GLOBAL TRENDS IN FOOD SUPPLEMENT REGULATION AND POLICY

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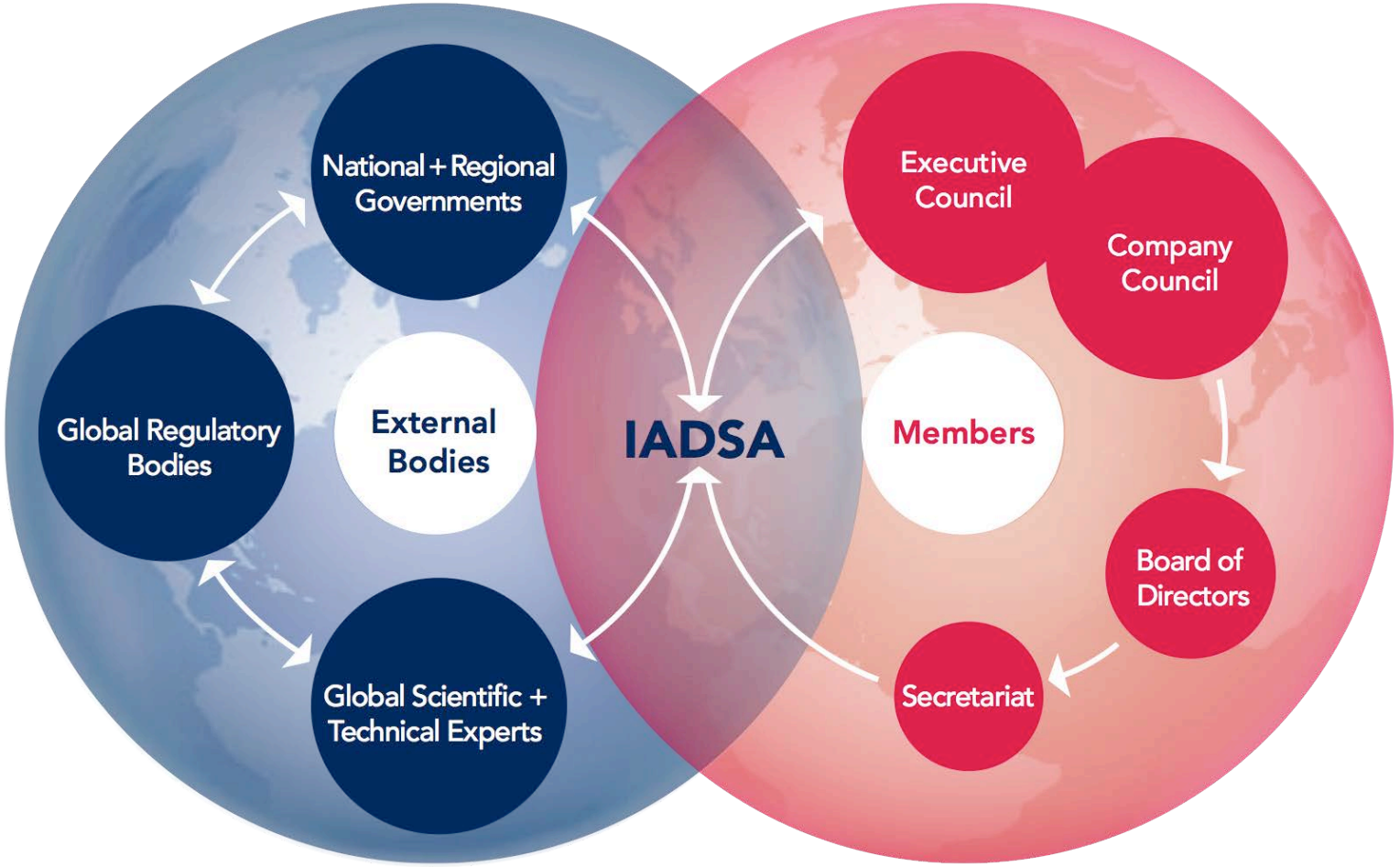
WHO ARE WE?

