

EXHIBIT 22
WIT. Klibanov
DATE 3-24-22
KRAMM COURT REPORTING

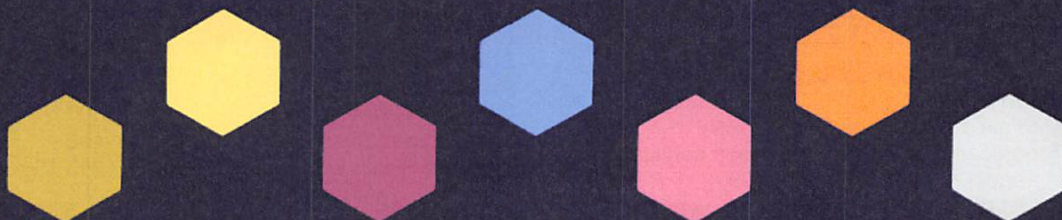
WHO DRUG



INFORMATION

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PROPOSED INN LIST 95
INTERNATIONAL NONPROPRIETARY NAMES
FOR PHARMACEUTICAL SUBSTANCES



WORLD HEALTH ORGANIZATION · GENEVA

WHO Drug Information

Contents

Regulatory Issues		Fluoxetine approved for children and adolescents	89
Drug Regulation in 2006: vision and challenges	61	Withdrawal of marketing application for Surfaxin®	89
International Conference of Drug Regulatory Authorities (ICDRA): recommendations	61	Resumed marketing of natalizumab	90
		EU Regulation on compulsory licensing published	90
Safety and Efficacy Issues		Emerging Diseases	
Tenofovir and nonsteroidal anti-inflammatories: acute renal failure	69	Tissue infectivity and transmissible spongiform encephalopathies	91
Update on status of contraceptive skin patch	69	ATC/DDD Classification	
SSRI antidepressants linked to lung disorder in newborns	70	ATC/DDD Classification (temporary)	97
ACE inhibitors and birth defects	70	ATC/DDD Classification (final)	100
ACE inhibitors and pregnancy	71	Recent Publications, Information and Events	
Gadolinium-containing contrast agents and nephrogenic systemic fibrosis	71	Interagency Emergency Health Kit 2006	103
Gatifloxacin and blood glucose disturbances	72	Therapeutic guidelines for rheumatology	103
Essential Medicines		Specifications for pharmaceutical preparations	103
WHO Model List of Essential Medicines and developed countries: a comparison with the Lothian Joint Formulary	73	New guidance for pharmacists on counterfeit medicines	104
Adherence to WHO's Model List of Essential Medicines in two European countries	78	Marketed unapproved drugs — policy guide	104
Regulatory Action and News		WHO guidelines on avian influenza	104
Transgenic antithrombin alfa approved	86	WHO analgesic ladder	105
EMA Management Board moves for greater transparency	86	Resources for paediatric formulations	104
Bupropion approved for seasonal depression	86	Consultation Document	
Decitabine approved for myelodysplastic syndromes	87	International Pharmacopoeia: revision of monographs for antimalarials and draft proposals for antiretrovirals	
Medical device innovation initiative	88	Artesunate	106
Topotecan/cisplatin for late-stage cervical cancer	88	Artesunate tablets	107
Rapid approval of vaccine for prevention of cervical cancer	89	Lamivudine oral solution	107
Rasagiline approved for Parkinson disease	89	Lamivudine tablets	109
		Zidovudine and lamivudine tablets	112
		Proposed International Nonproprietary Names: List 95	
			115

Regulatory Issues

Drug regulation in 2006: vision and challenges

The Twelfth International Conference of Drug Regulatory Authorities (ICDRA) held in Seoul, Republic of Korea, from 3 to 6 April 2006 has once again provided drug regulators with a unique opportunity to meet and discuss the particular challenges of medicines regulation. The continuing need to harmonize and strengthen collaboration is underscored by the increasing complexity of the medicines market and technical skills needed to regulate innovative products. The latest ICDRA was hosted by the Korea Food and Drug Administration in collaboration with the World Health Organization. The event was highly appreciated by developed and developing countries for its continuing role in fostering a regulatory forum where matters of urgency and international relevance can be openly debated. On this occasion, the event led to adoption of the following recommendations which regulators consider important in assuring the quality, safety and efficacy of medical products.

