorganisation of the administrative practice in regard to the naming of medicinal products, which

[1] AkdÄ, http://www.ap-amts.de/ taken from the Internet on November the 21st, 2015
[2] AkdÄ, http://www.akdae.de/AMTS/Massnahmen-2008-2009/M24-25.html, taken from the Internet on November the 21st, 2015
[3] Koordinierungsgruppe Aktionsplan AMTS, protocol of the meeting of February the 23rd 2011 http://www.akdae.de/AMTS/Protokolle/20110223.pdf, TOP4; AkdÄ, http://www.akdae.de/AMTS/Massnahmen/M32.html, taken from the Internet on November the 21st, 2015
[4] Bundesministerium für Gesundheit, June the 4th 2013 „Aktionsplan 2013 – 2015 des Bundesministeriums für Gesundheit zur Verbesserung der Arzneimitteltherapiesicherheit in Deutschland" section 2.3 page 14

started in 2010 with the announcement of modifications to administrative practice in regard to name change procedures and found its peak in 2013 with the self-binding of the administrative body to the new German guideline of the BfArM and the Paul-Ehrlich-Institute in regard to naming of medicinal products, the so called "*Leitlinie des Bundesinstituts für Arzneimittel und Medizinprodukte und des Paul-Ehrlich-Instituts zur Bezeichnung von Arzneimitteln*" (referred to as "Naming Guideline" in the further text and given in Annex II).

1.2. Scope of the thesis and description of method approach used under inclusion of method approach originally intended

The following is going to describe and evaluate, from today's point of view, the impact of the changes in German administrative practice from 2010 to 2013. The review will chiefly focus on BfArM, excluding other German Competent Authorities (CA) dealing with marketing authorisations of human medicinal products, namely the Paul-Ehrlich-Institute (PEI), since the changes where predominantly initiated by the BfArM. Consequently, medicinal products falling under the competent jurisdiction of the BfArM will be used as examples. Nevertheless it should be emphasized that not only the BfArM, but also the PEI committed itself to the Naming Guideline, which means that the interpretation the Naming Guideline communicates is applicable to both CAs.

The first approach, next to other methods, included a data analyses based on the BfArM-internal database. How this approach was planned and conducted, as well as the reasons for not including it in the evaluation, will be explained in the following.

An analysis of the name change rejections concerning authorised marketing authorisations between 2008 and 2015 was conducted in order to evaluate, whether the administrative practice change influence to be discussed also had a visible effect on the name change rejection figures.

It was planned to analyse, if the figures could lead to affirmative, additional or controversial conclusions in regard to the impact the administrative practice change had. It was planned to display the numbers, to explain and evaluate them. To do so the BfArM-internal AM87 database was used. The AM87 database is connected to the German medicinal product information system, the so-called "*Arzneimittelinformationssystem*" (further on referred to as AMIS) and includes datasets of all applications for change processed by the BfArM (varations as well as purely national *Änderungsanzeigen*). In each data set additional information on the change is given, for instance, general information on the medicinal product concerned or the kinds of changes applied for.

The data search included the compilation of a search profile. The search profile is given within Annex III and gives all included and excluded search parameters. To summarize, the search profile includes all applications, which also contained a name change, from January 2008 to October 2015, excluding changes to so called *Standardzulassungen* (a specialised form of authorisation in Germany),

changes to parallel imported medicinal products, changes to centrally authorised products (since the administrative practice change have been of purely national impact), testing datasets and purely internal changes. Furthermore, only closed name change procedures have been included, which means that name change applications still under legal evaluation were not to be displayed. The search profile finally gives the number of accepted applications (search step No 13) and rejected applications (search step No 14).

The execution of the search profile revealed 241 rejected applications (search step No 14)[5] between January 2008 and November 2015. But even if the number of changes per month could be displayed, an evaluation based on the raw data was not reasonable and consequently additional raw data selection was needed. This conclusion was reached, because even if the search profile incorporated all rejected applications including a name change, it does not necessarily mean that the name change had been the cause for rejection.

To solve this problem the main problems were identified and a systematic approach to classify the data was tried to design. Every single dataset was evaluated on grounds of additional information given in the individual data sets.

Four systematic case groups were identified: Firstly, rejections due to naming matters (n). Secondly, cases in which the name change was connected to another change, which happened to be crucial to the name change, and where the other change had been rejected and consequently the name change was effected too (n+a). Thirdly, cases where the additional analysis could not reveal the grounds for refusal (u). Finally, rejections not based on naming matters, e.g. procedural matters (o). Additionally, every case group was divided into changes to medicinal products, subject to prescription (Rx) and not subject to prescription (nRx).

Another problem identified was the amount of directly connected submissions. Displaying the connected changes in their original number would have obfuscated an analysis, since high rejection numbers for one month would have remained unexplainable. So if, for example, an identical name change approach was submitted by the marketing authorisation holder (MAH) to a group of medicinal products it is shown with the qualifier "z" (standing for the German word "*zusammenhängend"*, meaning in English "connected") For example, "2+2z" means two unconnected individual applications and two connected application were refused.

On the basis of information given in the individual data set, the changes were classified according to the case groups. In order to do this initially, the notes given to the data sets were evaluated. Provided a classification was possible after that step the rejections were classified. If not, additional data analyses, based on AMIS data, were applied to the individual medicinal product (e.g. had the identical name change been accepted afterwards, which would lead to the assumption that the name change was not the cause for the rejection of the application).

[5] search conducted on November the 22nd, 2015, so only data until October 2015 are complete

Results of the evaluation are displayed in table 1, Annex IV. The sum of rejected applications per month is given at the end of the lines and the sum of rejected applications per case group is given at the end of every column.

After the systematic approach had been conducted in order to solve the problems described, the author of the thesis came to the conclusion that not only was an evaluation based on the raw data unreliable, but so was an evaluation based on the classified raw data. Additionally, other conceivable approaches to objectively classify the data would not have lead to reliable results. The problem lies in the basis of every classification approach, since the data base includes no searchable parameter displaying the reason for rejection without including company or business secrets. Only the notes given to the changes can be used to find out the reason for rejection. Unfortunately they are not appropriate to base a reliable, systematic and objective classification on. The notes given are firstly confidential, so they cannot be displayed openly and secondly, the notes are not comparable in the content of information given which militates against any systematic and objective classification approach, which could have been made public. Consequently, an interpretation of the data generated would lead to invalid and not publicly verifiable results.

As explained above, an additional data analyses based on BfArM internal data, used to evaluate the changes made, had been deemed unreliable, therefore another approach including only public data had to be conducted. However, the data base research, not suitable to base a discussion of impact on it, additionally provides the number on accepted name changes. The comparison of this number with the number of name change rejections is a fact not needing additional interpretation, which can be used to illustrate the significance of the examples discussed, which will be used in the final conclusion.

Since a database analysis was deemed unreliable, the approach conducted in order to evaluate the impact is composed of the following. Firstly, the legal and historical background will be given, secondly the changes in administrative practice will be explained and finally the changes will be evaluated in regard to their impact. Specialised literature, court decisions and AMIS data will be used in order to explain and evaluate this impact. Furthermore, even if the administrative practice change also affected new applications for marketing authorisations as well as renewal procedures, the thesis uses primarily examples concerning applications for name changes to existing marketing authorisations, since public data is available on them and since they cover the crucial topics.

English citations of original German law texts and court decisions will be translated freely by the author of this thesis or the translation of the so called "*Arzneimittelgesetz*" (further on referred to as "AMG" or "German Drug Law") provided by the Language Service of the Federal Ministry of Health will be used. However the translation is not legally binding therefore the original and legal binding original German texts can be found in the law or in the court decisions itself. Footnotes given, display the important data to identify the decision and if applicable the marginal note referred to. The annexed

list of court decisions gives links to the juris-database source used, as well as to a purely public source, in case a juris account is not available and a purely public source is available. The source of literature, displayed in the footnotes, as well as sources directly referenced in the text, is additionally given in the list of literature.

2. Hard law requirements of European and German legislation in regard to the naming of medicinal products

When reviewing the applied administrative practice and the Naming Guideline of Germany, firstly the legal framework has to be considered, since it constitutes the limitations for every regulatory action.

It is important to mention that the legal background given is not only based on purely national law, but is also embedded in European legislation. The basic requirements the European regulation gives in regard to the naming of the medicinal products, next to the definition of the name, are the affiliations to the marketing authorisation and the labelling requirements. European Directive (EC) 2001/83/EC, as amended (further on referred to as Dir. 2001/83/EC) is not directly legally binding for itself, nonetheless the legally binding character is derived from the commitment of the member states of the European Union to implement legal requirements given by the directive. Nevertheless, the adoption of the existing law in the setting of every country's unique legal background gives room for differing ways of implementation. Both the direct translation, as well as analogous transformation is possible. The following will, in cases where a direct translation exists, mention the source of information in both laws. If an analogous transformation is in place, next to the source of information, the differences will be described.

In contrast to the plain definition of the "name of a medicinal product" Art. 1(20) of Dir. 2001/83/EC gives, the German Drug Law does not contain a legal definition of the term "name of a medicinal product". Nevertheless, several paragraphs of the German Drug Law refer to the German terms "*Bezeichnung*" or "*Name*" of the medicinal product, which are to be seen as synonyms and as similar to the English "name of a medicinal product". Some of these paragraphs are, for example the labelling requirements sec. 10-11a AMG or the sections described underneath. Consequentially, legal requirements for the name of a medicinal product and its utilization, based on German drug law, can only be derived from paragraphs which mention it, but the precise definition in one single passage is missing. However, even with the background definition given in European legislation, in the time frame to evaluate, it was up for discussion whether or not the name of a medicinal product consists of

a main part and lateral part(s) or if the name always has to be seen as whole. This issue will primarily be discussed in the evaluation of impact on umbrella brand concepts.

Art. 8(3) b of Dir. 2001/83/EC, as well as section 22 sub-section 1 sentence 2 AMG dictates that the name of a medicinal product must be part of its marketing authorisation, which in respect of section 25 sub-section 1 sentence 1 No 1 and No 7 AMG means that a marketing authorisation can only be granted, if a valid name for the medicinal product is given, which does not infringe existing laws. Consequently, the name check has to be part of the CAs evaluation when reviewing an application for marketing authorisation. Furthermore for renewals, continuity (revocation, suspension and withdrawal) or changes to an existing marketing authorisation the name check based on non-infringement with existing laws, section 25 sub-section 1 sentence 1 No 7 AMG, must also be considered. It has to be emphasized that the remit of the review of section 25 sub-section 1 sentence 1 No 7 AMG is primarily based on drug law requirements and does not specifically include trademark or intellectual property aspects, which only under private law is of concern[6]. The evaluation of the name could have an influence on these aspects, but the main issue of the review is to secure the safety of the medicinal product based on legal requirements.

However, especially in regard to name changes to authorised medicinal products, the dimension of intervention power has been viewed as controversial. This will be analyzed, among other things, in regard to the administrative practice alteration to name change procedures in 2010.

The power of intervention of German Competent Authorities responsible for medicinal products in regard to the infringement of existing laws, section 25 sub-section 1 sentence 1 No 7 AMG, is mainly given with section 8 sub-section 1 sentence 1 number 2 AMG, the so called "*Verbote zum Schutz vor Täuschung*", which means prohibitions to prevent deception. According to this section it is prohibited to manufacture medicinal products or active substances or to place them on the market when they bear misleading name, labelling or presentation.

Furthermore, it has to be mentioned that the German Drug Law is a specialised law applicable to medicinal products only. Nevertheless, the requirements and especially these in regard to deception partially overlap with other German laws. The German law on the advertising of medicinal products, the so called "*Heilmittelwerbegesetz*"(HWG), and the law against unfair competition, the so called "*Gesetz gegen den unlauteren Wettbewerb*"(UWG), also deal with prohibitions in regard to deception. Consequently, one can assume that the term "deception" is used equivalently in these laws, which can be important for interpreting court decisions as well as for the discussion on the standard of evaluation to be used to assess the possibility of deception.

European legislation does not include an identical ground for denying approval. Nevertheless, related requirements in regard to misleading names can be extracted from European Community law

[6] cf. *Menges/Winnands*, in: Fuhrmann/Klein/Fleischfresser [ed.], „Arzneimittelrecht", version 2 of 2014, section 10 m.n. 275

in context with promotional statements Art 62 Dir 2001/83/EC. Likewise Art. 61(2), in connection with Art. 54 and following of Dir. 2001/83/EC, lead to the assumption that misleading statements cut down on clearness and intelligibility of packaging and package leaflet, which in reverse should be restricted[7].

Additionally, section 25 sub-section 3 AMG has to be mentioned regarding the decision on marketing authorisation. It prohibits the authorisation of a medicinal product which differs, in the nature or the quantity of its active substances, from a medicinal product bearing the same name which has been authorised for marketing or is already on the market. Nonetheless, according to sentence 2 of this section, the difference in the quantity of active substances shall be harmless if the medicinal products differ in their pharmaceutical form. The interpretation of this legal requirement, especially in connection with considerations in regard to the name definition, has been discussed controversially over recent years. This discussion and its outcome are directly linked with the evaluation of the Naming Guideline's impact on umbrella brands, which will be described in the thesis.

3. Historical retrospection on the development of the change in administrative practice during 2010 and 1013

The hard law requirements described above constitute the basis for every regulatory action in regard to naming. In spite of this, the legal requirements given are rather abstract and as a consequence further interpretation is needed in order to substantiate the law and establish a transparent administrative practice. The interpretation of the law concerns both the marketing authorisation holder as well as the CAs, since the CAs will decide on the law conformity of the name chosen by the applicant in the borders of their jurisdiction and on basis of the administrative practice established, which can conversely lead to legal consequences for the applicant. This means that, even if the published interpretation and guidance documents are not directly legally binding for themselves, they can be crucial if they are in conformity with the fundamental hard law requirements. Changes to administrative practice including new guidance documents therefore are important milestones, which can influence the medicinal product market significantly. Despite this, not only are the results important for their evaluation, but so is their historical development, which will be described in the following.

Already in parallel to the Sound- and Look-Alike-Workshops, and the decision to develop a new guidance document in regard to naming, it became obvious that the BfArM wanted to pursue a stricter way of interpreting the law in regard to the naming issue. Before 2010 this new way was unofficially highlighted by the name choices the BfArM rejected, but with the announcement of the administrative

[7] cf. *Kösling*, in: Fuhrmann/Klein/Fleischfresser [ed.], „Arzneimittelrecht", version 2 of 2014, section10, m.n. 71

practice change in 2010 in regard to name change procedures it became official. This announcement already lead to controversial discussion, but the discussion was fully ignited after court decisions to the previously questioned name rejections had been issued.

The most important decision at that time was the so called 1st "Fenistil"-decision issued in April 2011[8], since it was the first official decision to underline the stricter interpretation of the law by renouncing the liberal position of Germany in regard to umbrella brands. Beforehand, specialised literature maintained Germany was comparatively one of the most liberal countries on that topic[9]. After the decision had been issued pharmaceutical industry was especially anxious that established umbrella brand concepts were endangered[10]. Even if other umbrella brand concepts had been rejected to that time from the BfArM, too, this decision has to be highlighted, since it, by supporting the BfArMs tendency, gave reason that the BfArM on this legally legitimated ground would implement this position in the new guideline. The latter was proven true with the first presentation of the new Naming Guideline draft version in November 2011 which abnegated the possibility to extend umbrella brands to other active substances and above that contained further restrictions to name choice beyond the requirements given in previous guidance documents.

However, opportunity was given for the stakeholders to comment on the draft version. This opportunity was used extensively, and not only were statements given, but also expert advice was additionally obtained and submitted. The final amended version of the Guideline was published nearly 15 months later on March the 19th, 2013. But even if the final version of the Guideline, in contrast to the draft, considered some of the stakeholder statements and included the risk based approach, the perception of the guideline in the public was split. The BfArM itself, in the introduction of the Naming Guideline, had announced their expectations in regard to the influence of the administrative practice change very clearly. It was stated that the aim was to meet the AMTS requirements by giving a working and decision making tool for pharmaceutical industry as well as for CAs based on the normative requirements[11]. While healthcare professional magazines welcomed the new approach with positive feedback and headings like "*Arzneimittelnamen: Schluss mit "super Nasensprays" und "Blutreinigungstee Express*""[12], meaning "Medicinal product names: finish with "super nasal spray" and "blood purification tea express"", the pharmaceutical industry and other interest groups still doubted the juridical legitimacy of some crucial aspects.

[8] cf. D.f. VG Köln, of April the 12th, 2011, reference number 7 K 4284/09 – juris
[9] cf. *Schraitle*, in: Fuhrmann/Klein/Fleischfresser „Arzneimittelrecht" [ed.],, version 1 of 2010, section 6, m.n. 76
[10] cf. Britta Ginnow in Pharmareport-Newsletter June 2013 version 2/3 p. 13 published on the BPI homepage http://www.bpi.de/presse/pharmareport/pharmareport-2013/ taken from the internet on November the 21st, 2015
[11] see Naming Guideline Introduction
[12] see Andrea S. Klahre, 28. März 2013 *Arzneimittelnamen: Schluss mit „super Nasensprays" und „Blutreinigungstee Express*"" http://praxis.medscapemedizin.de/artikel/4900922 taken from the Internet on November the 5th 2015

Given that some years passed since the changes were established, the following is going to analyze how the administrative practice change between 2010 and 2013 has to be evaluated in regard to applicability and importance from today's point of view and will try to give answer on the questions which stakeholders expectation could finally be met.

4. Impact of the administrative practice change in regard to name change procedures in 2010

4.1. Description of the change regarding name change procedures in 2010

As mentioned above, in August 2010 the BfArM announced the change in its administrative practice in regard to applications for name changes of purely national medicinal products. This change was based on a new interpretation of section 29 sub-section 2 AMG, which states that in cases of a name change the marketing authorisation notice shall be amended accordingly.

Before 2010 the practical execution of this section led to the assumption that the name change does not need the approval through the Competent Authorities, in German it is called "*nicht zustimmungspflichtige Änderung*". This means that after a name change had been announced through a purely national application for change, the so called "*Änderungsanzeige*", the Competent Authorities were considered to be bound to take note of the name change[13]. Name changes had consequently been registered, but the marketing authorisation had not been changed with an official note of change to the marketing authorisation notice.

If the higher federal authority wanted to plead concern in regard to the congruity with the prohibitions to prevent deception, section 8 sub-section 1 number 2 AMG, they could do it within an appealable notice of assessment or alternatively through informing the responsible surveillance authority, which could than take measures according to section 67 AMG. Nevertheless, even if the name change did not need approval, the CAs were not bound to wait with their intervention until the name change was conducted[14]. If the applicant refused the evaluation of the CA he could challenge the notice of assessment and in parallel file a common action for performance in order to get the notice of marketing authorisation changed. The latter was possible since the change of the notice of the marketing authorisation was considered to be a real act[15]

[13] cf. OLG Köln, D.f. May the 28th, 2008 reference number 6 U 27/08, m.n. 13 - juris
[14] cf. *Kösling*, in: Fuhrmann/Klein/Fleischfresser [ed.], „Arzneimittelrecht", version1 of 2010, section 10, m.n. 85
[15] cf. VG Berlin, D.f. August the 7th, 2000 of , reference number 14 A 251.96 m.n. 14 - juris

In August 2010 the BfArM announced that the administrative practice with the 15th of September 2010 would change. According to the announcement, future applications for purely national name changes would be completed with an official note of change to the marketing authorisation notice. This change finally emphasized the legal requirement given within section 29 sub-section 2 sentence 1 AMG, which states that the marketing authorisation notice has to be changed when a name change is conducted. Above which it was stated that, if the medicinal product is to be put on the market with another name than stated in the marketing authorisation notice, the medicinal product is put on the market without a marketing authorisation notice[16].

