# 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

## 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 multidisciplinary 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

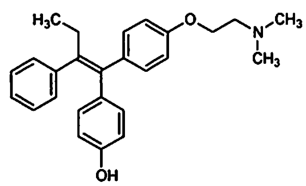
**afimoxifenum**

afimoxifene — 4-(1-{4-[2-(dimethylamino)ethoxy]phenyl}-2-phenylbut-1-enyl)phenol
*antiestrogen*

afimoxifène — 4-[1-[4-[2-(diméthylamino)éthoxy]phényl]-2-phénylbut-1-ényl]phénol
*antioestrogène*

afimoxifeno — 4-[1-[4-[2-(dimetilamino)etoxi]fenil]-2-fenilbut-1-enil]fenol
*antiestrógeno*

$C_{26}H_{29}NO_2$ 68392-35-8



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

**afliberceptum***

aflibercept — 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*

aflibercept — (211-211':214-214')-bisdisulfure du dimère de la dès-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*

aflibercept — (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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