Overview of the Pharmaceutical Regulatory Environment in Italy

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Management of Intellectual Property in Pharmaceutical Industries

Intellectual Property protection is essential to sustain pharmaceutical sector’s continuing investments in new research and development.
Legislation:

- **Italian Leg. Decree No. 219/2006** (and amendments) implementing directive 2001/83/EC of the EU Parliament on the **Community Code relating to Medicinal Products for Human Use** (and amendments)

- **Italian Intellectual Property Code**  
  Decree No. 30/2005

- **Consumer Code**  
  (Legislative Decree 206/2005) for product liability claims
Pharmaceutical companies invest in years of R&D and a lengthy regulatory approval process before their products ever reach the market.

IP laws are intended to give the investors an opportunity to recoup their costs through:

✓ Patents
✓ Trademarks
✓ Designs
✓ Copyright
Pharmaceutical Trademarks

Issues relate to the choice of the name of the drug

1. Risk to be generic

Pharmaceutical trademarks risk being ‘weak’ since tend to describe or suggest their active principles or their therapeutical effects
II. EU Pharmaceutical Names undergo Assessment by two Separate Authorities

**Health Authorities** (Obligatory)
- EMA (European Medicines Agency)
- National Healthcare Authorities (Ministry of Health and AIFA)

**Trademark Offices** (Optional)
- OHIM
- National Trademark Office (UIBM)
Registration of a Pharmaceutical Name with EMA (European Medicines Agency):

Art. 1 (20) of Directive 2001/83/EC (relating to medicinal products for human use)

The name of the medicinal product may be either:

1) an invented name

2) a common or scientific name, accompanied by a trade mark

3) the name of the marketing authorisation holder
Registration of a pharmaceutical name with EMA (European Medicines Agency):

The (Invented) Name Review Group (NRG) reviews the invented names of medicinal products being assessed by the EMA.

**Main role:**

to consider whether the invented name proposed by a product's manufacturer could create a public-health concern or potential safety risk (*part of the Agency’s role in evaluating the safety of medicinal products in the centralised marketing authorisation procedure*).
1) an **invented name** must not:

- be liable to cause confusion with the common name or with the (invented) name of an existing medicinal product in print, handwriting or speech;
- convey misleading therapeutic connotations;
- be ambiguous with respect to its composition.
2) a **common or scientific name**, usually refers to the **International Non-proprietary Name (INN)** administered by the World Health Organization. These names are public property (i.e. generic).

**INN** is a unique identifier for every pharmaceutical drug, globally recognized.
Criteria for assessing the likelihood of confusion by the EMA:

- Conveyance of misleading therapeutic and/or pharmaceutical connotation;
- Conveyance of misleading information with respect to the composition of the products;
- Possible confusion in print, handwriting or speech with an existing medical product;
EMA evaluates the safety of a drug as well by assessing:

- whether the name will cause the product to be confused with another by examining what medical problem the products will be used to treat;
- How the drug is administered;
- How the product will be supplied (i.e. by prescription)
Case of Pharma Regulatory Agency Rejection

✓ On 2001, the Committee for Medicinal Products for Human Use (CHMP) rejected the marketing authorisation for Genzyme Europe B.V.’s CAMPATH, intended as a treatment of patients with chronic lymphocytic leukemia (CLL) due to the presence of Pfizer’s product CAMPTO, used to treat cancer.

CAMPATH was then converted into MABCAMPATH.
A trademark application may be rejected or opposed on the basis of

**Absolute grounds**

MUST BE:
- Distinctive
- Capable of being represented graphically

MUST NOT BE:
- Descriptive
- Deceptive
- Contrary to public policy

**Relative grounds**

MUST NOT BE
- Confusingly similar to a pre-existing registered mark
- Based on the reputation of an earlier trademark registered or applied for dissimilar goods or services
Criteria for assessing the likelihood of confusion by the Trademark Office:

- comparison of signs
- comparison of goods and services
- relevant public/the average consumer of the products

Challenging in the pharmaceutical sector
Two Strands of Case law

Over-the-Counter-Medicines

✔ Healthcare professionals (doctors and pharmacists)
✔ Patients

Case: RESPICUR v. RESPICORT (CJEU, T-256/04)

Prescription-only-Medicines

Former case law:

✔ Healthcare professionals (doctors and pharmacists)

