Notice of Compliance with Conditions -NOC/c (Therapeutic Products)

What is a Notice of Compliance with Conditions (NOC/c)?

An NOC/c is authorization to market a drug that is issued under the Notice of Compliance with Conditions Policy. This indicates that the sponsor has agreed to undertake additional studies to confirm the clinical benefit of the product. The NOC, qualifying under the NOC/c Policy, is issued under section C.08.004 or C.08.005 of the Food and Drug Regulations.

What is the purpose of an NOC/c?

Market authorization under the NOC/c Policy allows Health Canada to provide earlier market access to potentially life-saving drugs. Conditions associated with market authorization allow Health Canada to monitor the drug through enhanced post-market surveillance.

Which drug products are eligible for NOC/c consideration?

Eligibility is restricted to promising new drug therapies intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases or conditions for which a) there is no alternative therapy available on the Canadian market or, b) where the new product represents a significant improvement in the benefit/risk profile over existing products.

When would Health Canada consider a drug for NOC/c status?

Consideration for NOC/c status is given to eligible drugs which have demonstrated promising clinical effectiveness in clinical trials. The products must be of high quality and possess an acceptable benefit/risk profile.

What types of conditions are associated with an NOC/c?

Sponsors of drugs authorized under the NOC/c Policy must agree to carry out additional clinical trials to verify the clinical benefit of the drug. In addition, conditions will include: a requirement to undertake increased monitoring of the drug and reporting to Health Canada; a requirement to provide educational material, including the nature of the conditions of use, for health care practitioners and patients; and restrictions on advertising and labelling.

Are NOC/c drugs covered under public and private drug plans?

Public and private drug plans may or may not cover the costs of drugs authorized under the NOC/c Policy because, although promising, the clinical benefit of these drugs has not yet been confirmed.

What happens when a company fulfills the conditions associated with an NOC/c?

Once a sponsor provides Health Canada with satisfactory evidence of the drug's clinical effectiveness, and Health Canada is satisfied that all the conditions agreed upon at the outset have been met, the conditions associated with market authorization will be removed in accordance with the NOC/c Policy.

Canada

For further information:

Refer to “Guidance for Industry - Notice of Compliance with Conditions (NOC/c)” or

Write:

Therapeutic Products Directorate
Holland Cross, Tower B
1600 Scott Street, 2nd Floor
Address Locator 3102C1
Ottawa, Ontario
K1A 0K9

Tel: 613-957-6451
or visit our Web site:
http://www.hc-sc.gc.ca/dhp-mps/index_e.html

Canada