PHARMA LEADERS
IP CONFERENCE 2015

23 September 2015

A day of discussion and debate on intellectual property issues and opportunities in the pharmaceutical sector
Pharmaceutical Trade Marks

September 2015

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C_{22}H_{30}N_{6}O_{4}S  \quad \text{C}_{26}H_{44}N_{2}O_{10}S
sildenafil citrate   salbutamol sulphate
Badge of...

- Origin
- Quality
- Reputation
- Safety / Trust
- Effectiveness
Choosing a Brand

- **Globally effective** (works in various languages, doesn’t have any negative connotations culturally)
- **Trade Mark Offices** insist the mark is distinctive and not descriptive and does not conflict with any earlier trade marks on record
- **Marketing department** wants a concise name that is related to the indication (generally causing problems on descriptiveness grounds)
- **Competitors** want you to stay away from their well established brands
- **Regulatory authorities** (the EMA in Europe and FDA in the US) are primarily concerned with patient safety
- **WHO** wants you to avoid using the INN as part of your brand name

Medicinal Products Directive
2001/83/EC

Regulation (EC) 726/2004
Routes to Authorisation (EU)

• Centralised Procedure

• Mutual Recognition Procedure

• Decentralised Procedure

• National Procedure (e.g. MHRA in the UK)
• “Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure”

• Naming Review Group (NRG)

• Committee for Human Medicinal Products (CHMP)
Guidelines

• EMA/CHMP/287710/2014 - Rev. 6
• 1 January 2015
Aloxi 13, Aloxi B, Aloxil 3?
# Salagen v Selegiline

<table>
<thead>
<tr>
<th>5 mg tablets</th>
<th>5 mg tablets</th>
</tr>
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<tbody>
<tr>
<td>Treats dry mouths conditions</td>
<td>To Treat Parkinson’s disease (generic)</td>
</tr>
</tbody>
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Telephone order made for Salagen

Selegiline supplied in response to telephone order

Source: EMA / ISMP
Legal Framework

Article 1 (20) of the Medicinal Products Directive (2001/83/EC):
“The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.”

Article 6 of Regulation (EC) No 726/2004:
“Each application for the authorisation of a medicinal product for human use (...), otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a single name for the medicinal product.”
NRG Meetings 2015/16

Deadlines for submission of proposed (invented) names and dates of NRG discussion/CHMP adoption follow the CHMP time schedule:

<table>
<thead>
<tr>
<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td></td>
<td>Submission deadline for new (invented) name applications and justifications</td>
</tr>
<tr>
<td></td>
<td>NRG meeting/discussion</td>
</tr>
<tr>
<td>28 November 2014</td>
<td>28 January</td>
</tr>
<tr>
<td>6 February</td>
<td>25 March</td>
</tr>
<tr>
<td>27 March</td>
<td>20 May</td>
</tr>
<tr>
<td>15 May</td>
<td>1 July</td>
</tr>
<tr>
<td>3 July</td>
<td>30 September</td>
</tr>
<tr>
<td>2 October</td>
<td>25 November</td>
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</tbody>
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Where Medication Errors Occur

- Prescribing: 39%
- Transcription: 12%
- Dispensing: 11%
- Administering: 38%

Source: EMA
NRG Considerations

The (invented) name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the (invented) name of another medicinal product.
NRG Considerations

- The indication(s)
- The patient population(s)
- The pharmaceutical form(s)
- The route(s) of administration
- The strength(s)
- The setting for prescription, dispensing and use
NRG Considerations

- Medicinal product subject to medical prescription
- Medicinal product not subject to medical prescription
- Medicinal product subject to special medical prescription
- Medicinal product subject to restricted medical prescription
- Medicinal product subject to special and restricted medical prescription
NRG Considerations

- Orphan (designation) status
- (Potential) new pharmaceutical forms, routes of administration, etc.
- Degree of similarity v. potential for harm
- Not convey misleading therapeutic indications
- Similar or allude to pharmaceutical company names
- Misleading with respect to composition
- Phonetics / EU languages
- Very short names potentially problematic
- Not convey a promotional message
- Not be offensive
- Not comprise wholly of initial letters (acronyms) or code numbers and should not include punctuation marks.
International Non-proprietary Name (INN)
acorafloxacinum
acorafloxacin 7-[(3E)-3-(2-amino-1-fluoroethylidene)piperidin-1-yl]-1-cyclopropyl-6-fluoro-8-methoxy-4-oxo-1,4-dihydroquinoline-3-carboxylic acid

acorafloxacine acide 7-[(3E)-3-(2-amino-1-fluoroéthylidène)pipérïdin-1-yl]-1-cyclopropyl-6-fluoro-8-méthoxy-4-oxo-1,4-dihydroquinoléïne-3-carboxylique

acorafloxacino ácido 7-[(3E)-3-(2-amino-1-fluoroetilideno)pipérín-1-il]-1-ciclopropil-6-fluoro-8-metoxi-4-oxo-1,4-dihidroquinolina-3-carboxílico

\[ \text{C}_{21}\text{H}_{23}\text{F}_{2}\text{N}_{3}\text{O}_{4} \]

\[
\begin{array}{c}
\text{OCH}_3 \\
\text{H}_2\text{N} \\
\text{F} \\
\text{F} \\
\end{array}
\]
Obtaining an INN