Cases:
- MEDREL v. MEDROL (OHIM, R 366/01-4)
- RIBOMUNYL v. RIBOMUSTIN (OHIM, R 304/03-1)
- QUARTAMIN v. TAMIN (OHIM, R 1154/00-4)

Recent case law:

✔ Healthcare professionals (doctors and pharmacists)
✔ Patients

Case: TRAVATAN v. TRIVASTAN (CJEU, C-412/05)
Case Law

Italian and EU decisions ruling on likelihood of confusion among pharmaceutical trademarks are almost homogeneous.
**Case R 2387/2014-5**  
*(OHIM - Fifth Board Of Appeal - Decision Of 26 November 2014)*

<table>
<thead>
<tr>
<th><strong>TEVA PHARMACEUTICAL INDUSTRIES LIMITED</strong></th>
<th><strong>CYTOCHROMA DEVELOPMENT INC.</strong></th>
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<tr>
<td><strong>ALPHA3</strong></td>
<td><strong>ALPHAREN</strong></td>
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<tr>
<td>Class 5: pharmaceutical preparation for regulating calcium</td>
<td>Class 5 – Pharmaceutical and veterinary preparations containing magnesium iron hydroxy carbonate or hydrotalcite for pharmaceutical and veterinary purposes; pharmaceutical and veterinary preparations for use in renal dialysis and in the treatment of renal diseases and kidney ailments; phosphate binders for use in the treatment of hyperphosphataemia</td>
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</table>

- **Comparison of the signs**: visually, phonetically and conceptually similar to a certain extent.
- **Comparison of the goods**: highly similar.
- **Relevant public**: kidney patient consumer (reasonably well informed, observant and circumspect since these products affect their state of health)
GLAXOSMITHKLINE SPA  
LABORATÓRIOS WELLCOME DE PORTUGAL  
THE WELLCOME FOUNDATION LTD  
(jointly ‘The Applicants’)

OHIM  
SERONO GENETICS INSTITUTE SA

**LANOXIN**

Class 5: medical, pharmaceutical substances

**FAMOXIN**

Class 5 – pharmaceutical preparations for the treatment of metabolic disorders adapted for administration only by intravenous, intra-muscular or subcutaneous injection

- The Applicants filed three applications before the OHIM for declarations of invalidity of CTM FAMOXIN, relying on their earlier trade mark registrations LANOXIN.

- The Cancellation Division rejected cancellation applications. The decision was appealed by the Applicants. According to the First Board of Appeal, the signs were only slightly similar in light of their visual and aural differences as well as a low level of conceptual similarity. Therefore it dismissed the appeal.

- The CJEU upheld the Board of Appeal’s decision on the basis that the public’s degree of attentiveness was higher than average and therefore there was no likelihood of confusion between the signs.
Decision N. 27/2014  
(UIBM – Italian Trademark Office -  
Opposition Division - Decision Of 4th March 2014)

SUDMEDICA GMBH CHEMISCH  
SCHEMBARI ITRIA

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<th>EUFLUX</th>
<th>v.</th>
<th>FLUX</th>
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<td>Class 5: pharmaceutical preparations</td>
<td></td>
<td>Class 5 - mixes and syrups aids in recovery the physiological function of the respiratory tract</td>
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☑️ **Comparison of the signs**: high visual, phonetical and conceptual similarity between the signs.

☑️ **Comparison of the goods**: highly similar.

☑️ **Relevant public**: patient consumer, reasonably well informed but without a level of technical knowledge comparable to that of health care professionals that would allow them to distinguish between pharma products marked with similar brands.
Court of Appeal of Milan
Decision of 30 March 2010

BAYER AG and
BAYER S.P.A.

ELABORADOS DIETETICOS S.A. (ED)

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<th>ASPIRINA</th>
<th>v.</th>
<th>HERBASPRINA</th>
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<tr>
<td>Class 5: pharmaceutical preparation</td>
<td></td>
<td>Class 5 – foods and beverages dietetic substances adapted for medical use</td>
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- In 2005, the Court of Milan declared ED's "HerbAsprina" invalid and granted Bayer's claims for damages.

- ED appealed to the Court of Appeal of Milan, arguing that the Bayer's ASPIRINA was widely used by Italian consumers to cure generic diseases, thus becoming the generic name to identify the products.

