Johnson & Johnson response:

European Commission GREEN PAPER
Promoting healthy diets and physical activity: A
European dimension for the prevention of
overweight, obesity and chronic diseases
COM (2005) 637

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1. Introduction

As the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services for the consumer, nutritional, pharmaceutical, medical devices and diagnostics markets, Johnson & Johnson is fully committed to playing its part in improving health care and consumer protection.

As part of this objective, we welcome the European Commission's Green Paper "Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases - COM (2005) 637" and the opportunity to share our thoughts in relation to this initiative.

Our response will firstly outline some general remarks to the Commission's approach in this field, then respond in greater detail to the specific questions as set out in the Green Paper.

2. General comments

Johnson & Johnson maintains that health should be approached in a holistic way. Activities in the area of public health should not only focus on health promotion and disease prevention; they should also take serious account of illnesses which are not necessarily a consequence of unhealthy choices or lifestyle. This is particularly relevant in the area of obesity, as the condition is generally viewed as a consequence of unhealthy choices, or lifestyle.

While we recognise that primary prevention is absolutely crucial, secondary prevention (i.e. treatment to prevent further health loss) and tertiary prevention (i.e. the best possible care and quality of life for those suffering from chronic disease and disability) are equally important to individuals. Therefore, when considering a response to obesity we believe a concerted European response to this major public health concern should also be holistic and address issues related to management, treatment and care, as well as to weight maintenance and living with obesity.

Engaging in dialogue with civil society (e.g. patient and health advocacy groups) and other stakeholders in this area is important in this respect, gauging their expectations and priorities before the concrete activities of a future strategy are being decided – we therefore welcome the Commission's intention to develop a broad and inclusive consultation. In addition to involving stakeholders in the definition of any future strategy in this field, it will be crucial to actively involve civil society in its actual implementation and evaluation.

As with any policy initiative, linkage with existing EU projects and programmes is of the utmost importance to ensure continuity and consistency. Any plans with regard to obesity should take into account the outcome of the 2004 Commission Reflection process for a new EU health strategy, the Commission's proposal for a new health and consumer

protection strategy and other relevant ongoing policy developments. The Commission's current efforts in relation to the Open Method of Coordination in relation to health and long term care (with a focus on quality, access and sustainability) and the ongoing development of a new Framework Programme in the area of research and development are clearly related to a consistent EU approach in this area. For instance, the proposal for the new R&D Programme refers to the need to address major diseases, such as diabetes and obesity; for the former, the focus will be on aetiologies of the different types of diabetes, and their related prevention and treatment. For the latter, the focus will be on the multidisciplinary approaches including genetics, life-style and epidemiology.

Linkage to the EU's R&D Programmes will also indirectly support the competitiveness of European health-related industries and businesses.

3. Specific responses to relevant sections of the Green Paper

IV. 3 Health across EU policies & IV. 4 The Public Health Action Programme

Johnson & Johnson welcomes the Commission's intention to develop this new strategy, emphasising the importance of improving health and consumer confidence. The Commission's explicit recognition of the crucial importance of health to all individuals and the positive contribution of health to productivity and growth clearly underlines the intention to develop a concrete and coherent set of actions. A healthy population will greatly contribute to reaching the EU's overall objectives, as formulated by the "Lisbon agenda", as a driver of competitiveness and sustainable development.

With respect to inclusion of stakeholders and dissemination to interested parties we are somewhat concerned with the potential risk of participatory bias. The European Parliament, while calling for an increased budget, has voiced similar concerns. For example, the voice of patients' organisations may be lost, given that consumer organizations are better structured and organised and have more experience in providing input into EU policy developments.

V. 1 Consumer Information, advertising and marketing

As stated within the Green Paper, unhealthy diets and lack of physical activity are the leading causes of avoidable illness and premature death in Europe and the United States. High cholesterol levels predominate, despite healthy eating campaigns.

Profound changes have taken place with respect to physical activity and attitudes within society. Changing behaviours will require more than just education — engaging all stakeholders ensures a more holistic and comprehensive approach. It is imperative that responses in the field of obesity employ new thinking and resolve for the long term. Whilst this may sound obvious there is an urgent need for a fundamental re-think around food, nutrition and exercise in general. New concepts and paradigms may need to be defined, understood and accepted. Novel technological responses, particularly in the

areas of nutrition and medicine – so called "innovative foods" - should be explored and embraced where appropriate.