In particular, the stricter interpretation of the law regarding the latter faced vehement criticism from the pharmaceutical industry, since it implicated that the new medicinal product name could only be used after the marketing authorisation notice had officially been changed. In practice, according to stakeholders, this would lead to the duty to obtain consent and to a constitutive character of the change of marketing authorisation notice[17], a duty the AMG, from there point of view, would originally not have intended.

Court decisions of the following years can be utilized to evaluate whether this administrative practice change and with it the stricter interpretation of the law was conducted righteously and how this change took influence.

4.2. Evaluation of the administrative practice change in regard to procedural classification

Under administrative law there is a difference between a real act and an administrative act. The administrative practice change of 2010 implicates that legal action against the CA's decision on changing the marketing authorisation notice is an administrative act and no longer considered to be a real act. As a result this would mean that, if courts do conform to the BfArM's interpretation of the legal act, only the action for the issue of an administrative act would be the right type of action in order to institute proceedings against the CAand that challenging the notice of assessment in parallel to filing a common action for performance would no longer be suitable[18].

In April 2011 the Administrative Court of Cologne issued the first court decision[19] to confirm this classification by accepting a so-called *Verpflichtungsklage*, meaning "an action for the issue of an

[16] cf. BfArM: „Bekanntmachung zur Änderung der Verwaltungspraxis bei der Bearbeitung von nationalen Anzeigen zur Änderung der Arzneimittelbezeichnung nach § 29 Absatz 2 Satz 1 AMG" of August the1st, 2010 http://www.bfarm.de/SharedDocs/Bekanntmachungen/DE/Arzneimittel/aender/bm-aender-20100913-Verwalt_Praxis_Bez_AeA-pdf.pdf?__blob=publicationFile&v=4 taken from theInternet on November the 15th, 2015

[17] cf. *Kozianka/Winnands*, PharmR 1/2011 p.7-9, section I

[18] c.f. Kösling, in: Fuhrmann/Klein/Fleischfresser „Arzneimittelrecht", version 1 of 2010, section 10, m.n. 87

[19] cf. VG Köln, April the 4th, 2011, reference number 7 K 4284/09 juris

administrative act", in regard to a name change according to section 29 sub-section 2 AMG. According to the reason given to the judgement, section 29 sub-section 2 AMG, which states that in cases of a name change the marketing authorisation notice shall be amended accordingly, the name of a medicinal product is a crucial part, not only of the marketing authorisation dossier, but also of the decision to grant marketing authorisation and that the name therefore shares the same legal nature as the latter; Thus the refusal of the name change as well as the connected change of the marketing authorisation has to be considered to be an administrative act[20]. Following court decisions[21], some even issued from the next higher level of jurisdiction, additionally confirmed this judgement by also accepting actions for the issue of an administrative act in regard to rejected name changes, and with it the BfArM's interpretation of the law which led to the new administrative practice.

Even if the new administrative practise classification had been jurisdictionally justified in 2013, it was still the case that juridical interpretation of the legality of putting a medicinal product with a new name on the market, before the official change of the marketing authorisation notice had been conducted, was needed. A form of jurisdictional interpretation had finally been given in 2013 in connection with the case described in the following.

4.3. Evaluation of the administrative change in regard to legality of implementation of the name change before approval

A showcase took place in July 2010. Shortly before the new administrative practice had been announced, a marketing authorisation holder (MAH) had submitted an application to change the name of its medicinal product from "M. with C." to "M. Forte with C.". This name change was refused by the BfArM with an official notification in 2011. In 2011 the MAH filed a suit with the reference number 7 K 4343/11 in which the complainant asserted that the medicinal product had already been placed on the market with the new name and that therefore ascertainment was needed concerning the following issues: Firstly, the name change does not need approval of the BfArM. Secondly, the BfArM is obligated to change the marketing authorisation notice. And finally, no measures of the authorities are to be issued against MAH with respect to the placement of the medicinal product on the market, if the BfArM refuses the name change[22].

In parallel to filing a suit, opposition proceedings against the official notification were refused by the BfArM and let to an additional law suit in the form of an action for the issue of an administrative act

[20] cf. VG Köln, April the 4th, 2011, reference number 7 K 4284/09 juris
[21] cf. for example D.f. VG Köln, April the 9th 2013, reference number 7 K 2050/11, m.n. 24 - juris; D.f. OVG für das Land Nordrhein-Westfalen, June the 17th 2013, reference number 13 A 1113/11 and July the 19th 2013, reference number 13 A 719/13 – juris;
[22] cf. D.f. VG Köln, September 3rd, 2013, reference number 7 K 1759, m.n. 8-9 - juris

of the MAH in 2012. The Administrative Court of Cologne issued court decision in 2013[23], which claimed the refusal of the name change in regard to section 25 sub-section 1 sentence 1 No 7 AMG in connection with section 8 sub-section 1 No 2 AMG to be legitimate. Within this decision the Administrative Court did not decide on the subject matters of law suit reference number 7 K 4343/11, since these subject matters, according to the court, were not significant in order to decide on the lawfulness of the refusal of the name change[24]. Nevertheless, a note in regard to the fact that the MAH had placed the product on the market with the new and not yet confirmed name was given.

According to the reasons for the decision[25], it might not be, in contrary to the widespread public opinion, permissible to place a product with a new name on the market before the marketing authorisation notice has officially been changed by the BfArM or if the BfArM refuses to change the marketing authorisation. The line of arguments the court made are as follows: This would be the consequential result derived from section 29 subsection which contains the duty of the BfArM to verify congruity with the law before changing a marketing authorisation. If the medicinal product is placed on the market with the new name, without having the marketing authorisation changed accordingly, it would be marketing a medicinal product without a legitimate marketing authorisation. Therefore this would infringe the obligation of section 21 AMG which states that a medicinal product is only to be placed on the market if a marketing authorisation which includes the essential characteristics is granted.

Furthermore the decision claimed that this interpretation would not be inconsistent with the taxonomy of section 29 AMG. According to the Court, since it is not specifically listed as change needing approval under section 29 subsection 2a AMG, the name change is considered to be a change not needing approval, falling under section 29 subsection 1 AMG. Nevertheless, the legislator ceded the name change to need a special regulation by establishing an additional regulation in section 29 sub-section 2 AMG, which modifies and supplements requirements given in section 29 subsection 1 AMG. Consequently, this special regulation would not be needed if the name change was to be conducted automatically.

As described above, the explications made in the court decision in regard to this matter had been identified as remarks. Nevertheless the complainant withdrew the pending law suit reference number 7 K 4343/11, directly dealing with the placement of the product on the market before marketing authorisation notice had officially been changed, shortly before official hearing. It can be suspected that it was withdrawn because of the note the court in the decision to the parallel lawsuit, referenced above, gave. Moreover, the court decision gave reason to believe that the courts would by trend support the BfArM's classification, since the arguments of the opponents especially in regard to taxonomy of section 29 AMG had been addressed and evaluated by the court.

[23] cf. D.f. VG Köln, September 3rd, 2013, reference number 7 K 1759 - juris
[24] loc. cit. m.n. 36 - juris
[25] loc. cit. m.n. 37 - juris

Despite the trend derived from the administrative court's remarks, a civil court in 2014 gave a contrary decision[26] in regard to the interpretation discussed. Since May 2013 the defendant placed the medicinal product *"…pp. Ibuprofen 5% Gel*", containing the active substance ibuprofen, on the market. In parallel the product *"… pp. Schmerz-Salbe*", containing the active substances peppermint-, eucalyptus- and rosemary-oil, was marketed from the same MAH. The name of *"… pp. Schmerz-Salbe*" had been changed from the MAH in 2011. The approval of the name change submitted in 2011 is still pending in 2015, since the AMIS still lists the old name "T.-S."[27], nevertheless the MAH already markets the product under the new name[28].

The Complainant, an organisation which fights unfair competition in all its manifestations, issued action against the MAH. Amongst other things a reason for the complaint had been the marketing of the product with the name *"… pp. Schmerz-Salbe*" before the name change had officially been approved, which would according to the complaint infringe section 29 sub-section 2, section 21 and following AMG as well as section 8 AMG, as well as section 3 HWG, since a medicinal product without valid marketing authorisation is marketed[29] The civil court rejected that the medicinal product is placed on the market without valid marketing authorisation according to section 21 AMG by following the predominant interpretation of this legal requirement, which was supported by the literature commenting the AMG, and by agreeing that the taxonomy of section 29 AMG does not prohibit the marketing of the product with the new name before approval is given. According to the court all changes needing approval are listed in section 29 sub-section 2a, in which the name change is not mentioned[30].

Since both court decisions described, lead to contrary results in regard to the marketing issue, it has to be evaluated which decision carries more weight. In the "forte"-case the court only gave remarks in connection with this issue and no decision was made, therefore the"… pp.Schmerz-Salbe"-case, giving a real decision, can be considered to be of more relevance. Nonetheless, there are two more points that contradict that assumption. Firstly, another decision of the Administrative Court of Cologne, which rejected an action for a declaratory judgment on a similar issue[31], also emphasized the point of view advanced in the "forte"-case. Secondly, it has to be questioned whether a civil court is able to give a fundamental decision in regard to administrative law, an issue treated also in other

[26] cf. D.f. Saarländisches Oberlandesgericht Saarbrücken 1. Zivilsenat, of October the 15th, 2014, reference number 1 U 24/14; - juris
[27] search conducted on November the 5th, 2015 in AMIS database public part via the PharmNetBund access; search for active substances contained, pharmaceutical form creme and name of the MAH
[28] http://www.latschenkiefer.de/de/produkte/muskeln_gelenke/bei_muskelschmerzen/proff_schmerz_salbe search conducted on November the 5th, 2015
[29] cf. D.f. Saarländisches Oberlandesgericht Saarbrücken 1. Zivilsenat, of October the 15th, 2014, reference number 1 U 24/14, m.n. 10; - juris
[30] cf. D.f. Saarländisches Oberlandesgericht Saarbrücken 1. Zivilsenat, of October the 15th, 2014, reference number 1 U 24/14, m.n. 60; - juris
[31] cf. D.f. VG Köln 7. Kammer, of November the 19th, 2013, reference number 7 K 1367/12; m.n. 53 - juris

administrative court decision and negated[32]. Therefore the only assumption can be that the issue could not be resolved at that time.

On top of this, the importance of discussing and solving this issue has to be scrutinized. Would the MAH place it's product on the market without permission, this may be legally acceptable, however there is a financial risk for the MAH, which is not to be underestimated either. If the product is launched and gains ground on the market with the new name, it could have great financial and logistical consequences for the MAH if the name is rejected afterwards, which also from MAH's point of view would plead for a duty to obtain approval of the name change before marketing[33]. Following this line of thoughts, for the MAH it would be reasonable to wait with marketing the new name until approval is granted no matter whether the marketing is legally conducted or not. However, even if the result in both cases, for the MAHs is, to wait until approval is given, the clarification on the legitimacy was presumably sought, as a CA within a constitutional democracy does not stand above the law and therefore cannot change interpretations of the law arbitrarily. And even if a putative legitimating seems to be given, especially if contrary adoptions of the matter are advocated by the involved parties, administrative practice changes should be challenged officially, in order to find a legal common ground.

4.4. Evaluation of the administrative change's impact respecting integration of purely national variations into Regulation (EC) 1234/2008

The administrative practice change of 2010 caused many discussions and a judicial interpretation was sought. Either way, in 2013 another legal change took place, which put the administrative practice change into perspective. In August 2013 the so called "Variation Regulation", Regulation (EC) 1234/2008, became applicable for purely national marketing authorisations. Beforehand, only marketing authorisations granted through DCP or MRP fell under that regulation. The directly binding character of this regulation also changed the modalities for the name change significantly.

Ever since the implementation, name changes have to be conducted according to the rules given within this regulation, which means not as national "*Änderungsanzeigen*", but as variations. The classification of the variation type for the name change under European law, given through the Classification Guideline, is important. According to the guideline the name change is classified as Type IB variation meaning that it is a so-called "Tell, Wait and Do"-procedure, where the holder must wait a period of 30 days to ensure that the notification is deemed acceptable by the relevant authorities before implementing the change. Only if the competent authority confirms the acceptability (within 30

[32] c.f. D.f. Oberverwaltungsgericht für das Land Nordrhein-Westfalen, of July the 19th, 2013, reference number 13 A 791/13 m.n. 41 - juris

[33] cf. *Kozianka, Winnands* „ Neue Verwaltungspraxis des BfArM bei Änderungen der Arzneimittelbezeichnung" PharmR 2011, pp. 8-9

days or within the correction procedure) or does not give note on the acceptability of the change within 30 days the MAH is allowed to implement the change without awaiting the update of the marketing authorisation[34]

The question of why this put the administrative practice changes into perspective, will be answered through the following assumptions.

Firstly, the administrative practice change the BfArM conducted in 2010 has to be seen as a preterm approximation to European law requirements, trying to treat all marketing authorisations in the same way and not to disadvantage purely national authorisations. This is also confirmed by new timelines the BfArM announced in 2010, which, with 30 days, are similar to the timelines given for Type IB variations. Furthermore, in 2015 the BfArM announced another administrative practice change[35] confirming the thesis, by renouncing the possibility of conducting informal pre-procedural evaluations of the name change, established with the administrative practice change in 2010. According to this announcement the pre-procedural evaluation, had only been allowed in order to handle purely national procedures as fast as European procedures and consequently, with the Implementation of Reg. (EC) 1234/2008 this procedure would be outdated.

Secondly, the European law affirms, like the courts did in regard to the change of 2010, the competence of the CA to evaluate the name check and to refuse it, if applicable. Furthermore, by classifying the name check as Type IB variation it solves the controvertible question on whether the name change needs approval (so called "*zustimmungspflichtig*") or not (so called "*nicht zustimmungspflichtig*") According to the classification it is neither one nor the other, but lies in between both classification, which would also confirm with the German special regulation given for the name change with section 29 sub-section 2 AMG and the systematic of section 29 AMG.

Currently, for the majority of name change applications the requirements given through European regulation and within legitimated Classification Guideline are applicable. Today, old law requirements are only applicable for a few national exceptions (mentioned in the announcement of the BfArM in regard to the change of Reg. (EC) 1234/2008[36]), for notional authorisations (in German so called "*fiktive Arzneimittel"*) and for still pending name change applications (submitted before the legal

[34] see Classification Guideline section 2.2.3

[35] see BfArM: announcement of February the 11th, 2015, "Änderung der Verwaltungspraxis des BfArM zu informellen Vorabanfragen zu Arzneimittelbezeichnungen" http://www.bfarm.de/DE/Arzneimittel/zul/folgeverfahren/aenderung/variations/news/aenderung_verwaltungspraxis_vorabfragen_ambezeichnungen.html taken from the internet on November the 25th, 2011

[36] see BfArM: announcement of July the 12th, 2013 „Bekanntmachung über die Anzeige von Variations für rein nationale Zulassungen gemäß Kapitel IIa der Verordnung (EG) Nr. 1234/2008 ab dem 04.08.2013 ,die gemäß § 77 AMG in die Zuständigkeit des BfArM fallen" http://www.bfarm.de/SharedDocs/Bekanntmachungen/DE/Arzneimittel/aender/bm-aender-20100913-Verwalt_Praxis_Bez_AeA-pdf.pdf?__blob=publicationFile&v=4 taken from the Internet on November the 15th, 2015

change took place, but not closed yet). For applications submitted after the legal change the requirement to implement the change after implicit or explicit approval through BfArM is applicable. Therefore the question of whether or not the name change can be conducted without change of marketing authorisation, from today's view, is considered to be secondary.

4.5. Summary of the evaluation of the Impact of the administrative practice change of 2010

In summary the administrative practice change the BfArM announced in 2010 had been a preterm adaptation of purely national procedures to European legislation, which was relativised when Reg. (EC) 1234/2008 also became effective for these procedures. Nevertheless, before this additional change took place in August 2013, courts confirmed the administrative classification of the name change, but the necessity to wait for the implementation of the name change until the application had been accepted by the BfArM was still questionable. However, the courts confirmed the substantive competence of the CAs to evaluate the name change. Therefore, the interpretation of the legal requirements given in section 29 AMG in connection with the taxonomy of this section lead to the assumption that the name change possesses a exceptional position in the AMG being neither solely "*zustimmungspflichtig*" nor "*nicht zustimmungspflichtig*".

Additionally, it can be assumed that the administrative practice change of 2010 was inevitably linked to the elaboration of the Naming Guideline and the subsequent administrative practice change, binding the administrative body to this new guideline. Both changes were conducted in order to strengthen BfArM's competence to evaluate names, the change of 2010 by legitimating the assessment of the BfArM and the release of the Naming Guideline in 2013 by communicating the assessment rules transparently.

From today's point of view and with the analysis made above it could be shown, that the court decisions supported the BfArMs competence to evaluate medicinal product names. This competence was also affirmed by Regulation (EC) 1234/2008, which became applicable for purely national authorisations in August 2013. Whether or not the Naming Guideline and its newly elaborated evaluation standards met the expectations, too, will be discussed in the following sections.

5. Evaluation of the impact of the Naming Guideline

In order to discuss the Naming Guideline and its impact on the market, first, the historical background will be given, followed by an analysis of its impact, by using significant examples, with inclusion of the most controversial subjects.

5.1. German soft law requirements before reorganisation took place during 2010 and 2013

In Germany until 2013, next to additional European guidance documents, which could be used for orientation, e.g. the "*Guideline on the acceptability of names for human medicinal products processed through the centralised procedure*" and the "*QRD recommendations on the expression of strength in the name of centrally authorised products (as stated in section 1 of SmPC, and in the name section of labelling in PL)"*[37], purely national rules in regard to naming have been derived out of the German announcement on references and recommendation to avoid misleading names of the former German Health Authority (BGA) and the PEI, the so called "*Bekanntmachung des BGA und des PEI über Hinweise und Empfehlungen zur Vermeidung von irreführenden Bezeichnungen*", published in 1991 in the Federal Gazette (further on referred to as "Announcement of 1991" and given with Annex I). Originally published to illustrate rules for naming of German re-registration products, so called "*Nachzulassungsarzneimittel*", this document also contained common principles to avoid misleading naming and played an important role in German administrative practice for several years[38].

Nevertheless, already before the AMTS efforts described in the introduction of this thesis started, it became increasingly obvious that the Announcement of 1991, that has never been reworked or amended, lost track with the state of regulatory knowledge. Since 1991, the surrounding conditions had changed, in particular: European law had been amended, European guideline, addressing naming issue had been published, the AMG had been amended several times, the *Nachzulassung* had been completed and several court decisions with regards to naming had been issued. The reference to European guidance documents in specialised literature of 2010, which has been cited above in regard to European soft law requirements, is one of the many examples where German soft law requirements fell behind and additional interpretation of the hard law requirements was needed. It can be assumed that the AMTS efforts served as an important catalyst to speed up the reorganisation of German administrative practice, but the displacement of the Announcement of 1991 had been long overdue.

As already explained in the section that illustrates the historical development of the administrative practice changes, the stricter direction the BfArM took, by reorganising the administrative practice in regard to the naming issue, was not welcomed by all interest groups. The evaluation, from today's point of view, will consequently address the most significant matters of dispute, but also include other examples which demonstrate the impacts the elaboration of the Naming Guideline had or did not have. Some could argue that the direct and full comparison of the Announcement of 1991 with the Naming Guideline is missing but from the author's point of view, both guidance documents are too different,

[37] cf. *Schraitle*, in: Fuhrmann/Klein/Fleischfresser[ed.], „Arzneimittelrecht", version 1 of 2010, section 6, m.n. 78 and 79
[38] cf. *Menges/Winnands*, in: Fuhrmann/Klein/Fleischfresser [ed.], „Arzneimittelrecht", version 1 of 2010, section 10, m.n. 296-298

not only in structure and composition, but also in regard to the scope and background. Therefore, a direct comparison would have been an inappropriate instrument to evaluate the impact of the Naming Guideline. Nevertheless, some of the most controversially discussed differences will be included when reasonable.

