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RECOGNISING ACHIEVEMENT

ADVANCED SUBSIDIARY GCE

HUMAN BIOLOGY

Growth, Development and Disease

F222

INSERT 1 Advance Notice

Monday 1 June 2009
Afternoon
Duration: 1 hour 45 minutes

OCE/V01901

INFORMATION FOR CANDIDATES

- Questions 1 and 2 are based on the Case Studies that follow on pages 3 to 5 of this Insert.
- This document consists of **8** pages. Any blank pages are indicated.

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Case Study 1

DRUG TREATMENT FOR OBESITY

On 29th June 2006, the BBC reported the launch of a drug to treat obesity. The drug, Rimonabant®, had been assessed in a series of randomised, placebo-controlled clinical trials. These trials involved over 5000 obese and overweight people in Europe and North America. All the participants taking part were encouraged to exercise and were also given a diet that reduced their energy intake.

As in all trials, participants would have had to sign a clinical consent form. These forms explain the purpose of the study and what would happen to the participant if they decide to take part. Various questions must also be asked, so prospective candidates for the trial are called for an interview. In the case of the Rimonabant® study, the research team had to establish that the patient was not diabetic and did not have cardiovascular disease.

It is usual for the initial interview to be followed by relevant tests. In this case, cholesterol and triglyceride levels would probably have been measured, as would blood pressure. If the interview or subsequent follow-up tests revealed that the participant did have either diabetes or cardiovascular disease, then they were excluded from the study. After the interview and tests, there followed a 'run-in' period in which participants followed the given diet and exercise plan. During this period, the mean weight loss across the whole group was between 1.9 and 2.0 kg. The participants were then randomised and allocated either the drug or the placebo.

The trial ran for one year. At the end of the year, the weight loss was significantly greater in the group receiving Rimonabant® than in the group receiving the placebo alone.

So, does this mean the drug will be available for prescription immediately?

This depends on the appraisal of the drug by NICE. The drug will undergo a 'technology appraisal'. This will result in recommendations on the use of the drug. The appraisal can take some time – at least two years in most cases. Consultees and the terms of the appraisal have to be identified. Independent academic centres are then asked to review the evidence, such as the outcome of the studies described above. Their findings are then looked at by the consultees, who are selected from a range of backgrounds – they could represent patient and carer organisations, the pharmaceutical industry, the NHS or research scientists. Their final recommendations can then be issued as guidance by NICE.

Why does it take so long to reach a decision?

Some consideration must be given to the long-term cost of this drug.

What length of treatment are we talking about?

The trial lasted for one year initially, but then the remaining participants taking Rimonabant® were re-randomised with half continuing and half coming off the drug. Those coming off the drug regained the weight they had lost. Current NICE guidelines for other established drugs used to treat obesity recommend treatment of no longer than one year. However, given that it has been estimated that, in the UK, 1 in 5 men and 1 in 4 women are obese, even the cost of one year's treatment may be considerable.

References:

1. Obesity pill now available in UK, *BBC News Online*, 29 June 2006, http://news.bbc.co.uk/1/hi/health/5128312.stm (accessed 27 October 2008)
2. New Drug Evaluation No. 78, *Regional Drug and Therapeutics Centre*, November 2006
3. Developing NICE technology appraisals, *National Institute for Health and Clinical Excellence*, http://www.nice.org.uk/page.aspx?o=114218 (accessed 27 October 2008)

Case Study 2

TACKLING CHILDHOOD OBESITY

A national programme of weighing and measuring schoolchildren for population monitoring was introduced by the Government in the 2005–06 school year. On a 'non-pupil' day, teaching staff and classroom assistants in a primary school are taking part in a training day designed to inform them about the programme and to teach them how to measure the children correctly. Randa, a representative of the Primary Care Trust (PCT), is leading the session. She is answering questions from the staff who are present.

Randa:	Is everyone clear what the purpose of the day is?
Head Teacher:	I think it would be useful if you could take us through the key points, Randa.
Randa:	By all means. You are probably aware that the Health Survey for England in 2005 showed that rates of obesity are rising among children. In boys and girls between 2 and 10, rates of obesity increased from 11% in 1995 to 17% in 2005. The Government has set a target of "halting the year on year rise in obesity among children aged under 11 by 2010 in the context of a broader strategy to tackle obesity in the population as a whole". That's a direct quote from what they call a Public Service Agreement or PSA.
Kimberley: (Year 2 teacher)	Can I ask what you feel about the target? We are used to target setting in school of course and sometimes targets can be a bit ambitious! Is this an ambitious target Randa?
Randa:	Well, in the last decade, British children have got fatter faster than anywhere else in Western Europe. We are at risk of an epidemic of diseases as a result. It is ambitious, but I think it *has* to be ambitious. The Government has made diet a big part of 'Every Child Matters'. The Government has introduced several initiatives, as you know – things like the National Healthy Schools Programme, the Food in Schools Programme, the school Fruit and Vegetable Scheme and others. School meals are even included in OFSTED reports! (*There are groans around the room*) The point about the National Child Measurement Programme is that we can see how effective these strategies are.
Catherine: (Year 1 teacher)	Randa, can I say that I am a bit worried that we are measuring how fat children are! It's going to create a lot of issues.
Randa:	We appreciate this, and if you look in the second section of your handout – (she *pauses while folders rustle*) – you will see that actually what we are asking you to measure is not 'fatness', but a height and a weight. In the second session after coffee, we'll go through these procedures very carefully. You'll find the guidelines quite strict but they are designed to keep distress to children to an absolute minimum. The measurements will be done twice – once in reception class and again in Year 6.

Kimberley:	Is the measuring compulsory?
Randa:	No, but as part of this programme, school nurses and other people from the PCT, such as myself, are permitted to weigh and measure children without the need for formal consent. Parents will, however, be sent a letter explaining the purpose of the exercise and be given the opportunity to opt their child out of it – and certainly last year some did opt out. We have been given a target of 80% coverage of the primary school population – so you see I'm no stranger to ambitious targets either! (*Kimberley smiles*)
Head Teacher:	That's an awful lot of data – where will it be stored and what will it be used for?
Randa:	This programme will give us one of the largest sets of child growth data in the world. You're absolutely right though – it's what we do with it that counts. We could chat about that over coffee, then I really need to get down to the main point of the day which is to cover the practicalities of the programme. Shall we go?

References:

1. The National Child Measurement Programme, *Department of Health*, http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Healthyliving/DH_073787 (accessed 27 October 2008)
2. Child obesity 'doubles in decade', BBC News Online, 21 April 2006, http://news.bbc.co.uk/1/hi/health/4930264.stm (accessed 27 October 2008)

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