

Medicinal Product, Medical Device or Combination Product - Challenges and Opportunities

Anne Juppo* and Kirsi Rosenqvist

University of Helsinki, Faculty of Pharmacy, Division of Pharmaceutical Chemistry and Technology, Formulation and Industrial Pharmacy, Helsinki, Finland

*Corresponding author: Anne Juppo, Helsinki University, Faculty of Pharmacy, Division of Pharmaceutical Chemistry and Technology, Industrial Pharmacy, Helsinki, Finland, **E-mail:** anne.juppo@helsinki.fi

Now a days there are several medical device products available for us. We might not know that we are using medical devices, since those are sometimes so close to medicines. The definition for medical devices is 'Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the: 1) Diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap, 2) Investigation, replacement or modification of the anatomy or of a physiological process, or 3) Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such mean'[1]. It is easy to understand that heart or hip implant is a medical device, but there are products like the macrogol products used for stomach function and eye drops for dry eyes that can be registered as a medical device, too. These products can be registered either as medicines or medical devices depending the decision made by the company. On the other hand, bioactive glass used for e.g. as a bone filler is classified as a medical device [2]. In Europe this means that all these products are so called CE-marked products and have market authorisation in Europe. Basically, this means that any substance having no pharmacological effect, but may have effect to body function, is medical device.

Even if these products have no pharmacological effect, they must be safe and effective. Moreover, these products have huge opportunity for us in several ways. First as combination products, combining the medical device function and medicine together in order to get best result in the treatment of the disease e.g., bioactive glass and antibiotic-loaded calcium-based bone substitutes in the treatment of chronic osteomyelitis [3]. Another great opportunity offered for us is that we can use the medical device as the carrier for the APIs or even enhance the effect of the API, as described in our previous study with clodronate and bioactive glass [4,5].

These combination products are really challenging e.g., for those taking care of design, development, market authorisation and regulatory aspects since the product should fulfil the both demands and legislations, those of a drug and those for a medical device. This sometimes causes for the

company the building of double quality systems, but when being clever a clear synergy between these two can be obtained to the benefit of the product and the patient using the product.

Very little academic research is done on the regulatory aspects of medical devices in the interface of pharmaceuticals. Therefore, it is crucial to investigate what strategic decisions the pharmaceutical companies are facing while making decisions, which way to go, to get the market authorisation as a pharmaceutical product or build up the quality system for a medical device. The work load for medical device registration may be much less than that of pharmaceuticals especially in class I and II medical devices. However, from the marketing point, it can be beneficial to have the product as a pharmaceutical product. Therefore, it would be important to study how the registration process and the life cycle management of these two options are differing from the pragmatic point of view. Further, it is essential to investigate the resources needed in the registration processes: FTEs of the staff, their use of time and the effect on their work description. This information would also help the companies in their decision making in future and give the regulatory bodies valuable information on what demands of resources and challenges the current regulations are causing.

References

1. European Commission (1993) Medical Device Directive (93/42/EEC).
2. Profeta AC, Huppa C (2016) Bioactive-glass in oral and maxillofacial surgery. *Craniomaxillofac Trauma Reconstr* 9: 1-14.
3. Romanò CL, Logoluso N, Meani E, Romanò D, De Vecchi E, et al. (2014) A comparative study of the use of bioactive glass S53P4 and antibiotic-loaded calcium-based bone substitutes in the treatment of chronic osteomyelitis - a retrospective comparative study. *Bone Joint J* 96: 845-850.
4. Rosenqvist K, Airaksinen S, Fraser SJ, Gordon KC, Juppo AM (2013) Interaction of bioactive glass with clodronate. *Int J Pharm.* 452: 102-107.
5. Rosenqvist K, Airaksinen S, Vehkamäki M, Juppo AM (2014) Evaluating optimal combination of clodronate and bioactive glass for dental application. *Int J Pharm* 468: 112-120.

Received date: 19 Apr 2016; **Accepted date:** 20 Apr 2016; **Published date:** 25 Apr 2016.

Citation: Juppo A, Rosenqvist K (2016) Medicinal Product, Medical Device or Combination Product—Challenges and Opportunities. *J Pharm Anal Insights* 1(3): doi <http://dx.doi.org/10.16966/2471-8122.e103>

Copyright: © 2016 Juppo A, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.