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QUESTION 1

As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?

A. Site license

B. Product license

C. Import license

D. Export license

Correct Answer: A

QUESTION 2

Which of the following statements regarding the off-label use of drugs is CORRECT?

A. Although the regulatory authority reviews and approves drugs for specific indications, theapproval does not limit the use of those drugs in clinical practice.

B. The regulatory authority does not restrict physician prescribing for off-label indications orregulate the manufacturer\\'s promotion for such use.

C. Sponsors are allowed to distribute publications about unapproved uses of approved drugs and devices as long as the marketing application is under review by the regulatory authority.

D. The peer-reviewed literature can ensure high-quality off-label promotion of medications, thereby increasing accessto much needed drugs and devices.

Correct Answer: A

QUESTION 3

A company is developing a new product for the global market. A new international guideline will recommend relevant studies in the pediatric population, and the guideline will be effective before the approval of the company\\'s new product. What is the BEST advice the regulatory affairs professional can provide to minimize the impact of this guideline on the successful registration of the new product?

A. The company should consult with relevant regulatory authorities to determine the potential impact on the current registration plan.

B. The new guideline has no impact on the current registration plan, but the company must be prepared to defend its decision.

C. The new guideline has no impact on the current registration plan since all relevant registration studies are almost completed.

D. The company should initiate the required pediatric studies immediately to avoid costly delays to the current registration plan.

Correct Answer: AD

QUESTION 4

A company is developing a new line of products in an area that is new to the company. What is the BEST approach?

A. Ask the trade association representative to provide an overview of the new product area to the marketing team.

B. Obtain competitor research and provide the information to the management team.

C. Obtain regulatory documents and history and provide the information to RandD.

D. Summarize regulatory documents and history and provide the information to the management team.

Correct Answer: D

QUESTION 5

Under which of the following circumstances would a regulatory authority require a more detailed premarket submission, a more rigorous audit, and/or the provision of more performance evaluation data than would normally apply to an IVD device of that risk class?

A. The device is an updated version of a compliant device from the same manufacturer and contains no substantive change.

B. Internationally recognized standards are available to cover the main aspects of the device and have been used by the manufacturer.

C. The manufacturer\\'s experience level with the type of IVD medical device is limited.

D. The device incorporates well-established technology that is already present in the market.

Correct Answer: C