



# Herbal Food Supplements

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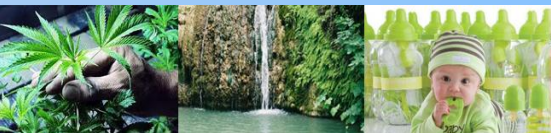


- Food Supplements are concentrated sources of nutrients or other substances whose purpose is to supplement the normal diet.
- They correct nutritional deficiencies or maintain adequate intake of certain nutrients.
- **They, in no case, substitute the balanced nutrition** (e.g. fruits, vegetables, fish, lean meat and whole-wheat cereals) by which all the necessary nutrients for a healthy diet are taken: vitamins, trace elements, amino acids etc.





- Food Supplements are regulated as Food Legislation (Directive 2002/46/EC) which focuses on vitamins, minerals, aminoacids, fibres, essential fatty acids and various herbal extracts as ingredients.
- Annex II contains a list of permitted vitamins and mineral substances only that may be added for specific nutritional purposes in Food Supplements.
- Annex II has been amended by Regulation 1170/2009.





# WIDE USE OF FOOD SUPPLEMENTS

- Their use is continuously increasing due to Changes in lifestyle ,new consumer perceptions ,new dietary needs etc
- They are widely used among vulnerable groups of people such as –pregnant women, young people
- It has been estimated that the worldwide trade in 2006 covered more than 60 billion dollars !





# Herbal Food Supplements

- Increased and wide use due to the perception / belief

“anything herbal is SAFE”

and

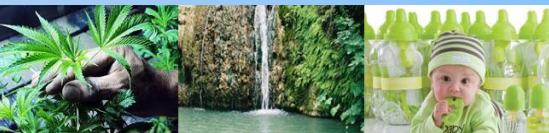
“any herbal product is safer than a synthetic product”





# Health problems reported

- Their increased and wide use has brought to light a number of cases appearing in literature, where health problems have been reported (Gabardi S. et al 2007):
- Nephrotoxicity with food supplements containing Creatine, Germanium, Uncaria tomentosa (Cat's Claw), Salix daphnoides (willow Bark), Pausinystalia yohimba, Larrea tridentate (chaparral).
- Hepatotoxicity with food supplements containing Hydrazine Sulphate, Rhizoma Kava etc
- Nephrolithiasis with food supplements containing Ascorbic acid (high does), Ephedra





# Concomitant use of Herbal Food Supplements with Medicines

- Food Supplements bought with no prescription/over the counter
- are freely used with Medicines
- bear no warnings with possible interactions with Medicines





# Interactions of Food Supplements with Medicines

- Interactions of constituents of food supplements with medicines with possible severe health risks have been reported (Heck AM et al 2000) :
- warfarin with herbal food supplements: Angelica root, Capsicum, Anise, Sweet Clover, passion flower herb, ginger ginko etc.
- Interactions of Amitryptiline and other antidepressants, digoxin and theophylline with supplements containing St John's Wort (*Hypericum perforatum*) have also been reported (Izzo AA, Ernst E, 2001)







# Interactions of Food Supplements with Medicines

- Interactions of constituents of Herbal and Non herbal food supplements such as
- Ginseng, Papain, Devil' claw, Co-enzyme Q10, and Vitamin E, with warfarin have been reported
- according to Heck AM et al 2000 the above have the potential to increase the danger of hemorrhage or decrease the efficacy of warfarin giving rise to possible thrombolytic cases





# Herbal Food Supplements During Pregnancy

- Many women during pregnancy also use herbal food supplements
- Effect of estrogens on embryo
- The embryo may possibly be affected from the estrogenic effect of some food supplements with phyto estrogenic effect. (Rousseaux CG Schachter H. 2003)

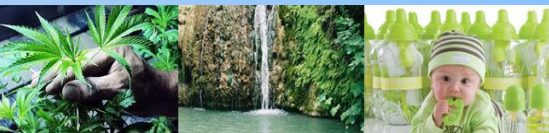




# Long Term Use

- Food supplements are sold over the counter as “safe” and as “natural” giving a false perception to consumers that there is no potential danger from their use, even when
- Taken over a long period (even vitamins, proteins etc)

