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FOI 11/148: Yellow Cards and Warning regarding unlicensed herbal medicines on sale over the internet

Dear Ms Cocking

Thank you for you recent enquiry regarding unlicensed herbal medicines and their sale over the internet. It might be helpful if I give you some background on the role of the Medicines and Healthcare products Regulatory Agency and the Yellow Card Scheme.

The Medicines and Healthcare products Regulatory Agency (MHRA) and Commission for Human Medicines (CHM) run a spontaneous adverse drug reaction reporting scheme (the Yellow Card Scheme) which collates suspected adverse drug reaction (ADR) reports from health professionals, patients and indirectly via the pharmaceutical industry.

Since the commencement of the Yellow Card Scheme in 1963, 1,382 ADR reports have been received in association with herbal/plant ingredients of which 29 have been associated with a fatal outcome. It should be noted that 10 of these reports also had another licensed medicine listed as a suspected medicine as well as the herbal/plant ingredient. Although these reports have a fatal outcome it does not necessarily mean that the medicines or herbal/plant ingredient were responsible for the patients death, some patients may have died due to progression of their underlying life-threatening medical condition.

We are unable to provide you with a breakdown of the figures above for the number of reports received for licensed and unlicensed herbal medicines; Yellow Card reports often just list the active ingredient and do not specify the brand, therefore you cannot distinguish the number of reports for licensed and unlicensed herbal/plant ingredients.

Please see attached a breakdown of the suspect herbal/plant ingredient and the suspected ADRs reported for each of these cases. When looking at this data it is important to note that the plant ingredient listed could be a single ingredient product or part of a multi-ingredient herbal product. It is also important to note that products containing herbal ingredients can have many different uses and that these products may be classified as medicinal herbal products, medical devices, homeopathic products, foods or cosmetic preparations. The Yellow Card scheme accepts all reports. However, the MHRA can only take regulatory action in relation to licensed medicinal products. We liaise with colleagues in other agencies if a safety issue is identified with a herbal ingredient that has multiple uses.

In addition the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions in the general population to these medicinal products as this scheme is associated with an unknown level of under-reporting. With herbal medicines various factors may inhibit reporting rates for suspected ADRs: often doctors don't ask, and patients don't tell about the latter's usage of herbal medicines; also patients' perception that natural equates to safe may reduce awareness of possible risk. Healthcare professionals are asked to report suspected adverse reactions on a voluntary basis and the submission of a report does not mean that the reaction cited was definitely caused by the medicine or herbal product. Originally the Yellow Card scheme only accepted reports relating to licensed herbal medicines, it was expanded to all herbal products in 1996, also the number of reporters accepted has expanded over the years and since 2006 all healthcare professionals, patients and their carers have been able to submit reports of suspected adverse reactions to the Yellow Card scheme.

With regards to your question on actions taken as a result of the receipt of Yellow Cards relating to herbal medicines; Every Yellow Card report it is entered onto our database and evaluated. Yellow Card reports are evaluated each week to find possible previously unidentified hazards and other new information on the side effects of medicines. Regulatory action is not necessarily taken on each case received. Since 2006, each Yellow Card report received for a herbal product has also been presented and discussed at the Herbal Medicines Advisory Committee, an independent body that works with the MHRA to advise health Ministers on traditional herbal medicines.

If it is deemed necessary, then further action will be taken which can include regulatory action to ensure that the medicinal product is used in a way that minimises risk and maximises benefits to the patient such as adding a new side effect to the product information for the authorised products. The MHRA regularly circulates communications to healthcare professionals and patients via our bulletin Drug Safety Update www.mhra.gov.uk/drugsafetyupdate or on our Herbal Safety News page on our website as issues are identified: http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/index.htm. If the risks are considered to outweigh the benefits then the product may be banned and removed from the UK market as was the case with herbal products containing Aristolochia or Kava-kava.

With regards to the statement "Be wary of any herbal medicine not licensed in the UK which is advertised for serious medical conditions. These unauthorised claims only serve one purpose – to persuade vulnerable groups to part with their hard earned money." This statement is based on a variety of evidence which can be viewed on our website at http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/index.htm.

Please do not hesitate to contact us should you have any further questions.

Yours sincerely

Central Enquiry Point
Medicines and Healthcare products Regulatory Agency

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