IADSA

Created due to the increasing regulation at global, regional and national level and the need for access to a global expertise and experience on scientific, technical, regulatory and policy issues.

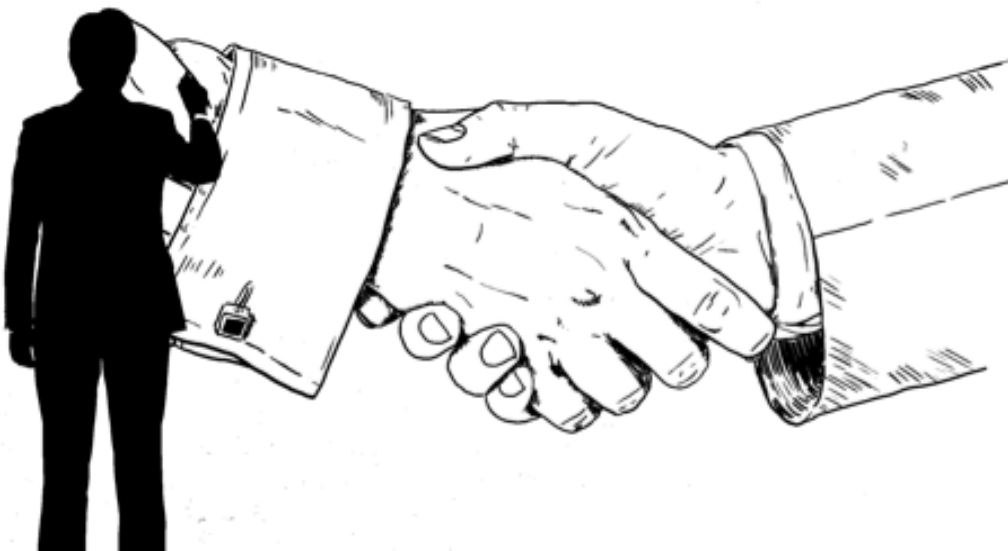
We are a non-profit organization with nearly 20 years close involvement in Codex Alimentarius.


National + Regional Governments
Global Regulatory Bodies
External Bodies
Global Scientific + Technical Experts
IADSA
Executive Council
Company Council
Members
Board of Directors
Secretariat

IADSA APPROACH

Partnership with government, scientists, technical, policy and economic experts.

We learn from each other and work with each other to build best practice.



THE CHALLENGE

More than 70 governments worldwide are developing or significantly amending legislation in the food supplement area.

Health supplements have their own specific requirements.

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GMP

BOTANICALS

CODEX RULES

MAXIMUM LEVELS

NUTRITION & HEALTH CLAIMS

GOVERNMENT ENDORSEMENT

MARKET ACCESS

The journey is long & often unclear

1. TRUSTED INFORMATION ON BEST PRACTICES

2. REFERENCE POINTS: DON'T WANT TO REINVENT THE WHEEL

3. TECHNICAL & SCIENTIFIC SUPPORT

4. GUIDANCE ON PROCESS

5. SUPPORT OF GLOBAL SECTOR

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TECHNICAL

SCIENTIFIC

2015

2014

Certificates of Analysis for Supplement Ingredients: Guidelines on Their Preparation and Use

Nutritional risk analysis approaches for establishing maximum levels of vitamins and minerals in food (dietary) supplements

2013

Shelf-Life Recommendations for Supplements

Vitamin and Mineral Safety handbook 3rd Edition

2012

Global Guide to the Handling of Adverse Event Complaints

Bioactive Food Components: Changing the Scientific Basis for Intake Recommendations

Ensuring micronutrient adequacy for vulnerable groups around the world: the role of food supplements