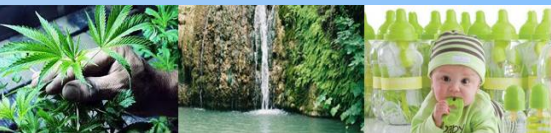
Creatine taken over a long time may cause severe harm to health) (Phua DH et al 2009)





- **Herbal Food Supplements containing undeclared active pharmaceutical ingredients and contaminants**

Gabardi S. et al 2007, reported the presence of undeclared Aristolochia (nephrotoxic indomethazine, mefenamic acid, phenylbutazone) in food supplements as well as contaminants such as Arsenic, Lead and Mercury





# Distribution / Sale of Herbal Food Supplements

Freely sold:

- in supermarkets,
- gym and sport centres,
- Internet and
- Pharmacies.

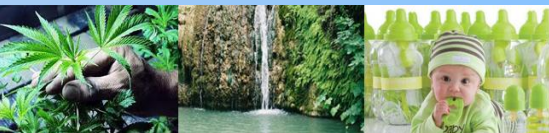
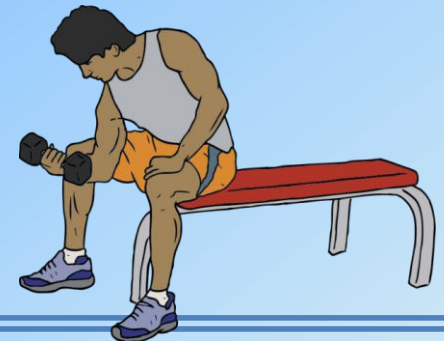




# Is their easy access a problem?

The Ministry of Health in Cyprus, wanted to ensure the safety of these “food products” that are **consumed, mainly by young people, by pregnant women, without guidance** and are easily accessible through the internet as well as in gym centres which are places that should promote healthy living.

Could there be a potential risk?





## Cyprus responded to such possible risks by setting up a strict control through a monitoring/surveillance programme

- The State General Laboratory (SGL)(Ministry of Health) in co-operation with the Competent Authorities on a yearly basis, since 2004, has been implementing an integrated programme which includes surveillance/monitoring of the market and analysis of samples, targeting on suspicious samples.





# Analytical Results of the SGL-Cyprus

HERBAL FOOD SUPPLEMENT				
Year	Number of Herbal samples Analysed	Senter	Analysis	Result
<b>2004</b>	10 herbal samples	Police	Anabolic Steroids and Stimulants	There are no records
<b>2005</b>	No herbal samples			
<b>2006</b>	1 herbal sample	Health inspection services	Anabolic Steroids and Stimulants & Sildenafil	Nil
<b>2007</b>	4 herbal samples	Health inspection services	Anabolic Steroids and Stimulants	Nil







# Analytical Results of the SGL-Cyprus

## HERBAL FOOD SUPPLEMENT

Year	Number of Herbal samples Analysed	Sender	Analysis	Result
<b>2009</b>	26 herbal samples	Health inspection services	Anabolic Steroids and Stimulants	Nil





# Analytical Results of the SGL-Cyprus

HERBAL FOOD SUPPLEMENT				
Year	Number of Herbal samples Analysed	Sender	Analysis	Result
2010	20 herbal samples	Health inspection services	Anabolic Steroids and Stimulants (Analysed 20 samples)	Nil
			Sibutramine (Analysed only 1 sample)	Nil
			We analysed only the 2 samples for 3 heavy metals (Pb,Cd,Hg)	Nil





