The European Medicines Agency and Family Doctors

A Agência Europeia de Medicamentos e os Médicos de Família

Keywords: Drug Approval; European Union; Government Agencies; Physicians, Family
Palavras-chave: Aprovação de Medicamentos; Médicos de Família; Órgãos Governamentais; União Europeia

The European Medicines Agency (EMA) acts as an approver of new drugs in Europe and, though it has been established in London since 1995, it has only in the last decade involved the participation of General Practitioners/ Family Doctors (GP).[1] GPs not have been involved in previous decision-making sessions though they have been present as expert witnesses in one particular drug field.

The main contributors have been pharmaceutical companies and hospital specialists who have reviewed the drug action, side effects and benefits in order that it may be licensed.

The European Union of General Practitioners (UEMO), made reccomendations to the EMA that since GPs were, by a significant majority, the long-term prescribers of any medication, they ought to be included in any consideration of drug approval, and their opinions sought before the drug was licenced for distribution.

The EMA acknowledged the validity of this argument and have invited UEMO, since then, to participate in the review meetings when new drugs are brought forward by pharmaceutical companies.

It has been interesting work and, at present, the task is shared between two UEMO members who report back to the UEMO Board and ultimately to the UEMO General Assembly where delegates of European Medical Associations are represented. A recent meeting focused on the possible effects of Brexit on drug shortages and supplies. The EMA was anxious to ameliorate adverse effects as much as possible and a two day meeting, attended by both UEMO delegates on a “one day each” basis, covered the change, from London to Amsterdam, of the EMA headquarters and moves to make the transition as smooth as possible.

UEMO also spoke as a witness at a public hearing convened to discuss the use of quinolones and fluoroquinolones. There were statements from patients describing side effects of the drugs and statements from hospital specialists about their value in drug-resistant TB as well as other respiratory and renal infections.

UEMO offered a sensible GP perspective, recognising the usefulness of these drugs in certain limited scenarios, while stating that they should be used with caution, never used as a first line antibiotic and reserved for those bacterial isolates where there was proven sensitivity, a good chance that either complications would be avoided or a severe infection cleared quickly at a benefit to the patient, and where there was no less problematic alternative.

General Practitioners, as daily prescribers and as doctors familiar with their patients, are more likely to pick up adverse side effects in a timely manner.

In involving European GPs, through UEMO, in their decision making, the EMA are acting with due diligence.

REFERENCES

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A Nova Prova Nacional de Seriação: Um Gigantesco Passo de Um Milímetro

The New Medical Licensing Examination in Portugal: A Gigantic Millimeter Leap

Palavras-chave: Avaliação Educacional; Competência Clínica; Licenciatura em Medicina
Keywords: Clinical Competence; Educational Measurement; Licensure, Medical

Acabo de ler o Editorial na AMP sobre A Nova Prova Nacional de Seriação (PNS).[1]

Acho que a classe médica está de parabéns por finalmente ter sido abandonada uma PNS largamente desacreditada. A meu ver, passou-se de uma máquina a vapor para um motor de combustão interna, alimentado através de um carburador e ligado às rodas através de uma caixa manual de três velocidades. Uma pena, dado que os carros híbridos e elétricos já estão no mercado há anos.

O que quero dizer é que, ao fazer a mudança, perdeu-se uma oportunidade única de saltarmos para o século XXI.

Isto tem que ver com o que se entende por “qualidade” do médico recém-formado. Enquanto persistir a mentalidade que a “qualidade” se define apenas pela vertente dos conhecimentos biomédicos, continuamos firmemente amarrados à primeira metade do século XX. Muito longe de