



RESULTS OF THE QUESTIONNAIRE :
FINANCIAL POLICY FOR PKU FORMULA
AND PKU FOOD IN EUROPE

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11 out of 23 countries answered on the questionnaire

Content:

- General informations about PKU societies – members of the E.S.PKU
- Financial policy for PKU formula (mix)
- Low protein (PKU) food financing
- Tax and other reliefs, benefits and receipts
- Conclusion

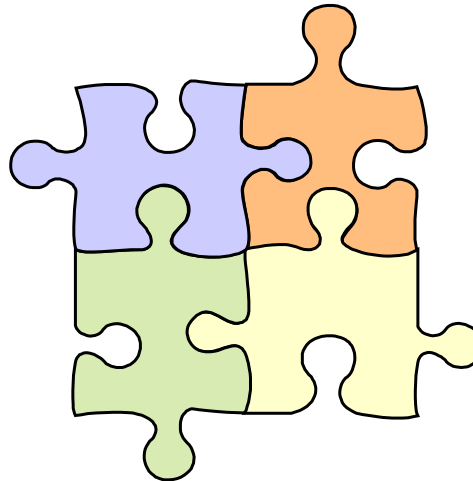
1. General information about PKU Societies



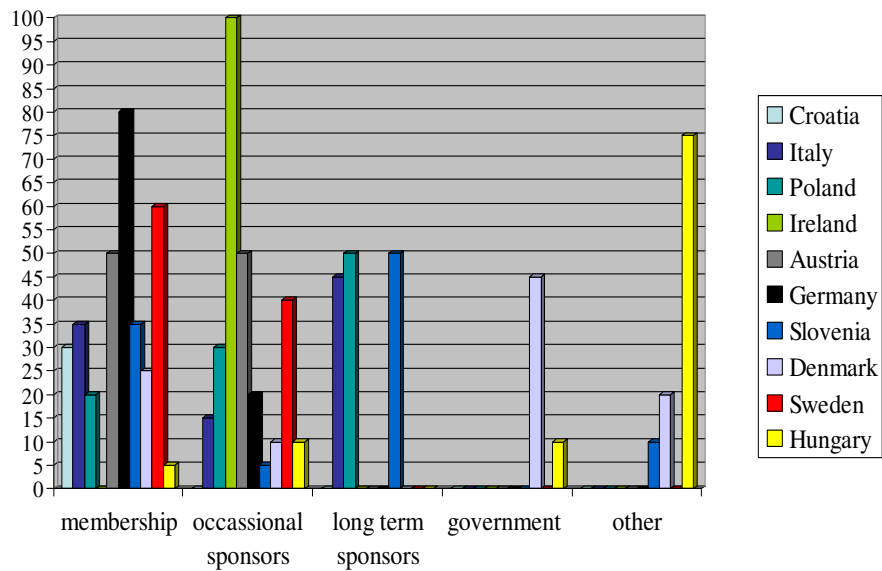
a) Number of members:

- Hungary = 400
- Sweden = 145
- Denmark = 220
- Austria = 143
- Ireland = 30
- Slovenia = 120
- Croatia = 139
- Poland = 1500
- Italy = 1757 (only APMMC)

All E.S.PKU members = 17.000



b) Sources of financing:





Conclusions:

1. Germany has the highest level of financing by membership fees (80%)
2. Ireland has the highest level of financing by occasional sponsorship (100%)
3. Denmark has the highest level of financing by government (45%)
4. Hungary has the highest level of financing by other means (75%)
5. Other sources of financing:
 - competition (Hungary)
 - tipsmidler (Germany)
6. Small portion of financing by government (except Denmark)
7. Only Slovenia, Italy and Poland have a long term (sponsor) financial resources other than membership and government financing
8. Financing by membership and occasional sponsorship prevail.
9. Relationship between PKU Societies financing and financial policy for PKU formula & food ?