Innovative foods, such as products containing stanols, could be promoted more across Europe, as they are effective in reducing absorption of cholesterol, are backed by medical science and would reduce the risk of heart disease (Law, 2000¹). In addition, support to increase research in this new and emerging field, indirectly promotes an innovative, knowledge-based economy.

The Green paper makes several references to the concern of the increasing burden of diabetes to society. In this respect the Commission should consider the important role sweeteners could play in the management of diabetes and ways in which education can support informing consumers of the need to replace sugar to further reduce this burden.

The Green Paper questions what kind of measures should be taken to ensure that the credulity and lack of media literacy in relation to vulnerable consumers are not exploited by advertising, marketing and promotion activities. Johnson & Johnson takes this point extremely seriously. Any health claims associated with a particular foodstuff should clearly be based on scientifically substantiated criteria. In the same manner, restrictions on the use of health claims should only be undertaken on the basis of scientific criteria. The EU can provide a vital service to Member States and citizens by demonstrating what evidence there is for the success of policies and initiatives and by distinguishing between pure marketing practices and evidence-based approaches.

When considering consumer education in the field of nutrition and food labelling the Commission should consider the value of endorsement from third parties, in particular health and medical professionals. Provided that the claim is scientifically substantiated, we believe it valuable that qualified health professionals, in addition to medical doctors (e.g. nurses, pharmacists, nutritionists and dieticians) are also able to provide valuable advice, and information to consumers with respect to innovative foodstuffs.

V. 2 Consumer education

One of the objectives of consumer policy should be to empower people to make informed choices regarding their diet and treatment options. Citizens need reliable and user-friendly information about how to stay in good health and the effects of lifestyle on health. When ill, they need information about their condition and treatment options. Information is the key, enabling citizens to make the right choices, and is therefore indispensable.

'Health competent consumers' – a concept that Johnson & Johnson has been advocating over recent years – take responsibility for their health and care options and contribute to the reduction of unnecessary healthcare spending. Research has shown that the first step towards improving the quality of healthcare is information on how to stay healthy, get

¹ Law, M (2000) British Medical Journal, March 25, V320, 861) 864

better and live with disease. Johnson & Johnson maintains that the healthcare industry is a legitimate and authoritative source of product and health related information (disease awareness campaigns), which consumers should have the right to access.

As stated previously, changing behaviours requires more than just education. The EU can play a significant role by promoting evidence-based good practice and act as a catalyst for encouraging innovation in this area. To make change happen all stakeholders should be engaged and committed — the healthcare industry should be considered a relevant partner and, should not be excluded. We would be pleased to further support a drive towards more widespread use of evidence-based strategies for effectively addressing the current healthcare challenges.

Lastly, key messages on nutrition and physical activity must be developed with the scientific community and underpinned by peer-reviewed evidence to support public health initiatives.

V. 3 A focus on children and young people

Johnson & Johnson welcomes the focus on children and young people. Our company has significant experience in running and collaborating within public-private partnerships and we would be keen to share our experiences following two recent successful programmes we have been involved in: the Diabetes Education Programme (UK), and the Prevention Obesity Programme (NL). More information on these initiatives can be found in Annex I

V. 4. Food availability, physical activity and health education in the work place

Johnson & Johnson welcomes any Community or Member State initiative, which could encourage improved nutrition and physical activity education in the workplace. We would be pleased to share our experiences from our involvement with the National Business Group on Health in the USA. The National Business Group on Health has prepared several position papers and toolkits for employers to help promote weight management in the workplace, for example the issue brief "Promoting Better Nutrition in the Workplace: Employer Strategies" (July 2004 Vol. 2, No. 2).

Other areas to potentially explore could be how to develop fiscal incentives to encourage employers and individuals to promote exercise and well-being.

V. 5 Building overweight and obesity prevention and treatment into health services & V. 6 Addressing the obesogenic environment

Johnson & Johnson has significant experience in the field of obesity prevention and treatment. Two areas of relevance to this consultation are J&J's experience in the field of blood glucose monitoring related to the management of diabetes, and our experience in the field of morbid obesity and the importance of medical recognition for the condition.

Any activity we undertake with patients includes an emphasis on the self-management of weight/ obesity. Studies² have shown that glycemic control with self-monitoring of blood glucose improves patient outcomes, with only minor increases in costs. If prevention is not taken the costs of complications with diabetes quickly become crippling for health authorities. We would welcome specific focus on diabetes, particularly following the conclusions of the Austrian EU Presidency conference on the Prevention of Type-2 Diabetes held on 15 and 16 February 2006.