5.2. Evaluation of impact on the future medicinal product market using the positive list of affixes published in the Naming Guideline as example

To begin with the evaluation, the tools given with the Naming Guideline should be analyzed to reveal if they, like the BfArM had announced, were practical working and decision making tools and how they are able to influence the market. To evaluate the working tools, the affix-list given with the Naming Guideline, will be used as example. With the Naming Guideline an Annex including a list of valid affixes to names was given[39]. Next to listing the usable terms, an explanation on the requirements to use them was given. For example, according to the Annex the affix "forte" would be applicable for a medicinal product of a higher dose than a comparable medicinal product. Furthermore the basis for comparison, which constitutes the requirement to use this term, was given. For the given example "forte" this requirement would be: the medicinal product carrying the affix "forte" shall not only be relatively higher dosed than comparable medicinal products of the MAH's own product line, but it also shall be absolutely higher dosed than comparable medicinal products of the whole market.

In regard to the positive list three questions have to be asked in order to evaluate its significance. Firstly, it is important to ask for the purpose of the list given and if the list is able to fulfil this purpose. It can be assumed that the BfArM with the positive list wanted to give, in line with the explanation given to the purpose of the Naming Guideline in the introduction of the same, an additional working and decision-making tool. Consequently, the list recommends only such affixes of which the common understanding has been established in the market and/or which have been legally affirmed. The meaning of the word "forte" and the predictions to use it, for example, has been treated juridically several times: in the "forte"-case as described in the thesis above, as well as in other court decisions [40]. The herewith applied approach gives an advantage to both the CA as well as the MAH, preconditioned that terms are used within the scope published in the list. On the one hand, the BfArM can assume the safe connotation with the affix, while on the other hand, the MAH will not have to fear rejection of the name.

[39] see Naming Guideline ANNEX I. Liste der möglichen Bezeichnungszusätze
[40] cf. D.f. OVG für das Land Nordrhein-Westfalen 13. Senat, December the 19th, 2007, reference number 13 A 1178/05 or D.f. OLG Hamburg 3. Zivilsenat, July the 12th, 2007, reference number 3 U 39/07 or D.f. VG Köln 7. Kammer, September the 3rd, 2013, reference number 7 K 1759/12 - juris

Secondly the question has to be solved why a positive list and not a negative list approach has been chosen. To answer this question a look at the message the different kinds of list give, with regards to the applicability of affixes, is helpful. The positive list's message is, that the affixes used within the recommended modalities the list provides, are legitimated and that the usage of all other affixes is, per se, questionable. A negative list, on the contrary, would have lead to the conclusion that all affixes listed are prohibited, while all other affixes are presumably allowed. As can be seen, the different lists create different burdens of proof, if affixes which are not listed are used. Therefore, it seems to be reasonable that the BfArM chose the approach giving the MAH the burden of proof. Furthermore, the risk based approach is highlighted by implicating that every deviating affix would have to be assessed based on the additional section, regarding the choice of affixes, the Naming Guideline offers.

Finally, it is important to ask if the length of the list can provide evidence on the dimension of influence the list has. In comparison to the vast use of affixes in the medicinal product market, the positive list published in the Naming Guideline is rather short, which would lead to the conclusion that the impact on the market cannot be very severe. However, this assumption can be refuted.

With release of the Naming Guideline, the affix "akut", with its requirements has also been published, which, from first sight, was not in line with the considerations given above, since in that case the discussion on the meaning of the affix was still ongoing. In regard to the affix "akut", the publication in the positive list not only wanted to give a well established example, but also served as tool to communicate the BfArM's point of view and to influence the market.

This can be proven by the following example. Until 2009 the active substance omeprazole was subject to medical prescription, but in 2009 the general classification for supply changed for particular omeprazol-containing products to OTC-products, which are available in pharmacies only and are not to be placed in the free choice area. In the same year, many MAHs switched the classification of their omeprazol-containing products to the latter and wanted to use the affix "akut" in the names. This change led to discussions, since it was controversial whether "akut" means "medicinal product with a fast onset of action" or "medicinal product against acute disorders". In 2010 the Higher Regional Court of Munich, a civil court, declared the latter comprehension to be true[41]. Nevertheless, not following this interpretation and assuming that the other understanding of the affix "akut" to be common and established, the BfArM refused the name change which had been treated in the court decision in 2010. Above that the BfArM also refused other name change applications wanting to use the term "akut" for omeprazole-containing products. Additionally, to refusing these name changes, the BfArM advanced its point of view 2013 in the Naming Guideline. According to the positive list the affix "akut" is to be used for medicinal product with a particular fast onset of action.

In 2013 the Higher Regional Court Cologne solved this matter juridically. According to the explanation of the decision, both understandings of the affix "akut" are acknowledged. However, in

[41] cf. D.f. OLG München 29. Zivilsenat, February the 25th, 2010, reference number 29 U 5347/09,sentence for orientation and m.n. 7 – juris

regard to the prohibitions to prevent deception, section 8 sub-section 1 No 2 sentence 1 AMG, the omeprazole-containing products, with an onset of action within an hour, are not in line with both corresponding connotations and could therefore lead to deception of a non negligible part of the consumers[42]. With this decision, the refusal of the name change and the publication in the positive list had been backed.

A research in the AMIS data base conducted in November 2015, resulted in 26 marketable omeprazol-containing OTC products[43]. None of these products includes the affix "akut", instead other affixes like "protect" or "*bei Sodbrennen*" (meaning "in cases of heartburn") are used, which supports the assumption on the power to influence the market. Yet one could argue that the reason for the influence on the market was not the publication in the list but the court decision. This cannot be fully denied, since the court decision that backed the BfArM's position presumably had the most influence. Nevertheless, two facts remain. Firstly, the BfArM's vast experience and with it, their competence to make the right appraisals in borderline cases, cannot be fully denied. Secondly, the publication alone would have influenced the MAHs not to question the BfArMs point of view in regard to that affix. This may have lead to a more extensive use of the affix in connection with fast acting medicinal products. Finally, even without the backing court decision, this could have had the same effect by changing the consumer's perceptions in regard to this affix in the long term.

To summarize the positive list can be seen as good example of the function of the Naming Guideline as a decision making aid in context with a risk based approach. Furthermore, by distributing the BfArMs point of view, the Naming Guideline and all decision making tools given in it, like the positive list or the illustrating examples given with almost every section, are able to influence future name choices and consequently the image of the future market and with it the perception of the consumers.

The BfArM itself acknowledged the above mentioned „akut"-decision of the Higher Administrative Court of Cologne as an important contribution to consumer protection, which was published in a press release on July the 31st, 2013.[44] The press release not only emphasized the important role of the BfArM in regard to the decision, but also used the occasion to once more highlight the aim of the Naming Guideline. According to the article the Naming Guideline was published, from BfArM's point of view, in order to set stricter boundaries regarding name choices, with the aim to exclude future

[42] cf. D.f. Oberverwaltungsgericht für das Land Nordrhein-Westfalen, July the 19th, 2013, reference number 13 A 719/13 –, juris

[43] AMIS database, public part, access via PharmNetBund; search parameter Verkaufsabgrenzung=?Apothekenpflichtig? and Stoffname=Omeprazol?, search conducted on November the 7th, 2015

[44] see BfArM: press release number 08/13 „Gericht untersagt irreführenden Arzneimittel-Namenszusatz: Wo „akut" draufsteht, muss auch schnelle Wirkung drin sein" http://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/mitteil2013/pm08-2013.html taken from the Internet on November the 4th, 2015

confusion and misapplication caused by unclear, misleading and trivialised names. Whether this aim could be reached will have to be discussed further, since the evaluation of the positive list and its role in influencing the market might attribute to the conclusion that this aim could be reached. However, the influence on the stock market and the objections the stakeholders mentioned still have to be analyzed.

5.3. Evaluation of the impact of the Naming Guideline on stock market

While the section above dealt with influence on the future market, the established stock market also has to be considered. In case of the omeprazole-containing products described above, taking influence to that extend was possible, since the classification in regard to supply to that time had recently changed and no comparable established stock market of OTC omeprazole-containing products had existed. Even, if other medicinal products had been on the market carrying the affix "akut", the preceding court decision had pointed out that these could be neglected in regard to decision making, because the products had been authorised with other indications[45]. A statement that had been affirmed with the connected following decision of the higher instance as referenced above.

According to a press article of a German pharmacist magazine, the BfArM also commented on that issue by abnegating the intent to change stock market "akut"-products, as long as they did not endanger patients. Furthermore, it was stated that the court decision should only be considered regarding new marketing authorisations and applications for name changes[46]. This attitude towards stock market seems also to have influenced the release of the Naming Guideline. The Naming Guideline contained stricter rules regarding naming, so with its release it would have been an opportunity to intervene in established medicinal product stock market. However, such intents have not been communicated with the release of the Naming Guideline.

As a working hypothesis it will be assumed that a thorough intervention on stock market simply could not have been shouldered, especially not without assistance from pharmaceutical industry's side. The latter presumably was, and still is not to be expected, since intervention would affect established medicinal product names and with it, marketable values. But even if the stock market was not officially forced to adapt to the new rules, with official statements like the one mentioned above the BfArM communicated that the stock market did not possess a right of continuance, but was to be evaluated on a risk based approach. That said, this attitude carried the risk that not only would the stock market have influence on the Naming Guideline, but also that the stock market appearance could

[45] cf. D.f. VG Köln, February the 5th, 2013, reference number 7 K 6575/10, m.n. 73 –, juris
[46] see *Juliane Ziegler* July the 31st, 2013, "Zusatz "akut" nur bei schnellerer Wirkung" http://www.deutsche-apotheker-zeitung.de/recht/news/2013/07/31/zusatz-akut-nur-bei-schneller-wirkung/10673.html taken from the internet on November the 6th, 2013

outweigh Naming Guideline recommendations. Whether or not such effects have emerged is going to be evaluated in the following using two significant examples.

In regard to the first question the BfArM highlighted in the Naming Guideline itself the influence of the stock market, in connection with the salt-base-difficulties.

5.3.1. Evaluation of the impact of the Naming Guideline on stock market under inclusion of recommendations given in regard to salt-base-difficulties

Section 10 sub-section 1 No 2 AMG not only gives labelling requirements, but also the information is contained, that the strength of a medicinal product can be part of the medicinal product name. The Naming Guideline gives further guidance on how the strength should be expressed. The Guideline refers to European SmPC-Guideline as well as to the *QRD Recommendations on the expression of strength in the name of centrally authorised medicinal products* [47]. Consequently it would be state of the art to express the strength on the basis of the active moiety, in most cases the free base. In contrast many stock market medicinal products do not express the strength based on the free active substance but based on the heavier salt. This can lead to potential confusion, especially when generic medicinal products of originators, which still express the strength in the name on the basis of the salt, follow state of the art labelling and express the strength in the name based on the free base. Additionally also the usage of different salts, e.g. the fumarate or the succinate of one active moiety adds to the potential confusion.

By elaborating the Naming Guideline, the BfArM considered this confusion potential and so the Naming Guideline explicitly suggests the usage of the amount of the salt, if the originator used the salt as basis for the expression of strength[48]. On the one hand, this approach can be seen reasonable, since it tried to avoid future confusion potential, respecting the fact that adapting the stock market was not possible. On the other hand, it underlines the influence of the stock market on the Naming Guideline and future market, since not only European recommendations are undercut, but also a solution is communicated, which cannot solve the problem ultimately. Following this line of thought, the approach the BfArM communicates by respecting stock market influence, leads to inhomogeneous future market appearances in regard to strength declarations of medicinal product names.

While the communicated different approaches are rather reasonable, as both ways try to ensure the similar handling regarding one active substance, the biggest problem to arise would be an inconsequential handling of these approaches. This can be shown through the following example.

[47] Naming Guideline section 1.1
[48] Naming Guideline section 1.1 b)

Ibuprofen-containing products up to 400mg ibuprofen-base can be authorised as medicinal products not subject to medical prescription. According to an AMIS research (search profile, see Annex V and list of results, see table 2 Annex VI) today 13 medicinal products containing 400mg ibuprofen in the form of the lysine salt of ibuprofen in an amount of 684mg and in the pharmaceutical form "film-coated tablet" are marketed as OTC products.

It becomes noticeable, when comparing the names (see table 2 Annex VI), that not only the invented name approach, but also the generic name approach, stating active substance + name of the MAH + strength + pharmaceutical form, is used. The search only included the lysine salts of ibuprofen in an amount of 684mg, so all products contain the same active substance in the same amount. Regarding the generic approach the table shows that six products follow the European recommendation using the ibuprofen-base as basis for the strength, resulting in strength of 400mg. Only two exceptions give the lysine salt as basis for the strength, resulting in strength of 684mg. Both naming approaches make true statements, since the name gives the base on the one hand and the salt, in abbreviated form, on the other hand. In spite of this, the fact that both medicinal products are similar regarding active substance and strength, the name cannot show on its own. Only background knowledge, counsel from a healthcare professional or a closer look to composition of the medicinal product can lead to this result. The question whether this can be considered actually misleading or not, is not going to be analysed or answered in this thesis, however, it demonstrates that the Naming Guideline was not able to present a final solution regarding salt-base-difficulties and therefore, the market will have to adapt to such phenomena.

Looking at the marketing authorisation dates, it is noticeable that both marketing authorisations using the salt as basis were authorised before the Naming Guideline was released, and the ones stating the base afterwards. It can be suspected that the BfArM after the release of the Naming Guideline regarding ibuprofen-containing products wanted to follow European recommendations. However, the risk in regard to already authorised deviating strength statements, up to now, seems not to have been classified high enough to follow the second approach the Naming Guideline offers or to take action against the names of already authorised products.

Thus the salt-base-difficulty in connection with the ibuprofen example shows, that stock market conditions definitely influence the Naming Guideline. Also, this influence, to a certain extent, is accepted consciously, if, like in the salt-base-difficulty example, additional risk potential is assumed by following only recent European approaches. Such influences, as the example shows, can lead to inhomogeneous market appearances and above that, carry the risk, if approaches offered are applied inconsequentially, of additional deviations carrying confusion potential. But comments from the press show, similar to that referred to above, that the BfArM was aware that accepting the influence of the stock market in such a way could lead to additional responsibilities regarding the intervention if patient safety is at risk. Nonetheless, it can be assumed that at this point this could lead to future

problems, especially if pharmaceutical industry is not willing to follow the BfArM position voluntarily and if AMTS reasons are not obvious or severe enough to interfere legally, as it seems to be the case regarding ibuprofen containing products.

However, the influence of the stock market on the Naming Guideline could be constrained. To answer the question whether the stock market influence is also able to outweigh Naming Guideline recommendations and with it BfArM's intentions behind them, will be investigated in connection with recommendations the Naming Guideline gives for stating indications within the name.

5.3.2. Evaluation of the impact of the Naming Guideline on the stock under inclusion of recommendations given regarding medicinal product names including indication statements

Regarding the usage of statements reflecting indication(s) within the name of a medicinal product, the Naming Guideline outlines that this is only acceptable if all indications authorised are appropriately covered from the statement given[49]. For example, the term "Grippe" can only be used if the medicinal product is actually authorised for the treatment of "influenza A virus infection", whereas the usage of this term for a medicinal product authorised to treat "influenzal infection" in German "*grippaler Infekt*" would not be acceptable. Authorisations with the latter indications can contain acronyms of the German term for influenzal infection, for example "grippo" or "grippin", but "Grippe" itself would not be acceptable. With the sections regarding indications, the Naming Guideline not only intends to prevent the highlighting of artificial subsets of authorised indications, but also originally wanted to prevent the usage of terms referring to subordinate indications.

The following court decision[50] is used as example to show, firstly, that BfArM used administrative practice changes of 2010 to apply stricter rules regarding subordinate indication statements, secondly, that this intention was indirectly communicated through the Naming Guideline and, finally, that stock market conditions were used to successfully challenge BfArM's line of argumentation regarding subordinate indications.

With an official note in 2012, BfArM refused the application for name change, wanting to change the name of a cutaneous herbal medicinal product to "… *Schmerz-Salbe*", meaning "… pain ointment". The medicinal product had been authorised for the indication "supportive external treatment of rheumatic disorders and muscle pain". BfArM, next to other objections, rejected the name component "*Schmerz*", since this subordinate description could lead the consumer to expect that the medicinal product is also authorised for other forms of pain than muscle pain, which would extend the

[49] Naming Guideline section 2.3 a)
[50] cf. D.f. VG Köln, September the 2nd, 2014, referenc number 7 K 4739/12 –, juris

indications authorised and therefore infringe the prohibitions to prevent deception, given in section 8 sub-section 1 sentence 2 No 2 AMG. A court procedure followed, filed by the MAH in August 2012, in which the complainant, the MAH, in regard to the "*Schmerz*" issue, advanced the view of a not misleading character; the MAH also claimed that the term "Schmerz" would not point out a specific indication, but would make unspecific reference to a subjective sensation[51]. Furthermore, a list of comparable authorised stock market products was given to underline the MAH'S point of view[52].

BfArM, wanting the action to be dismissed, refuted these statements by claiming that stock market could not be used as standard for comparison. According to the BfArM, the legal error regarding "*Schmerz*" also applies for stock market products and that it had not been possible to change stock market appearance yet, but it was planned to do so[53].

The procedural process until that point shows that BfArM definitely had the intention to apply stricter rules in regard to subordinate indications and that the MAH challenged this intention by using, amongst other things, stock market condition.

Concerning the arguments given, the court followed the argumentation of the complainant and expressed that in regard to consumer expectations, BfArMs future intention to reassess the stock market product names containing the term "*Schmerz*", was insignificant for the evaluation and furthermore, that the consumer expectation is based on current market appearances and since stock market products did not differentiate the term "*Schmerz*", such could also not be expected from the product name applied for[54].

Consequently the rejection of the name component "*Schmerz*" had been cancelled with the described court decision of September the 2nd, 2014. Also the appeals procedure the BfArM applied for was rejected from the Higher Administrative Court in May 2015. This court decision also underlined that the stock market appearance of the name component "*Schmerz*" formed the consumer expectation and that the consumer did not expect the product to act against all kind of pains, but would consult additional product information, in this case the indication statement on the outer package, to inform himself or herself on the detailed indication[55].

With the decision of 2015, the former court decision became legally binding, which had a significant impact. Not only had the reassessment of products containing the name component "*Schmerz*" been made virtually impossible, but also BfArM's future intention to prevent terms referring to other subordinate indications had been endangered, since the strongest argument of the BfArM, that

[51] cf. D.f. VG Köln, September the 2nd, 2014, referenc number 7 K 4739/12, m.n. 14 - juris
[52] loc. cit. m.n. 11-13
[53] D.f. VG Köln, September the 2nd, 2014, referenc number 7 K 4739/12 m.n. 27 –, juris
[54] loc. cit. m.n. 61
[55] cf. D.f. Oberverwaltungsgericht für das Land Nordrhein-Westfalen, of May the 11th, 2015, reference number 13A 2007/14, m.n. 3 –, juris

subordinate indication statement would mislead consumers, was successfully challenged by using exactly the stock market appearances the BfArM questioned.

And even if the Naming Guideline only includes a generalised recommendation on the indication issue and not a concrete guidance on subordinate terms, one of the intentions behind this statement had been shown in the example described above. At the moment it cannot be proven that subordinate indications, for example "*Schwinde*l", meaning "dizziness", or "*Schnupfen*", meaning "sniffels", in general will have to be accepted. Nevertheless, it can be suspected, that the decision described above could further on function as decision of general principle.

5.3.3 Summary of Evaluation of impact of the Naming Guideline on the stock market

To summarize, the administrative practice change and the release of the Naming Guideline could have been an opportunity to reassess stock market. However, since such an approach was not deemed to be possible, from today's point of view a significant impact on the stock market has to be negated.

