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Regulation of regulatory affairs regarding veterinary products in MENA region

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The huge numbers of countries pertaining to MENA region and the absence of treaties governing pharmaceutical regulatory affairs in general conduct to a real gymnastics when a part of MENA region is assigned to a position in a pharmaceutical company (producing human or veterinary products). This situation requires a perfect knowledge of the regulation of each country which might be a big challenge when you join regulatory affairs for the first time. This presentation will bring a general overview of regulatory affairs organization in MENA region, the evaluation of the approach followed in North Africa and Middle East and finally, how should these countries improve their regulation in order to pass from a “semi-regulated countries” to a “regulated countries” status in matter of veterinary products regulatory affairs. For the needs of the study, several regulations were consulted and the following ones have been chosen as samples (Algeria, Morocco, Egypt and UAE) for showing the general regulation organization in MENA region. In this way, the different requirements for first registration, renewal, variation and packaging validation constituted the criteria to explore the approach of these countries in matter of veterinary regulatory affairs. And last but not least, the study of these complicated and not harmonized regulations by comparing them to the EMA (European Medicine Agency) requirements will highlight the points to improve in order to get a strong, logic and constant regulation in MENA region.

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