Regulatory aspects of radiopharmacy

FIP VIRTUAL 2020 SEPTEMBER

Katrina Frey, Lilian M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

email: katrina.frey.17@um.edu.mt

L-Università ta' Malta
Faculty of Medicine & Surgery

Department of Pharmacy

INTRODUCTION

Radiopharmaceuticals have been around for several decades. The increasing applications of radiopharmaceuticals have revolutionized diagnostic and therapeutic fields whilst at the same time specific regulatory requirements have evolved to ensure safety requirements.

AIMS

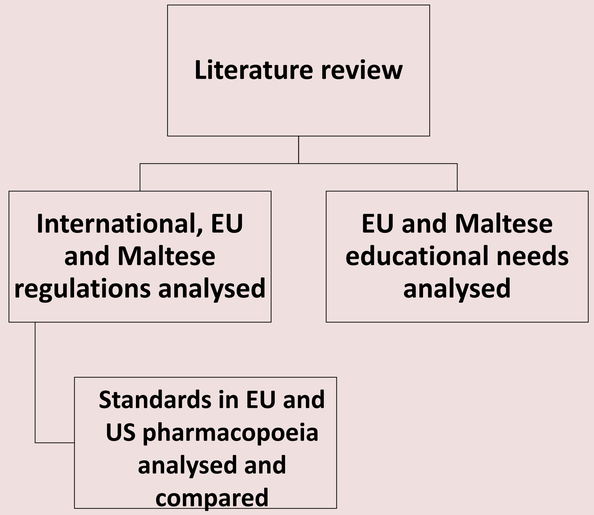
- To review international, EU and local regulations regarding radiopharmaceuticals
- To identify educational needs about awareness and protection of patients and healthcare professionals

METHODOLOGY

- The study adopted a comparative approach of international, EU and local regulations relevant to radiopharmaceuticals so as to identify areas covered.
- Monographs for gallium citrate (67Ga) injection, ammonia (13N) injection and fludeoxyglucose (18F) injection in the EU and US Pharmacopoeia were chosen at random and general chapters mentioning radiopharmaceuticals were compared.

METHOD

Figure 1: Data mining procedure adopted



RESULTS

- 25 regulations were identified: 5 international, 14 EU and 6 Maltese (Table 1).
- The international regulations reviewed were from ICH, IAEA and WHO. The reviewed documents focused on safety and Good Manufacturing Practices, with 2 being specifically on radiopharmaceuticals.
- The EU regulations reviewed focused on general pharmaceutical requirements, good manufacturing practices and clinical trials, with 3 of them being specifically on radiopharmaceuticals.
- Local regulations reviewed focused on radiation safety and public health, as well as general pharmaceutical requirements with 3 being specifically on radiation safety.
- The USP has more detailed procedure description whereas the EP is more general and allows for more flexibility. Within the specific monographs, differences can be attributed to information being provided in general chapters rather than in the specific monograph (Table 2).

Table 1: Areas covered in regulations

	International	EU	Maltese
Regulations identified	5	14	6
Summary	3 different regulatory bodies • Safety • Good manufacturing practices	• General pharmaceutical requirements • Clinical trials • Good manufacturing practices	• Public health • Radiation safety • General pharmaceutical requirements

Table 2: Pharmacopoeias comparison

US Pharmacopoeia	European Pharmacopoeia
• Information mostly found in specific monograph	• Information mostly found in general chapters
• Subdivisions	• Subdivisions not used a lot
• Methods specified	• Brief description of test
• Few impurities specified	• Several impurities specified
• Fewer tests required for identification and qualification	• More tests required for identification and qualification

CONCLUSION

Over the last few decades radiopharmaceuticals have become more regulated however, it can be noted that there is still a lack of regulation and lack of harmonisation across regions. Radiopharmaceuticals are a promising technology where safety is of the upmost importance and regulations do reflect this important aspect.