# Analytical Results of the SGL-Cyprus



## HERBAL FOOD SUPPLEMENT

Year	Number of Herbal samples Analysed	Sender	Analysis	Result
<b>2010</b>	<b><u>OUT OF PROGRAME</u></b>			
	1 herbal sample	RASSF research (Health inspection services)	Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Caffeine	Sibutramine /Caffeine
	2 herbal sample	Limassol Post Office (Health inspection services)	Sibutramine	Sibutramine
	3 herbal sample	Limassol Post Office (Health inspection services)	Sibutramine	Sibutramine
	4 herbal sample	Larnaca Post Office (Health inspection services)	Sibutramine	Sibutramine / Phenophthalein / Dinorsibutramine
	5 herbal sample	Larnaca Post Office (Health inspection services)	Sibutramine	Sibutramine
	2 herbal samples	Health inspection services(Nicosia,Limassol)	Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Caffeine	Sibutramine / Synephrine
	1 herbal sample	Limassol Post Office (Health inspection services)	Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Caffeine	Sibutramine / Synephrine
	2 herbal sample	SGL	Sibutramine	Sibutramine





# Analytical Results of the SGL-Cyprus



## HERBAL FOOD SUPPLEMENT

Year	Number of Herbal samples Analysed	Sender	Analysis	Result
<b>2011</b>	13 herbal samples	Health inspection services	Anabolic Steroids/Stimulants/Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Yohimbine	Nil
	<b><u>OUT OF PROGRAME</u></b>	<b>Sender</b>	<b>Analysis</b>	<b>Result</b>
	2 herbal samples	Limassol Post Office (Health inspection services)	Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Caffeine/Yohimbine/Phenolphthalein	Sibutramine/Phenolphthalein
	2 herbal samples	Health inspection services(Nicosial)	Anabolic Steroids/Stimulants/Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Yohimbine	Sibutramine
	3 herbal samples	Health inspection services(Nicosial)	Anabolic Steroids/Stimulants/Sibutramine/Hydrochlorothiazide/Triamterene/Synephrine/Yohimbine	Caffeine





- **Product Name:** BOOM!
- **Label:** A food supplement based on Herbs and Vitamins
- **Substances found:** Sildenafil
- **Origin:** unknown





# Worrying Cyprus results from the analysis of a botanical preparation (100% natural soft gel)

The same product (but 5 different lots), were tested and found to contain:

- First lot (2009): **Sibutramine (10mg/cps)**
- Second lot (2010): **Sibutramine (15,7mg/cps) and synephrine**
- Third lot(2010): **Sibutramine, dinorsibutramine and Phenolphthalein**
- Forth lot (2011): **Sibutramine (8,2mg/cps) and Phenolphthalein (46,2mg/cps)**
- Fifth lot (2011): **NIL**  
-no uniformity of capsules size/weight

**European Medicines Agency has stopped the use of Simbutramine as a medicine since early 2010 !**





## Distribution of Herbal Supplements through the *Internet – a major problem*

- The supply of Food Supplements through questionable and not licensed pathways such as the internet or from door to door is a serious problem, since such products may have an unknown/doubtful origin and traceability and their quality can not be guaranteed.





# Herbal food supplements used as a vehicle for counterfeit drugs

- More and more herbal food supplements have mislabelling or in complete labelling and used as vehicles for counterfeit medicines
- They find easy distribution channels as food
- If they were distributed as medicines they requirements would be strict
  - stringent quality control
  - license for production, importation, registration, distribution, placing on the market