2011

Global Guide to Good Manufacturing Practice for Supplements

The scientific Substantiation of Health Claims: A Global Analysis

2010

2016

Stability Testing for Shelf Life Determination of Supplements

The Updated Risk Assessment of Vitamin D

2009

BOTANICAL SUPPLEMENTS

Mapping global regulation and policy

IADSA REGULATOR ROUNDTABLE ON BOTANICALS

- **VERONA, 2014**
- **SINGAPORE, 2015**
- **PRAGUE, 2016**
- **SEOUL, 2017**

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WORLD

LATEST DEVELOPMENTS

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CHINA | Notification

INDIA | Full system

PACIFIC ALLIANCE | Full system harmonisation

EU | Botanicals

SOUTH AFRICA | Full system

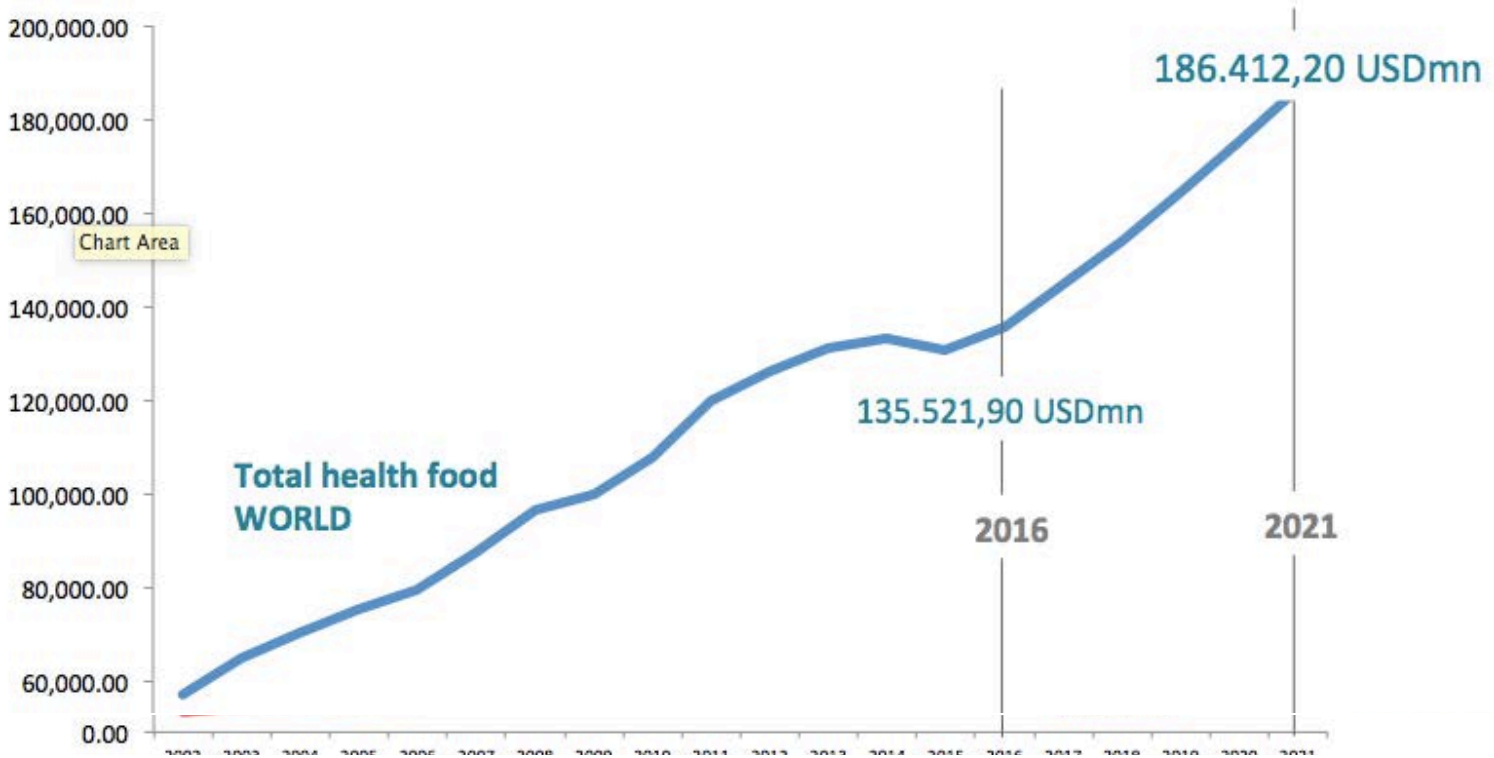
CANADA | Claims

NEW ZEALAND | Full system

ASEAN | Full system harmonisation

MARKET SIZE, RETAIL VALUE RSP

EUROMONITOR DATA



GOVERNMENTS

WHAT ARE GOVERNMENTS REFLECTING ON?

