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Läkemedelsinformation från Läkemedelsverket, Finland

Drug information from the National Agency for Medicines, Finland



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TABU julkaisee lähinnä lääkevalvontaa, lääkehuoltoa sekä terveydenhuollon laite- ja tarvikevalvontaa käsitteleviä kirjoituksia. Julkaisu tarjoaa palstatilaansa myös lääkeasioista kiinnostuneille keskustelijoille. Lehdessä julkaistut kirjoitukset eivät edusta Lääkelaitoksen virallista kantaa, ellei nimenomaan toisin mainita. Kirjoitusten sisältöä voi lainata lähde mainiten. Kokonaisen kirjoituksen lainaamiseen tulee kuitenkin saada kirjoittajan lupa.

TABU publicerar närmast artiklar om läkemedelsövervakning, läkemedelsförsörjning samt övervakning av medicintekniska produkter. Också debattörer med intresse för läkemedelsfrågor bereds spaltutrymme. De artiklar som publiceras i TABU representerar Läkemedelsverkets officiella ståndpunkt om och endast om detta uttryckligen omnämns. Innehållet i artiklarna kan citeras med angivande av källan. För återgivning av en hel artikel erfordras emellertid tillstånd av artikelförfattaren.

TABU publishes mainly articles dealing with medicines control, pharmaceutical services, and the control of medical devices. The periodical also serves as a forum for debate or discussion input from authors sharing an interest in the subject matter. The articles published in TABU do not reflect the official views of the National Agency for Medicines, unless specifically stated otherwise. Any articles published may be quoted provided that the source is mentioned. An entire article may, however, not be reproduced without obtaining the author's permission prior to publication.

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Fimea – the Finnish Medicines Agency – starts its work

Fimea is a key agency of the Ministry of Social Affairs and Health, promoting the health and safety of the population through the regulation of drugs and blood and tissue products, and by developing the pharmaceutical sector. The agency's responsibilities lie in the areas of marketing authorisation and regulation, and research and development. A legislative basis has been established for the new Finnish Medicines Agency, Fimea. The Parliament ratified the Act on the Finnish Medicines Agency on 16.6.2009, and a decree based on this Act was issued on 13.8.2009.

Future challenges facing the pharmaceutical sector include an ageing population, the increasing use of medicines, ever more complex medical treatments, and growing cost pressures in the social and healthcare services system. Meeting these challenges is one of the aims of the reorganisation of the administration of pharmaceutical services, which is based on the principles of the *Social and Healthcare Strategies 2015* of the Ministry of Social Affairs and Health. The legislation provides a basic framework, but will not solve everything. The organisational structure of the agency, its management system and strategic starting points and choices will create a basis upon which the newly-established agency can work to meet the challenges facing it.

What should the characteristics and working principles of the new agency be? It should be a totally new actor whose core expertise should be not only ensuring safe and effective pharmacotherapy, but also developing the pharmaceutical sector and furthering cooperation, managing information in the pharmaceutical sector, and using it effectively. The Finnish Medicines Agency is an independent, international force that is prepared to commit to what it believes in. It will do everything in its power to promote the safety of drugs and pharmacotherapy as a single entity. It safeguards a targeted and effective chain from the laboratory to the consumer. It is strategically important that the agency is also prepared to actively predict prevailing trends in the industry, and developments in its own area of activity.

We must keep at the forefront of developments rather than remain at a standstill, or even go into re-

verse. Legislative preparatory documents regarding this administrative reorganisation – for example the government proposal relating to the administrative act on the agency – include a number of sections providing guidelines for developing the new agency, such as the following: *the aim of the agency should be to further improve customer service and the effectiveness of working methods in pre- and post-regulation*. Within the context of the agency's responsibilities relating to marketing authorisation and regulation in the pharmaceutical services field, its aims include developing novel solutions relating to information technology and administrative organisation, for instance enabling the use of electronic customer contacts and automated office administration systems. Aims relating to restructuring include identifying working methods and processes that are in need of development, and on that basis enhancing their appropriateness for customers in order to generate added value for interest groups and customers of the agency.

