

RULES OF CONDITIONS FOR THE IMPORT OF MEDICINES AND MEDICAL DEVICES WHICH DO NOT HAVE THE MARKETING AUTHORIZATION

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I. GENERAL PROVISIONS

Article 1

The Rules shall regulate conditions for the import of medicines, i.e. medical devices, which do not have the marketing authorization in the Republic of Serbia (hereinafter referred to as the "import").

Article 2

Terms used herein shall have the following meanings:

- 1) A Party proposing the import shall be a healthcare institution or a veterinary organization to which the Medicines and Medical Devices Agency of Serbia (hereinafter referred to as the „Agency”) shall submit a request for approval of import;
- 2) A medicine importer, i.e. a medical device importer, shall be a legal entity which has an authorization to market medicines or medical devices in the wholesale, issued by the competent ministry, and the importer shall carry out the import and distribution in accordance with the Rules (hereinafter referred to as the „Importer”);
- 3) The competent ministry shall be the Ministry of Health – for medicines and medical devices for human use, i.e. the Ministry of Agriculture, Forestry and Water Management - for medicines and medical devices for veterinary use;
- 4) A Tariff Code is a product code determined on the basis of regulations governing the customs tariff;
- 5) A Pharmacy is a healthcare institution which, in accordance with the law governing healthcare, carries out the pharmaceutical healthcare activity.

Article 3

The Agency may, at the request of a healthcare institution or a veterinary organization, approve the import of medicines, i.e. medical devices, intended for the treatment of a particular patient or a group of patients, provided that their delivery and/or issuance is carried out by the Importer, i.e. Pharmacy.

The request for the import of a medicine and request for the import of a medical device referred to in paragraph 1 of the Article are attached to the Rules and make their integral part (Attachment 1 and Attachment 2).

The quantity of an imported medicine, i.e. medical device, should not exceed annual needs of a health institution, i.e. a veterinary organization.

Article 4

A request for the import of medicines, i.e. medical devices, intended for scientific or medical research shall be submitted to the Agency.

The request referred to in paragraph 1 of the Article shall be submitted by a legal entity which carries out scientific or medical research in accordance with the law.

The quantity of the imported medicines and medical devices referred to in paragraph 1 of the Article should match the needs of scientific or medical research.

II. IMPORT OF MEDICINES WHICH DO NOT HAVE THE MARKETING AUTHORIZATION

Article 5

The Party proposing the import may submit the request for the import of medicines referred to in Article 3 of the Rules to the Agency, in the following cases:

- 1) When there is no medicine with the same generic name on the Serbian market, i.e. with the same generic composition and the same pharmaceutical form for which the marketing authorization is issued;
- 2) When a medicine is intended for the treatment of rare human diseases;
- 3) When it is necessary to provide sufficient quantities and types of medicines in the event of epidemics, epizooties, natural disasters and other extraordinary circumstances, at the proposal of the competent ministry;
- 4) When it is difficult to safely provide health care, i.e. when there are insufficient quantities and types of medicines on the market with issued marketing authorizations due to the problems in manufacturing and trade, at the proposal of the competent ministry;
- 5) When a medicine is used rarely and exclusively for veterinary purposes, i.e. when it is used for the treatment of less present target animal species.

The list of rare diseases referred to in paragraph 1, item 2) of the Article is attached to the Rules and makes its integral part.

Article 6

The Party proposing the import may, in addition to the request for the import of a medicine, submit to the Agency the following:

- 1) A detailed proposal for the import of a medicine issued by a doctor specialized in the relevant branch of medicine for the import of a medicine for human use, i.e. issued by a graduated veterinary for the import of a medicine used exclusively for veterinary purposes (hereinafter referred to as the "Proposal for the import of a medicine") issued 30 days before the date of submission of a request;

- 2) A medical prescription prescribed by a doctor competent for medicines issued on a medical prescription, i.e. for a medicine used by a patient as continuation of hospital treatment, which is valid 30 days from the date of prescribing;
- 3) A confirmation of the competent authority confirming that a medicine has the marketing authorization in the manufacturer's country and evidence that the medicine is in circulation in the manufacturer's country (Free Sales Certificate), i.e. for the medicine referred to in Article 5, paragraph 1, item 2) of the Rules, a confirmation of the competent authority that the medicine has the marketing authorization in the countries of the European Union or in the countries that have the same requests for the issuance of the marketing authorization;
- 4) A written proposal of the competent ministry for the import of a medicine in the case referred to in Article 5, paragraph 1, items 3) and 4) of the Rules;
- 5) A confirmation of the competent authority that a medicine is made in accordance with the Guidelines for Good Manufacturing Practice (GMP Certificate).

