

New regulations require new proof of your risk effectiveness

Nostrapharmus Column in Pharma Magazine: March/April 2008

If you work in drug safety you will know that all marketed drugs require an assessment of the need for a risk management plan, the first step of which is to conduct a risk assessment. If there are no important potential risks found as a result, then it is acceptable to perform only routine pharmacovigilance. If the assessment finds either important potential risks, or some missing information, then it becomes necessary to perform either a risk minimisation action, or conduct further studies to find the absent data respectively.

So far, so routine. But are you aware of the extra layer of complexity that new regulations require? From now on all pharma companies conducting risk minimisation actions on marketed drugs are required to *prove* their effectiveness.

Is this news to you? Well, wait until you have heard the next bit. Although the regulators are seeking enforcement options, including fines, to punish those companies who don't implement their planned risk management actions, there are no set or recommended models for how companies should satisfactorily achieve or report this.

So, how do you go about tackling this new requirement? Nostrapharmus is not entirely convinced that the agencies appreciate the full extent of what they are asking for yet, and feels at this stage there is only so much that companies can do. However, the first step is surely to look at the different ways to minimise risk and to set the safety objectives for each of them. If, for example, you identified a potential risk to either pregnant women or their foetus, your safety objective would be to prevent pregnant women from using the drug. Your risk minimisation actions might include putting a specific warning advising against this type of patient on the label, setting up an education programme with the pharmacists and physicians who would advise them, an action to make the patient requirements stiffer ('Do not prescribe this drug unless a pregnancy test has been conducted'), or in the case of higher potential risk, setting up a restricted distribution programme.



Simplify what you do

New regulations require new proof of your risk effectiveness

Once you have set up your risk minimisation actions you will need to put some compliance measures in place i.e. are you doing what you say you will? You might put some steps in here that help ensure your sales force are doing what they need to mitigate risk, for example, did they deliver their education programme to GPs? Did they sit with Doctors and give them a presentation that adequately explained the potential risks to users and leave them collateral they could share with their patients? Was there a plan in place where the team could record every time they briefed a GP?

However, how you then measure how successfully you have met your safety objective is more difficult. One reactive measure would be to monitor adverse event reports for pregnancy. But this is not entirely satisfactory as not only is it a measure of failure, but it is comparable to an experiment without a control. The missing information is, how many pregnant women might have taken this drug without the additional risk minimisation action? You may need to seek a control population to help your effectiveness measure i.e. what percentage of women with the indication you are treating are pregnant? Or even what is the rate of pregnancy in the population as a whole?

If your company has not addressed the new requirements yet, you are not alone. At a recent ISoP event last year the MHRA reported that of all the companies who had identified the need to conduct further studies as part of their risk management plans, one third had not yet started any study, one third had not provided an expected update and only the remaining one third had provided the required update.

Nostrapharmus says: This is a new area for everyone and a big challenge to implement effectively. But, the implications of not doing so are frightening, not only in terms of patient safety, but also the future of the pharma business. The very least you can start with is a clear safety objective, some risk minimisation actions, and a plan on how to measure and report on what you are doing. Then when regulators come knocking you can prove your willingness to mitigate risk proactively and effectively. So, what are you waiting for?

Email: nostrapharmus@wcigroup.com



Simplify what you do