<u>Press release: MHRA warns athletes to avoid potentially dangerous DMAA</u>

As many people embark on a new-year fitness boost, athletes at all levels of sport are being urged to steer clear of the potentially dangerous ingredient DMAA.

DMAA can be found in unlicensed medicines marketed as sports supplements and it has been linked with high blood pressure, tightening in the chest, strokes, heart attacks and even death.

The warning has been issued by the Medicines and Healthcare products Regulatory Agency (MHRA) as a significant number of products containing DMAA continue to be found on sale in the UK.

MHRA has launched a 'Week of Action' between 30th January and 5th February supported by a number of leading national organisations to alert people to the potential dangers.

The Week of Action aims to improve awareness and will include an animated social media campaign, health & fitness bloggers sharing their stories and a video featuring Team GB Olympic weightlifters at the National Sports Stadium in Crystal Palace.

People who either suspect a product contains DMAA or want to check whether it is present are being encouraged to check online. If you find products on the market, immediately contact us via our dedicated mailbox dmaa@mhra.gsi.gov.uk

Named on the World Anti-Doping Agency's (WADA) Prohibited List, DMAA is banned during sports competition and the safety concerns are well documented.

When MHRA find unlicensed medicinal products containing DMAA on the market, urgent action is taken to remove them from sale. Last year MHRA took urgent action to remove a number of products containing DMAA from the market.

Dr Chris Jones, MHRA Medicines Borderline Section Manger said:

As always, we will continue to take robust action when unlicensed medicinal products containing DMAA come to our attention.

We first removed these products from sale in 2012, and will protect public health by continuing to do so. Although the sale of DMAA products has dropped since 2012, any companies selling this unlicensed medicine is one company too many.

Ashley Metcalfe, British Weight Lifting CEO said:

Weightlifting is a fantastic sport, not least because of the health and wellbeing benefits associated with strength training. However, as with all sports, it is very important that lifters participate in a safe and controlled manner, and are aware of the dangers of taking anything that could be potentially harmful — as has been proven with DMAA.

We are proud to support this campaign and hope that it encourages lifters that wish to use sports supplements to choose only those that are properly regulated, and remain well-informed about the dangers of using unlicensed medicines.

Dr Adam Carey, Chair of the European Specialist Sports Nutrition Alliance (ESSNA) said:

We fully support the MHRA's efforts to raise awareness of the dangers of supplements which contain DMAA. MHRA has classified such products as medicinal products and they have no place in legitimate sports nutrition supplements.

The dangers of consuming DMAA are significant and well-proven. We urge all sportspeople to avoid it at all costs — and emphasise that sportsmen and woman can only do this by making sure they're only buying their sports supplements from responsible and reputable retailers.

Nicole Sapstead, UK Anti-Doping Chief Executive said:

Any athlete who takes supplements containing DMAA in-competition — either deliberately or inadvertently — is not only risking their career, but is also risking their health.

If you are considering taking a supplement make sure you assess the need first by speaking to a qualified nutritionist. If you need to take a supplement, make sure you understand the risks and consequences by undertaking thorough research.

This 'Week of Action' is part of the FakeMeds campaign aimed at young adults and highlights the pitfalls of buying unlicensed medicines online.

Visit here for more information about the 'Week of Action'.

Background

- 1. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.
- 2. All our work is underpinned by robust and fact-based judgements to

ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health.

- 3. The approach for the classification of Borderline products is set out in Part 9 of the 2012 Human Medicines Regulations (as amended). A borderline product is a product which does not have a relevant authorisation or registration that the Licensing Authority regards to be medicinal product. Unless exempt unlicensed medicines may not be placed on the UK market without the appropriate authorisation.
- 4. MHRA classifies products (not substances) according to the definition of a medicinal product.
- 5. MHRA's Medicines Borderline Section reaches a determination on whether a product is or is not a medicinal product on a case by case basis, and in the light of:
 - ∘ the definition of a medicinal product
 - following an assessment of all the available evidence
 - relevant European Court Judgments and domestic Court precedents.
- 6. MHRA first classified a product containing DMAA to be <u>medicinal products</u> <u>in 2012</u>. MHRA has since determined a number of products which contain DMAA to be medicinal products and may not be placed on the UK market without the appropriate authorisation.
- 7. DMAA is regarded as being capable of significant modification to human physiology. Products containing DMAA have already been subject to regulatory controls in various countries around the world following a series of suspected links to serious adverse effects. It is MHRA's view that the uncontrolled sale and supply of products containing DMAA poses potential risks to public safety.
- 8. MHRA is responsible for ensuring that medicinal products work and are acceptably safe and is not responsible for the licensing of products such as sports supplements which are used by athletes to improve their performance. MHRA will investigate instances of the sale and supply of unauthorised medicinal products, including those that may be present in sports supplements.
- 9. We have been working with British Weightlifting, UK Anti-Doping, ESSNA, UK Active, National Food Crime Unit (FSA) and Sporting Integrity Ltd for the DMAA 'Week of Action.