• International Nonproprietary Names: revised procedure (EB115/11 - 2004)

• File a request via the WHO
  https://extranet.who.int/tools/inn_online_application/

• The proposed name is reviewed/examined by the ‘INN Expert Group’ (which meets every six months) and published for comments / objections

• If no objections/oppositions are received after 4 months the proposed name obtains the status of a recommended INN
Process Flow-Chart

Phase I
- New INN application
  - Basic processing
  - Data validity check
  - Recording application

Phase II
- INN Expert’s Consultation
  - Experts discussion
  - Expert voting
  - Final decision

Phase III
- Implementation of decision
  - Final review and implementation
  - Applicant notified

Phase IV
- Publication in proposed list
  - Data finalised
  - Report generated
  - List number identified
  - List created

Phase V
- Publication in recommended list
  - Objections handling
  - Publication of amendments (if any)
INN Guidance

General Guidance:

http://www.who.int/medicines/services/inn/en/

- General principles for guidance in devising International Nonproprietary Names for pharmaceutical substances:
  http://www.who.int/medicines/services/inn/selection/en/

- On-line access to published INN:
  http://mednet.who.int
WHO Resolution (WHA46.19)

“It would therefore be appreciated if invented names were not derived from International Non-Proprietary names (INNs) and if INN stems were not used in invented names”
“The applicant/MAH is strongly advised to review INN similarity and/or INN stem inclusion before requesting that the proposed invented name(s) be considered for a medicinal product”

Guideline Para. 4.2
Similar to INN

PROPOSED DECISION TREE: Invented Name (IN) similar to INN

Invented Name (IN)

Similarity with

Own INN

- Closeness either in writing &/or speech identified
  - Yes: IN not accepted
  - NO: IN accepted

Different INN

- Closeness either in writing &/or speech identified, taking into account similarity in setting, &/or route of administration
  - Yes: IN not accepted
  - NO: IN accepted
Contains INN

PROPOSED DECISION TREE:
Invented Name (IN) containing INN stem(s)

Invented name contains INN stem

YES

Same therapeutic class

Public health concern identified

YES
IN not accepted

NO
IN accepted

Different therapeutic class

Similar medical setting, &/or Condition of use &/or route of administration

YES
IN accepted

NO
IN not accepted

IN accepted

IN accepted
**Outcome**

- NRG conclusions/recommendations presented to CHMP
- Applicant Informed of the outcome
- Reasons and source of any objection raised is provided
- Appeal process
- Submit additional names for approval
Trade Marks
Requirements for Trade Mark Registration

According to the EU Trade Marks Directive (89/104/EEC):

- **Not descriptive** (as regards, kind, quality, quantity, intended purpose, value, geographical origin, time of production, or other characteristics)
- **Not devoid of distinctive character** (i.e. banal, not likely to be viewed as a trade mark)
- **Not customary** in the language or bona fide and established practices of the trade
- Not contrary to **public policy** or accepted principles of **morality**
- Must not **deceive** the public (for instance as to the nature, quality, quality of geographical origin of the goods)
Article 8 (1) of the Community Trade Mark Regulation (40/94)

Upon opposition by the proprietor of an earlier trade mark, the trade mark applied for shall not be registered:

• (a) if it is **identical** with the earlier trade mark and the goods or services for which registration is applied for are identical with the goods or services for which the earlier trade mark is protected;
• (b) if because of its identity with or **similarity** to the earlier trade mark and the identity or similarity of the goods or services covered by the trade marks there exists a likelihood of confusion on the part of the public in the territory in which the earlier trade mark is protected; the likelihood of confusion includes the likelihood of association with the earlier trade mark.
Confusion

• Visual, phonetic and aural considerations

• Consideration of the goods, the channels of trade, uses and users

• Assess the likelihood of confusion given all of the relevant circumstances
Identical trade marks
Negative meaning
INN database
Inherent distinctiveness

Name creation

Initial screening searching
Top 50 - 100 names

Top 4 - 8 names

Full searches in home country

First filings

6 month priority period begins

Full searches in all markets of interest

Examination - distinctiveness - earlier rights

Application refused

Trade mark clearance work

Publication

Opposition procedure

International filing programme for top 3 marks within 6 months of first filing

Registration

Registration within two years (3 - 4 if opposed)
When?

- 3 - 4 years to generate and register a trade mark globally for a single product
- Several hundred candidate names for 1 registration and 2 back up marks
- Initial screening / testing (analysing how the mark looks when written by hand, INN issues, linguistic issues, etc.)
- Trade Mark searching wherever the product is to be sold (starting with key markets; usually EU and US)
- Start process during **Phase I** or start of **Phase II** clinical trials
The Future?

Have a break, have a KitKat
Any Questions?
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