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COMPLEXITY & BORDERLINES

ADULTERATION

HOW TO SUBSTANTIATE CLAIMS

HOW TO REGULATE BOTANICALS & INTEGRATE HISTORY OF USE/ TRADITION

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TRENDS

WHAT ARE THE 5 MAJOR TRENDS IN REGULATION & POLICY?

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1 MAJOR TRENDS IN REGULATION & POLICY

HARMONISATION

Comparative approaches
Key reference points

1 MAJOR TRENDS IN REGULATION & POLICY

	EU	ASEAN	P. ALLIANCE
POPULATION	510 million	625 million	217 million
NB OF MSs	28	10	4
INDUSTRY INVOLVEMENT	Industry consulted	Industry partner	Industry initiated
HOW LONG ?	1989-2002	2004-2017?	2014-2017?

2 MAJOR TRENDS IN REGULATION & POLICY

MOVEMENT FROM PRODUCT REGISTRATION TO NOTIFICATION

Brazil
China
India

Reasons:

- Takes up significant resources
- Resource better spent on enforcement
- Can improve regulatory compliance

2 MAJOR TRENDS IN REGULATION & POLICY

MOVEMENT FROM PRODUCT REGISTRATION TO NOTIFICATION

Government focus on post-market surveillance

+

higher risk products

3 MAJOR TRENDS IN REGULATION & POLICY

PARTNERSHIP WITH THE PRIVATE SECTOR

ASEAN
India
Pacific Alliance

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4 MAJOR TRENDS IN REGULATION & POLICY

SEARCHING FOR THE RIGHT ROUTE ON CLAIMS ON SUPPLEMENTS

- Searching for a balanced approach
- Increasing understanding that at the very least products need indications of their purpose.

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5 MAJOR TRENDS IN REGULATION & POLICY

INCREASING UNDERSTANDING OF THE POTENTIAL VALUE TO SOCIETY

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5 MAJOR TRENDS IN REGULATION & POLICY

