RAC-GS$^{Q\&As}$

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

You discover that your company\\'s top selling product in the last two years has been used off-label. The off-label use is estimated to be about 70%, and it has been consistent since the product was first released to the market. Which of the following is MOST appropriate?

A. Discuss with regulatory authorities to investigate how to have the off-label indication approved.

B. No action is required since it is an off-label use.

C. Advise the senior management to send a "Dear Dr." letter.

D. File a report to regulatory authorities and advise the marketing department to prevent future off-label use.

Correct Answer: A

QUESTION 2

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

A. "Product X is a guaranteed cure for arthritis."

B. "Product X is effective for the treatment of arthritis."

C. "Product X is safe for arthritis and without side effects."

D. "Product X is effective in all patients with arthritis."

Correct Answer: B

QUESTION 3

Which question is pertinent to demonstrate a new pharmaceutical\\'s effectiveness during evaluation by a reimbursement agency?

A. "Is the product profitable for the manufacturer?"

B. "Is the product better than currently available alternatives?"

C. "Has the product been approved for morand4nan 10 years?"

D. "Is the product an established gold standard?"

Correct Answer: B

QUESTION 4

A protocol for a pivotal registration trial of a new product is submitted to a major regulatory authority for review and

approval. The regulatory authority issues the company a written commitment that if the studies are completed as outlined in the protocol and the results meet the pre-specified criteria for efficacy and safety, the product will be approved.

During the final week of the review of the marketing application, which has fully met all pre- specified criteria, the company receives a letter from the regulatory authority stating that it no longer believes that

the product will be approved based on a recent withdrawal of a similar product in another country.

What is the BEST response?

A. Notify the regulatory authority regarding Its obligation to honor the commitment to approve the application.

B. Consult with the legal department to discuss the best course of action.

C. Review the regulatory guidelines to determine how to proceed.

D. Request a meeting with the regulatory authority to discuss the application.

Correct Answer: D

QUESTION 5

During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product Is distributed globally.

Which of the following is the most appropriate action to take FIRST?

A. Withdraw the affected product from the markets.

B. Send a "Dear Dr." letter to customers.

C. Notify the global regulatory authorities.

D. Assess the potential safety risk.

Correct Answer: C