FEB. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

New european regulation: Medicated feed and veterinary medicinal products

two significant new EU Regulations came into force on 28 January 2022. The first is Regulation (EU) 2019/4 of the Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed ("**Medicated Feed Regulation**"). The second is Regulation (EU) 2019/6 of the Parliament and of the Council of 11 December 2018 on veterinary medicinal products ("**Veterinary Medicinal Products Regulation**").

These newly published regulations mark a milestone in the adaptation of the legislation to the real situation of the veterinary medicinal products and ensure the legal framework is better adapted to the practical reality of this sector.

In fact, the implementation of the new Veterinary Medicinal Products Regulation will provide a greater incentive for innovation in medicinal products. At the same time, it will ensure greater protection for public, animal and environmental health. Besides this, the procedures of the mechanisms for evaluating veterinary medicinal products and those relating to manufacturing and the supply chain will be improved.

In turn, the new Medicated Feed Regulation will make it possible to consolidate in legislation the most up-to-date technical-scientific concepts regarding the production, manufacture and use of medicated feed and intermediate products.

Eduardo Nogueira Pinto
Ricardo Rocha
Bartolomeu Soares de Oliveira
Healthcare, Life Sciences & Pharmaceuticals team

The new Veterinary Medicinal Products Regulation will provide a greater incentive for innovation in medicinal products. At the same time, it will ensure greater protection for public, animal and environmental health.

In this regard, the European Medicines Agency ("**EMA**") has already provided information on the implementation of the new Regulations. Specifically, it has published information on the new model for the summary of product characteristics of veterinary medicinal products, labelling and package leaflet.

Until publication of new Portuguese legislation, the rules set out in Decree-Law 148/2008 of 29 July will remain in force in all matters that do not conflict with the new provisions of the new Regulations. ■

In this regard, the European Medicines Agency ("EMA") has already provided information on the implementation of the new Regulations.