Socio-economic challenges

Role of food supplements

Productivity

Working life time

Ageing population

Social security system

Nutrition landscape

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UNITED STATES

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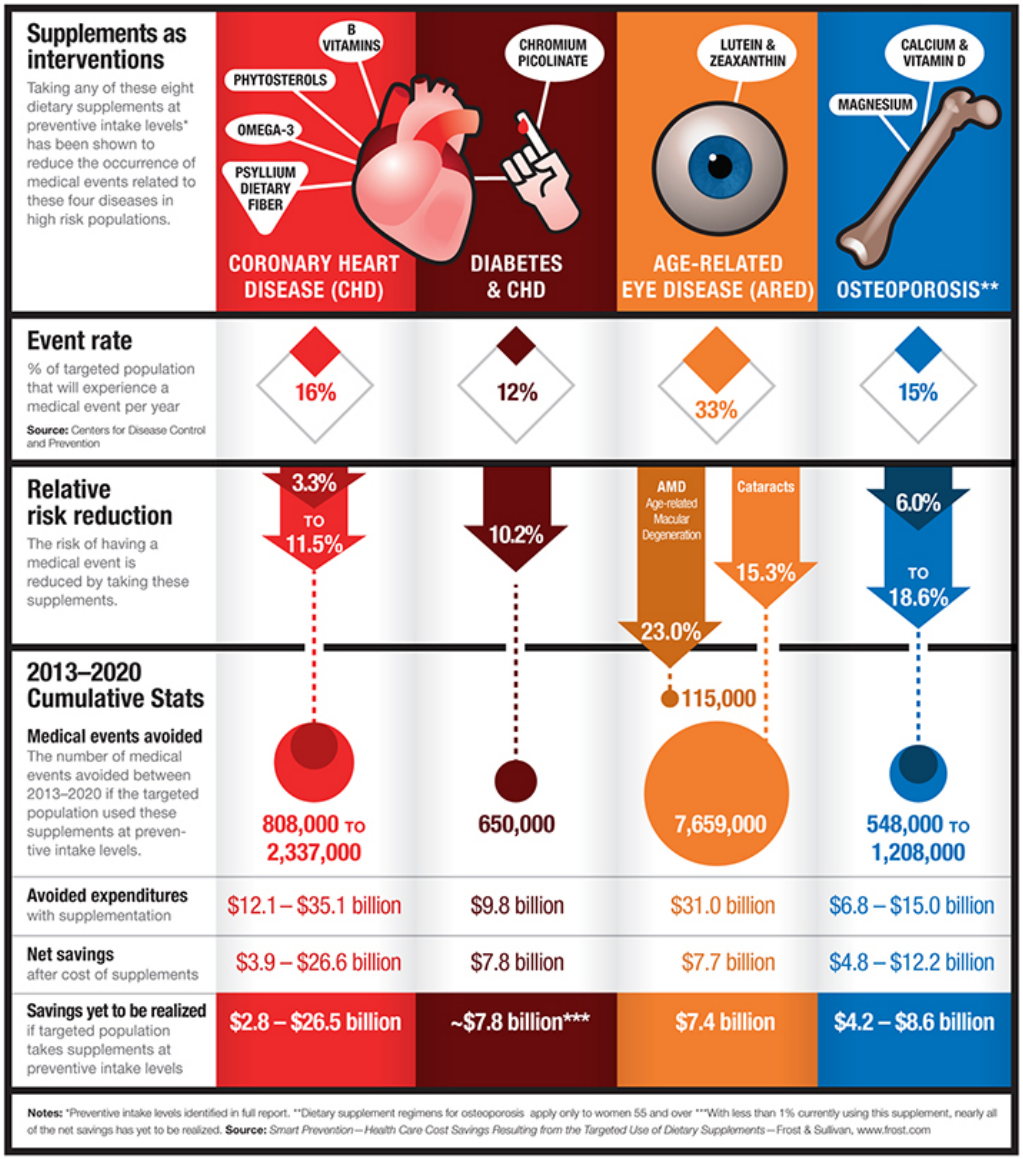
HEALTH CARE COST SAVINGS

Dietary Supplements for Smart Prevention

A new economic report shows that taking specific dietary supplements can provide significant individual and societal healthcare savings, by reducing the number of hospitalizations and other costly medical events associated with chronic diseases. The report looked at eight dietary supplement regimens and four conditions in a targeted population of U.S. adults 55+ who have the specific conditions or are at high risk for the disease.



Notes: *Preventive intake levels identified in full report. **Dietary supplement regimens for osteoporosis apply only to women 55 and over ***With less than 1% currently using this supplement, nearly all of the net savings has yet to be realized. **Source:** *Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements*—Frost & Sullivan, www.frost.com

