Gerencia de Atención Integrada Alcázar de San Juan

DI-069

REVIEW OF OFF-LABEL APPLICATIONS IN ORDER TO IMPROVE THE USE

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Background

Nowadays in hospitals it is more frequent to use drugs for a different use than the ones mentioned in the summary of product characteristic.

Purpose

To analyze the applications for off-label use of drugs, done in a third level hospital with the aim of reviewing their approval procedures and to set up the measures to improve their use.

Material and methods

An observational and retrospective study was carried out for the applications of off-label use drugs applied from January 2010 to September 2014. A case report form was designed using the variables: drug, therapeutic use, department, OCEBM 2011 levels of evidence and type of approval (approval, conditional approval, and non-approval).

The drugs requiring a protocol approved by hospital Pharmacy and Therapeutics Committee were excluded.

COMPLEJO HOSPITALARIO LA MANCHA CENTRO

SOLICITUD DE AUTORIZACIÓN DE MEDICAMENTOS EN CONDICIONES DISTINTAS A LAS AUTORIZADAS EN FICHA TÉCNICA

Fecha de solicitud: ___/___/_____

Datos del Medicamento

Nombre del principio activo: ..... Nombre Comercial: .....

Indicación: .....

Dosis para la indicación solicitada: .....

Duración prevista del tratamiento: .....

Datos del Paciente

Nombre: ..... Apellidos: .....

HC: ..... Edad/Fecha Nacimiento: .....

Diagnóstico: .....

DEBE ADJUNTARSE CON ESTA SOLICITUD INFORME MÉDICO Y BIBLIOGRAFÍA.

Datos del médico prescriptor

Nombre: ..... Apellidos: .....

Servicio médico: .....

☐ La solicitud es urgente

Justificación:

☐ Si se autoriza el uso de este medicamento me comprometo a obtener el consentimiento informado y a dejar constancia por escrito en la HC del paciente

NOTA: Es obligación del médico responsable del tratamiento y de la Dirección del centro hospitalario informar al paciente en términos comprensibles de la naturaleza del tratamiento, su importancia, implicaciones y riesgos, y obtener su consentimiento informado por escrito o, en su caso, el de su representante, conforme a lo establecido en la Ley 41/2002, de 14 de noviembre.

Fdo:

Results

128 applications for 59 different therapeutic uses;

✓ **117 (91.4%) were approved**, from which 16 were conditionally approved due to the low level evidence of studies.

➢ 11 applications were denied, for 2 of which another therapeutic use was suggested and accepted.

The most of the applications were done for:

- **Rituximab**; 24 applications (***18,7%***), for 16 different therapeutic uses;
- **Omalizumab**; 10 applications,(***7,8%***);
- **Bevacizumab** and **Tacrolimus**, both of them with 7 (***5,5%***) application each.

The departments with more applications were Oncology and Haematology (24 applications, 18.7%), Neurology (19 applications, 14.8%), Internal Medicine, Ophthalmology, y Allergology departament, with 10 applications.

For most of the applications, physicians took into account studies with low evidence (case-series studies, follow-up studies and no randomized), level of evidence 3-4.

Conclusion

Due to the high number of applications for different therapeutic use and the low evidence of these, it is necessary to review the criteria for their approval and to follow up their compliance in order to guarantee their correct and efficient use.

eahp european association of hospital pharmacists