J Pharm Drug Deliv Res 2016, 5:5
http://dx.doi.org/10.4172/2325-9604.C1.006

Regulatory challenges in drug delivery: Pharmaceutical pricing

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We are unfortunately subject to an optimistic bias when we evaluate how, and to what extent, drugs and other medical therapies will be available, affordable, and accessible to patients. In developed countries, the pricing and affordability of medicines is a controversial issue that highlights health and economic inequalities, and great challenges for the future. The issue of unaffordable healthcare is rendered more challenging with technological advances and the demographic growth of the geriatric population. Legislation could be instrumental in the creation of equitable solutions. EU healthcare access and drug entry; the implementation of regulatory requirements aimed at ensuring quality, safety, and efficacy of medicines and vaccines for human use; and the European Transparency Directive (Council Directive 89/105) outlining procedural requirements for pricing and reimbursement of medicinal products will be discussed. These issues must be taken into account since few of the hundreds of drugs in clinical development ever reach the stage of final approval, having failed to produce the anticipated results expected by the investigators. These trials can take up to 20 years to complete, and several billion dollars to reach the stage of approval or denial by the regulatory agency involved. When failing to demonstrate viability, pre existing expenditures may be passed onto the price the pharmaceutical company charges patients. In the cancer industry for example, several new drugs cost up to $100,000 for a course of treatment. It is essential that the legislators in each of the countries where the medicinal product is to be introduced be able to negotiate a fee arrangement where the patient will not be denied treatment and the drug company be compensated reasonably for development costs.

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The use of bivalent vaccine in preventing infection in cervical carcinogenesis Human Papilloma Virus (HPV)

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Background: The HPV vaccines have shown promise in protecting against infection and the development of related injuries to some types of HPV (LEPIQUE; RABACHINI and VILLA, 2009).

Goals: To present the bivalent vaccine against high-risk HPV (16 and 18) as a way to prevent cervical cancer.

Methodology: Literature review, documental, retrospective based on national and international journals indexed and Qualis A.

Development: It was in this work specifically the bivalent vaccine was used because of the fact that a vaccine that only protects against the types of high oncogenic risk. The bivalent vaccine containing 20 micrograms like particle HPV L1, 16 and 20 micrograms of virus-like particle HPV 18 L1 at each dose associated with AS04 adjuvant containing 500 micrograms of aluminum hydroxide and 5 micrograms of monophosphoryl lipid- 3-deacylated. Clinical studies in humans have demonstrated that the HPV 16/18 VLP AS04 adjuvant with an initial induce significantly higher antibody response than that obtained with aluminum hydroxide as adjuvant alone, and that it stays response for at least 4 years (HARPER , 2008).

Conclusion: The vaccine has proven to be most effective when administered before onset of sexual activity and vaccination campaigns should target the tweens and teens. It is expected that the increase in the use of vaccine to be a prophylactic strategy to reach 70% or more of the cases of cervical carcinogenesis.

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