In contrary, it could be shown with the example regarding salt-base difficulties, that stock market appearances influence the Naming Guideline and not vice versa, which can finally lead to inhomogeneous market appearances by applying old and new approaches. The future market will have to deal with such inhomogeneous conditions, even if some of them could lead to additional deviations. Such deviations as future tasks, should be seen critical and intervention should be applied if patient safety is at risk. The latter will be part of BfArMs and CAs responsibility, but also other stake holders, like health-care professionals or pharmaceutical industry, will have to consider their obligations.

Furthermore, the BfArM, henceforth, accepted the risk of stock market conditions to exceed and successfully challenge their original intentions in connection with the administrative practice change and the development of the Naming Guideline, which could be proven with the example regarding the usage of subordinate indications.

Nevertheless, it should be noted that the assumptions in regard to influence on stock market, are based on current circumstances. Stock market had time to evolve over several decades, so maybe influence on the stock market will also need time to evolve. Therefore the analysis made so far, can give reliable evidence for the current situation, but only assumptions in regard to future development can be made.

As the evaluations made so far have shown, the administrative practice change in classification of applications for name changes in 2010 and the self-binding of the BfArM to the Naming Guideline in

2013 tried to apply stricter rules in regard to the naming of medicinal products. The change in 2010 gave the BfArM more competences regarding the rejection of name changes. The release of the 2013 Naming Guideline additionally ought to influence future market appearances by communicating the new rules applied to evaluation and by functioning as working- and decision making tool to simplify future naming procedures. However, with release of the Naming Guideline stock market appearance could not be changed and/or totally ignored, what, from today's point of view, handicaps the implementation of the original intentions. If nonetheless, one of the main objectives the BfArM wanted to reach could be accomplished, will be analysed in the following.

5.4. Evaluation of the impact of the Naming Guideline on umbrella brand concepts

As already shown in the historical background, it was one of BfArM's crucial intentions to take influence on umbrella brand concepts. In particular the BfArM wanted to prevent the extension of established umbrella brand concepts to other active substances/combinations of substances than those originally related to the umbrella brand. While the first draft of the Guideline published in 2011 abnegated the extension completely, the final version of the Naming Guideline contained an alleviated approach. Nevertheless, the same intention as in the first draft, especially in connection with the rejection of such naming concepts, was dominant in the assessment of name change applications.

The following will evaluate if the position communicated within the Naming Guideline was legitimate and if umbrella brand concepts could therefore be influenced. To begin with the main difference between the Announcement of 1991 and the Naming Guideline will be explained in the following.

5.4.1 Description of position change in regard to umbrella brand concept

The Announcement of 1991 applied a general risk based approach and the recommendation that a new name should be considered in cases where the old and new active substances are considerably different[56], the Naming Guideline in contrast tries to distinguish in regard to the extension of umbrella brand concepts between generic name concepts and invented name concepts.

In regard to generic name concepts (active substance + name of MAH + strength + pharmaceutical form) the Naming Guideline prohibits the usage of an invented name established for an active substance / a combination of active substances instead of the name of the MAH[57], a requirement which could not be derived out of the old announcement.

[56] see Announcment of 1991 section 3.2.2
[57] see Naming Guideline section 2.1.2 b)

In regard to invented names, the final version of the Naming Guideline contains a section emphasizing that the extension of an established invented name to another active substance/combination of active substances, ought to, in regard to section 8 AMG, be avoided[58]. But even if a risk based approach - like in the Announcement of 1991 - is assumed, the Naming Guideline applies stricter requirements in connection with the extension, not only referring to cases where the active substances involved differ "considerably". The Naming Guideline emphasizes the generally misleading character of these changes, not only concerning identical names, but also to phonetic or print face analogies. Above that, within the same section a catalogue of precise critical criteria is laid out, on which the risk evaluation should be based. The content of the latter was presumably based on comparable requirements given in the European *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure*[59] to that time.

Another important difference between the two German guidance documents, contributing to the discussion in regard to umbrella brand concepts, is the interpretation of affixes and their significance in being a distinguishing feature. The Naming Guideline also allows the combination of an invented name with affixes, but while the Announcement of 1991 confirmed their significance[60], the Naming Guideline attributes them to merely be of exemplifying and describing nature[61]. Additionally, the Naming Guideline permits a combination of an invented name with an affix referring to an active substance (active substance itself or abbreviation), but recommends that the affix in such cases should be the first part of the name, because of the significance the first name component has in regard to identification and recognition value[62]. The latter gives room for invented names being remindful of generic name concepts, but nevertheless such a naming concept has to be considered to fall under the recommendations regarding invented name approaches.

The recommendations given within the Naming Guideline are based on BfArM's interpretation of the legal requirements given with the AMG. To explain this visually the release of the Naming Guideline was only the tip of the iceberg, which was finally communicating BfArM's interpretation of the law, which had already been executed BfArM-internally. Name rejections and ensuing legal action against them, made these interpretations public before the Naming Guideline had been released.

The 1st Fenistil-decision in 2011 clearly showed BfArM's strict interpretation of the prohibition of identical names, section 25 sub-section 3 AMG, and the general assumption the BfArM applied in regard to the prohibitions to prevent deception, section 8 sub-section 1 sentence 1 number 2 AMG. The decision issued also showed that the court affirmed the BfArM position. In 2013, shortly after the

[58] see Naming Guideline section 2.2.1
[59] NRG Guideline, Revision 5 section 2.1.1
[60] Announcment of 1991 section 3.2.1
[61] Naming Guideline section 2.3
[62] Naming Guideline section 2.2.7 in connection with section 2.3.b

release of the Naming Guideline another court decision in regard to a seemingly comparable case the 1st Aktren-decision followed, which also affirmed the BfArMs position. But even if these first decisions backed BfArMs position the MAHs tried to take further action against them. How the discussion in regard to the controversial subject and the procedural processes evolved and if BfArM could hold its position, will be analysed in the following.

5.4.2 Evaluation of the legitimacy of BfArM's position in regard to umbrella brand concepts

Annex VII, Table 3 gives an overview on the lawsuits in chronological and tabulated order. The basic data and the most important aspects in regard to the controversial subjects to be discussed are given. The most recent decisions, the 3rd Fenistil- and 3rd Aktren-decision, of the Federal Administrative Court are not included in the table, since these decisions predominantly affirmed the legitimacy of the foregoing decision. If important additional information in regard to the topics analysed was given with any decisions it will be mentioned in the text.

5.4.2.1 Evaluation of the applicability of section 25 sub-section 3 AMG in regard to extension of umbrella brand concepts

As described in the section regarding the hard law requirements, section 25 sub-section 3 sentence 1 AMG prohibits that a medicinal product bears the same name as an already authorised/marketed medicinal product, which differs in nature or quantity of active substance. In the 1st Fenistil-, as well as in the 1st Aktren-decision, the BfArM according to the court decision, next to other issues, assumed violation of this legal requirement, basing their evaluation on the main part of the medicinal product name. This means the affixes given with the new name "Pencivir bei Lippenherpes" (meaning "Pencivir in case of orofacial herpes") in the Fenistil-case and "Naproxen" (name off the active substance contained) in the Aktren-case, are not considered for evaluation in regard to infringement, only the main parts of the new names "Fenistil" and "Aktren" are applicable. Since the main part of the already authorised products umbrella brand products is also "Fenistil", respectively "Aktren", and since the contained active substances differ, the new name would infringe the legal requirement. According to both court decisions the BfArM claimed that the AMG, not giving a definition of the name itself, only could have considered this assumption; if the whole name was to be considered, as the complainant claimed, the section would have no effect, since even insignificant name additions would allow the usage of different active substances under the same main product name[63]

[63] cf. D.f. VG Köln 7 Kammer, April the 12th, 2011 reference number 7 K 4284/09, m.n. 17 and April the 9th, 2013 7 K 2050/11, m.n. 19 - juris

The interpretation of the BfArM and the administrative court was not only questioned by the MAH, but also specialised literature took up the issue and claimed that the wording, taxonomy and historical development of the AMG, in contrary, would lead to the assumption that the assessment in regard to this section is only to be based on the whole medicinal product name[64].

As table 3 shows, the decisions discussed so far have been made before release of the Naming Guideline and shortly after. At that time it was crucial for pharmaceutical industry to get a different opinion from a higher authority in regard to this controversial discussion, since the acceptance of the interpretation would have consequently lead to the general abolition of umbrella brand concepts including different active substance/combinations of active substance under one umbrella brand name.

Consequently, the first decisions were questioned by the MAHs. On the basis of the decisions made so far, it was surprising that the higher instances firstly in the 2nd Fenistil-decision bypassed the answer on that issue and secondly the 2nd Aktren-decision abnegated the applicability of section 25 sub-section 3 AMG in connection with extension of umbrella brand concepts. According to the first head note of the decision, the utilisation of an umbrella brand in a multi-part medicinal product name did not infringe the prohibition of identical names of medicinal products, which only would interfere with completely identical wording. Furthermore the decision gave an extensive grammatical, taxonomic, historical and teleological analysis of that issue. That the latter analysis was legitimate was confirmed from the next higher instance[65], where the BfArM had lodged a complaint against the 2nd Aktren-decision, which therefore became effective.

So far the BfArMs interpretation in regard to the prohibitions of identical naming was not legitimated by jurisdiction in these cases.

Nevertheless, the BfArM based the rejection of the extension of umbrella brand concepts not only on that legal requirement but also the interpretation of the prohibitions to prevent deception, section 8 sub-section 1 sentence 1 number 2 AMG, which is to be discussed in the following.

5.4.2.2 Evaluation of the BfArM's general approach in regard to the prohibitions to prevent deception, section 8 sub-section 1 sentence 1 number 2 AMG

The BfArM was of the opinion that the misleading character of the extension of umbrella brand names to other active substances/combinations of substances could, per se, be derived from the suggestive function the main part of the name, the umbrella brand name part, has. This was also

[64] see *Pannenbecker, Blind* essay „*Eingriffsbefugnisse der Bundesbehörden bei Arzneimittelbezeichnungen*" PharmR 7/2011 pp. 272-282 section II sub-section 3 lit. a or *Reese* essay „ *Möglichkeiten und Grenzen der Verwendung von Dachmarken im Arzneimittelbereich*" PharmR 10/2011 pp. 392-401, section III No 1

[65] c.f. D.f. BVerwG, April the 29th, 2015, reference number 3 B 29/14, m.n. 6

communicated in the Naming Guideline, by stating that the extension should be avoided because of this general confusion potential[66]. The main part would, according to BfArM, consequently create an association with the established active substance/combination of active substances, and its main characteristics (e.g. their mode of action and their indications). According to BfArM, the latter was also underlined through the fact that the MAHs wanted to use the established trademark for other products in order to exploit the publicity of the established products, a fact that shows the suggestive character of the main part of the product name[67]. In the Fenistil- and Aktren-case the association would consequently deceive the consumer in regard to the active substance(s), mode of action and indication of the new medicinal product falling under the same umbrella brand name, which would infringe the prohibitions to prevent deception[68].

Table 3 shows that the court in the 1st Fenistil-decision as well as in the 1st Aktren- decision followed BfArM's assumption. The stakeholders criticized this interpretation, since it was stated that not a main part of the name would have to be considered in regard to medicinal products deviating in active substance, but also the signal function of name affixes and surrounding circumstances. Therefore, the individual circumstances would contribute to the misleading character and should consequently be the basis for evaluation of infringement of prohibitions to prevent deception[69].

As can be seen in table 3 in regard to Fenistil the 2nd-decision the court shortly after release of the Naming Guideline still followed the interpretation of the BfArM, even the head note stated that the usage of a umbrella brand would regularly be misleading, if another active substance is contained, then in the products already marketed under the umbrella brand[70]. However, this general assumption could not be maintained as the 2nd Aktren-decision showed. As shown in table 3, the court began to accept the stakeholders' arguments and included the surrounding circumstances in their assessment, coming to the conclusion that the name under the these additional aspects would not infringe the prohibitions to prevent deception, section 8 sub-section 1 sentence 1 number 2 AMG.

Within the following year it became obvious that the courts would further on follow the interpretation given in the 2nd Fenistil decision. Not only the complaint of the BfArM against this decision was refused[71], but also other court decisions followed[72] using the individual case assessment instead of a general approach to decide on the misleading character of a name change. The court

[66] see Naming Guideline section 2.2.1
[67] c.f. VG Köln April the 9th, 2013, reference number 7 K 2050/11, m.n. 20–, juris
[68] c.f. VG Köln, April the 12th, 2011, reference number 7 K 4284/09, m.n. 18 and April the 9th, 2013, reference number 7 K 2050/11, m.n. 20–, juris
[69] see Pannenbecker, Blind essay „*Eingriffsbefugnisse der Bundesbehörden bei Arzneimittelbezeichnungen*" PharmR 7/2011 pp. 272-282 section II sub-section 3 lit. b
[70] c.f. D.f. OVG für das Land Nordrhein-Westfalen, June the 17th, reference number 13 A 1113/11, head note – juris
[71] c.f. D.f. BVerwG, April the 29th, 2015, reference number 3 B 29/14 - juris
[72] c.f. D.f. VG Köln, September the 16th, 2014, reference number 7 K 4821/12 or OVG für das Land Nordrhein-Westfalen, June 3rd, 2015, reference number 13 A 2215/14 –juris

decisions therefore finally abnegated BfArM general approach to abolish the possibility to extend umbrella brand concept to other active substances, not originally part of the established umbrella brand.

5.4.2.3 Summary of the impact of the administrative practice change on umbrella brand concepts

As could be shown, BfArMs general approach to prevent the extension of umbrella brand name concepts to other active substances/combination of active substances, could not withstand juridical assessment. The general assumptions made in regard to the prohibition of identical naming, section 25 sub-section 3, as well as to the prohibition to prohibit deception, 8 sub-section 1 sentence 1 number 2 AMG, were not supported by the courts, which finally came to the conclusion that the evaluation should be based on the individual case circumstances and not on grounds of a general abnegation.

The BfArM's interpretation of both legal requirements mainly resulted from the basic conclusion that the name from BfArM's point of view is divided in a main part and additional lateral parts, at which the main part bears more importance in regard to influencing consumer's perception. It is noticeable to mention that this controversially discussed assumption was only possible, since the AMG does not give an actual definition of the medicinal product name and since European law seems not to be able to fill that legal gap, even by giving such a definition. The background was explained from authority representative, by pointing out that the German Drug Law, with section 10 sub-section 1 sentence 1 No 2 AMG, norms a purely national freedom of scope to include additional information (e.g. the strength, the pharmaceutical form) into the name not within the scope of the European law definition[73]. But even with presuming such a deviation of the law, the interpretation to divide the name into a main and lateral parts, given from the BfArM, failed in practical applicability and therefore also the intentions to take general influence on umbrella brand concepts could not be achieved.

But even if the general approach failed the court decisions also showed that the MAH is not totally free in the name choice, but limited through prohibitions to prevent perception, so while the Fenistil-case based on the individual circumstances could reveal a violation of deception the Aktren-case didn't. Additionally, these are examples to proof the fact that even if cases are considered to be rather similar they are not per se identical and therefore only a risk based approach instead of a general approach can be applicable.

[73] see cf. *Kösling*, in: Fuhrmann/Klein/Fleischfresser, „Arzneimittelrecht", version 2 of 2014, section 10, m.n. 75

Fortunately the BfArM already considered a risk based approach in the alleviated final version of the Naming Guideline in regard to umbrella brand concepts, so the Naming Guideline itself will not have to be adapted extensively, only the competent authority's evaluation practice will have to. It could be suspected that this approach for the Naming Guideline was chosen, since already with the comments received on the first draft of the Naming Guideline failure became possible. The latter can only be suspected, but not proven. Nevertheless, even the possibility of influence, emphasizes the importance of commenting new guidance documents while they are still under development, since the comments, by giving other points of view, can help to consider all possible settings.

5.4.3 Evaluation of the standard of evaluation in regard to prohibitions to prevent deception section 8 sub-section 1 sentence 1 number 2 AMG under inclusion of a potential future issue

Next to the issues already discussed, another subject arose during the discussion of umbrella brand concepts which can additionally have significant influence on future medicinal product names and their evaluation in regard to the prohibitions to prevent deception. Already in the Fenistil- and Aktren-lawsuits it became obvious, that the standard of evaluation to assess a potential violation of this legal requirement needs clarification, which is significant since the standard the courts apply should also constitute the standard for BfArM's assessment.

Table 3 shows that in all four cases the standard of evaluation included following presumptions: Firstly, even if OTC-Status was applicable for the medicinal product concerned the possibility to obtain counsel from health-care professionals, did not per se outweigh the need to evaluate the misleading character regarding consumers. Secondly, the consumer's perception to be evaluated is based on the perception of a well informed, considerate and rational standard consumer. Thirdly, the so called "S*trengeprinzip*" is applicable, which means that in order to exclude deception more severe requirements have to be considered, since the subject of protection "health" is of high significance and since the advertising impact of health-related advertisement is very high. The latter in numerical expressed would mean a deception of more than 10% of the addressed consumers[74].

The first assumption as table 3 shows had been sufficiently clarified by the courts and therefore BfArM was and will further on be able to include consumer's perception in regard to name assessment of OTC products.

[74] see *Pannenbecker, Blind* essay *„Eingriffsbefugnisse der Bundesbehörden bei Arzneimittelbezeichnungen"* PharmR 7/2011 pp. 272-282 section II sub-section 3 lit. b part bb

In regard to the second assumption it was questioned whether or not the court members, who finally decided on the misleading character in the discussed decisions, would have the qualification to do so, since their professional subject area already leaded to higher background knowledge in comparison to the standard consumer which would disqualify them to decide on that matter. A negation of that could have lead to the requirement to obtain market research data or additional evidence for the potential of deception in order to base the assessment on solid legal ground every time a name rejection is questionable.

As table 3 shows the higher instances gave assertion on the court member's power of assessment, but particularly in the decision on the complaint against the 2nd Fenistil-decision, not listed in table 3, the court dealt with this problem and solved it. According to the derivation to that issue the members of the court would be able to distinguish their additional gained professional knowledge on that matter from their experiences and expectation as consumer, therefore the court itself can choose whether or not additional evidence like market research date are to be consulted[75]. That this clarification was given is important for future evaluation, since neither the BfArM, nor the MAHs will be obliged to prove their assessment of deception potential during a procedural process by having for example market research data prepared.

However, even if those two matters seem to be solved, today's applied standard of evaluation is disputable, if it is shown that the picture of the standard consumer as well as the "*Strengeprinzip*" is not compatible with European law. That such an approach would be imaginable the law suit already used in section 4.3 of this thesis to evaluate the administrative practice change of 2010, the "… pp. Schmerz-Salbe"- case can show. Here not only the question on legitimacy of marketing a medicinal product without official name change in the marketing authorisation notice had been questioned, but also the applicability of the *Strengeprinzip*.

The defendant claimed that a deception of a significant part of the addressed consumers would have to be the basis to claim violation in regard to prohibitions to prevent deception[76]. The latter would be conforming to the quorum the civil courts and European law use for evaluation, numerical expressed a deception of more than a quarter or a third of the addressed consumers[77], and not to the lower Quorum the *Strengeprinzip* applies. Within the reasoning for the decision the court bypassed an answer to this question, but as specialised literature shows this could be a significant future topic[78], hence a new interpretation would also mean that Germany violated the European Community Law requirements.

Moreover the matter of fact "deception", as described in the section regarding hard law requirements, is part of AMG as well as of UWG and a new interpretation would

[75] c.f. D.f. BVerwG, March the 4th, 2014, reference number 3 B 60/13, m.n. 9-10 –, juris
[76] c.f. D.f. Saarländisches Oberlandesgericht Saarbrücken, October the 15th, 2014, reference number 1 U 24/14 – juris
[77] see *Pannenbecker, Blind* essay „*Eingriffsbefugnisse der Bundesbehörden bei Arzneimittelbezeichnungen"* PharmR 7/2011 pp. 272-282 section II sub-section 3 lit. b part bb
[78] see *Zindel, Vorländer* essay „Die Zulässigkeit von Arzneimittelbezeichnungen unter Verwendung von Dachmarken und das Verbraucherleitbild bei der arzneimittelrechtlichen Irreführung", PharmR 2/2015, p. 59-63

consequently mean that not only the evaluation of medicinal product names would be concerned but also other areas.

