

Social Media and Mobile Applications

New Trends and their Legal Traps

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Changes in Marketing (I)

- Traditional marketing and advertising was based on unidirectional media
 - print media,
 - television and
 - Radio
- Internet and social media has changed the world of communication in the past 15 years

Chances of Social Media

- Direct access to patients and physicians
- Provision of additional information, e.g. lifestyle information related to certain diseases
- Collection of feedback from patients and physicians regarding a certain product
- Information about upcoming trends
- Disease awareness campaigns

Challenges of Social Media

- Misleading advertisement for drugs
- Infringement of advertising limits, e.g. in case of Rx-products
- Liability for statements of third parties
- Product liability issues, i.e. product surveillance obligation
- Disguised advertisement
- Data protection aspects
- Mobile Apps can be Medical Devices

Advertising Limits – Example

- Advertising of Rx medicinal products, physicians, etc. is limited in many countries
- No advertising for prescription only medicinal products vis-à-vis the general public, e.g. patients
- Providing information related to Rx medicinal products in social media might be considered as being advertisement
- mentioning of name of a Rx-product and information in SPC does not constitute advertisement

Disguised Advertisement – Examples

- Advertisement has to be clearly identified as such by addressees
- Prohibition of disguised advertisement in many jurisdictions
- Providing information related to medicinal products, physicians' services, etc. can easily constitute disguised advertisement

Pharmacovigilance – Examples

- Pharmaceutical entrepreneur has to report cases of suspected adverse events to competent authorities
- Challenge in practice: proper surveillance of the existing channels for receiving adverse events reports
- Traditional reporting ways: report form, letter, fax, email
- Using social media (Facebook, Twitter, LinkedIn) creates new channels for reporting adverse events
- Communication channels have to be monitored by pharmaceutical entrepreneur (in Germany)
- What happens if an adverse event is reported to an employee of the company via LinkedIn?

Medical Device Law - Examples

- Mobile Apps used in Healthcare Sector can be Medical Devices under MDD if it is intended to be used for
 - diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
 - investigation, replacement or modification of the anatomy or of a physiological process,
 - control of conception,

Medical Device Law - Examples

- Manufacturer defines intended use of device
- Risk classification of software according to Annex IX of MDD
- Software as a medical device may be an
 - Active medical device!
 - Active therapeutical medical device?
 - Active diagnostic medical device?
- Further assistance for use of classification rules in part III of Annex IX of MDD
- Mobile App has to undergo a Conformity Assessment and needs to bear a proper CE-marking if it is a Medical Device

Follow Up – Examples

- Information provided by manufacturer related to medicinal products and medical devices has to be up to date
- Easy in case of unidirectional advertisement
- Challenges in case of Facebook, Twitter and other social media
- Old information has to be deleted and replaced by updated information
- Is it possible to secure that no old information is available?
- Who is responsible for the follow-up?

Data Protection – Examples

- EU data protection law requires an informed consent by data subject for collecting, using and storing personal data
- In some limited cases personal data can be collected, used and stored without a consent
- Additional requirements for sensitive personal data, such as personal health data
- Transfer of personal data to third countries (outside the EU) is subject to specific requirements (safe-harbor-agreement)

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