CANADIAN ADMINISTRATIVE LAW – SAMPLE QUESTION AND ANSWER

Session: Substantive Constraints

Topic: Standard of Appellate Review – Palpable and Overriding Error

Recommended time: 90 Minutes

Score: 100 Marks

Author: **Manuel Akinshola**

Facts

Sterling Health Biomedics Inc. (SHBI) appeals from the decision of the Federal Court that dismissed its application for judicial review.

The background facts are these: SHBI had applied to Health Canada seeking a licence for its new medical product, *Coroduin,* which is an oral herbal capsule formulation said to prevent the corona virus infection if ingested as prescribed. The company claims that the major ingredient of the product is derived from papaya leaves which prevents the corona virus from entering the healthy cells in affected people which in turn reduces its ability to make copies of itself to attack the lungs and other vital organs.

After reviewing the application, the Minister of Health concluded that the evidence submitted by SHBI was insufficient to support the safe use of the product. The decision noted particularly that the product would be classified and licensed under the natural health products (NHP) regulations which means that the product was to be available over the counter without prescription. However, the Minister observed that there is a risk of transient skin itching associated with the use of Coroduin and this could not be properly monitored if the drug was sold over the counter.

In its application for judicial review at the Federal Court, SHBI argued that the Minister had misclassified its drug as coming under NHP regulations rather than under the Food and Drug Regulations. This is because *Coroduin,* though a herbal formulation, is a prescription drug which

cannot be sold over the counter and should have been subject to regulations pursuant to the Food and Drug Regulations. SHBI believes that the Minister had misapplied the law because if the Minister had properly characterized the drug under the appropriate law, it would have enjoyed the provisions under clauses 72 and 95 of the Food and Drug Regulations which states thus:

> 72
>
> (i) The Minister may not reject any application for license on the sole basis that the usage of such drugs has or may likely have side effect(s) on the users where such side effect(s) are not considered fatal or permanent.
>
> (ii) In considering any application for license, the Minister shall seek submissions from the applicant as to any side effect(s) resulting from or to be encountered by users of the drug. Such submissions shall be reviewed by a panel of experts which shall make recommendations to the applicant on appropriate steps to be taken to address or reduce such side effects.
>
> (iii) The Minister may refuse any application for license where, pursuant to (ii) above, the applicant has received any recommendation from the panel and has failed or neglected to observe or implement this within three months after such recommendation was made.
>
> 95. Any party aggrieved with the decision of the Minister in respect of an application for license may appeal to the Federal Court for judicial review.

The Federal Court had considered SHBI's arguments and dismissed the application, holding that the Minister's act of classifying the drug is a discretionary act based on facts available to him, and therefore, the Minister's decision was reasonable and should be upheld.

On appeal, SHBI argues that the ruling of the Federal Court that reasonableness standard applies in this matter is erroneous. This according to the company is because the Minister's misclassification of the usage and side effect(s) of the drug is a matter of applying the law based on available facts from medical science analysis. The Minister, having adopted the wrong factual basis in this case, this had resulted in his error of misapplying the NHP Regulations to the facts

of this case instead of the Food and Drugs Regulations. The company therefore asks for the ruling of the Federal Court to be set aside.

Question

You are one of the judges on the Federal Court of Appeal panel and SHBI's appeal has been assigned to you for a decision. What is the standard of review applicable to this appeal? Please provide reasons for your answer.