From the point of view of the population, it is important that the efficacy, safety and quality of drugs used in Finland are safeguarded by means of effective drug regulation. From the point of view of society, it is important that drug regulation guarantees effective and efficient medical treatment, to allow people to recover quickly from diseases which reduce their capacity to work, and enable them to remain working until as late an age as possible. The principal aim for the agency here is to use its new responsibilities relating to research and development to monitor more closely the views of the population and patients who use medicines in the pharmaceutical field, within the context of social and health care. The Finnish Medicines Agency has the opportunity to generate research data to back up medico-political decision making. It also has the opportunity to contribute to slowing the growth of drug costs, and to generate added value for its interest groups and customers in accordance with its social aims.

We have the means at our disposal, and are now fine-tuning the Fimea engine together, to enable us to respond to future challenges.

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An increase in subliminal drug advertising is a concern for the authorities

TV soaps and social media are attracting drugs distributors

Over the past year, from 2008 to 2009, NAM was forced to intervene on as many as ten separate occasions in cases where information about prescription drugs had been disseminated to the public via various media. Increasingly, pharmaceutical companies are placing information about prescription drugs in real-life contexts, where they occupy a grey area between subliminal advertising and legitimate marketing. Companies are well aware that prescription drugs cannot be marketed directly to the public. In order for drug marketing to be lawful, it must be neither misleading nor inappropriate. Companies looking to grow by increasing their visibility on the market are nevertheless keen to identify new ways of distributing information about drugs. Today's communication and marketing channels give pharmaceutical companies the opportunity to employ new ways of working. Social networking websites attract companies wishing to make their information about prescription drugs more widely available, for example by placing references to the drug's trade name online. The most popular new media include the website YouTube and Finnish TV soaps and radio programmes. Information is disseminated inconspicuously and without the audience having requested it, either via the media or in locations encountered by people in their everyday lives.

In the summer of 2009 NAM found it necessary to examine the type of information currently available to members of the public who perform an internet search on the trade name of a specific prescription drug. A survey was carried out whereby statistical data were gathered on the basis of the Google hits obtained when the names of one hundred new prescription drugs were entered. The drugs' trade names were entered and the hits obtained were classified, and the sequence in which they appeared recorded (table). The survey considered Finnish search results only.

Certain websites appeared very frequently among the search results. Among the top hits were usually the websites of the European Medicines Agency (EMA)

Table. When an internet search was performed for the names of one hundred different medicinal products, the 100 pages of search results contained links to 948 different websites in total. The combined hits obtained by entering one hundred product names were as follows:

On 100 pages of hits	948 hits in total
80 % Lääkeinfo.fi web pages	96 hits from 100 searches
76 % EMEA web pages	136 hits
66 % Helsinki University Pharmacy web pages	117 hits
66 % Terveystoiminta	102 hits
53 % Tohtori.fi	65 hits
53 % Finnish pharmaceutical company web pages	84 hits
48 % Web pages related to therapeutic indication of drug	68 hits
47 % European Commission web pages	74 hits
43 % NAM web pages	62 hits
31 % Suomi24.fi	48 hits
15 % The Pharmaceutical Pricing Board web pages	15 hits

or the National Agency for Medicines (NAM). The official summaries of product characteristics (SPC), package information leaflets (PL) approved by the authorities, or evaluation reports (EPAR) are published on these websites for the various drugs. The EMEA website gives the SPCs and PLs of products which have been granted marketing authorisation via the centralised procedure, while the NAM website gives details of those products with marketing authorisation obtained via other procedures. The next most common hits were from the pharmaceutical companies' own websites, press releases, and Finnish healthcare or medical sector portals, particularly the *Terveystietti* website (maintained by Duodecim) and the sites *tohtori.fi* and *verkkoklinikka.fi* from Coronaria. Search results also often included the Helsinki University Pharmacy website. Other search results included, for example, web pages named after specific therapies and sponsored by pharmaceutical companies, and the websites of patient associations.

