IIHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-10 (2018-2020)

Medical Device

Term Examination

October 2019

Time - 3 Hour **MM-70**

Instructions:

- There are three sections for this exam. Section A contains 10 questions, carries 20 marks (each question 2 marks). You need to choose one answer from the options provided below each question. For each question, only one option has to be chosen. More than one choice marked, or overwriting done, will not be evaluated.
- Section B requires you to descriptively write on an issue provided there. This section contains 5 questions, carries 30 marks (each question carries equal marks).
- Section C is about situation-based question. Please carefully read the case and answer the questions. This question carries 20 marks.

SECTION-A:

Q.1: How Medical Device are classified by CDSCO according to the latest regulation in India?

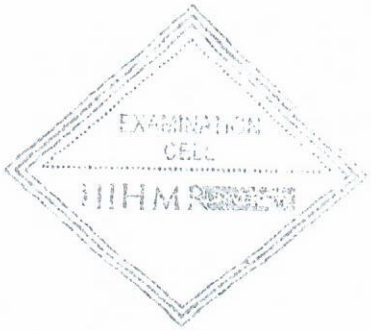
a. Medical Devices classified into four classes: A, B, C, D
b. Medical Devices classified into four classes: I, IIa, 11b, III
c. Medical Devices classified into three classes: A, B, C
d. None of the above

Q.2: What is 510 (K)?

a. A 510 (K) is a pre-market submission made to FDA to demonstrate that the device to be marketed is at ieast as safe and effective
b. A 510 (K) is a pre-market submission made to EU to demonstrate that the device to be marketed is at least as safe and effective
c. A 510 (K) is a post-market submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective
d. None of the above

Q.3: What is the primary purpose of ISO 13485?

a. The primary purpose of the ISO 13485 standard is the Harmonization of the Medical Device regulatory requirements for Quality Management Systems
b. The primary purpose of the ISO 13485 standard is to ensure organizations produce quality products and services.
c. None of the above
d. All the above



Q.4: When did Medical Device Rules launched in India?

a. 2014
b. 2017
c. 2010
d. None of the above

Q.5: What are the requirements for import of medical devices in India?

a. Registration Certificate in Form 41 and Import License in Form 10 are required as per provisions of the Drugs & Cosmetic Act & Rules.
b. Registration Certificate in Form 41 and Import License in Form 10 are required as per provisions of the FDA.
c. Registration Certificate in Form 40 and Import License in Form 17 are required as per provisions of the Drugs & Cosmetic Act & Rules.
d. None of the above

Q.6: What is AiMED?

a. Association of Indian Manufacturers of Medical Devices
b. Association of Medical Device Indian Manufacturers
c. All India Manufacturers of Medical Devices
d. All India Association of Medical Devices Manufacturers

Q.7: What are the examples of consumables?

a. Syringes and needles
b. Sutures and staples
c. Catheters and medical gloves
d. All the above

Q.8: According to a Deloitte report, India's medical-device industry is expected to become a $ 25-30 billion industry in India by 2025?

a. $15-20 billion
b. $20-25 billion
c. $25-30 billion
d. $30-35 billion

Q.9: What are the key drivers impacting medical device industry?

a. Technological development
b. Aging population
c. Chronic diseases
d. All the above

Q.10: What is CII?

a. CII is a for-profit, industry-led and industry-managed organization.
b. CII is a non-government, not-for-profit, industry-led and industry-managed organization.
c. CII is an industry-led international association.
d. None of the above

SECTION-B:

Q.11: What are the differences between healthcare technology, medical device and medical equipment? Elaborate your response with examples.

Q.12: What is the difference between market strategy and Go-to-market strategy?

Q.13: What is the significance of Medical Device in healthcare services in India?

Q.14: Describe Medical Device industry and its future?

Q.15: How to design procurement policies for Medical Device?

SECTION-C:

Q.16: SITUATION BASED QUESTION **(20)**

Situation: You are working as Marketing Manager responsible for diabetes disease portfolio at J&J, Mumbai. You have been asked to prepare a digital marketing plan for a newly launched point of care device (Glucometer, strips, lancet).

Task: You are expected to prepare the plan along with your recommendations addressing the following components:

a. Explain steps for preparing marketing plan for the new product portfolio?
b. Who are the stakeholders involved in each steps of the plan?
c. Describe the customer segmentation of the product portfolio?
d. Craft your recommendations for effective implementation of the marketing plan?