- The Court found that sometimes ASPIRINA is used to describe a category of medicinal remedies. However Bayer's continuous legal enforcement of its trademark was sufficient to establish that ASPIRINA has not become the generic name of the product and, therefore, the trademark was not invalid.
To maximize the chances for approval of a trademark for pharmaceuticals it is also useful to:

- Carry out a trademark clearance search in key countries jurisdictions;
- Avoid signs which have evident similarities to existing trademarks/generic names;
- Avoid incorporating evident references to ingredients.
Trademark Prosecution and Enforcement in Italy

- Administrative route;
- Pre-litigation;
- Judicial route.
1) Administrative Route

On July 2011, the Italian Ministerial Decree No. 11 May 2011 introduced the **Opposition procedure** in Italy.

✔ The Italian opposition procedure has been designed along the lines of the opposition proceedings before the OHIM.
IPTO has issued around **220 decisions**, but very few in the pharmaceutical sector:

- Clothes and accessories: 24%
- Other services: 38%
- Cosmetics: 6%
- Pharmaceutical: 4%
- [Nome Categoría]
2) Pre-litigation

Finding a Out of Court Solution...

**Cease & Desist letter:**
usually advisable strategy but not always!

**Pros:**
- low cost;
- Reduces risk of litigation;
- possibility of finding a ‘compromise’ resolution.

**Cons:**
- Opponent take pre-emptive action;
- Jeopardize possible claimant strategy.
3) Judicial Route

A. Preliminary Proceedings

B. Proceedings on the Merits

KEEP CALM
Preliminary Proceedings

Timings: 1-3 months

**Jurisdiction:**
Commercial Chambers (specialized in IP matters)

Preliminary injunctions can be requested either before or after commencement of proceedings on the merits.

Petitioners submit a motion and provide sufficient evidence of prima facie case and irreparable harm. Delay in seeking relief may have a negative impact on the request.

Possibility to appeal the order (within 15 days from issue)
Proceedings on the Merits

Timings: 2-3 years

Jurisdiction:
Commercial Chambers (specialized in IP matters)

Possibility to instigate preliminary proceedings in the framework of the main action.

Possibility to appeal the first instance decision and right of further appeal.
Further key aspects of branding for pharmaceutical companies
Italian Decree 219/2006 lays down certain minimum requirement to be included in the labelling, basically concerned in ensuring a degree of standardization with the EU, including the following:

- Medicinal products marketed with different indications in the EU shall list all the indications in the leaflet.
- The outer packaging must bear:
  - name of the marketing authorization holder;
  - name of any company responsible for marketing the medicinal product
- Reimbursable products must have a special bar code stamp identifying the product.
Repackaging

Repackaging of pharmaceutical products is allowed only if:

- It is **strictly necessary** (i.e. in order to avoid confusion with similar products);
- **Cannot affect** the original product inside the packaging;
- The new packaging clearly states the **name of the manufacturer** and of the company which repackaged the drug;
- The new packaging should not damage the **trademark reputation** nor that of its owner (i.e. be of poor quality, defective...);
- The importer should **give notice** to the trademark proprietor before the repackaged product is put on sale.
MARKETING

No medical product can be put on the market without either an:

✓ AIFA authorization (AIC)
✓ EU authorization granted in accordance with EMEA Regulation

The European system offers the following routes for the authorization of medicinal products:
✓ **centralised procedure**: lead to the granting of a European marketing authorisation by the Commission - binding in all Member States

✓ **mutual recognition procedure**: based on the principle of recognition of an already existing national marketing authorisation by one or more Member States.

✓ **decentralized procedure**: submitted simultaneously in several Member States, one of them being chosen as the "Reference Member State". National marketing authorisations are granted in Reference State and in other concerned Member States.
Advertising of Medicinal Products
(Art. 86 ff – Community Code relating to Medicinal Products for Human Use)

✓ is only possible for medicinal products for which a MA has been granted;

✓ should encourage the rational use of the product by presenting it objectively and without exaggerating its properties.

✓ shall not be misleading
Advertising of **Prescription-only Medicines** to consumers **is prohibited** in Europe.

These can only be promoted to **general practitioners and pharmacists** in specific circumstances.

All other advertisements of medicines require **authorisation from the Italian Ministry of Health**.
Risks associated with Social Media

Social media represents the most dynamic marketing tool available to business. However, pharma companies should consider that they might be responsible for:

- any communications on their own website, discussion boards, feeds, posts on their social media pages;
- employees’ communications on social media channels where the communications relate to company products or business activities;
- third party user generated content ("UGC") on social media channels over which the company has control, or which the company sponsors.
Pharmaceutical Companies Events

Pharma Companies can cooperate or contribute, either by direct or indirect funding (in Italy or abroad), to the organization of congresses, conferences and meetings.