Regarding product placement and subliminal advertising

Product placement has become an increasingly popular form of marketing. When applied to drugs, product placement is where a prescription drug appears in a context in a radio or television programme, or on the website YouTube, or in a newspaper article. People will not necessarily see this as sales promotion, but ultimately it is. Product placement raises awareness of a certain medicinal product and conveys a positive impression of that product. In the most glaring cases, the product will be mentioned by its trade name, and in some cases its name and packaging will appear together in the same image. Occasionally, only the company name and logo will be apparent. Product placement

Regulation of drug marketing

- *According to Section 91a of the Medicines Act (395/ 1987), prescription drugs may not be marketed to the general population. In order to meet freedom of speech requirements, neutral writing which is not aimed at promoting sales is permitted.*
- *Again according to Section 91a, drug marketing must not encourage people to use drugs in cases where they are not strictly necessary, must not give a misleading or exaggerated impression regarding the concentration of the product, its origin or its medical significance, and generally must be appropriate. In short, drug marketing must not be misleading.*
- *According to Section 25 of the Medicines Decree (693/ 1987), drug marketing includes all measures relating to communication and order procurement, with the aim of promoting the prescription, supply, purchase or consumption of drugs.*
- *Freedom of speech requirements also apply to communications relating to diseases, symptoms, and alternative forms of treatment. However, if a communication of this kind aims to promote sales of one or more medicinal products, then it is considered marketing. It is commonly considered that communications made by the pharmaceutical industry in connection with health issues must be balanced and objective, and indeed the National Agency for Medicines expects this. Information provided about various therapies must be balanced and, if reference is made to a medicinal product, all products on the market must be mentioned on equal terms. Communications regarding health issues where only one product is available for the prophylaxis of a certain disease are not acceptable. In that case, the communications would always be considered marketing.*

provides the viewer, listener or reader with information about a drug or a pharmaceutical company without his or her choosing to receive that information.

The National Agency for Medicines monitors the appropriateness of drug marketing. This monitoring work is managed according to the stipulations of the Medicines Act and Decree. Product placement of most other products in Finland apart from medicinal products is monitored by the Finnish Consumer Agency.

On its website, the Consumer Agency provides the following guidelines for companies regarding the legal principles relevant to product placement: *Through product placement of products, services, trade names etc. in various programmes, manufactures*

and distributors of products and service providers usually intend to increase sales of their products by boosting their visibility, i.e. it is usually done intentionally, for advertising purposes. Consumers always have the right to know when they are being influenced in their perception of a product.

What type of information can be accessed by the public by running an internet search on the name of a drug?

The purpose of the survey was to establish the type of information that people can access about a prescription drug when they perform an internet search on a product name. A table was compiled of the search results obtained when the name of a new

medicinal product was entered in a search engine, and the data obtained were analysed. The aim was to build up a general picture of the information available, and to see whether the information complied with the pharmaceutical legislation. The website YouTube was also examined to see whether drug information came up when a search was performed for the various product names. The survey was carried out as part of NAM's work on drug marketing regulation.

The survey looked primarily at the information available online about one hundred new products, all with marketing authorisation, and all available on the Finnish market. The products were introduced onto the market in the years 2006 to 2009, and generally contained new active medicinal substances.

Other websites (81 hits) where names of medicinal products were mentioned included: www.paihdelinkki.fi, www.tukiasema.net, <http://kaksplus.fi>, www.suomi24.fi, <http://sfnet.fi>, www.eurodrugstore.eu, www.medi uutiset.fi, www.hoitonetti.fi, <http://irc-galleria.net/>, <http://fundconnect.nordea.com>, www.hus.fi, www.napsu.fi, www.terkko.helsinki.fi, www.positiiviset.fi, <http://www.stm.fi/stm/neuvottelukunnat/hila/etusivu>, www.deski.fi, www.taitomyly.fi, www.digipaper.fi, www.cancer.fi and www.vaasankeskussairaala.fi.

Conclusion

In the survey completed on 6.8.2009, whereby the public run internet searches on the names of medicinal products, the information obtained was found to be appropriate and in accordance with the stipulations of the Medicines Act and Decree. Even the information found on the therapy groups website was neutral at the time of the survey. In order for a piece of information in which the name of a prescription drug was mentioned to be deemed appropriate, it was essential that all