www.supplementforsmartprevention.org
0913

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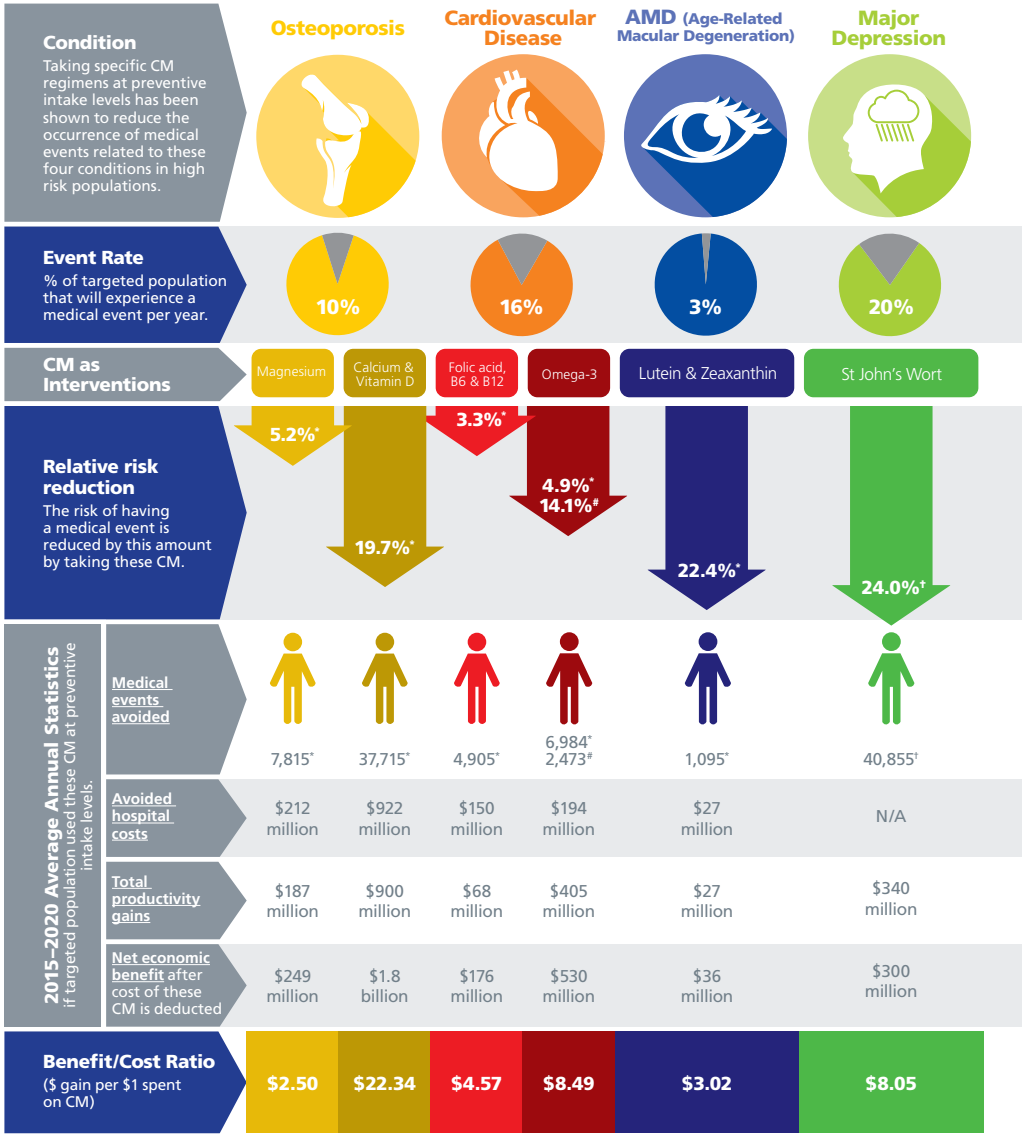
Health Care Cost Savings

TARGETED USE OF COMPLEMENTARY MEDICINES

A new economic report in Australia shows that taking specific complementary medicines (CM) can provide significant positive health outcomes and cost savings, by reducing hospitalisations and increasing productivity. The report looks at six complementary medicines regimens across four conditions in a targeted population of Australian adults who have the specific conditions or are at high risk for the disease.



Source: Targeted Use of Complementary Medicines: Potential Health Care Outcomes & Cost Savings in Australia – Frost & Sullivan.
Notes: *Hospital Separations, #Attributed deaths, †Successful Diagnostic Transitions.

EU

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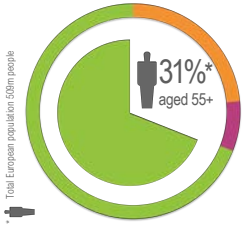
How Omega 3 could save €13bn a year in EU health care costs

Independent research company Frost & Sullivan explored the potential for generating health care cost savings in the EU through more widespread regular use of Omega 3 food supplements. The study focused on people aged 55 and over as this demographic group is considered to be at high risk of developing cardiovascular disease (CVD).



38.4m — 24%

Number and percentage of over 55s in the EU considered to be at risk of experiencing a CVD-attributed hospital event.