International Conference of Drug Regulatory Authorities (ICDRA): recommendations

Access to medicines: new regulatory pathways for public health needs

1. In the assessment of products, particularly those developed for public health needs, countries should make use of new regulatory pathways provided by highly-evolved regulatory agencies in order to avoid duplication of effort. This would enable optimal use of limited resources.
2. In cooperation with well resourced regulatory agencies, WHO is urged to assist Member States to provide training on the best use of regulatory information on product approvals available in the public domain.
3. WHO should continue its efforts to prequalify active pharmaceutical ingredients for medicines for priority diseases, including HIV/AIDS, malaria and tuberculosis. Information concerning prequalified products and approved sites should continue to be made public in the form of WHO public inspection reports.
4. WHO should assist national regulatory agencies to develop innovative approaches to improve access to safe and effective essential

medicines of quality which address public health needs.

Emerging diseases and crises management: regulatory challenges

1. The fight against emerging diseases requires global collaboration and multi-disciplinary effort. Member states should ensure their national regulatory agencies are closely involved in national strategic decision making processes and are engaged as key stakeholders in national contingency planning. In this context, national regulatory agencies should develop business continuity plans and may also have a role in facilitating vaccine and pharmaceutical research and development, and development of blood screening tests.
2. WHO should take a leading role in the global preparedness for pandemic infections. Central to its role as the global leading health agency, WHO should cooperate with Member States to ensure transparency of epidemiological information, co-ordinate information and technology transfer on clinical trials and research and assist Member States through developing WHO standards for pre-marketing

WHO Drug Information
e-mail table of contents
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afimoxifenum
afimoxifène

4-(1-[4-[2-(diméthylamino)éthoxy]phényl]-2-phénylbut-1-ényl)phénol
antiœstrogène

afimoxifène

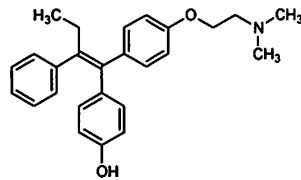
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afimoxifeno

4-[1-[4-[2-(diméthylamino)etoxil]fenil]-2-fenilbut-1-enil]fenol
antiœstrógeno

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and Z isomer
et l'isomère Z
y el isómero Z

afiberceptum*
afibercept

des-432-lysine-[human vascular endothelial growth factor receptor 1-(103-204)-peptide (containing Ig-like C2-type 2 domain) fusion protein with human vascular endothelial growth factor receptor 2-(206-308)-peptide (containing Ig-like C2-type 3 domain fragment) fusion protein with human immunoglobulin G1-(227 C-terminal residues)-peptide (Fc fragment)], (211-211':214-214')-bisdisulfide dimer
angiogenesis inhibitor

afibercept

(211-211':214-214')-bisdisulfure du dimère de la des-432-lysine-[récepteur 1 humain du facteur de croissance endothélial vasculaire-(103-204)-peptide (contenant le domaine Ig-like C2-type 2) protéine de fusion avec le récepteur 2 humain du facteur de croissance endothélial vasculaire-(206-308)-peptide (contenant un fragment du domaine Ig-like C2-type 3) protéine de fusion avec l'immunoglobuline G1 humaine-(227 résidus C-terminaux)-peptide (fragment Fc)]
inhibiteur de l'angiogénèse

afibercept

(211-211':214-214')-bisdisulfuro del dímero de la des-432-lisina-[receptor 1 humano del factor de crecimiento endotelial vascular-(103-204)-péptido (que contiene el dominio Ig-like C2-tipo 2) proteína de fusión con el receptor 2 humano del factor de crecimiento endotelial vascular-(206-308)-péptido (que contiene un fragmento del dominio Ig-like C2-tipo 3) proteína de fusión con la inmunoglobulina G1 humana-(227 restos C-terminales)-péptido (fragmento Fc)]
inhibidor de la angiogenesis

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