2. Financial policy for PKU formula (mix)



a) Type of PKU formula and average monthly costs:

Children :

Poland* : 392 EUR (P-AM Universal, Milupa 2, Pheny Free)
Croatia*: 511,6 EUR (PAM 2),
Italy: 700 EUR (PKU1, MAXAMAID XP1)
Sweden: 600 EUR (MAXAMAID)
Slovenia: 600 EUR (PKU 2)
Hungary: 360 EUR (PKU 1,2, PAM 1,2, MAXAMAID XP)
Denmark: babies: XP Analog LCP, other children: PKU gel, PKU Express, XP Maxamaid, XP Maxamum, Minaflex, Phenyldon, Phlexi 10 system (drink mix, bars, tablets, capsules) Avonil tablets and powder (price: see table below)

Teenagers:

Poland* : 548,8 EUR (PAM Universal, Milupa 2, Pheny Free, Pheny Free 2HP)
Croatia*: 741,8 EUR (PAM 3),
Italy: 1008 EUR (PKU 2, MAXAMAID XP2)
Sweden: n.a. (MAXAMUM)
Slovenia: 750 EUR (PKU 2)
Hungary: 480 EUR (PKU 3, PAM3, MAXAMUM)
Denmark: same as children and PREKUNIL tablets from 18yrs age if poor compliance on AA powder (price: see table below)

* costs are calculated from price/500 g and from a necessary intake



Adults:

Poland* : 548,8 EUR (PAM Universal, PKU 3, Phenyl Free, Phenyl Free 2HP)
 Croatia*: 741,8 EUR (PAM 3, PAM Universal),
 Italy: 764 EUR (MAXAMAID XP3)
 Sweden: n.a. (MAXAMUM)
 Slovenia: 1000 EUR (PKU 3)
 Hungary: 620 EUR (PKU 3, PAM3, MAXAMUM, PAM MATERNAL)
 Denmark: same as teenagers, for pregnancy PREKUNIL tablets can not be used (price: see table below)

Late diagnosed:

Denmark: Prekunil tablets, XP Maxamum

Prekunil tablets should cover only 20% of total protein requirement for teenagers, adults and late diagnosed, compared o the rest of products which should cover up to 80% of total requirement.

Denmark: Table of various aminoacid Mix prices



Name of AA	500 g powder 500 tablets in EUR	Price per 100 g equivalent in EUR
XP Maxamaid	136	109
Prekunil powder	138	49
Prekunil Tablets	419	195
XP Maxamum	226	116
Phenyldon Mix 2	170	62
Phlexy-10 tablets	518	104
Phlexy-10 drink mix	256	123
Phlexy-10 capsules	264	127
Phlexy-10 bars	(5.368)	129
XP Analog LCP	109	168
Minaphlex	196	135
Avonil tablets	226	105
Avonil powder	183	61
PKU gel	81	39
PKU Express	144	40



Average monthly costs of PKU formula in Denmark:

Childrens: 13.727 EUR (for 10 yrs old)
Teenagers: 15.559 EUR (for 16 yrs old)
Adults: 9.129 EUR (adults on Prekuniil tablets)
Pregnancy: 13.860 EUR (average for maternal PKU)

b) Ratio between average monthly costs of PKU formula and average monthly wage:

Italy = 30-50%
Denmark = 268% (adults)-457%(teenagers)
(average monthly wage in Denmark =3.400 EUR)
Slovenia = 84 % (babies)-140% (adults)
Hungary = 100%

For other countries data is not available



c) PKU formula status:

- Foodstuff for special medical purposes:
(Slovenia, Sweden, Austria, Italy, Poland, Denmark,) – EU directive
- Medical substance, drug (Hungary, Croatia?)
- Normal foodstuff (Germany)

d) Financial burden of PKU formula – state and insurance co. OR patients?

Slovenia: Health insurance Institute; but in the future: danger of transfer to the patients?(Health Insurance Act, Health security Act)

Croatia: Croatian Health Insurance Institute (Drug list of the Croatian Health Institute)

Austria: Insurance companies under compulsory health insurance services

Denmark: State budget: Ministry of Social affairs

Germany: State budget for civil servants, insurance companies uder compulsory or supplementary health insurance service (Law on mandatory health insurance in connection with the directive on drugs):

- some health insurance co. pretend that the diet is not necessary for adult patients, but when patients present a doctor's certificate, they normally cover costs; there are some dangerous developments because the lack of money;



Sweden: partly payable by patients (medical prescription legal basis: Law concerning benefits of medical drugs: www.norisum.se/mp/sls/lag/20020160.htm):
 * up to 16yrs=10 EUR/month (for formula&food)
 * after 16yrs: 20-150 EUR/month depends on geographical area (for formula&food),
 the rest is payable by the health insurance service and state budget;

