

Accelerated Regulatory Review Options in Canada: Biologics, Pharmaceuticals Including Orphan Drugs

Accelerated review options vary from one Regulatory Agency to another but the objective remains essentially the same: granting faster market access to products with highly positive clinical data or novel indications in serious or life threatening diseases. The advantages of applying an accelerated review strategy include: cutting down on regulatory review time, allowing patients to have earlier access to drugs and reducing product development costs.

While the FDA has the Fast Track Status, its Canadian counterpart, Health Canada has two options. The first, Notice of Compliance with Condition (NOC/c) applies to new drug submissions with promising evidence of clinical effectiveness. An NOC/c can be granted to a drug product which, after Phase II studies, proves its ability to 1) treat, prevent or diagnose a serious, life-threatening or severely debilitating disease or condition for which there is no existing therapy on the market or 2) demonstrate a significant improvement in the benefit/risk profile over alternative products available. The Sponsor must also agree with Health Canada on confirmatory studies and patient safety monitoring studies that will be completed after NOC/c approval. The second, Priority Review (PR) applies to new drug submissions or supplemental new drug submissions in which there is substantial evidence of clinical effectiveness. Contrary to NOC/c, a PR can be granted when Phase III studies are completed and the drug is proven to be effective to 1) treat, prevent or diagnose serious, life-threatening or severely debilitating diseases or conditions for which no existing therapy is presently marketed in Canada or 2) shows a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

Currently, no Orphan Drug Designation or Guidance is in place in Canada but discussions are underway towards creating a formal policy. Nonetheless, orphan drugs are increasingly being approved by alternative means, when standard Phase III trials cannot be conducted due to low patient population in the disease to be treated. A meeting with Health Canada is the best strategy to adopt to discuss and agree on the terms of a drug submission. This “case by case” approach is well received by both parties and has proven to be effective.

Highlights

Health Canada offers two strategies for accelerated regulatory approval of promising therapeutic products: Notice of Compliance with Condition and Priority Review. In both cases, the benefit/risk assessment has to be positive and clinical effectiveness compared to current or alternate treatment must be clearly demonstrated. As an Orphan Drug Policy has yet to be implemented in Canada, specific policies or guidelines are not available. Meeting on the forehand with Health Canada and outlining a mutually agreed plan is the best option.

SPharm can assist biopharmaceutical companies in planning the best regulatory strategy for their drugs or orphan therapy to be licensed in Canada.

SPharm Inc. info@spharm.ca