It is important to mention this future topic, because it also emphasizes that even if the measures the BfArM took can be criticized, they also contributed to re-evaluation of the interpretation of the legal requirements and to discuss them controversially. An important function, especially when considering that law and its interpretation is also influenced by the development of the society, like shown through the future topic and its relation to European Union Law development.

With the evaluation of the influence of the administrative practice changes on umbrella brand concepts regarding controversial subjects as well as future topics, finally, a whole summary on the evaluation of measures taken from the BfArM in regard to naming of medicinal products between 2010 and 2013 can be given.

6. Summary of the evaluation of impact of measures taken from the BfArM in regard to naming of medicinal products between 2010 and 2013

The analysis showed that the AMTS efforts of the German Ministry of Public Health were used as catalyst to initiate the reorganisation of BfArMs administrative practice regarding the medicinal product name assessment. Not only could these efforts, as the Sound- and Look-Alike list showed, help to identify risks, but they also gave additional safety reason for applying stricter rules and developing the Naming Guideline. Especially the latter had been overdue, since the Announcement of 1991 no longer had met actual theoretical and practical conditions and therefore a displacement was needed.

The package of administrative practice changes finally conducted between 2010 and 2013, namely the modification regarding name changing procedure in 2010 as well as the development of the Naming Guideline and the self-binding of the BfArM to it with release of the new guidance document in 2013, wanted to strengthen BfArM's position regarding the application of stricter rules in the assessment of medicinal product names, as for example the intention to weaken umbrella brand concepts showed. With the change in 2010 the BfArM therefore began their strategic approach by officially claiming their right to interfere with name change applications in a stricter manner. This announcement initiated controversial discussions but finally, not only the courts but also an additional change, the implementation of Reg. (EC) 1234/2008 in 2013, supported BfArMs interpretation.

The BfArM in parallel to development of the Naming Guideline, extensively used this competence, by rejecting name changes and applying their interpretation of the law. This interpretation and the

intent behind them, the reduction of AMTS risks, lead to a very strict assessment manner and consequently procedural processes followed.

And while in 2011 it looked like the courts would affrm the BfArM in its intent, which would have lead to significant influence on medicinal product market, the analysis shows that not all of BfArM's interpretation of the law, were able to work under legal pressure in the following years. Since courts partially renounced BfArMs decisions, the influence the Naming Guideline could have had was consequently lowered, especially in regard to the position on extension of umbrella brand concepts. Additionally the stock market, which had not been called on to adapt to the Naming Guideline requirements, not only influenced the Guideline itself, like the salt-base-difficulty-example shows, but also began to partially outweigh the recommendations given, as shown in regard to integrate subordinate indications within the name of a medicinal product.

So one could finally come to the conclusion that the given systematic working and decision making tools, which originally should have lead to restricting the MAHs distinctly in their name choice, was finally reduced to recommendations, which can be circumvented if the individual risk based case assessment justifies it. The individual case assessment will surely determine future name choices, which means that some borderline medicinal product names will have to be accepted if no significant AMTS concerns speak against them, but even if the measures the BfArM took, may not have been fully enforceable, the changes conducted served other important purposes.

By applying a stricter way of assessment and implementing the administrative practice changes the BfArM drew attention to the naming issue, which consequently led and still leads to the reassessment of the interpretation of the legal requirements given. The number of controversial discussed subjects and law suits definitely shows that clarification was and in some cases is still needed and that the law in regard to that issue is not self-explanatory enough to leave it without additional state of the art guidance. It is and will be, one of BfArM's tasks to follow and contribute to the clarification, as well as to adapt their assessment practice to the results and also the MAHs will have to.

Additionally the administrative practice change in line with the court decisions affirmed that the MAH is not totally free in its name choice and that the medicinal product name in the first place serves as identification and discrimination parameter and only in the second place as market value or advertising aid. And even if one cannot fully support the BfArMs approach, it was important to communicate and emphasize this once more, especially against the background that healthcare professional directly interacting with patientsdo see confusion potential here, as the great resonance to the public call to report Sound- and Look-Alike showed. Confusion potential out of naming issues is a risk easily to be prevented, not like for example possible side effects a medicinal product can have, therefore it should be avoided were possible.

Furthermore, it has to be mentioned, that the AM87 data research based on the search profile in Annex III, not included in the evaluation of impact of the administrative practice changes, nonetheless can give significant background information on how the analysis made above has to be seen in the wider context. The number of applications accepted constitutes 97,6% (search step 13), while rejected name changes only constitute 2,4% (search step 14). This fact shows that the number of name changes, the BfArM acknowledges to be in line with the recommendation given during 2008 and 2015 and therefore accepted them, are significantly higher than unacceptable changes. This leads to the assumption that most MAHs do follow the CAs recommendations and that questionable name changes only constitute a small number. This could lead to the conclusion that rejections and the discussion based on them are of minor importance. However, and as explained above confusion potential derived out of inappropriate naming has to be seen as preventable risk and consequently every individual case, as the ones used in the analysis, and there possible influence on future name choices is important in order to ensure patient safety. So the small number of problematic name choices only slightly relativises the importance of the evaluation conducted.

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Annex

List of Annexes

Annex I

Bekanntmachung des BGA über Hinweise und Empfehlungen zur Vermeidung von irreführenden Arzneimittelbezeichnungen vom 22. August 1991. BAnz. vom 2. Oktober 1991, S. 6971 (auch in Dtsch. Apoth. Ztg. 131 (1991) 2139-2140)

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Bekanntmachung über Hinweise und Empfehlungen zur Vermeidung von irreführenden Arzneimittelbezeichnungen

Vom 9./22. August 1991

1 Allgemeines

Die Bezeichnung des Arzneimittels trägt als Identifikations- und Unterscheidungsmerkmal zur Sicherheit im Verkehr mit Arzneimitteln bei. Arzneimittel mit irreführender Bezeichnung in Verkehr zu bringen, ist verboten (§ 8 Abs. 1 Nr. 2 AMG). Die Verletzung dieser Rechtspflicht ist unter Umständen strafbar und gefährdet die Verkehrsfähigkeit des betreffenden Arzneimittels.

Folgende Empfehlungen und Hinweise sollen irreführende Arzneimittelbezeichnungen soweit wie möglich vermeiden helfen.

Eine Arzneimittelbezeichnung darf — auch unabhängig von Verwechslungsmöglichkeiten — nach ihrem Wortlaut keine unzutreffenden Vorstellungen über die Qualität, therapeutische Wirksamkeit, Unbedenklichkeit oder sonstige erhebliche Merkmale des betreffenden Präparats wie Zusammensetzung oder Anwendungsart auslösen. Sie sollte auch nicht durch sprachliche Anklänge an ähnliche Worte mit Begriffsinhalten, die im Hinblick auf das konkrete Arzneimittel unzutreffend sind, falsche Assoziationen bei Laien oder Fachkreisen begünstigen.

Die Bezeichnung eines Arzneimittels soll sich von derjenigen eines anderen Arzneimittels deutlich unterscheiden. Je größer die Unterschiede der einzelnen Arzneimittel sind und je höher das Anwendungsrisiko eines Arzneimittels bei Gefahr der Verwechslung mit einem andersartigen Arzneimittel ist, desto deutlicher sollten die Unterschiede in der Arzneimittelbezeichnung sein.

Warenzeichenrechtliche Zusammenhänge sind nicht Gegenstand dieser Bekanntmachung.

2 Definitionen

2.1 Die Arzneimittelbezeichnung ist die vollständige Bezeichnung eines Arzneimittels, die die Hauptbezeichnung sowie ggfl. einen Bezeichnungszusatz enthält.

2.2 Die Hauptbezeichnung eines Arzneimittels kann aus mehreren Teilen bestehen und ist bei verschiedenen Arzneimitteln einer Arzneimittelserie stets gleich.

2.3 Der Bezeichnungszusatz ist ein zumeist kurzer Zusatz zu der Hauptbezeichnung, durch den in der Regel am Anfang oder am Ende der Arzneimittelbezeichnung auf ein bestimmtes Merkmal des einzelnen Arzneimittels hingewiesen bzw. ein Unterschied zu anderen Arzneimitteln mit gleicher Hauptbezeichnung deutlich gemacht werden soll.

2.4 Eine Arzneimittelserie umfaßt verschiedene Arzneimittel mit gleicher Hauptbezeichnung, die vom pharmazeutischen Unternehmer nebeneinander auf Dauer in Verkehr gebracht werden.

3 Einzelne Hinweise und Empfehlungen

3.1 Arzneimittelbezeichnung

Unterschiedlich zusammengesetzte Arzneimittel, die von demselben oder auch verschiedenen pharmazeutischen Unternehmern gleichzeitig oder nacheinander in Verkehr gebracht werden, sollten so bezeichnet werden, daß eine Verwechslung durch die Fachkreise und durch Patienten weitestgehend vermieden wird. Ein Arzneimittel sollte dabei unter einer Bezeichnung, die mit der früheren Bezeichnung eines unterschiedlich zusammengesetzten Arzneimittels identisch oder von dieser Bezeichnung nicht zumindest durch einen geeigneten Zusatz (s. u. 3.2) hinreichend unterschieden ist, nur dann in Verkehr gebracht werden, wenn diese Arzneimittelbezeichnung im Arzneimittelverkehr seit mindestens vier Jahren nicht benutzt worden ist.

Grundsätzlich unterscheiden sich verschiedene Arzneimittelbezeichnungen nachhaltiger, wenn sie anderslautende Hauptbezeichnungen aufweisen. Dabei ist allerdings zu beachten, daß im Einzelfall auch Übereinstimmungen bzw. Ähnlichkeiten im Klangbild oder im Schriftbild der Arzneimittelbezeichnungen ein Verwechslungsrisiko begründen können, das im Interesse der Arzneimittelsicherheit vermieden werden sollte.

3.2 Bezeichnungszusätze

3.2.1 Allgemeine Grundsätze

Die Benutzung von Bezeichnungsgrundsätzen bei identischer Hauptbezeichnung ist zur Unterscheidung unterschiedlich zusammengesetzter Arzneimittel vor allem in folgenden Fällen von Bedeutung:

- Bei Änderungen eines Arzneimittels in der Zusammensetzung nach Art und Menge der arzneilich wirksamen Bestandteile gem. § 29 Abs. 3 Nr. 1 AMG oder gemäß Artikel 3 § 7 Abs. 3a AMNG (zu den Besonderheiten s. u. unter 3.3 wird die bisherige Bezeichnung des Arzneimittels zur Unterscheidung mit einem Zusatz versehen; es ist § 25 Abs. 3 S. 1 AMG zu beachten;
- eine eingeführte Bezeichnung soll mit einem Bezeichnungszusatz für ein anderes Arzneimittel mit unterschiedlicher Zusammensetzung nach Art oder Menge der arzneilich wirksamen Bestandteile verwandt werden;
- ein pharmazeutischer Unternehmer bringt im Rahmen einer Arzneimittelserie verschiedene Arzneimittel mit identischer Hauptbezeichnung in Verkehr.

3.2.2 Spezifische Hinweise

Bezeichnungszusätze können in einer Silbe, einem Wortteil, einem Wort oder in Zahlenangabe(n) bestehen.

Ein etwaiger Hinweis auf den Namen des pharmazeutischen Unternehmens ist teil der Hauptbezeichnung und stellt keinen unterscheidungskräftigen Bezeichnungszusatz dar.

Ein Bezeichnungszusatz ist in der Regel geeignet und zweckdienlich, wenn er die Fachkreise und Verbraucher hinreichend deutlich darauf hinweist, daß bzw. in welchen Punkten sich die verschiedenen Arzneimittel mit gleicher Hauptbezeichnung materiell voneinander unterscheiden. Wenn ein Bezeichnungszusatz im Einzelfall diese Hinweis- und Signalfunktion nicht erfüllen kann und nicht geeignet ist, Fehlvorstellungen über Umfang und Tragweite der Unterschiede zwischen verschiedenen Arzneimitteln gleicher Hauptbezeichnung weitestgehend zu vermeiden, sollte die Hauptbezeichnung geändert werden — insbesondere, wenn infolge Verwechslungsgefahr Arzneimittelrisiken zu befürchten sind.

Ein bloßer Buchstabe kommt aus diesem Grund als unterscheidender Bezeichnungszusatz insbesondere bei Änderungen in Betracht, die lediglich in der Eliminierung von Wirkstoffen bzw. in der Reduzierung ihrer Menge bestehen (s. u. 3.3, 3. Absatz).

Zu Beginn der Arzneimittelbezeichnung kommt einem unterscheidenden Bezeichnungsteil — etwa einem Hinweis auf einen Wirkstoff — in der Regel größere Unterscheidungskraft zu. Nimmt ein Bezeichnungszusatz auf die jeweilige Wirkstoffmenge Bezug, so sollte der entsprechende Bezeichnungszusatz das Ende der Arzneimittelbezeichnung darstellen.

— Monoarzneimittel

Bei Monoarzneimitteln, die sich im wesentlichen in der Menge bzw. in der Art des arzneilich wirksamen Bestandteils von einem Arzneimittel gleicher Hauptbezeichnung unterscheiden, genügt es häufig, durch einen Zusatz einen Hinweis auf die absolute Menge oder Konzentration bzw. die Art des jeweiligen arzneilich wirksamen Bestandteils in die Arzneimittelbezeichnung aufzunehmen.

Bei Arzneimitteln mit unterschiedlichen Mengen des gleichen Wirkstoffs bzw. bei unterschiedlichen Stärken sollten bei allen Arzneimitteln einer Arzneimittelserie Bezeichnungszusätze verwandt werden. § 25 Abs. 3 S. 2 AMG bleibt unberührt.

— Kombinationsarzneimittel

Kombinationsarzneimittel, die zwei Wirkstoffe enthalten und sich ausschließlich in deren Menge unterscheiden, können in geeigneten Fällen mit zwei Zahlenzusätzen versehen werden, die sich auf die verschiedenen Wirkstoffmengen bzw. Konzentrationen beziehen. Ist dies nicht zweckdienlich, sollte ein anderer, hinreichend unterscheidungskräftiger Bezeichnungszusatz oder eine andere Hauptbezeichnung gewählt werden.

Für Mono- und Kombinationsarzneimittel, die nach Art der Wirkstoffe deutlich unterschiedliche Bestandteile enthalten, wird die Wahl verschiedener Hauptbezeichnungen empfohlen.

Für Mono- und Kombinationsarzneimittel dürfte nach diesen Grundsätzen ein Bezeichnungszusatz, der sich auf die Darreichungsform oder die Anwendungsart bezieht, jedenfalls dann nicht hinreichend unterscheidungskräftig sein, wenn sich die Arzneimittel in der Art der arzneilich wirksamen Bestandteile deutlich unterscheiden.

Wird bei der Änderung der Wirkstoffzusammensetzung eines Arzneimittels ein Teil seiner bisherigen Bezeichnung eliminiert, so sollte dieser — unabhängig von unten 3.3 — durch einen neuen und unterscheidungskräftigen Zusatz ersetzt werden.

3.3 Die gesetzliche Regelung des Artikels 3 § 7 Abs. 3a S. 3 AMNG

In Ergänzung zu Punkt A4) der 6. Bekanntmachung über die Verlängerung der Zulassungen vom 23. Oktober 1990 (BAnz. S. 5827) werden folgende Erläuterungen und Hinweise gegeben:

Die vorstehend unter 3.2 erteilten Hinweise und Empfehlungen sollten auch bei der Wahl eines unterscheidenden Bezeichnungszusatzes, mit dem die bisherige Arzneimittelbezeichnung bei Änderungen nach Artikel 3 § 7 Abs. 3a AMNG versehen werden muß, berücksichtigt werden. Dabei gelten folgende Besonderheiten:

Wird die Änderung darauf beschränkt, daß Wirkstoffe in ihrer Menge verringert oder gänzlich eliminiert werden, ist es im Regelfall ausreichend, die Hauptbezeichnung mit einem zusätzlichen Buchstaben oder einer geeigneten Zahlenangabe zu versehen. Weist die Bezeichnung bereits einen Buchstabenzusatz auf, dürfte die Anfügung eines zusätzlichen Buchstabens — ohne gleichzeitige Streichung des bisherigen Buchstabenzusatzes — jedoch nicht ausreichen.

Die bloße Eliminierung eines bisherigen Bezeichnungsteils verstößt in jedem Fall gegen das insoweit eindeutige gesetzliche Erfordernis eines Zusatzes als unterscheidendes Bezeichnungsmerkmal.

Statt eines Bezeichnungszusatzes kann bei einer Änderung nach Artikel 3 § 7 Abs. 3a AMNG auch eine neue Hauptbezeichnung gewählt werden, die nicht durch Übereistimmungen bzw. Ähnlichkeiten im Klang- oder Schriftbild mit der bisherigen Arzneimittelbezeichnung verwechselt werden kann. Innerhalb eines Zeitraums von mindestens fünf Jahren darf durch erneute Bezeichnungsänderung zu der alten Bezeichnung nicht zurückgekehrt werden (vgl. oben unter 3.1).

Wird ein unterscheidender Bezeichnungszusatz gewählt, so ist dieser für die Dauer von mindestens fünf Jahren beizubehalten, sofern nicht vor Ablauf dieser Frist eine erneute Änderung durchgeführt und angezeigt wird.

Berlin, den 22. August 1991
G — 7010 — 06 — 58/91

Bundesgesundheitsamt
Im Auftrag
Prof. Dr. A. G. Hildebrandt

Langen, den 9. August 1991

Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe
Prof. Dr. R. Kurth

Anhang

Beispielsfälle zur Erläuterung der Bekanntmachung über Hinweise und Empfehlungen zur Vermeidung von irreführenden Arzneimittelbezeichnungen

1. Irreführende Bezeichnung eines Arzneimittels, die unzutreffende Vorstellungen über die Zusammensetzung auslöst (zu Punkt 1. der Bekanntmachung):

   Bezeichnung „Schmidt-Vit", wenn das Arzneimittel keine Vitamine enthält.

   Bezeichnung „Ibu-Otto", wenn das Arzneimittel Ibuprofen nicht enthält.

2. Beispielsfall zur Veranschaulichung der Definitionen in Punkt 2 der Bekanntmachung:

Arzneimittelserie	Arzneimittelbezeichnung	Hauptbezeichnung	Bezeichnungszusatz
Tacetamol 1000 Tacetamol 125 Tacetamol 250 Tacetamol 500 (Supp.) Tacetamol 500 (Tabl.)	Tacetamol 1000	Tacetamol	1000

3. Beispiel für die zu vermeidende Wiederverwendung einer eingeführten Bezeichnung oder dieser ähnlichen Bezeichnung für ein andersartiges Arzneimittel (zu Pkt. 3.1 und 3.2 der Bekanntmachung):

   Auf die Zulassung für das Arzneimittel mit der Bezeichnung „Primadorm" (Wirkstoffe: Benactyzin, Methaqualon, Carbromal) wird nach langjährigem Inverkehrbringen verzichtet. Nach Rückruf bzw. Abverkauf des Arzneimitteles wird ein neu zugelassenes Mono-Arzneimittel (Wirkstoff: Flurazepam) mit der Bezeichnung „Primadorm N" versehen. Nach einigen Monaten wird dann der Buchstabenzusatz N eliminiert.

4. Beispiel der zu vermeidenden Bezeichnung eines Kombinationsarzneimittels mit identischer Art, aber unterschiedlicher Menge der Wirkstoffe (zu Pkt. 3.2.2 der Bekanntmachung):

   Das Arzneimittel „Gregom" enthält 250 mg von dem Wirkstoff A und 25 mg von dem Wirkstoff B; das Arzneimittel „Gregom 100" enthält 100 mg von dem Wirkstoff A und 25 mg von dem Wirkstoff B.

