Medical Advisor

Regulatory and Legal Aspects

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HEALTHCARE MARKETING
DR. UMBACH & PARTNER
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"Incorrect" Marketing

US Department of Justice vs "Big Pharma"

Pharma companies paid the following fines (Million US-Dollars) for improper marketing, mostly off-label promotion

Pfizer	2300	Eli Lilly	1400
Allergan	600	AstraZeneca	520
Novartis	442	BMS	515

Off-Label-Promotion?

"… should remind drug companies that try to cleverly design off-label marketing schemes that we will not allow them to compromise patient safety."

U.S. Attorney Ronald Machen

Off-Label Use: Basics

The regulatory system exists to protect patients by ensuring that marketed medicines meet three criteria of acceptable standards, namely safety, quality and efficacy in their indications.

Nonetheless, the use of medicines outside their authorised indications is possible and common: “off-label use”

Off-Label Use: Physicians

Good medical practice and the best interests of the patient require that physicians use drugs and devices according to their best knowledge and judgement.

If physicians use a product for an indication not included within the approved labelling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.

Exceptions

European medicine legislation does not apply to the following:
- medicines prepared in a pharmacy in accordance with a medical prescription for an individual patient (the ‘magistral formula’)
- medicines prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy (the ‘officinal formula’)
- medicines for research and development trials, covered by the “Clinical Trials Directive” (Directive 2001/20/EC)
- intermediate products intended for further processing by an authorised manufacturer
- any radionuclides in the form of sealed sources

European Regulatory System: SmPC

The terms in which a marketing authorisation is granted are specified in the Summary of Product Characteristics (SmPC), to which all advertising must comply.

The SmPC contains detailed provisions covering indications, recommended dosage, contra-indications, special warnings and precautions, and adverse effects associated with the medicine.

Special Populations and Therapeutic Areas

Off-label prescribing of medicines, and the prescribing of unlicensed medicines, is common in the areas of oncology, obstetrics, and infectious disease in particular in HIV/AIDS.

It is particularly common in the paediatric population.

Off-Label Use in Children

Many drugs used in children are either not licensed or are prescribed off-label.

A survey found out that at general paediatric surgical and medical wards 36% of children received at least one drug that was unlicensed or off-label during their in-patient stays.

In paediatric intensive care this figure may increase to 70% and in neonatal intensive care even up to 90%; in five European countries almost half of all prescriptions were either unlicensed or off-label.

New Paediatric Regulation

Following initiatives taken by the FDA to create incentives and obligations to conduct trials in children:

The European Commission published its own proposals, and in January 2007, a new Paediatric Regulation came into force, which established a system of incentives and requirements to improve the availability of licensed medicines for children.

No license without a PIP

The paediatric investigation plan (PIPs) requirement applies for all new medicines.

Furthermore it even applies, if a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorised and patented.

Numbers of PIPs

More than 1100 paediatric investigation plans have been submitted by the pharmaceutical industry within the last five years at the European Medicines Agency in London.

The EMA hosts the Paediatric Committee, Which meets every month for three days in order to discuss and decide upon all ongoing PIP procedures.