However they are subjected to a mix of administrative and criminal statutes.
Pharmaceutical Companies Events

Art.124 of LD 219/2006 (Leg. Decree implementing the Community Code relating to Medicinal Products)

**Absolute Prohibition** to use events as a showcase for directly advertising medical products.

When the event is related to **the use of drugs manufactured or distributed by the company**, it is subjected to a **formal notification to the AIFA** which should authorize the event.
Pharmaceutical Companies Events

✅ **Farmindustria Guidelines** (Italian Association of Pharma Companies)

In order to avoid that events organized by pharma companies influence the neutrality of people involved (i.e. doctors, managers of Public Entities, etc.), Farmindustria strongly recommends **the adoption of an organizational model for management and control** able to:

- Reduce the risk of criminal offences
- Demonstrate that any and all policies and procedures are adopted with this purpose
- Demonstrate that the Company is in full control of the investments made for events and direct or indirect promotional activities are in compliance with applicable rules and guidelines
Cosmetics

Cosmetic products are substances or mixtures of substances intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, etc.) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Art. 2.1(a) Regulation (EC) of 1223/2009
Advertising Cosmetic Products

LEGISLATION:

✓ Code of Marketing Communication
  (IAP - 59th edition effective January 1st, 2015);

✓ Guidelines of Italian Antitrust and Advertising Authorities;

✓ Consumer Code
  (Legislative Decree 206/2005)

✓ Unfair Competition Provisions, Art. 2985 c.c.
Marketing communication relating to cosmetics and personal hygiene products **should not encourage the belief that such products have characteristics, properties or functions other than** to be applied to

- the external parts of the human body,
- mouth or teeth for the exclusive or primary purpose of cleaning, freshening, changing their appearance or protecting them

in order to keep the body in good health or correct body odours.
Marketing communication may not present these products as having additional features preventing particular pathological conditions, provided they actually contain specific ingredients or formulations with such effects.

Under no circumstances, however, should consumers be led to consider cosmetic or personal hygiene products as substitutes for medication, medical aids, medical devices or therapeutic treatments.
Guidelines
AGCM (Italian Antitrust and Advertising Authority)

1) a cosmetic is not a drug;
2) pay special attention with promises of results;
3) reference to clinical tests only if relevant and accessible;
4) the maximum value obtained in trials does not represent the efficacy of the product;
5) clear limits of efficacy;
6) innovation claims only if scientifically demonstrated;
7) claim a patent only if granted;
8) self-assessment tests are different from scientific tests.
Remedies to Protect against Unfair Advertising by Competitors

Pre-litigation Strategies

- C&D Letter

Litigation

- Civil Court
- Advertising Authorities
  - IAP – Italian Advertising Authority
    (Istituto Autodisciplina Pubblicitaria)
  - AGCM - Italian Antitrust and Advertising Authority
    (Autorita’ Garante Concorrenza e Mercato)
L’Oréal Italia S.p.A. instigated proceedings against Henkel Marketing Communication before the IAP related to a hair colour marketing campaign ‘Igora Senea’, which was considered to be misleading.

The advertisement material stated that the product was recommended by dermatologists and Proderm (a private independent Institute) which could lead consumers to believe that the product had no health risks.

The Advertising was held to infringe Art. 23 of Code of Marketing Communication.
Decision N. 88/2011
(Italian Advertising Authority (Giurì) - Decision of 12th July 2011)

Henkel argued that the product was directed to a specialized public (hair-stylists only) thus avoiding any risk of deception.

The GIURì found the communication to be misleading since the product was directed both to experts in the sector and consumers and Henkel was ordered to cease use of this advertising claim.
An Italian woman instigated proceedings against the manufacturer of a tanning lotion (Eurocosmesi SpA) claiming compensation for damages suffered for second and third degree burns with permanent after-effects, allegedly due to the use of the tanning lotion.

- The Court of first instance ruled in favor of the Claimant.
The Court of Appeal of Catania and then the Supreme Court overturned the first instance decision finding in favour of Eurocosmesi SpA stating that:

- the damage per se was not sufficient to establish the manufacturer's liability, unless it could be ascertained that the product did not comply with the standards of safety prescribed by law.

Italian Supreme Court – Decision of 13 December 2010, No. 25116
Thank you for your attention

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