This represents a total cost of € 34,637 per event or an astonishing total of € 1.33 trillion over the next 5 years

-4.9%

Reduction in the relative risk of an individual aged 55+ experiencing a CVD-attributed hospital event through the daily consumption of 1000mg of Omega 3 EPA+DHA

€ 64.5 billion

Total savings generated in the EU over 5 years through more widespread regular use of Omega 3 supplements (equivalent to €12.9 bn per annum)

1.5 million

Number of preventable cases, over 5 years, of CVD in people aged 55+ through more widespread regular use of Omega 3 food supplements

food supplements europe

This infographic is based on The Health Care Cost Savings of Using Omega 3 Food Supplements in the European Union, a report produced by Frost & Sullivan forFood Supplements Europe, an international non-prot organisation.

Cost of dealing with bone fractures could plunge with wider use of Calcium + vitamin D supplements

Researchers from Frost & Sullivan examined the economic burden of addressing osteoporosis-attributed bone fractures among the 27.8 million over-55s in the EU with osteoporosis. This study is the second in-depth analysis commissioned by Food Supplements Europe to examine the positive impact of supplementation on EU healthcare costs.

17.6% of people aged 55 + in the EU living with osteoporosis

1.24m related fractures occurring every year

cost of dealing with these fractures €26.4bn/year €21,231 / event

Reduction of risk of osteoporosis-attributed fractures by regular consumption of 1000 mg Calcium + 15 mcg Vitamin D

-15%

19.8 billion

Total savings generated in the EU over 5 years through regular use of Calcium + Vitamin D supplements (equivalent to € 3.96 bn per annum)

186,690

osteoporosis-attributed bone fractures preventable every year

food supplements europe

This infographic is based on The Healthcare Cost Savings of Calcium and Vitamin D Food Supplements in the European Union, a report produced by Frost & Sullivan for Food Supplements Europe, an International Non-Profit Organisation

Phytosterols study strengthens case for healthcare cost savings through supplementation

The newly published phytosterols report is the third in a series by Frost & Sullivan. The first addressed Omega 3 and CVD, while the second explored the cost saving benefits of Calcium + Vitamin D supplementation in the context of avoiding bone fractures among the 27.8 million people in the EU aged over 55 and living with osteoporosis. It was found that savings of €3.96bn a year were achievable.

31.1m of people over 55 in the EU living with severe hypercholesterolemia

24.3% risk of experiencing a costly CVD-attributed hospital event

cost of addressing CVD 1,328 bn over the next 5 years € 34,637 per event over the same period

-2.3%

Reduction of risk of experiencing a CVD-attributed hospital event by regular consumption of 1.7 g phytosterol/day

Total savings generated in the EU over 5 years through regular use of pytosterol supplements (equivalent to € 5.3 bn per annum)

€ 26.5 billion

food supplements europe

This infographic is based on The Healthcare Cost Savings of Phytosterol Food Supplements in the European Union, a report produced by Frost & Sullivan for Food Supplements Europe, an International Non-Profit Organisation

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PLOS | ONE

RESEARCH ARTICLE

Public Health and Budget Impact of Probiotics on Common Respiratory Tract Infections: A Modelling Study

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Abstract

Objectives

Two recent meta-analyses by the York Health Economics Consortium (YHEC) and Cochrane demonstrated probiotic efficacy in reducing the duration and number of common respiratory tract infections (CRTI) and associated antibiotic prescriptions. A health-economic analysis was undertaken to estimate the public health and budget consequences of a generalized probiotic consumption in France.

Methods

A virtual age- and gender-standardized population was generated using a Markov microsimulation model. CRTI risk factors incorporated into this model were age, active/passive smoking and living in a community setting. Incidence rates and resource utilization were based on the 2011-2012 flu season and retrieved from the French GPs Sentinelles network. Results of both meta-analyses were independently applied to the French population to estimate CRTI events, assuming a generalized probiotic use compared to no probiotics during winter months: -0.77 days/CRTI episode (YHEC scenario) or odds-ratio 0.58 for $\geq$1 CRTI episode (Cochrane scenario) with vs. without probiotics. Economic perspectives were National Health System (NHS), society, family. Outcomes included cost savings related to the reduced numbers of CRTI episodes, days of illness, number of antibiotic courses, sick leave days, medical and indirect costs.