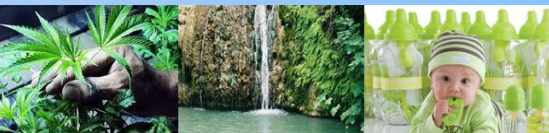






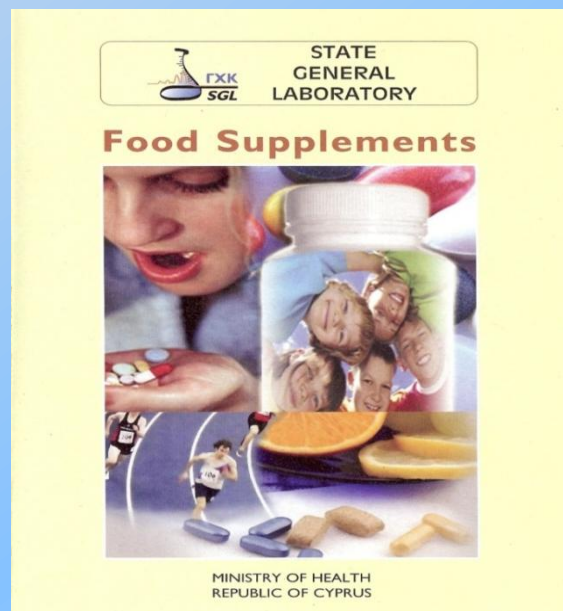
## Based on the above results the Ministry of Health in Cyprus as the Competent Authority for the Food Law has been requesting the following:

- Notification to the Ministry of Health for products that contain vitamins , minerals
- Such preparations must be supplied through stores under the supervision of qualified personnel: doctors, pharmacists, nutritionist, food scientists and others who get a license for this purpose from the Director of the Medical Services and Services for Public Health!



# Enhancing Consumer awareness :informative leaflet with warning of the possible dangers and possible emerging issues

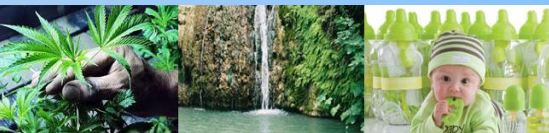
**Knowledge ..... for better preventive measures !**





# Further preventive Actions

- Maintain an international science watch
- Maintain a watch on trends in media and society
- Participate actively in European and International alert Networks
- *Initiate educational campaigns on the use of food supplements from September 2011 onwards among gym teachers in high schools who will transfer this knowledge to students*





# Problems: Legal Vacuum

- The existing Regulation does not even make reference that the presence of constituents other than vitamins, proteins, amino acids and the presence of any contaminants is not allowed
- Risk Managers, do not have any legal tool to take action when undeclared substances or contaminants are present in food supplements
- their actions can only be based after risk assessment based on Article 14 of Regulation 178/2002 EC





# Legal ambiguities

- When an undeclared pharmaceutical ingredient is found in a food supplement

How is it treated

- A Medicine ?
- A Food Supplement ?
- Pharmaceutical Services may say 'no it is not in their remit' as it is a pharmaceutical
- Food Authorities may say 'no it is not in their remit' as it is food
- Member States do not have a harmonised approach thus creating legal ambiguities in a common market





## Taking actions based on Risk Assessment

- Risk Assessment studies require data such as consumption data and upper tolerable limits
- Upper tolerable intakes do not exist for all nutrients (only for very few)
- This leaves the consumer very exposed to serious risks !





## Wide use by vulnerable people- Abuse and Misuse

- The sale of food supplements over the counter (supermarkets, food stores, gym centres etc) increases dangers to human health as there is no advice on the proper use, possible interactions with drugs, duration of use, side effects etc by competent persons (pharmacists, doctors, nutritionists)
- Studies show that 38% of food supplements are used by young people 15-32 years old (a sensitive group of people and more vulnerable (15-21))





- Should they be sold and distributed freely with no guidance/medical advice?
- Should the consumer be left so unprotected, with no warnings?
- Authorised manufacturers of herbal food supplements should also be protected and their financial interests not put at risk by pirates in this field
- Regular strict quality controls can differentiate between good quality and of questionable quality products







# Food Supplements **An emerging issue**



- The Food Supplement area is an area that needs to be thoroughly studied and documented as the data so far collected tend to send out a warning message :

**Food Supplements may well be an emerging issue and an amendment of existing Regulation should seriously be considered!!!**





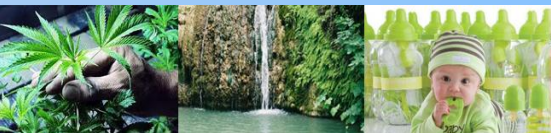
# *Problems therefore do exist !*

*Lets us not avoid them and start solving them!*





# Thank you for your attention



AOAC, Erlangen Germany, 9 – 12 October 2011