   Das Beispiel verdeutlicht, daß in der Praxis leider nicht alle Arzneimittel einer Arzneimittelserie mit einem unterscheidenden Bezeichnungszusatz versehen werden, sondern häufig das zuerst eingeführte Arzneimittel einer Serie, das zudem — wie hier — oftmals nicht dasjenige mit der geringsten Stärke bzw. Konzentration ist, in seiner Bezeichnung keinen unterscheidenden Zusatz aufweist. Dies sollte zur Vermeidung unzutreffender Rückschlüsse auf die Zusammensetzung des Arzneimittels unbedingt vermieden werden.

   Im vorliegenden Fall ist darüber hinaus die Verwendung lediglich der Zahl 100 in der Bezeichnung „Gregom 100" ungeeignet, da nicht ersichtlich ist, auf welchen Wirkstoff sich diese Zahl bezieht.

   Die Arzneimittel sollten deshalb, wird nicht eine anderslautende Hauptbezeichnung gewählt, etwa so bezeichnet werden:
   Gregom 250/25
   Gregom 100/25

   Anmerkung: Bei der Verwendung von Zahlen als Bezeichnungszusätze sollte darauf geachtet werden, daß sich die Zahlen auf in den Fachkreisen gebräuchliche Maßeinheiten beziehen und nicht etwa Stückzahlen bzw. Packungsgrößen beziffern sollen.

5. Beispiel für die Bezeichnung von Kombinationsarzneimitteln mit deutlich unterschiedlicher Wirkstoffzusammensetzung und verschiedener Darreichungsform (zu Pkt. 3.2.2 der Bekanntmachung):

   Das Arzneimittel „Velener Tabletten" enthält die Wirkstoffe Paracematol und Coffein; das Arzneimittel „Velener Zäpfchen" enthält die Wirkstoffe Paracetamol, Procain und Ethenzamid.

   Die oben genannten Bezeichnungen legen den Schluß nahe, daß die Zusammensetzungen der Arzneimittel in der Art der arzneilich wirksamen Bestandteile identisch sind und Unterschiede lediglich in der Darreichungsform und ggfl. in der Menge der arzneilich wirksamen Bestandteile bestehen. Tatsächlich ist die Zusammensetzung in der Art der arzneilich wirksamen Bestandteile jedoch deutlich unterschiedlich.

   Verwechslungsrisiken dürften hier nur durch eigene Hauptbezeichnungen hinreichend minimiert werden.

Annex II

Leitlinie des Bundesinstituts für Arzneimittel und Medizinprodukte und des Paul-Ehrlich-Instituts zur Bezeichnung von Arzneimitteln

Leitlinie

des

Bundesinstituts für Arzneimittel und Medizinprodukte

und des

Paul-Ehrlich-Instituts

zur

Bezeichnung von Arzneimitteln

Leitlinie zur Bezeichnung von Arzneimitteln

Inhaltsverzeichnis:

Anhang: Fundstellen der in der Leitlinie genannten Rechtsgrundlagen im Internet

Leitlinie zur Bezeichnung von Arzneimitteln

Was bezweckt diese Leitlinie?

Die Bezeichnung eines Arzneimittels trägt als Identifikations- und Unterscheidungsmerkmal zur Sicherheit im Verkehr mit Arzneimitteln bei, sie soll nicht zu Irreführungen führen bzw. Verwechslungen oder Fehlanwendungen (Arzneimittelmissbrauch) z.B. durch Verharmlosung begünstigen.
Um diesem Ziel der Arzneimitteltherapiesicherheit gerecht zu werden, stellt die nachstehende „Leitlinie zur Bezeichnung von Arzneimitteln“ eine Arbeits- und Entscheidungshilfe für Antragsteller und Zulassungsinhaber von Humanarzneimitteln bei der Wahl der Bezeichnung und deren Gestaltung und für die Bundesoberbehörden bei der Überprüfung der Bezeichnungs-vorschläge auf der Basis der normativen Grundlagen dar. Diese sind das Arzneimittelgesetz (AMG), hier insbesondere §§ 10 – 11a AMG (Kennzeichnungsvorschriften) und § 8 Abs. 1 Nr. 2 AMG (Verbot der Irreführung) sowie die Richtlinie 2001/83/EG, jeweils in ihrer aktuell geltenden Fassung (entsprechende Internet-Links finden sich im Anhang dieser Leitlinie).
Darüber hinaus sind auch die auf europäischer Ebene abgestimmten Umsetzungsvorschriften wie die „Guideline on Summary of Product Characteristics“, die „Guideline on the acceptability of names for human medicinal products processed through the centralised procedure“, die „FINAL QRD Recommendations on the Expression of Strength in the Name of Centrally Authorised Human Medicinal Products” und die „EDQM Standard Terms“ heranzuziehen.
Diese Leitlinie wird an die aktuellen europäischen Entwicklungen und die daraus resultierenden Vorschriften angepasst, sie tritt an die Stelle der Bekanntmachung des Bundesgesundheitsamtes und des Paul-Ehrlich-Institutes über Hinweise und Empfehlungen zur Vermeidung von irre-führenden Arzneimittelbezeichnungen vom 9./22. August 1991.

Beispiele zu den einzelnen Themenkomplexen sollen die Orientierung für Zulassungsinhaber und Antragsteller erleichtern und sind als Entscheidungshilfen gedacht.

Die Beurteilung einer neuen Bezeichnung durch die zuständige Bundesoberbehörde im Rahmen ihrer Zuständigkeiten erfolgt auf der Grundlage dieser Leitlinie risikobasiert im Einzelfall und unter Berücksichtigung der Faktoren, die die Anwendungssicherheit des jeweiligen Arzneimittels bestimmen.

Hinweis:
Die Leitlinie wurde in erster Linie für Arzneimittel mit chemisch definierten Stoffen entwickelt. Für Arzneimittel der besonderen Therapierichtungen (Phytotherapie, Homöopathie und Anthroposophie) sowie für Arzneimittel in der Zuständigkeit des PEI ist sie anwendbar, soweit ihr nicht diesbezüglich andere europäische Leitlinien oder Regelungen widersprechen.

I. Einleitung

Wie unterscheiden sich die „Bezeichnung“ und die „erweiterte Bezeichnung“ eines Arzneimittels?

Die „**Bezeichnung**“ wird europäisch (Art. 1 Ziffer 20 Richtlinie 2001/83/EG) definiert als:
“*entweder ein nicht zu Verwechslungen mit dem gebräuchlichen Namen führender Phantasiename oder ein gebräuchlicher oder wissenschaftlicher Name in Verbindung mit einem Warenzeichen oder dem Namen des Inhabers der Genehmigung für das Inverkehrbringen.“*

Daneben gibt es in der Richtlinie 2001/83/EG die erweiterte Bezeichnung des Arzneimittels („Name gem. Art. 54 Buchstabe a“), die aus folgenden Elementen besteht:
*„**Name des Arzneimittels, gefolgt von der Stärke und der Darreichungsform**,*
und gegebenenfalls den Hinweis, ob es zur Anwendung für Säuglinge, Kinder oder Erwachsene bestimmt ist*.“*

Die *SmPC-Guideline* und alle darauf basierenden Empfehlungen und Hinweise zur Umsetzung der europäischen Vorgaben[1] der Richtlinie 2001/83/EG unterscheiden dementsprechend zwischen der erweiterten **Bezeichnung des Arzneimittels** (im Sinne des Art. 54 Buchst. a) und der eigentlichen **Bezeichnung** (Name im Sinne des Art. 1 Ziff. 20):

ERWEITERTE BEZEICHNUNG DES ARZNEIMITTELS
{Name (Phantasiebezeichnung) des Arzneimittels – Stärke - Darreichungsform}

Hinweis:
Anstelle des deutschen Begriffes “Bezeichnung“ wird in den Übersetzungen europäischer Vorschriften auch der Begriff “Name“ verwendet, der damit synonym verwendet werden kann.

II. Hauptteil

1. Was versteht man unter der „erweiterten Bezeichnung des Arzneimittels“?
Die erweiterte **„Arzneimittelbezeichnung**“ besteht aus den folgenden Elementen:
{<„Bezeichnung des Arzneimittels“> <Stärke > <Darreichungsform> *sowie, falls geboten,* <Angaben zum Anwenderkreis>}

Beispiel
- für Bezeichnungen von Generika:

Ibuprofen Pharma 100 mg Tabletten
für Kinder von 6 bis 12 Jahren

- für Phantasiebezeichnungen:

Phantasin 100 mg Tabletten
für Kinder von 6 bis 12 Jahren

Die Altersangabe kann innerhalb von Anwenderkreisen präzisiert werden, sofern dies mit der zugelassenen Indikation übereinstimmt.

[1] Vgl. zum Beispiel die Formatvorlagen des BfArM für die Einreichung von Gebrauchs- und Fachinformationen im Zulassungsverfahren, erstellt auf der Grundlage der QRD-Templates und der SmPC-Guideline.

1.1 Wie wird die Stärke des Arzneimittels wiedergegeben?

Die Stärke des Arzneimittels ist gem. Art. 1 Ziffer 22 Richtlinie 2001/83/EG „je nach Darreichungsform der Wirkstoffanteil pro Dosierungs-, Volumen- oder Gewichtseinheit“. Bei der Angabe der Stärke sind insbesondere die Vorgaben der jeweils aktuellen SmPC-Guideline zu beachten. Auch auf die Besonderheiten bei der Verwendung der Maßeinheiten und der Bezugsgrößen ist zu achten.
Zur korrekten Angabe sind die *„QRD-Recommendations on the expression of strength in name of centrally authorised human medicinal products“* zu berücksichtigen.
Reine Zahlenangaben ohne Maßeinheiten sind als Stärkeangabe unzulässig; die Maßeinheit ist immer anzugeben. Bei zwei oder mehr Wirkstoffen ist jede Stärkeangabe separat mit der jeweiligen Maßeinheit anzugeben.

Beispiel:
<*Bezeichnung*> 50 ***mg***/250 mg statt <Bezeichnung> 50/250 mg

1.1 a) Ausnahme:

Entgegen den sonstigen Regelungen zur Einhaltung der Reihenfolge in dieser Leitlinie können die Stärkeangaben für Arzneimittel mit 3 oder mehr Wirkstoffen wie folgt dargestellt werden:

Beispiel:
<Bezeichnung> Tabletten
Wirkstoff 1: xxx mg
Wirkstoff 2: yyy mg
Wirkstoff 3: zzz mg
…

1.1 b) Umgang mit älteren Arzneimitteln:

Bei Generika finden sich häufig Arzneimittel im Verkehr, bei denen sich der erstmals zugelassene Wirkstoff nicht auf die aktive Substanz (in der Regel die Base) bezog:

Beispiel:
Metoprololsuccinat (statt Metoprolol als eigentlichem Wirkstoff)

Dann richtet sich die Stärkeangabe nach dem Gesamtgewicht von Wirkstoff **und** Salz und liegt somit höher als das Gewicht des Wirkstoffs. In diesen Fällen kann diese Angabe des Gesamtgewichts auch als Basis für Angabe bei Folgezulassungen verwendet werden.
Hierbei ist es zweckmäßig, das jeweilige Salz als Wirkstoff in die Bezeichnung des Generikums aufzunehmen.
In Übereinstimmung mit der SmPC-Guideline muss außerdem zwingend die tatsächliche Stärke des Wirkstoffs als Base („active substance“) zusätzlich genannt werden.
Auch im Rahmen der Wirkstoffangabe gem. § 10 Abs. 1 S. 1 Nr. 8 AMG sollte daher deutlich sichtbar eine Umrechnung auf der **äußeren Umhüllung** und in der **Fachinformation sowie in der Packungsbeilage** für die jeweilige Bezugseinheit vorgenommen werden:

Beispiel:
Metoprolol-Pharmapharm 78 mg Tabletten
[Zusammensetzung:]
1 Tablette enthält: Metoprololsuccinat entsprechend 78 mg Metoprolol

1.2 Wie wird die Darreichungsform dargestellt?

Grundsätzlich ist die Darreichungsform gemäß den europäischen Standard Terms anzugeben. Besteht noch kein entsprechender *Standard Term*, ist im Einklang mit den europäischen Leitlinien ein neuer Standard Term bei der EDQM zu beantragen.

Die Angabe der Darreichungsform in der Phantasiebezeichnung oder dem Bezeichnungszusatz ist zulässig, wenn sie nicht irreführend ist und Anwendungsfehler nicht begünstigt; dabei ist dem *Standard Term* der Vorzug zu geben. Es erfolgt eine risikobasierte Prüfung des Einzelfalls**.**

1.3 Wie wird der Anwenderkreis definiert?

AMG und europäisches Recht sehen vor, dass – sofern dies erforderlich ist – ein Hinweis in die Bezeichnung aufzunehmen ist, dass das Arzneimittel zur Anwendung für Säuglinge, Kinder oder Erwachsene bestimmt ist. Eine Spezifizierung dieser Angaben ist im Grundsatz möglich und dann sinnvoll, wenn in den Produktinformationen klare Aussagen zur Begrenzung der Altersgruppe gemacht werden:

Beispiel:
Montelukast 4 mg Kautabletten
für Kinder von 2 bis 5 Jahren

2. Was versteht man unter der „Bezeichnung des Arzneimittels“?

Die „Bezeichnung“ stellt danach die eigentliche Produktbezeichnung dar, **ohne** dass bereits Angaben zu Stärke, Darreichungsform oder ggf. Anwenderkreis enthalten sein müssen; diese werden in der „erweiterten Bezeichnung des Arzneimittels“ wiedergegeben.

Abb.:

Erweiterte Bezeichnung des Arzneimittels:

Bezeichnung des Arzneimittels:	Stärke:	Darreichungsform:
- Generikabezeichnung → II. 2.1)	**→ II. 1.1)**	**→ II. 1.2)**
- Phantasiebezeichnung → II. 2.2)		
	- SmPC-Guideline	*- Standard Terms*
	- QRD-Recommendations	

Die „B**ezeichnung eines Arzneimittels**“ kann grundsätzlich auf zweierlei Weise gebildet werden:
als „**Generika-**“ (1a) oder als „**Phantasiebezeichnung**“ (1b).
Wird eine Bezeichnung nicht entsprechend den nachstehend aufgeführten “Regeln für Generikabezeichnungen“ gebildet, handelt es sich um eine Phantasiebezeichnung. Zu den Phantasiebezeichnungen zählen auch Mischformen der Namensgestaltung, wie die Verbindung von Wirkstoffabkürzungen mit dem Namen des Zulassungsinhabers oder der Marke (siehe Abschnitt 2.2.6) sowie alle Bezeichnungen mit Bezeichnungszusätzen.

2.1 Wie werden Bezeichnungen von Generika gebildet?

Diese entsprechen dem folgenden Muster:

Wirkstoffname (i.d.R. INN)	plus	Name des Zulassungsinhabers oder geeignete Abkürzung des Namens des Zulassungsinhabers oder Marke („Warenzeichen“/„trade mark“)

Hinweis:
Die Angabe eines Bindestriches zwischen Wirkstoffnamen und Namen des Zulassungsinhabers ist möglich, aber nicht zwingend.

2.1.1 Wirkstoffangabe:

Die Angabe jedes Wirkstoffs soll gemäß europäischem Recht als INN („International Non-proprietary Name“) erfolgen; der INN wird von der WHO auf Antrag vergeben. Liegt ein solcher nicht vor, kann die Angabe durch einen „gebräuchlichen wissenschaftlichen Namen“ („common or scientific name“) im Sinne von Art. 1 Ziff. 21 RL 2001/83/EG ersetzt werden. Im weiteren Text der Leitlinie wird für das bessere Verständnis nur noch der INN verwendet.

Sowohl nach dem AMG als auch nach den europäischen Vorgaben, insbesondere der SmPC-Guideline, ist mit „Wirkstoff“ in der Regel die aktive Substanz (meist Base) gemeint und nicht die Kombination als Wirkstoff-Substanz mit Salzen, Ester, Ether, Isomeren, Mischungen von Isomeren, Komplexen oder Derivaten des Wirkstoffs (vgl. § 24b AMG).

Generikabezeichnungen werden mit dem Namen des Wirkstoffs gebildet. Um die Arzneimitteltherapiesicherheit und die Transparenz für die beteiligten Verkehrskreise zu stärken, ist daher gerade bei Generika wesentlich auf die SmPC-konforme Angabe des Wirkstoffs/der Wirkstoffe (also in der Regel bezogen auf die Base) zu achten.

Die **konkrete Formulierung der jeweiligen Wirkstoffangabe** hat auch Auswirkungen auf die Stärkeangabe in der Arzneimittelbezeichnung. Eine ausschließlich auf den Wirkstoff bezogene Namensgebung in der Bezeichnung **eines Generikums** hilft, trotz möglicher Unterschiede bei den verwendeten Salzen/Ester/Ether/Isomeren/Komplexen oder Derivaten wirkstoffgleiche Generika in der Praxis vergleichbar zu machen.

Hinweis:

Die Verbindung von Wirkstoffabkürzungen mit dem Namen des Zulassungsinhabers oder der Marke sind möglich und werden im Abschnitt 2.2.6 behandelt.

Beispiele anhand der Vorgaben der *SmPC-Guideline*:

Abhängig von der Wirkstoffangabe Toremifen oder Toremifencitrat in der Bezeichnung muss die Stärkeangabe jeweils der Wirkstoffmenge entsprechen:

Toremifen Pharmapharm 60 mg Tabletten

„Eine Tablette enthält: 60 mg Toremifen (als Citrat)“.

Toremifencitrat Pharmapharm 88,4 mg Tabletten

„Eine Tablette enthält: 88,4 mg Toremifencitrat entsprechend 60 mg Toremifen“

2.1.2 Name des Inhabers der Genehmigung für das Inverkehrbringen/Marke:

Das europäische Recht sieht bei Bezeichnungen von Generika die Nennung des „Namens des Inhabers der Genehmigung für das Inverkehrbringen“ (also: Zulassungsinhaber) vor.

Gemäß Art. 1 Ziffer 20 Richtlinie 2001/83/EG kann die Angabe des Wirkstoffs auch durch eine Marke ergänzt werden, wenn nicht der Name des Zulassungsinhabers genannt wird.

2.1.2 a) Verkürzung des Namens des Zulassungsinhabers:

Der Name des Zulassungsinhabers kann auch verkürzt verwendet werden. Bloße Einzelbuchstaben oder Buchstabenfolgen, die zu Verwechslungen/Irreführungen führen können und nicht als Abkürzung des Namens des Zulassungsinhabers erkennbar sind, sind jedoch nicht mehr zulässig.

Zulässiges Beispiel:

Name des Zulassungsinhabers: „Pharma Health Business GmbH“.
Generikabezeichnung: „Ibuprofen Pharma Health“

Unzulässiges Beispiel:

Name des Zulassungsinhabers: **„AAA-Pharma“.**
Generikabezeichnung: „Ibuprofen AAA“

2.1.2 b) Marke anstelle des Namens des Zulassungsinhabers:

Alternativ zu dem Namen des Zulassungsinhabers oder einer geeigneten Verkürzung des Namens des Zulassungsinhabers kann eine andere Marke verwendet werden, die nicht auf den Zulassungsinhaber hinweist. Solche Marken können zum Beispiel für eine Vertriebslinie, ein Preisversprechen oder einen bestimmten qualitativen Anspruch stehen. Die Marke darf nicht zuvor bereits als Phantasiebezeichnung für ein anderes Arzneimittel oder eine andere Arzneimittelserie verwendet worden sein und auf einen anderen Wirkstoff bzw. eine andere Wirkstoffkombination hinweisen. Die Marke darf auch nicht in sonstiger Weise im Hinblick auf den zugelassenen Anwendungsbereich oder die therapeutische Wirksamkeit irreführend oder anpreisend sein.