As stated before, whilst primary prevention is absolutely crucial with respect to obesity, secondary and tertiary prevention are equally important to individuals – this is particularly the case with respect to morbid obesity. We fully appreciate that the EU's competence is limited in the field of management and treatment of obesity. However we would welcome the EU's further guidance to the Community in general of how to build obesity management programmes into healthcare systems.

As the Green paper rightly highlights, obesity is a complex issue and should not simply be reduced to lifestyle behaviour and habits. Obesity leads to other serious conditions and diseases. Morbid obesity is life threatening in itself. The condition is incurable, but treatable.

Importantly, morbid obesity and its life threatening co-morbidities (i.e. type 2 diabetes, dyslipidemia, hypercholesterolemia, hypertension, etc.) can be prevented by treatment interventions, such as bariatric surgery. It has been scientifically proven that both (malabsorptive and restrictive) bariatric procedures are the only effective preventive and treatment options to improve (cure) morbid obesity and/or its related co-morbidities in the long term. The National Conference of State Legislatures³, the European Association for Endoscopic Surgery (EAES)⁴, and the French and Canadian HTA authorities (CNAMTS, AFFSAPS and AETMIS) have arrived at similar conclusions.

The World Health Organisation (WHO) has appropriately identified morbid obesity as a major health threat (WHO Consultation on Obesity, 1999 & Obesity preventing and managing the global epidemic: report of a WHO Consultation, 2000). The WHO has recognised morbid obesity as a medical condition in itself (with strong genetic and other multi-factoral causal factors), rather than a mere cause of a given disease. With a view to adequately tackling this major health threat, it would be appropriate for the European Union to also focus on morbid obesity and further understand the causative factors, including underlying genetic factors.

The current approach with respect to the EU platform on Diet, Physical Activity and Health should be applauded. However, to tackle morbid obesity more needs to be done

² Palmer A, Bhattacharjya A, Dinneen S, Gavin J, Gray A, Herman W, Karter A; Cost-utility analysis in a UK setting of self monitoring of blood glucose in patients with type 2 diabetes; abstract submitted to ISPOR Europe

³ National Conference of State Legislatures Vol. 13, No. 32

⁴ Sauerland S, Angrisani L, Belachew M et al., Obesity surgery; Evidence-based guidelines of the EAES; (2005) 19: 200 - 221

than promote improved diets and physical activity. The Green Paper rightly recognises that obesity treatment options should be addressed. Recognition of morbid obesity, as done by the WHO, would help to shift focus and resources to understanding the needs and options with respect to the treatment of morbid obesity.

Besides medical intervention, follow-on treatment is of great importance, including counselling when considering the certain stigma associated with obesity. Unlike the USA, morbidly obese patients are often left on their own due to the lack of applicable treatment paths in Europe. The UK's National Institute for Clinical Excellence (NICE) has produced guidance declaring that obesity is also associated with decreased quality of life, in particular social stigmatisation⁵.

A way forward would be to consider how the EU may facilitate a discussion, as well as potential initiatives, around treatment paths and solutions to morbid obesity. For example, the next EU R&D Programme will emphasise the development and validation of new therapies, diagnostic tools and technologies; there may be synergies here with respect to a future strategy on obesity, as well as concrete possibilities to assess, or explore new forms of treatment.

V. 9 Recommendations for nutrient intakes and for the development of food-based dietary guidelines

J&J recognises the challenge and complexity of supporting food choice behaviour and, in particular, the complexities involved in developing systems/models that are required to be applied in different cultural settings, among individuals of differing age/gender/health status and among vulnerable groups.

Supporting food choice is more complex than providing information and needs a greater understanding of the wider issues. We recognise the need for and support the establishment of research initiatives to develop the European evidence base to develop systems to enable/empower consumers to make wise dietary choices.

To date, limited experience exists of profiling methodologies and those that exist have varied objectives, such as, assisting decision-making in relation to marketing directed at children, identification of foods eligible for health claims, helping consumers to make food choices, evaluating nutritional quality of foods to promotion of healthy dietary choices. Thus, the aims and intended health/nutritional outcomes of any system intended for Europe-wide application need to be clearly articulated at the outset and the system developed in accordance with sound scientific principles. Furthermore, it is important that consultation on such matters is open, broad-based and inclusive as exemplified by the process followed by the Food Safety Authority in this area.