Results

For France, generalized probiotic use would save 2.4 million CRTI-days, 291,000 antibiotic courses and 581,000 sick leave days, based on YHEC data. Applying the Cochrane data, reductions were 6.6 million CRTI days, 473,000 antibiotic courses and 1.5 million sick days. From the NHS perspective, probiotics' economic impact was about €14.6 million saved

SOUTH KOREA

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Nutrition Research and Practice 2015;9(4):400-403

http://e-nrp.org

Evidence-based estimation of health care cost savings from the use of omega-3 supplementation among the elderly in Korea

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BACKGROUND/OBJECTIVES: By the year 2050, thirty-eight percent of the Korean population will be over the age of 65. Health care costs for Koreans over age 65 reached 15.4 trillion Korean won in 2011, accounting for a third of the total health care costs for the population. Chronic degenerative diseases, including coronary heart disease (CHD), drive long-term health care costs at an alarming annual rate. In the elderly population, loss of independence is one of the main reasons for this increase in health care costs. Korean heath policies place a high priority on the prevention of CHD because it is a major cause of morbidity and mortality.
SUBJECTS/METHODS: This evidence-based study aims to the estimate potential health care cost savings resulting from the daily intake of omega-3 fatty acid supplementation. Potential cost savings associated with a reduced risk of CHD and the medical costs potentially avoided through risk reduction, including hospitalizations and physician services, were estimated using a Congressional Budget Office cost accounting methodology.
RESULTS: The estimate of the seven-year (2005-2011) net savings in medical costs resulting from a reduction in the incidence of CHD among the elderly population through the daily use of omega-3 fatty acids was approximately 210 billion Korean won. Approximately 92,997 hospitalizations due to CHD could be avoided over the seven years.
CONCLUSIONS: Our findings suggest that omega-3 supplementation in older individuals may yield substantial cost-savings by reducing the risk of CHD. It should be noted that additional health and cost benefits need to be revisited and re-evaluated as more is known about possible data sources or as new data become available.

Nutrition Research and Practice 2015;9(4):400-403; doi:10.4162/nrp.2015.9.4.400; pISSN 1976-1457 eISSN 2005-6168

Keywords: Cost-effectiveness, omega-3 fatty acid, functional food, health cost, elderly

INTRODUCTION

By 2050, thirty-eight percent of the Korean population will be over the age of 65 [1]. Health care costs for Koreans over age 65, measured by expenditures of the national health insurance service, reached 15.4 trillion Korean won in 2011, accounting for a third of the total health care costs for the population [2]. Chronic degenerative diseases, including coronary heart disease (CHD), drive long-term health care costs at an alarming annual rate [3]. In the elderly population, loss of independence is one of the main reasons for this rate increase. Korean heath policies place a high priority on the prevention of CHD because it is a major cause of morbidity and mortality.

The potential health benefits gained from the consumption of omega-3 fatty acids, such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), have been widely reported, with the predominant literature indicating that omega-3 fatty acids can prevent or reduce the risk for CHD in humans [4]. The anti-inflammatory, anti-thrombotic, and anti-atherosclerotic effects of omega-3 fatty acids are believed to play a key role in the reduction of CHD and its clinical manifestations. The use of omega-3 supplementation improves health and reduces total costs under various scenarios [5,6], although each study has theoretical limitations. It has been reported that giving each member of the Medicare program in the United States (US) approximately 1,800 mg of omega-3 fatty acids per day would prevent 374,000 hospitalizations from heart disease and would thus reduce hospital and physician costs by $3.2 billion over five years, as measured using the Congressional Budget Office (CBO)'s accounting methods [5]. Supplementation with omega-3 fatty acids is implicated in fewer fatal myocardial infarctions and less cardiovascular mortality, as well as cost-savings compared

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THANK YOU!

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