Beispiele für unzulässige Generika-Bezeichnungen mit einer Marke:

„Phantasin mit dem Wirkstoff Metronidazol“, wenn **„**Phantasin“ bisher als Phantasie-bezeichnung für ein Arzneimittel z.B. mit Ibuprofen verwendet wurde = **„Ibuprofen Phantasin“.** *In diesem Beispiel steht außerdem der Wirkstoff nicht an erster Stelle, diese Bezeichnung folgt somit nicht den Regeln zur Bildung von Generika-Bezeichnungen*

„Ketoconazol-Fiktionin“, wenn **„Fiktionin**“ bisher als Phantasiebezeichnung für ein Arzneimittel z.B. mit Paracetamol verwendet wurde.

„Oxymetazolin-XXL gut&billig“

(siehe Abschnitt **2.2.1 Verwendung einer etablierten Phantasiebezeichnung für andere Wirkstoffe)**.

2.1.2 c) Fortführung einer etablierten Firmenbezeichnung

Wurde in einer Generikabezeichnung bisher der Name eines Unternehmens aufgeführt, kann dieser Name auch nach einem Unternehmensverkauf, einer Fusion oder Umbenennung des Unternehmens o.ä. fortgeführt werden.

2.2 Wie werden Phantasiebezeichnungen gebildet?

Eine Phantasiebezeichnung kann (ungeachtet weiterer Bezeichnungszusätze, → Annex I: nicht abschließende Liste der möglichen Bezeichnungszusätze) aus einem oder mehreren Wörtern bestehen. Hierbei wird ausdrücklich die Einhaltung der **Ein-Wort-Regel** empfohlen.
Die Phantasiebezeichnung soll grafisch als **Einheit** erkennbar sein. Damit soll dem Bedürfnis nach Erkennbarkeit der eigentlichen Arzneimittelbezeichnung Rechnung getragen werden.

2.2.1 Verwendung einer etablierten Phantasiebezeichnung für andere Wirkstoffe:

Die Erstreckung einer für einen Wirkstoff/Wirkstoffkombination etablierten Phantasie-bezeichnung auf andere Wirkstoffe ist nach Maßgabe des § 8 AMG wegen der dadurch begründeten Verwechslungsrisiken zu vermeiden.
Dabei gilt der risikobasierte Grundsatz:
Je größer die Unterschiede der einzelnen Arzneimittel sind und je höher das Anwendungsrisiko eines Arzneimittels bei Gefahr der Verwechslung mit einem andersartigen Arzneimittel ist, desto deutlicher sollten die Unterschiede in der Arzneimittelbezeichnung ausfallen.

Der nachfolgende Kriterienkatalog gibt dazu eine Entscheidungshilfe:

- Anwendungsgebiete (→ ATC Code/Pharmakotherapeutische Gruppe)
- Patientengruppe/Vertriebsweg/Verschreibungspraxis
- Art der Anwendung
- Darreichungsform/Stärke
- Verschreibungsstatus
- Nebenwirkungsspektrum

Eine schriftbildliche Ähnlichkeit kann zum Beispiel durch die Wortlänge oder die Anzahl und Stellung identischer Buchstaben begründet werden. Eine phonetische Ähnlichkeit kann durch ähnliche Vokale und/oder Konsonanten begünstigt werden. Auch die Anzahl der Silben, die Silbengliederung oder die Vokal- bzw. Konsonantenfolgen können eine Ähnlichkeit begründen.
Von bereits zugelassenen Arzneimitteln sollte sich eine neue Phantasiebezeichnung in mindestens drei Buchstaben unterscheiden, denn eine größere Ähnlichkeit begünstigt das Verwechslungsrisiko.

2.2.2 Übertragung bzw. Weiterverwendung einer Phantasiebezeichnung:

Die Übertragung bzw. Weiterverwendung einer Phantasiebezeichnung für ein anderes Arzneimittel mit einem anderen Wirkstoff ist im Grundsatz möglich, wenn er für das ursprüngliche Arzneimittel nicht mehr verwendet wird und durch die künftige Weiterverwendung der Bezeichnung keine Risiken in der Arzneimittelanwendung zu erwarten sind.
Aus Gründen der Arzneimitteltherapiesicherheit sind allerdings zeitliche Abstände zwischen dem Abverkauf und Verbrauch des bisherigen Arzneimittels sowie der Markteinführung des neuen Arzneimittels einzuhalten, um keine Verwechslungsrisiken - insbesondere bei Verbrauchern - zu begünstigen.
Der Zeitraum zwischen der Anzeige der „Aufgabe“ der bisherigen Bezeichnung (z.B. durch Bezeichnungsänderung, Zulassungsverzicht, Löschung oder Rückruf der bisherigen Zulassung) und der Markteinführung des neu bezeichneten Arzneimittels sollte fünf Jahre betragen. Abhängig vom Grund der Bezeichnungsänderung kann ein Arzneimittel ggf. auch nach der Mitteilung über eine Aufgabe im Rahmen des Abverkaufs in Verkehr gebracht werden. Damit wird die Marke im Hinblick auf die Eintragung in ein Markenregister weiter markenerhaltend genutzt.
Im Zeitraum von fünf Jahren enthalten sind ggf. ein Abverkauf sowie der Chargenverbrauch. In der Regel befindet sich nach Ablauf dieser Frist kein Arzneimittel unter der früheren Bezeichnung mehr im Markt oder beim Verbraucher.

2.2.3 Ähnlichkeit einer Phantasiebezeichnung zu einem INN (International Nonproprietary Name):

Die Phantasiebezeichnung kann an einen INN angelehnt sein, sofern dadurch keine Verwechslungsgefahr mit anderen Wirkstoffen begünstigt wird und nicht der Eindruck erweckt wird, es handle sich um einen (originären) Wirkstoff, der nicht enthalten ist oder nicht existiert.

Beispiel:	*akzeptabel:*	*Phantasur, Wirkstoff: Phantasin*
	unerwünscht:	*Phantasur, Wirkstoff: Fiktionin*

2.2.4 Einbindung von Anwendungsgebieten in die Phantasiebezeichnung (als Wortbestandteil):

Wird die Indikation in der Bezeichnung selbst erwähnt, also als Wortbestandteil, z.B. „Phantasin-krupp“ [Krupphusten] oder „Schmerzphantasin“ [Schmerzmittel], kann sie als Teil einer Phantasiebezeichnung verwendet werden, wenn die Indikation dadurch zutreffend abgebildet wird.
Das Hervorheben nur einzelner Indikationen aus mehreren ist zu vermeiden, um den Eindruck zu vermeiden, das Arzneimittel sei für einen Teil des Indikationsspektrums besonders geeignet.

2.2.5 Einbindung von Darreichungsformen/Art der Anwendung in die Phantasiebezeichnung (als Wortbestandteil):

Wird die Darreichungsform oder die Art der Anwendung in der Bezeichnung selbst angedeutet, also als Wortbestandteil, z.B. „Phanta-plast“ [für ein Schmerz-Pflaster] bzw. „Phant-oral“ [für eine orale Anwendung], muss die Bezeichnung die Darreichungsform oder Art der Anwendung zutreffend beschreiben, damit es nicht zu Anwendungsfehlern kommt.

Beispiel:
akzeptabel: *Phant-oral, Art der Anwendung: Zum Einnehmen*
unerwünscht: *Phant-oral, Art der Anwendung: Zur intravenösen Anwendung*

2.2.6 Verbindung von Wirkstoffabkürzungen mit dem Namen des Zulassungsinhabers/Marke

Die Kombination aus einer eindeutigen Wirkstoffabkürzung und dem Namen des Zulassungsinhabers oder einer Marke ist zulässig, wenn kein Verwechslungs- oder Irreführungsrisiko besteht. Die dadurch gebildeten Phantasiebezeichnungen entstehen vielfach durch verkürzte INN.

Zulässige Beispiele:
Irbe- [Name des Zulassungsinhabers] ➔ **Irbe-Pharm**
Wirkstoff: Irbesartan, Zul.-Inhaber: Pharma GmbH
Irbecomp-[Name des Zulassungsinhabers] ➔ **Irbecomp-Pharm**
Wirkstoffe: Irbesartan und Hydrochlorothiazid, Zul.-Inhaber: Pharma GmbH

Die entsprechenden INN-Silben müssen auf den Wirkstoff hinweisen und dürfen dabei keine irreführenden Assoziationen wecken:

Zulässiges Beispiel:
Cefac- [Name des Zulassungsinhabers] ➔ **Cefac-Pharm**
Wirkstoff: Cefaclor; Zul.-Inhaber: Pharma GmbH

2.2.7 Reihenfolge der Angaben:

Da vom ersten Wort einer zusammengesetzten Arzneimittelbezeichnung ein stärkerer Kennzeichnungs-, Assoziations- und Wiedererkennungswert ausgeht, sind Verwechslungs- und Irreführungsrisiken ungleich größer, wenn eine Marke oder der Name des Zulassungsinhabers an erster Stelle stehen. Daher sollte bei Verwendung einer sinnvollen, allgemein verständlichen Abkürzung des Wirkstoffs dieser aus Sicherheitsgründen zuerst genannt werden:

Zulässiges Beispiel:
Paracet- [Name des Zulassungsinhabers] ➔**Paracet-Pharm**;
Zul.-Inh.: Pharma GmbH

2.2.8 Unterschiedliche Verkaufsabgrenzungen:

Bei Arzneimittelserien können wirkstoffgleiche Arzneimittel teils verschreibungspflichtig, teils apothekenpflichtig bzw. freiverkäuflich sein. Dies kann auf unterschiedlichen Anwendungsgebieten, der Patientenpopulation oder der Packungsgröße beruhen. Ist die unterschiedliche Verkaufsabgrenzung wesentlich durch unterschiedliche Anwendungsgebiete begründet, sollten auch unterschiedliche Bezeichnungen gewählt werden.
Eine Änderung der Verkaufsabgrenzung von Arzneimitteln kann daher unmittelbare Auswirkungen auf die Bezeichnung haben. Da das verschreibungspflichtige Arzneimittel im Bestandsmarkt bereits etabliert ist und i.d.R. keinen Indikationszusatz in der Bezeichnung enthält, sollten Indikationsangaben nur für die apothekenpflichtigen bzw. freiverkäuflichen Arzneimittel verwendet werden. Bei nebeneinander bestehenden verschreibungs- und apothekenpflichtigen Arzneimitteln mit identischer Stärke sollte einer Verwechslungsgefahr durch einen Indikations-Zusatz für das apothekenpflichtige Arzneimittel begegnet werden.

Beispiel:
Phantasin-Pharma bei Sodbrennen 20 mg Tabletten (apothekenpflichtig) ***vs.***
Phantasin-Pharma 20 mg Tabletten (verschreibungspflichtig)

2.3 Bezeichnungszusätze:

Die bisher dargestellten Bezeichnungen können nach Maßgabe der nachfolgenden Hinweise durch Zusätze ergänzt werden, die der jeweiligen „Bezeichnung des Arzneimittels“ zugeordnet werden, vgl. dazu auch Annex I. ***Liste der möglichen Bezeichnungszusätze***.

Die Bezeichnungszusätze haben eine erläuternde oder beschreibende Funktion:

2.3 a) Angabe von Indikationen

Die Angabe von Indikationen als Bezeichnungszusatz ist bei nicht verschreibungs-pflichtigen Arzneimitteln sinnvoll, wenn die zugelassene(n) Indikation(en) dadurch eindeutig und zutreffend reflektiert werden.

2.3.b) Wirkstoffangaben

Die Angabe des Wirkstoffs/der Wirkstoffe ist auch als Bezeichnungszusatz bei Phantasiebezeichnungen möglich. Sofern sie keine Verwechslung oder Irreführung begünstigen, sind außerdem eindeutige Abkürzungen des Wirkstoffs bzw. der Wirkstoffe möglich.

2.3 c) Unterschiedliche Indikationen bei gleichem Wirkstoff

Ist ein Wirkstoff in **unterschiedlichen Stärken bzw. Darreichungsformen** für **verschiedene Indikationen** zugelassen, sollten auch unterschiedliche Bezeichnungen gewählt werden. Ist dies nicht möglich oder gewünscht, da z.B. der Wirkstoff bereits Teil der Bezeichnung ist, empfiehlt sich zur besseren Unterscheidung die Angabe der Indikation in der jeweiligen Arzneimittelbezeichnung oder zur Unterscheidung mindestens bei einem Arzneimittel.

Beispiel:
Phantasin protect 100 mg/Tabletten *zur Thrombozytenaggregationshemmung* ***vs***
Phantasin 500 mg/Tabletten bei „Schmerzen und Fieber“

2.3 d) Hinweis auf den Anwenderkreis

Hinweise auf den Anwenderkreis in der Bezeichnung sind dann möglich, wenn sie im Rahmen der erweiterten Bezeichnung gemäß § 10 Abs. 1 S. 1 Nr. 2 AMG (Anwenderkreis) näher konkretisiert werden und nicht irreführend sind (siehe Abschnitt **1.3 Wie wird der Anwenderkreis definiert?).**

Beispiel:
Montelukast ***Junior 5 mg*** Kautabletten
für Kinder von 6 bis 14 Jahren

2.3 e) Angaben zur Darreichungsform oder der Art der Anwendung

Hinweise auf die Darreichungsform bzw. Art der Anwendung in der Bezeichnung selbst („Erkältungstrunk“, „Heißgetränk“) sind dann möglich, wenn sie im Rahmen der erweiterten Bezeichnung durch die Angabe der korrekten Darreichungsform gemäß § 10 Abs. 1 S. 1 Nr. 2 AMG (Darreichungsform) konkretisiert werden und nicht irreführend sind (siehe Abschnitt **1.2.Wie wird die Darreichungsform dargestellt?).**

Beispiel:
*Phantasin **Schmerzgel** 2,5 % (25 mg/g) **Gel***

2.3 f) Hinweis auf das Primärbehältnis oder eine Applikationshilfe

Ein Hinweis auf das Primärbehältnis oder eine Applikationshilfe kann im Einzelfall in die Arzneimittelbezeichnung aufgenommen werden, sofern dies zur Unterscheidung von Arzneimitteln mit gleicher Darreichungsform sowie demselben Wirkstoff/derselben Wirkstoffkombination erforderlich ist (vgl. *Standard Terms - General Principles - Instructions for the use of the list*, s. 1.4.).

Beispiel: Ein identisch zusammengesetztes Arzneimittel liegt vor
* als Fertigspritze **und** als Durchstechflasche
* als Pump- **und** als Dosierspray
* in einem Behältnis zur Einmal- **und** in einem Behältnis zur Mehrfach-entnahme.

In diesem Fall sind Hinweise auf Applikationshilfen sinnvoll (Bsp. Easyhaler/Turbohaler/ DosePro).

2.3 g) Fremdsprachliche Begriffe

Sie sind in der Arzneimittelbezeichnung dann möglich, wenn sie allgemein verständlich und nicht irreführend sind.

2.3 h) Einzelbuchstaben, Zahlen, Kombinationen aus beidem

Bloße Einzelbuchstaben oder Buchstabenfolgen, die zu Verwechslungen/Irreführungen führen können und nicht als Abkürzung des Zulassungsinhabers oder des Namens eines Wirkstoffs (z.B. ASS für Acetylsalicylsäure) erkannt werden, sind mit einem risikobasierten Ansatz allenfalls in besonderen Ausnahmefällen vereinbar. Dies gilt auch für (erfundene) Kombinationen aus Buchstaben und Zahlen.

Beispiel: Phantasin Z 40 mg ist unerwünscht, aber
Phantasin Z-Pharma 40 mg ist akzeptabel.

Daher sollten auch andere Phantasie-Buchstabenkombinationen vermieden werden, die keine Entsprechung zu Eigenschaften des Arzneimittels aufweisen.
Die Angabe von Zahlen ist unter der Voraussetzung möglich, dass diese als Hinweis auf die jeweilige Dosierungsanweisung verstanden werden und nicht verwirren. Die Angabe von Zahlen ist insbesondere dann zu begrüßen, wenn der gleiche Wirkstoff bei unterschiedlichen Dosierungen unterschiedlich oft eingenommen bzw. angewendet wird und dies durch die Zahlenangabe verdeutlicht werden soll. Auch kann die Einnahmesicherheit erhöht werden, wenn zum Beispiel die Einnahme nur einmal täglich erfolgen soll.

Beispiel: **1mal täglich** ist akzeptabel.

Anhang: Fundstellen der in der Leitlinie genannten Rechtsgrundlagen im Internet

Arzneimittelgesetz:
http://bundesrecht.juris.de/amg_1976/index.html

Richtlinie 2001/83/EG:
http://ec.europa.eu/health/ documents/eudralex/vol-1/index_en.htm

„**Guideline on Summary of Product Characteristics**“ (SmPC-Guideline):
http://ec.europa.eu/health/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf

„**Guideline on the acceptability of names for human medicinal products processed through the centralised procedure**“:
http://www.ema.europa.eu/pdfs/human/regaffair/032898en.pdf

„**Final QRD Recommendations on the Expression of Strength in the Name of Centrally Authorised Human Medicinal Products**”:
http://www.ema.europa.eu/htms/human/qrd/docs/70722909en.pdf

„EDQM Standard Terms“:
http://www.edqm.eu/en/Standard_Terms-590.html

ANNEX I.