The proposal for the import of a medicine referred to in paragraph 1, item 1) of the Article is attached to the Rules and makes its integral part (Attachment 3).

Article 7

In addition to the data referred to in Article 6 of the Rules, the Party proposing the import of serums and vaccines shall, in addition to the request submitted to the Agency, also enclose an opinion of the Institute of Public Health of Serbia "Dr Milan Jovanović – Batul", i.e. of the Institute for Anti-Rabies Protection in Novi Sad for the vaccines used for veterinary purposes in scientific institutes, i.e. laboratories with accredited and validated methods.

In addition to the data referred to in Article 6 of the Rules, the Party proposing the import of medicines derived from human blood shall, in addition to the request, also submit to the Agency an opinion of the Institute of Blood Transfusion of Serbia.

The opinion referred to in para. 1 and 2 of the Article shall contain data on the possibilities of supply with these medicines from domestic manufacturers.

Article 8

For the import of hormone products, serums, vaccines, medicines derived from blood, radiopharmaceutical medicines and gelatine capsules, the Party proposing the import shall in addition to the request submitted to the Agency also enclose a confirmation of the manufacturer that medicines do not contain specific hazardous materials related to transmissible spongiform encephalopathies (TSE).

In addition to the request for the import of medicines containing prescribed specific hazardous materials of animal origin, if necessary, the Party proposing the import shall submit evidence of the absence of the risk of transmissible spongiform encephalopathies.

The evidence may be in the form of a statement of the marketing authorization holder from the country of origin, i.e. in the form of a statement of the manufacturer, or an appropriate TSE certificate.

Article 9

A specialist, i.e. a graduated veterinary, shall fill in the proposal for the import of a medicine referred to in Article 6, paragraph 1, item 1) of the Rules in two copies, one of which shall be submitted to the Agency and the other one shall be kept to themselves.

The competent doctor shall fill in the prescription referred to in Article 6, paragraph 1, item 2) of the Rules in two copies, one of which shall be submitted to the Agency and the other shall be kept to himself or herself.

The proposal for the import of a medicine and the prescription referred to in para. 1 and 2 of the Article shall be kept as medical records in accordance with the law governing health care records.

Article 10

In terms of the import of medicines referred to in Article 4 of the Rules, the Party proposing the import shall in addition to the request for the import of a medicine intended for scientific or medical research also submit to the Agency a written statement of the manager of the institution about the aim of the use of the medicine, i.e. about the aim of scientific or medical research, which contains a statement that the medicine shall not be used for clinical trials, and that it shall not be used on patients - customers.

Article 11

The Agency shall, at the request of the Party proposing the import of a medicine, approve every individual import of a medicine.

The Party proposing the import of a medicine shall submit to the Importer approvals for the import of a medicine issued by the Agency.

The import of a medicine may be carried out only on the basis of an original approval for the import of a medicine issued by the Agency.

Article 12

The Party proposing the import shall biannually submit to the competent ministry information on carried out import of medicines.

The information referred to in paragraph 1 of the Article shall contain the following data: reasons for the import referred to in Art. 3 and 4 of the Rules; in which of the cases referred to in Article 5 of the Rules the import has been carried out; the name of a medicine and international name of every active substance; the strength of a medicine; a pharmaceutical form and packaging; the name and address of the manufacturer and marketing

authorization holder in the country from which a medicine was imported; the imported quantity of every individual medicine; the batch number; the date of import; the name and address of the Importer.

III. IMPORT OF MEDICAL DEVICES WHICH DO NOT HAVE THE MARKETING AUTHORIZATION

Article 13

The Party proposing the import of medical devices may submit the request for the import of medical devices referred to in Article 3 of the Rules to the Agency, in the following cases:

- 1) When there is no medical device with the same or similar purpose on the Serbian market for which the marketing authorization is issued;
- 2) When it is necessary to provide medical devices of an appropriate purpose and quantity in the event of epidemics, epizooties, natural disasters and other extraordinary circumstances, at the proposal of the competent ministry;
- 3) When it is difficult to safely provide health care, i.e. when there are insufficient quantities of medical devices of an appropriate purpose on the market with issued marketing authorizations due to the problems in manufacturing and trade, at the proposal of the competent ministry;

Article 14

The Party proposing the import of medical devices may, in addition to the request for the import of a medical device, submit to the Agency the following:

- 1) A detailed proposal for the import of a medical device signed by a manager of a health care institution, i.e. by a veterinary organization, for the import of a medical device for human use, i.e. medical device used exclusively for veterinary purposes (hereinafter referred to as the "Proposal for the import of a medical device") issued 30 days before the date of submission of a request;
- 2) A medical prescription prescribed by a doctor competent for a medical device issued on a medical prescription, i.e. for a medical device used by a patient as continuation of hospital treatment, which is valid 30 days from the date of prescribing;
- 3) Evidence that a medical device is in circulation in the manufacturer's country (Free Sales Certificate);
- 4) A written proposal of the competent ministry for the import of a medical device in the case referred to in Article 13, items 2) and 3) of the Rules;
- 5) A Declaration of Conformity;
- 6) CE Certificate (except for medical devices of "class I" and for other "in vitro" diagnostic medical devices);
- 7) Evidence of insurance against consequences of the use of a medical device (policy insurance).

The proposal for the import of a medical device referred to in paragraph 1, item 1) of the Article is attached to the Rules and makes its integral part (Attachment 4).

Article 15

The proposal for the import of a medical device referred to in Article 14, paragraph 1, item 1) of the Rules shall be populated in two copies, one of which shall be submitted to the Agency and the other one shall be kept by a healthcare institution, i.e. by a veterinary organization.

The proposal for the import of a medical device referred to in paragraph 1 of the Article shall be kept as medical records in accordance with the law governing health care records.

Article 16

For the import of medical devices of animal origin, the Party proposing the import shall, in addition to the request, also submit to the Agency a confirmation of the manufacturer that a medical device does not contain specific hazardous materials related to transmissible spongiform encephalopathies (TSE), i.e. that it does not originate from them.

In addition to the request for the import of medical devices containing prescribed specific hazardous materials of animal origin, if necessary, the Party proposing the import of medical devices shall submit evidence of the absence of the risk of transmissible spongiform encephalopathies. The evidence may be in the form of a statement of the manufacturer or an appropriate TSE certificate.

Article 17

In terms of the import of medical devices referred to in Article 4 of the Rules, the Party proposing the import shall in addition to the request for the import of a medical device intended for scientific or medical research also submit to the Agency a written statement of the manager of the institution about the aim of the use of the medical device, i.e. about the aim of scientific or medical research, which contains a statement that the medical device shall not be used for clinical trials, and that it shall not be used on patients - customers.

Article 18

The Agency shall, at the request of the Party proposing the import of a medicine, approve every individual import of a medical device.

The Party proposing the import of a medical device shall submit to the Importer original approvals for the import issued by the Agency.

The import of a medical device may be carried out only on the basis of an original approval for the import issued by the Agency.

Article 19

The approval of the Agency referred to in Article 11, paragraph 1 and Article 18, paragraph 1 of the Rules shall contain data on the name and quantity of a medicine, i.e. medical device; a health care institution; an Importer; a foreign manufacturer; a foreign supplier; and the value of every individual import of a medicine, i.e. medical device, and other information.

Article 20

The Party proposing the import shall biannually submit to the competent ministry information on carried out import of medical devices.

The information referred to in paragraph 1 of the Article shall contain the following data: reasons for the import referred to in Art. 3 and 4 of the Rules; in which of the cases referred to in Article 13 of the Rules the import has been carried out; the name of a medical device and manufacturer; the class and category of a medical device; the name of the marketing authorization holder in the country from which a medical device was imported, i.e. that a medical device has been recorded in the register of medical devices at the competent authority; the imported quantity of every individual medical device; the date of import; the name and address of the Importer.

IV. TRANSITIONAL AND FINAL PROVISION

Article 21

The Agency shall issue an approval of import to the Party proposing the import, which submitted a request for the import of medicines and medical devices, by the date of entry into force of the Rules, for those medicines and medical devices whose quality, safety and efficacy is proved in the licencing process in accordance with the law regulating the field of medicines and medical devices.

Article 22

The Rules shall enter into force eight days after the date of its publication in the "Official Gazette of the Republic of Serbia".

Attachment 1

REQUEST FOR THE IMPORT OF A MEDICINE

Name of the medicine:

Quantity of the medicine:

Generic name:

Price:

Tariff code:

Name and strength of active substances:

Is the medicine marketed in the country of origin:

1. YES

2. NO

A list of countries in which the medicine has the marketing authorization:

Has a request for obtaining the marketing authorization been submitted to the Medicines and Medical Devices Agency of Serbia:

1. YES 2. NO

If YES, please state:

1. Date of submission:

2. No. of a request:

3. Date of expiry of the marketing authorization:

4. Registration number of the previous marketing authorization:

If NO, please state the reasons:

The medicine shall be introduced at the request of a health care institution/veterinary organization in which the medicine shall be issued.

