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Regulatory challenges in drug delivery: Pharmaceutical pricing and affordability

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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 become available and accessible to patients on the global level in which pharmaceutical enterprises operate. 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. According to the New York Times article Lawmakers Look for Ways to Provide Relief for Rising Cost of Generic Drugs (November 24th 2014), "the cost of many generic medications has increased so much over the past year that prices for many common generic drugs in the USA have surpassed those of their brand-name equivalents in other developed countries". The issue of unaffordable healthcare is more challenging with technological advances and the demographic growth of the geriatric population, including those with cancer and cardiac disease. Legislation can be instrumental in the creation of equitable solutions. The EU member state's management of 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) which defines 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, preexisting expenditures are allowed to be passed onto the price the pharmaceutical company charges patients. In the cancer industry for example, most new drugs require the patient or insurance company to pay 50-100,000 dollars for a course of treatment which may not offer more than several months of improvement in the clinical response. It is essential that the legislators in each of the countries where the drug 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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Nanopharmaeuticals for drug delivery: Characterization and its applications for bioavailability enhancement and targeted drug delivery

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The current advancement in nanotechnology will have profound impact on ingested medicines through different routes. Day-by-day this improvisation in the techniques and a lot of work is ongoing in the fabrication, characterization, and application of novel techniques for controlling shape and size at nanometer scale to develop highly advanced drug delivery system to design better pharmaceutical products. Research conducted on Novel nanostructure like biodegradable nanoparticles, nanomicelles for inhalational targeted drug delivery as well as nanoemulsions, self nanoemulsifying drug delivery system for ocular, oral as well topical route of administration with multifunctional attribute had been focused on to resolve issues of solubility and permeability to achieve highest bioavailability and targeted drug delivery system containing different molecules. The size of nanoparticles/ nanodroplet (less than 100nm) enables penetration over biological barriers and extended bioavailability in organ tissues. The more lucrative feature of nanoformulations is that it's possible to control the properties of nanoparticles including size, shape, and surface characteristics illustrated that the developed nanoemulsion is a promising formulation for improving oral absorption of drug with poor aqueous solubility. Targeted nanomedicine delivery system raises hopes for a number of clinical disorders for which the satisfactory treatment is currently not available. The most outstanding feature is it can act at a molecular level.

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