⁵ NICE (2002), Guidance on the use of surgery to aid weight reduction for people with morbid obesity, Technology appraisal guidance – No. 46 – July 2002 – ref: N0119

Many research questions that are germane to profiling have been highlighted and need to be studied further, such as:

-Scope: should all foods be taken into account, specific food categories, only foods bearing health claims, PARNUT (Foods for particular nutritional purposes) foods or only to foods that make a significant contribution to nutrient intake; should certain foods be exempted e.g., traditional foods such as milk, fermented milk, olive oil or where there is a formulation, regulatory or technological limitation

-Criteria: the choice and balance of nutrients/ physiological ingredients that should be taken into account; the requirement of robust validation of the criteria established for individual foods. In addition, determination of the reference portion needs detailed consideration.

In the context of public health, the strengths, weaknesses, opportunities and potential threats (if any) of profiling initiatives need to be determined in relation to other methods which might be as/more effective depending on the required outcome, e.g. mandatory fortification (e.g. folic acid), incentives for foods with proven scientific benefits. Potential negative impacts of profiling should be addressed, such as, potential for increased obsessive behaviour, exclusion of foods that may contribute to the overall nutrient intake, impact on European R&D. In addition, methods developed need to be complimentary to existing systems e.g. label information, otherwise confusion may ensue. Systems must be tested for their ability to assist consumers to choose a healthy diet as a whole not just choosing healthy foods. Furthermore, audit mechanisms should be developed to monitor outcomes and continuous improvement processes should be considered to ensure that any system could be amended in a timely manner if required.

Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. The more than 200 Johnson & Johnson operating companies employ approximately 115,000 (over 33,000 in Europe) men and women in 57 countries and sell products throughout the world. For more information, visit www.jnj.com.

Annex I

Prevention Obesity Programme (NL)

The Dutch Johnson a Johnson companies (J&J Medical BV, Cordis, Janssen-Cilag, Centocor and Lifescan) have developed a successful obesity prevention programme as part of their broader "Health-connection" initiative. The 3-year project, started in 2005, is a collaboration with national organizations and consists of three major projects:

- 1. The "Kids in Balance©" project for schoolchildren. This project brings together three essential elements: movement and energy, medical facts and figures, and the value of good food. The flagship programme consists of three workshops, run over a period of four weeks. Teachers are briefed beforehand, and receive material for follow-up work in the class, and children are given workbooks with food ideas to try out at home. Parents can attend and participate in the workshops (www.balancematters.org).
- 2. Information exchange platform a symposium where scientists, policy makers, administrators and special interest groups on obesity meet. This is run by NASO (Nederlandse Associatie voor de studie van Obesitas).
- 3. Internal Employee Programme J&J employees are given the opportunity to visit an in-house dietician. Free fruit is available at all coffee corners and the company restaurant menu now provides a majority (90%) of healthy options.

In its first year of operation 35 schools participated in the programme. It is expected that this number will grow to 120 schools by 2007.

Diabetes Education Programme (UK)

LifeScan is a Johnson & Johnson company committed to improving the quality of life for people with diabetes. LifeScan offers a range of blood glucose monitoring products and Customer Care services to meet these different needs more closely.

LifeScan has worked in partnership with two other groups in the UK to deliver the Diabetes Education Programme aimed at helping to further educate both people with diabetes and the healthcare professionals who care for them. Responding to an element of the government's National Service Framework for Diabetes, which emphasized the need for more education for people with diabetes and healthcare professionals, LifeScan sat down with key stakeholders, Warwick Diabetes Care (part of Warwick University) and the Focus Group for Asians with Diabetes (FAD), to agree an approach aimed at helping to fill the gap. The Diabetes Education Programme's two key initiatives were born out of these discussions.

The first initiative provides diabetes education workshops for healthcare professionals across the UK. Facilitated by six Diabetes Nurse Specialists from Warwick Diabetes Care, the workshops are also supported by an interactive CD Rom, which was

specifically designed for the Programme. The second initiative, aimed at providing language sensitive diabetes education to the Asian community, led to the development of a multi-lingual video/DVD, which is now available in diabetes education centres across the country.

Both healthcare professionals and patients, previously daunted by diabetes' perceived complexity, have reported feeling more empowered and confident as a result of the workshops and video. Ultimately, LifeScan hope this initiative will help reduce the burden of diabetic complications on both patients and healthcare professionals, helping the communities in which the company operates.

This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.