Consumer protection requirements

- *Marketing must not be inappropriate or misleading. Marketing must always be recognisable as marketing. (www.kuluttajavirasto.fi)*
- *The commercial purpose of marketing activities must be obvious, and the company responsible for the marketing must be identifiable. It should always be possible to recognise an advertisement as an advertisement, commercial messages must not be hidden in other forms of communication, and the identity of the advertiser must be clear. Subliminal or hidden advertising is never acceptable. (www.kuluttajavirasto.fi)*
- *The stipulations of the Consumer Protection Act apply to all parties, i.e. both the advertiser and advertisement distributor, and the television company. There are stipulations regarding television broadcasters' responsibility for the advertising that they disseminate in the Act on Television and Radio Operations, which also applies restrictions to product placement and subliminal advertising. (www.kuluttajavirasto.fi)*
- *The responsibilities of the Finnish Communications Regulatory Authority (FICORA) also include overseeing compliance with regulations regarding subliminal advertising and sponsorship. Subliminal advertising on television is prohibited, and a sponsor of a television programme may not influence the content of the sponsored programme in such a way that it would violate the responsibilities or independence of broadcasting of the television operator. (www.ficora.fi)*

other forms of therapy and medicinal products were mentioned with equal emphasis, so that no product was favoured above any other. The top hits obtained when names of prescription drugs were entered into the search engine were websites approved by the authorities, and included published summaries of product characteristics and package leaflets. Reference to the trade name of a medicinal product is not currently a problem in terms of drug marketing regulations, and the web pages examined by NAM were in this regard appropriate.

TV, radio and the internet are the most difficult types of media to regulate. In future, drug marketing will increasingly be regulated in such a way as to take account of those media which are associated with product placement. Drug information provided via these media is a prime exam-

ple of how some pharmaceutical companies display poor ethical standards in their methods of working. It is inevitable that drug marketing standards will increasingly be violated in one way or another in the years to come. The Finnish Communications Regulatory Authority, which regulates the lawfulness of product placement, has increasingly intervened in cases associated with drugs this year.

Regulating product placement is the responsibility of a number of players. The Council for Mass Media in Finland has on several occasions demanded that the various players display ethical responsibility and respect for the need for credibility, in order to get rid of hidden advertising. The web pages of the Consumer Agency stress that independence from commercial interests is considered essential for maintaining editorial credibility. The Finnish

Communications Regulatory Authority oversees the legality of product placement in Finland.

Drug marketing posing as neutral communication has become more common, but this can be combated jointly by all of the players in the health sector, including the public. Communications to the public regarding diseases or health issues, without their having requested it, must not exclusively market a specific prescription drug, even indirectly.

Literature

Sections 91 to 93b of the Medicines Act (395/1987)

Sections 25 to 25i of the Medicines Decree (693/1987)

Consumer Protection Act (38/1978)

The Finnish Consumer Agency website www.kuluttajavirasto.fi provides up-to-date news regarding consumer rights, and information on how product placement is actually hidden advertising.

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More drug companies turning to Internet advertising. <http://www.ihealthbeat.org/Articles/2009/6/16/Pharmaceutical-Firms-Turn-to-Social-Media-To-Market-Products.aspx>

The Finnish Communications Regulatory Authority website www.ficora.fi – TV and radio operations, product placement.

Responsibilities of NAM's Medical Devices department transferred to Valvira

Ritva Raunio, Department secretary

The National Agency for Medicines' Medical Devices department regulates the manufacture and marketing of medical devices, and promotes the safety of their use. The responsibilities of the Medical Devices section have been the responsibility of NAM since 1995.

In 2008, the Ministry of Social Affairs and Health introduced a plan to reform the administration of pharmaceutical services. In the summer of 2009, a new Act was passed regarding the Finnish Medicines Agency, Fimea. Fimea is responsible for promoting the health and safety of the population by regulating drugs and blood and tissue products, and by developing the pharmaceutical sector.

According to the Act, the responsibilities of the Medical Devices section will be transferred to the National Supervisory Authority for Welfare and Health as of 1.11.2009.

The National Supervisory Authority for Welfare and Health (Valvira) is a new central body that was formed on 1.1.2009 by a merger between the National Product Control Agency for Welfare and Health (STTV) and the National Authority for Medicolegal Affairs (TEO). By offering guidance

and supervision, Valvira works to improve the management of health risks in the environment, the standard of legal protection, and the quality of social welfare and health services.

From 1.11.2009, the new contact details for all issues relating to medical devices will be as follows:

Valvira
(National Supervisory Authority for Welfare and Health)
Lintulahdenkuja 4
PL 210
FI-00531 Helsinki

Tel: +358-(0)9-772 920
(exchange)

Fax: +358-(0)9-772 2138

E-mail:
firstname.surname@valvira.fi
kirjaamo@valvira.fi

www.valvira.fi

