Title: ***The Era of Nanomedicine***

Journal of Pharmacy and Bioallied Sciences is now in its 7th issue and in the way that has been paved so far, it is possible to find some works on nanomedicine. This term encompasses the applications of nanotechnology in the diagnosis and treatment of diseases and comprises an emerging field that is believed to have the potential to revolutionise individual health in the present century. The outstanding approach of nanomedicine is that it offers the delivery of potential drugs which were previously beyond the capacities of microscale technologies, due to specific biological barriers. Currently, several nanotherapeutics are approved or are undergoing clinical trials and application of nanotechnologies is expected to extend to many more commercial products in the near future.

Particularly in the case of the administration of biopharmaceuticals, a group of molecules that includes proteins, peptides, genes and vaccines, which discovery has been accentuated in the recent years, nanomedicines have been referred as a real tool to improve delivery efficacy. In fact, these are not exactly “new” therapeutic molecules, because hormones, serum proteins and enzymes have been finding therapeutic applications ever since the commercial introduction of insulin in 1923. However, recent progress in biotechnology, biochemical synthesis and molecular biology, together with the better understanding of the role of biopharmaceuticals in physiopathology, has attracted increasing interest over the potentialities of these biodrugs. Actually, some of them have successfully entered the market and play leading roles alongside other established therapies. Nevertheless, severe difficulties have been generally limiting their effective application, as these biomacromolecules exhibit two main properties that hamper their systemic administration, related with the high molecular weight and the strong hydrophilic character, thus posing a real challenge to the pharmaceutical industry in demanding overcoming the successive limitations imposed by their physicochemical properties.

As recognising the need to provide non-invasive administration alternatives for new molecules entering the market, most of the academic and industrial efforts are being directed towards the development of needle-free options. It is exactly in this point that nanomedicines find their great pathway. With an increased surface-to-volume ratio, they display improved drug loading capacity, as well as evidence the ability to increase drug absorption by reducing epithelial resistance to transport and inclusive have shown, in occasions, the capacity to carry the encapsulated drugs through the epithelium.

The first generation of nanomedicines, mainly liposomes and nanoparticles, has been entering routine clinical use for almost 20 years and many individuals have already benefited from their potentialities. Nevertheless, as the scope of nanotechnology applications in biomedicine evolves and nanostructures are becoming more complex, a concern is emerging and gaining even more importance every day, which is related to the risk-benefit balance. In fact, Kipen and Laskin have stated that *Smaller is not always better: nanotechnology yields nanotoxicology* and, although this is not necessarily true, because there is a lack of toxicological data on engineered nanomedicines that does not allow for an adequate risk assessment, it is becoming clear that new generation nanomedicines must build on lessons learnt from the past. The event of nanotoxicology is growing in importance these days and many efforts are being directed to this topic, in order to clarify the adequacy and safety of nanoscaled materials. It is well recognised that physicochemical properties of materials can alter dramatically at nanoscopic scale. As such, it is very important to recall that nanomedicines have new and unique biological properties, thus generating potential different risks as compared to the raw materials of the same chemistry, therefore demanding careful assessment of unexpected toxicities and

biological interactions. In fact, with a multitude of opportunities for nanomaterials application in pharmaceutical and medical applications, a thorough understanding of associated systemic toxicity is critical. The demonstration of nanomedicines safety is indeed the necessary step for the great achievement of making stable effective drugs from unstable biopharmaceuticals.