Liste der möglichen Bezeichnungszusätze

Übersicht von in nationalen Verfahren möglichen Bezeichnungszusätzen; alphabetisch sortiert (diese Liste ist nicht abschließend und sie wird laufend fortgeschrieben)

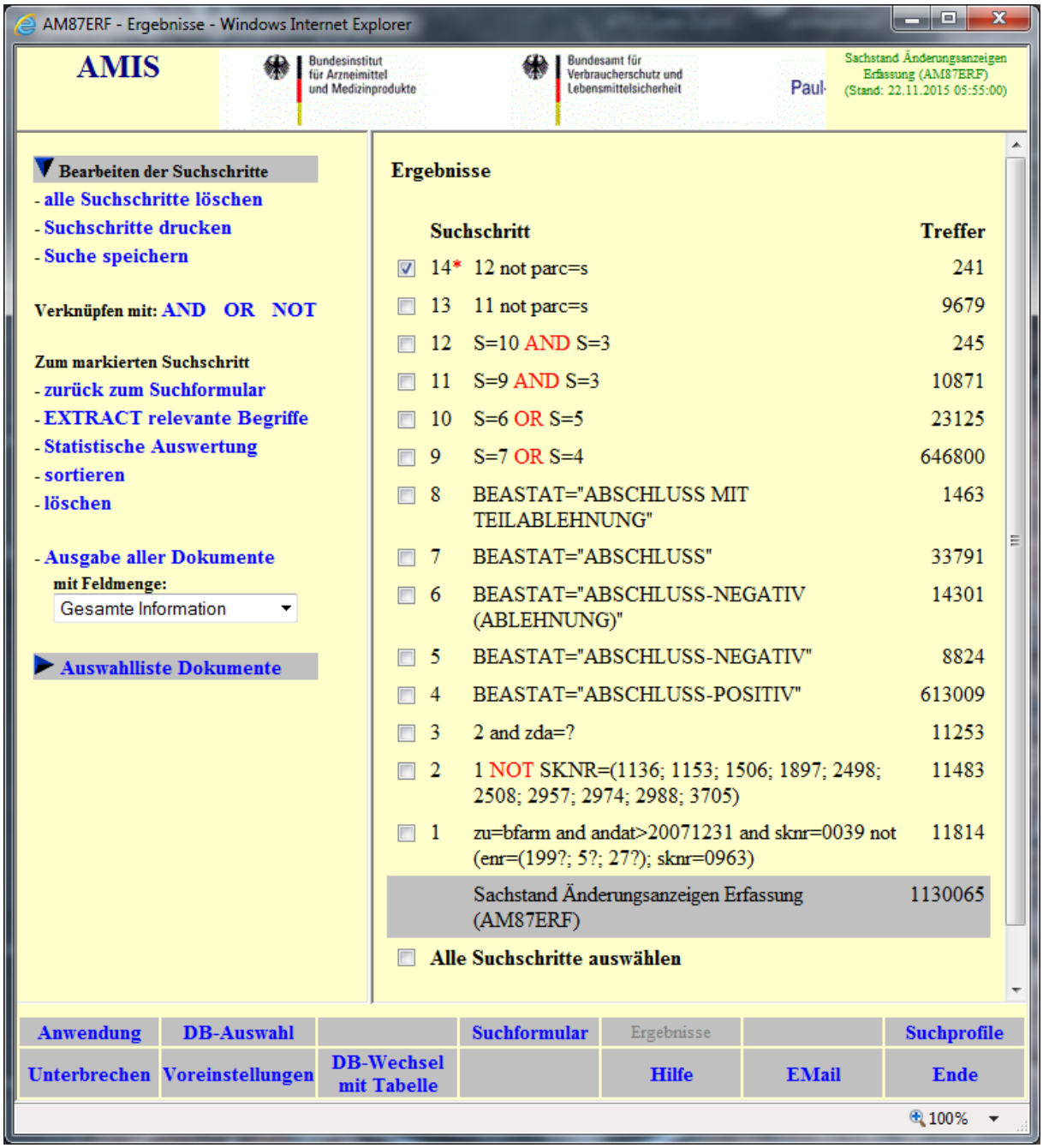
akut	bei besonders schnell wirkenden Arzneimitteln (schnelle Freisetzung)
Combi, Kombi	2 Arzneimittel in einer Packung (Tablette und Creme; Augentropfen und Nasenspray)
comp., comp	* bei Kombinationsarzneimitteln der besonderen Therapierichtungen * bei Kombinationsarzneimitteln der Allopathie mit zwei oder mehr Wirkstoffen (Einzelfallprüfung); die Wirkstoffangabe muss nicht in den Namen aufgenommen werden
cutan; kutan	Für die Anwendung auf der Haut
duo	als Teil einer Arzneimittelserie, wenn unter dem Phantasienamen bereits ein Monopräparat vermarktet wird und zu dem Wirkstoff des Monopräparates ein weiterer Wirkstoff aufgenommen wird (im Gegensatzzu mono)
Elixier	ggf. bei besonderen Therapierichtungen akzeptabel, wenn es der eigentlichen Darreichungsform nicht widerspricht.
forte	steht für ein „stärker dosiertes Arzneimittel“. Vergleichsmaßstab ist nicht nur die Produktlinie eines Zulassungsinhabers, sondern auch die Stärke des Arzneimittels absolut. „Forte“ ist also dann zu akzeptieren, wenn das Mittel **relativ** zu anderen Arzneimitteln des Zulassungsinhabers und **absolut** zum Markt einen höheren Wirkstoffgehalt aufweist.
mit <Geschmacks- oder Geruchs-korregentien>	z.B. als Hinweis auf Aromen („mit Zitronengeschmack“).
mite	steht für eine schwächere Dosierung („die Hälfte“). Vergleichsmaßstab ist nicht nur die Produktlinie eines Zulassungsinhabers, sondern auch die Stärke des Arzneimittels absolut. „Mite“ ist also dann zu akzeptieren, wenn das Mittel **relativ** zu anderen Arzneimitteln des Zulassungsinhabers und **absolut** zum Markt einen geringeren Wirkstoffgehalt aufweist.
Mono/uno	wenn das Arzneimittel nur einen Wirkstoff enthält
plus	als Hinweis auf einen weiteren Wirkstoff zusätzlich zum bisherigen „Standard-wirkstoff“/„Standardwirkstoffkombination“ dieses Arzneimittels; der weitere Wirkstoff soll hinter dem „Plus“ genannt werden, um das Verwechslungsrisiko zu minimieren.
pure	bei Desinfektionsmitteln als unterscheidendes Merkmal, wenn dieses Arzneimittel keine „Zusatzstoffe“ enthält (Farbstoffe, Duftstoffe etc.)
rektal	bei Anwendung in den Mastdarm/After
retard	bei verzögerter Freisetzung (Alternativen: Depot/prolong nur im Einzelfall)

sine	als unterscheidendes Merkmal, wenn dieses Arzneimittel keine Konservierungsstoffe/Farbstoffe (mehr) enthält, jedoch vergleichbare Arzneimittel aus der Serie mit Konservierungsstoffen/Farbstoffen angeboten werden.
Tonikum	bei besonderen Therapierichtungen akzeptabel, wenn es der eigentlichen Darreichungsform nicht widerspricht.
TTS	Transdermales Therapeutisches System (Transdermales Pflaster mit systemischer Wirkung)

Annex III

AM87 search profil,e applications in connection with name changes

Annex III: AM87 search profile, applications in connection with name changes



Annex IV

table 1, classified rejected name change applications

table 1
classified rejected name change applications between January 2008 and October 2015

	name change as reason for rejection (n)	name change as reason for rejection (n)	rejection of another change being crucial for the name change (n+a)	rejection of another change being crucial for the name change (n+a)	uncertain cases (u)	uncertain cases (u)	other reasons for rejection not in connected to name change (o)	other reasons for rejection not in connected to name change (o)	
	Rx	n RX	Rx	nRx	Rx	nRx	Rx	nRx	sum
Jan 08									0
Feb 08		1		2z					3
Mrz 08		1		3z+2z				5z	11
Apr 08		1				1	2	1	5
Mai 08			2z			2z	4z		8
Jun 08		1				1		2z	4
Jul 08			1						1
Aug 08			1			1		1	3
Sep 08				1				1	2
Okt 08									0
Nov 08	4z	1							5
Dez 08		1							1
Jan 09									0
Feb 09		1						2	3
Mrz 09		2z					3z		5
Apr 09									0
Mai 09		1+2z			1				4
Jun 09		1+2z			1	1	3		8
Jul 09	1	2z			3				6
Aug 09								1	1
Sep 09							2		2
Okt 09				1		1			2
Nov 09		1			2			1	4
Dez 09					1+2z			1+2z	6
Jan 10							1+2z		3
Feb 10		1					2z	1	4
Mrz 10		1	5z		1	1	1		9

AM87 research conduted with the BfArM internal data base on November the 22nd, 2015 and classified by Anja-Simone Wiedemann

table 1
classified rejected name change applications between January 2008 and October 2015

Apr 10	1	1					1	2z	5
Mai 10		2z	2z						4
Jun 10		5					1+2z		8
Jul 10		1							1
Aug 10		2+2z		1	6z		1		12
Sep 10							1	1	2
Okt 10						1		2	3
Nov 10		3	1			2z			6
Dez 10		3							3
Jan 11	1								1
Feb 11		3							3
Mrz 11		2		1					3
Apr 11		1+2z							3
Mai 11		2							2
Jun 11		1+8z				1			10
Jul 11		2							2
Aug 11	1	1							2
Sep 11	1	2			1(3z)				6
Okt 11						1			1
Nov 11									0
Dez 11	1	2z							3
Jan 12	3z	1							4
Feb 12									0
Mrz 12		1			1				2
Apr 12		2z+2z							4
Mai 12		1	1				2z		4
Jun 12		1							1
Jul 12									0
Aug 12		1					1+4z		6
Sep 12									0
Okt 12									0
Nov 12									0
Dez 12									0
Jan 13		1							1
Feb 13									0

AM87 research conduted with the BfArM internal data base on November the 22nd, 2015 and classified by Anja-Simone Wiedemann

table 1
classified rejected name change applications between January 2008 and October 2015

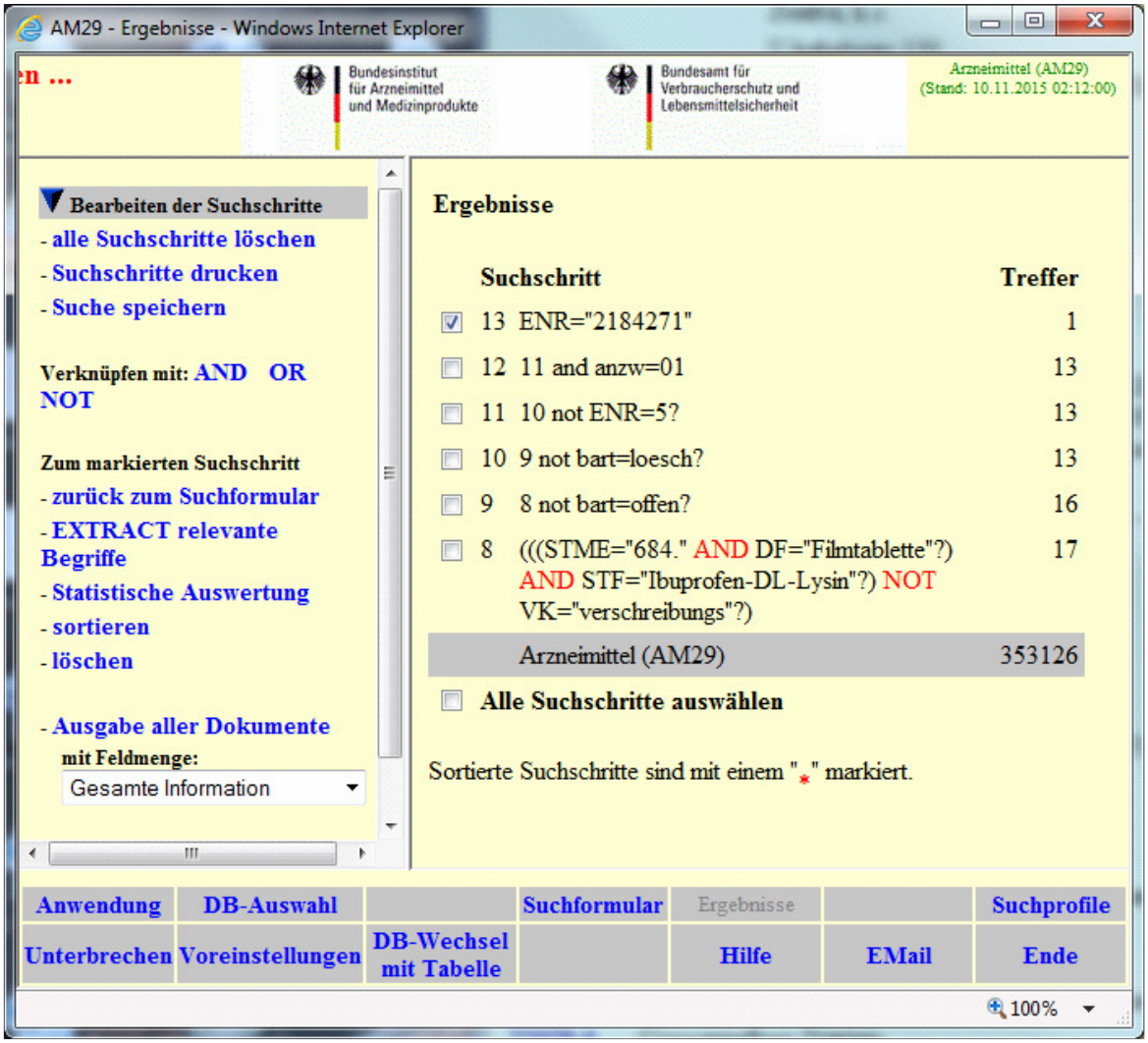
Mrz 13						1			1
Apr 13		1					3z	1	5
Mai 13		1							1
Jun 13		2	1						3
Jul 13		1	2z	2	1				6
Aug 13									0
Sep 13					3z				3
Okt 13		1	1						2
Nov 13								1	1
Dez 13									0
Jan 14									0
Feb 14									0
Mrz 14		2							2
Apr 14									0
Mai 14									0
Jun 14		1							1
Jul 14		1							1
Aug 14									0
Sep 14	1								1
Okt 14									0
Nov 14		1							1
Dez 14		1					1+2z		4
Jan 15	1	1							2
Feb 15							2z	1	3
Mrz 15	1								1
Apr 15									0
Mai 15		1							1
Jun 15									0
Jul 15									0
Aug 15									0
Sep 15									0
Okt 15									0
sum	16	89	17	13	25	14	41	26	241

AM87 research conduted with the BfArM internal data base on November the 22nd, 2015 and classified by Anja-Simone Wiedemann

Annex V

AM87 search profile, ibuprofen-containing OTC products

Annex 5
AM87 search profile, ibuprofen containing products



Annex VI

table 2 , ibuprofen-containing OTC products

Zul.-Nr.	Arzneimittelbezeichnung	Zulassungs-datum
37451.00.00	Dolormin extra	11.06.1998
44998.00.00	Dolormin Migräne Filmtabletten	22.02.1999
44997.00.00	Tispol Ibu-DD	22.02.1999
51452.00.00	Dolormin extra	24.09.2001
43917.01.00	Nurofen Immedia 400 mg Filmtabletten	18.09.2003
57568.00.00	Neuralgin extra Ibu-Lysinat	04.10.2005
57567.00.00	Thomapyrin TENSION	04.10.2005
79780.00.00	Ibu-LysinHexal 684 mg Filmtabletten	30.06.2011
79779.00.00	IBU-LYSIN-ratiopharm 684 mg Filmtabletten	30.06.2011
79874.00.00	Irfen 400 mg Filmtabletten	19.04.2012
83299.00.00	Ibuprofen Perrigo 400 mg Filmtabletten	11.03.2013
88909.00.00	Ibuprofen Pfleger 400 mg Filmtabletten	14.02.2014
86726.00.00	Ibuprofen Mylan 400 mg Filmtabletten	05.06.2014

Table 2, ibuprofen-containing OTC-products

Annex VII

table 3

Chronological, tabulated display of important aspects of the Fenisitl- and Aktren-decisions during April 2011 and February 2014

Table 3
Chronological, tabulated display of important aspects of the Fenisitl- and Aktren-decisions during April 2011 and February 2014
note: reference to marginal notes in the court decision is given in brackets

	1st Fenistil decision	**1st Aktren decision**	**2nd Fenistil decision**	**2nd Aktren decision**
court	VG Köln 7 Kammer	VG Köln 7 Kammer	OVG für das Land Nordrhein-Westfalen 13. Senat	OVG für das Land Nordrhein-Westfalen 13. Senat
date	April the 12th, 2011	April the 9th, 2013	June the 17th,2013	February the 2nd, 2014
reference number	7 K 4284/09	VG 7 K 2050/11	13 A 1113/11	13 A 1377/13
reason for action	name change application "Pencivir bei Lippenherpes" to "Fenisitil Pencivir bei Lippenherpes" rejected; MAH questions refusal of name change	name change application "Aleve" to "Aktren Naproxen" rejected; MAH questions refusal of name change	originally MAH gave notice of appeal, questioning the 1st Fenistil decision but than a new application to change the name had been submitted to BfArM; with the submission the main cause of the decision had been settled since the new name change negated the old one; court issued the decision, since it was of interest for the defendant	MAH gave notice of appeal, questioning the 1st Aktren decision
umbrella brand **active substance mode of action**	Fenistil dimetindene antihistamine	Aktren Ibuprofen NSAID	Fenistil dimetindene antihistamine	Aktren Ibuprofen NSAID
active substance to be integrated into umbrella brand, mode of action	Penciclovir virostatic agent	Naproxen NSAID	Penciclovir virostatic agent	Naproxen NSAID
Court decision in regard to section 25 sub-section 3 AMG	violation of 25 sub-section 3 sentence 1 AMG (m.n. 37)	violation of 25 sub-section 3 sentence 1 AMG (m.n. 42)	doubted the applicability of section 25 sub-section 3 sentence 1 AMG (m.n. 44)	no violation of section 25 sub-section 3 sentence 1 AMG (m.n. 21)
Reasoning in regard to section 25 sub-section 3 AMG	main part "Fenisitl" of the new name is relevant for evaluation, while lateral parts are of minor interest; main part of the name is considered to be the same as in previous product, but since active substance including mode of action changes this would be against the requirements given (m.n. 37)	main part "Aktren" of the new name is relevant for evaluation, while lateral parts are of minor interest; main part of the name is considered to be the same as in previous product, but since active substance changes this would be against the requirements given; (m.n. 41) interpretation is consistent with European requirements (m.n. 54)	note was given which doubted the applicability of the legal requirement, but a final answer or an explanation for this assumption had not been given (m.n. 44)	is only applicable if the names are identical in all parts of the name, therefore the integration of a umbrella brand into a multi-part name could be acceptable and does not automatically lead to violation (m.n.24)

Table 3
Chronological, tabulated display of important aspects of the Fenisitl- and Aktren-decisions during April 2011 and February 2014
note: reference to marginal notes in the court decision is given in brackets

	1st Fenistil decision	**1st Aktren decision**	**2nd Fenistil decision**	**2nd Aktren decision**
Court decision in regard to section 8 AMG	violation of 8 sub-section 1 sentence 1 No 2 AMG (m.n. 47)	violation of 8 sub-section 1 sentence 1 No 2 AMG (m.n. 59)	violation of section 8 sub-section 1 sentence 1 No 2 AMG (m.n. 48)	no violation of section 8 sub-section 1 sentence 1 No 2 AMG (m.n. 42)
Reasoning in regard to section 8 sub-section 1 Nr. 1 AMG	main part "Fenisil" would lead to the connection with the active substance (dimetindene) or at least it's antihistaminic mode of action therapeutical area left; (m.n. 53); lateral parts of the name like affixes in regard to indication are irrelevant in regard to consumer expectation since the main part is essential for forming opinion (m.n.54)	main part "Aktren" would lead to the connection with the active substance Ibuprofen, which the new product does not contain; lateral parts of the name like affixes in regard to active substance are irrelevant, furthermore in this case it could lead to the misleading assumption that the product contains ibuprofen as well as naproxen (m.n. 65)	main part "Fenisil" would lead to the connection with the active substance (dimetindene) or at least it's antihistaminic mode of action; therapeutical are left; lateral parts of the name like affixes in regard to indication are irrelevant in regard to consumer expectation since the main part is essential for forming opinion (m.n. 59-60)	decision on violation has to be based on the circumstances given for the individual case (m.n. 34 and 61); in regard to the present case the new name is not misleading since indications and side-effect spectrum are identical; therapeutical not left; (m.n. 63 -65) degree of brand awareness also applicable and minor in that case (m.n. 71-73); other similar umbrella brand concepts for pain indication already marketed (m.n. 74) ; Inclusion of the affix stating the active substance Naproxen sufficient to distinguish (m.n. 77)
standard of evaluation	OTC-status irrelevant for evaluation: healthcare professional would not be mislead but patient has to be considered (m.n. 49-53); well informed , considerate and rational standard consumer (m.n. 47); *Strengeprinzip* (m.n.47)	OTC-status irrelevant for evaluation: healthcare professional would not be mislead but patient has to be considered (m.n. 51-65); well informed , considerate and rational standard consumer (m.n. 59); *Strengeprinzip* m.n. 59)	OTC-status irrelevant for evaluation; healthcare professional would not be mislead but patient has to be considered (m.n. 50); well informed , considerate and rational standard consumer (m.n. 52); *Strengeprinzip* (m.n. 46) assertion was given that the court members were able to decide on the misleading character without additional evidence e.g. market research data (m.n. 62-64)	OTC-status irrelevant for evaluation; healthcare professional would not be mislead but patient has to be considered (m.n.45-46); well informed , considerate and rational standard consumer (m.n.47); *Strengeprinzip* (m.n.43) assertion was given that the court members are able to decide on the misleading character without additional evidence e.g. market research data (m.n.)

Declaration of Authenticity

Hiermit erkläre ich an Eides statt, die Arbeit selbständig verfasst und keine anderen als die angegebenen Hilfsmittel verwendet zu haben.

Bonn der 25.11.2015