Poland: only a small fraction is paid by the patient (children=4EUR, teenagers=8 EUR, adults = 12 EUR monthly), the rest from the state budget (Ministry of Health);

Hungary: Health Insurance Institute (medical prescription legal basis: Health Official Journal)

Italy: SSN covers costs, medical prescription must be confirmed by ASL (medical prescription legal basis: DM 279/2001)

Ireland: Ministry of Health (state budget) and insurance company (compulsory health insurance), medical prescription is confirmed by Metabolic Unit of Temple Street Children Hospital

Table 1: PKU formula coverage		✓ free of charge
Slovenia	✓ up to 26yrs, from 26 yrs up -case by case not from compulsory health insurance	Medical prescription, confirmation
Croatia	✓ compulsory health insurance	Medical prescription, no confirmation
Austria	✓ compulsory health insurance	Medical prescription, no confirmation, but in the future-Yes
Germany	✓ compulsory + supplementary health insurance	Medical prescription, no confirmation
Denmark	✓ No limitations	Medical prescription, confirmation by J.F.Kennedy Institute to manufacturer**
Sweden	Partly payable by patients and partly by the government and insurance service	Medical prescription – limited up to 16yrs old
Poland	✓ compulsory health insurance	Medical prescription, no confirmation
Hungary	✓ (formula = medical substance)	Medical prescription Confirmation only for atypical PKU (BH4)
Italy	✓ compulsory health insurance	Medical prescription, confirmation
Ireland	✓ compulsory health insurance	Medical prescription, confirmation
Swiss	Up to 20yrs social insurance for PKU formula and food, after that – depends on individual insurance scheme (formula=drug)	
Spain	✓ (only SHS and Mad Johnson)	n.a.

****Denmark:** PKU formula is ordered every 3 months by patient of JFK Institute, by phone, directly to manufacturer, based of prepared prescription of Metabolic specialist as confirmed by JFK Institute. Bill is sent directly to JFK Institute and refunded by State of Denmark. No limitations.

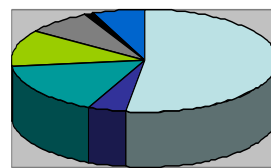


3. Financial policy for PKU food

a) Average monthly costs for PKU food:

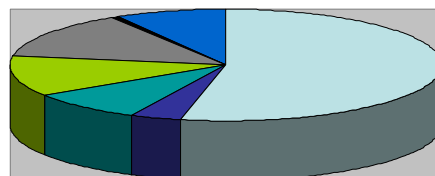
Baby:

Italy = 326 EUR
 Poland = 15-30 EUR
 Croatia = 50-100 EUR
 Hungary = 50 EUR
 Sweden = 6 EUR/month for food and formula
 Ireland = all covered by medical card
 Slovenia = 30-45 EUR
 Denmark = 72 EUR



A child:

Italy = 700 EUR
 Poland = 30-50 EUR
 Denmark = all covered by local municipal authority (=average 115 EUR)
 Croatia = 60-150 EUR
 Hungary = 180 EUR
 Sweden = 6 EUR/month for food and formula
 Ireland = all covered by medical card
 Slovenia = 110 EUR





Teenager :

Italy = 1008 EUR
Poland = 50-70 EUR
Denmark = 148 EUR (all covered by local municipal authority)
Croatia = 100 – 200 EUR
Hungary = 280 EUR
Sweden = 6 EUR/month for food and formula
Ireland = all covered by medical card
Slovenia = 200 EUR

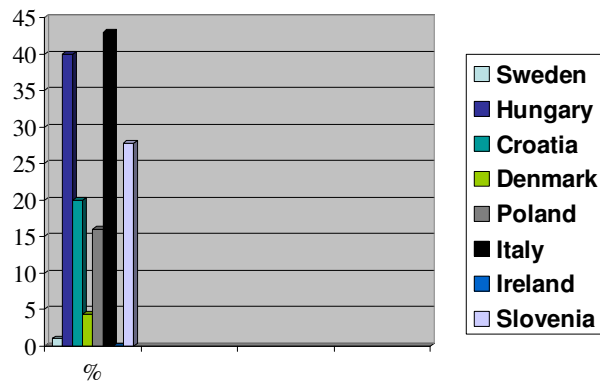
Adult:

Italy = 764 EUR
Poland = 50-90 EUR
Denmark = 148 EUR (all covered by local municipal authority)
Croatia = 100 – 200 EUR
Hungary = 350 EUR
Sweden = 20 - 150 EUR/monthly for food and formula
Ireland = all covered by medical card
Slovenia = 220 EUR



b) Ratio between average monthly costs of PKU food and average monthly wage:

Sweden = 1% for adults, for smaller under 1%
Hungary = 40%
Croatia = 20%
Denmark = 4,3%
Poland = 8-20%
Italy = 43,7%
Ireland = 0%
Slovenia = 29,5





c) PKU food status:

- Foodstuff for special medical purposes (Italy, Sweden, Hungary, Denmark, Croatia)
- Medicinal product (Ireland)
- Foodstuff for special purposes – dietary food (Germany, Slovenia)

d) Financial burden of PKU food – state and insurance co. OR patients?

- Patients (Poland, Slovenia, Germany, Hungary, Croatia except for flour which is covered from state budget, Swiss except flour and pasta)
- State budget – Ministry of Health (Ireland)
- SSN (Italy) under the legislation: DM 279/2001
- Local municipal authority budget: Denmark

Table 2: PKU food financing		✓ free of charge
	PKU food	
Slovenia	payable	
Croatia	✓ flour, other is payable	
Austria	Family support for PKU children	
Germany	payable	
Denmark	✓ Families receive monthly fixed amount of money	
Sweeden	Payable by patients: up to 16yrs = 6 EUR/month after 16yrs: 20-150 EUR/month depends on geographical area for PKU formula and food	
Poland	payable	
Hungary	payable	
Italy	✓ compulsory health insurance / on medical prescription	
Ireland	✓ On medical prescription	
Swiss	✓ flour and pasta is payed by insurance/ other is payable	
Spain	In some regions there is help of the government	

4. Tax reliefs, benefits and receipts



Country	Tax reliefs and other benefits	Receipts
Slovenia	No (but personal income Act's change is expected - 50% income deductions for parent of PKU child)	83 EUR/month childcare allowance
Germany	3.700 EUR/year deductible from taxable income of parent with PKU child 924 EUR/year deductible for nursing a child -Certificate that the patient can't survive without help (granted until the age of 14)	205 EUR/month for disability allowance
Denmark	Practical help up to 10hrs/week (cleaning, gardening, housekeeping), work compensation up to 10hrs/week Refund of practical tools (baking machine, scales, etc.), NB that are not dependant on income! Extra attendance of the child in nursery/kindergarden by parents All for PKU patient who is a surviving dependant	For PKU patient who is not surviving dependant: refund of practical tools (baking machine, scales, etc.). If late diagnosed, living in a care facility: no benefits except almost 100% payment of Prekunil tabletes, 600 EUR fixed amount is payed by patient
Sweden*	No	Up to 250 EUR/month childcare allowance
Hungary	48 EUR/year personal income tax relief for adult PKU. Special aid for mothers with PKU child: 10 yrs at home	60 EUR/month childcare allowance



Croatia, Poland, Ireland, Italy – there is no benefits, receipts and tax reliefs
Austria: no data available

Legal basis for benefits, receipts, tax reliefs:

Hungary: Legal basis for tax reliefs and benefits: Official journal 2003/17.1514

Germany: Legal basis for tax deductions: Income tax Law

Sweden: Legal basis for childcare allowance is Social Insurance Act:

conditions for childcare allowance:

- the child need special supervision and care for at least 6 months
- childcare allowance up to 19 yrs old,
- after 19 yrs: disability allowance or the child is being cared for in hospital continuing allowance for 6 months or if the child is severely ill, further 6 months child allowance

Denmark: Law on Social Services, article 29

Conclusions:

- Tax deductions or reliefs are rare and the users of those reliefs/deductions are parents of the PKU child and not the adult PKU (except Hungary)
- Most commonly there is childcare allowance

5. Conclusions



- Although there is a common EU legal framework for PKU formula, it is too general and allow different national implementation;
- Mostly PKU formula is covered under the compulsory insurance scheme, but there are some fear that PKU formula coverage will became a financial burden for the PKU patients;
- There is a need to harmonize financial policies for PKU formula and food in such a way to achieve the highest standard of social and health insurance for PKU patients;
- Slovenia need a support from E.S.PKU and from its member organizations in order to achieve those standards: PKU formula coverage from compulsory insurance regime.