Indications:

Imported quantities of the medicine in the current calendar year:

Name and address of the medicine importer:

PHONE/FAX:

I herewith guarantee for the import of the medicine by the above stated importer, as well as that I will keep records of the import and issuance of the medicine.

Date

Signature (seal) of the authorized person

Attachment 2

REQUEST FOR THE IMPORT OF A MEDICAL DEVICE

Quantity of the medical device:

Name of the medical device:

Generic name:

Class:

Price:

Tariff code of the medical device:

A list of countries in which the medical device has been marketed:

Is the medical device marketed in the country of the manufacturer:

1. YES

2. NO

Has a request for obtaining the marketing authorization been submitted to the Medicines and Medical Devices Agency of Serbia:

1. YES 2. NO

If YES, please state:

1. Date of submission:

2. No. of a request:

3. Date of expiry of the marketing authorization:

4. Registration number of the previous marketing authorization:

If NO, please state the reasons:

The medical device shall be imported at the request of a health care institution / veterinary organization in which the medical device shall be used.

Purpose of the medical device:

Imported quantities of the medical device in the current calendar year:

Name and address of the medical device importer:

PHONE/FAX:

I herewith guarantee for the import of the medical device by the above stated importer, as well as that I will keep records of the import and issuance of the medical device.

Date

Signature (seal) of the authorized person

Attachment 3

PROPOSAL FOR THE IMPORT OF A MEDICINE

Name of the doctor:

Information about the patient

Name:

ID No.:

Personal identification number:

Gender: M/F

Date of birth:

Diagnosis:

Indications:

Medical reasons for prescribing the medicine without the marketing authorization:

Prescribed dosage and method of use:

Daily dosage:

Quantity of the medicine and period of treatment with the required medicine:

Information about the doctor:

Name:

Address:

Specialty:

Licence No.:

Name of the health care institution:

Address of the health care institution:

I herewith take full responsibility that the medicine is necessary for the above mentioned patient, and that I will keep records of prescribing and proposing the import of the non-registered medicine:

Seal of the health care institution

Signature and facsimile of the doctor

Date

Attachment 4

PROPOSAL FOR THE IMPORT OF A MEDICAL DEVICE

Name of the medical device:

Purpose of the medical device:

Medical reasons for the procurement of the medical device without the marketing authorization:

Quantity of the required medical device:

Information about the health care institution:

Name of the health care institution:

Address of the health care institution:

I herewith take full responsibility that the medical device is necessary for the above mentioned health care institution, and that I will keep records of proposing the import of the non-registered medical device:

Seal of the health care institution

Signature of the manager of the health institution

Date

LIST OF RARE DISEASES

1. Brugada syndrome
2. Erythropoietic porphyria
3. Guillan-Bare syndrome
4. Familial melanoma
5. Genetically-conditioned autism
6. Tetralogy of Fallot
7. Scleroderma
8. Transposition of the great vessels
9. Focal Dystonia
10. Marfan syndrome
11. Non Hodgkin's lymphoma
12. Retinitis pigmentosa
13. Gelineau disease
14. Multiple myeloma
15. Alpha 1-antitrypsin deficiency
16. Congenital diaphragmatic hernia
17. Juvenile idiopathic arthritis
18. Neurofibromatosis type I
19. Congenital esophageal atresia
20. Polycythemia vera
21. Charcot-Marie-Tooth disease
22. Recessive form of polycystic kidney disease
23. VATER anomalies
24. Coffin-Lowry syndrome
25. Rendu-Osler-Weber disease
26. Dermatitis herpetiform
27. Small bowel atresia
28. Duodenal atresia
29. Ehlers-Danlos syndrome
30. Hirschsprung's disease
31. Microdeletions 22q11
32. Hereditary spherocytosis
33. Turner syndrome
34. Familial dilated cardiomyopathy
35. Familial breast cancer
36. MELAS syndrome
37. Leucinosi
38. Medium-chain acyl-coA dehydrogenase (MCAD) deficiency
39. Lennox-Gastaut syndrome
40. Fragile X syndrome
41. Primary biliary cirrhosis, Sickler syndrome
42. Williams syndrome
43. Willebrand disease
44. Gastroschisis
45. Microphthalmia
46. Omphalocele
47. Sarcoidosis

48. MURCS Association
49. Stargadt's disease
50. Glioblastoma
51. Multiple endocrine neoplasia type I
52. Prader-Willi syndrome
53. Alopecia totalis
54. Neophroblastoma
55. Cystic fibrosis
56. Duane syndrome
57. Neuroblastoma
58. Hodgkin's disease
59. Dermatomyositis
60. Polymyositis
61. Tuberous sclerosis
62. Congenital Adrenal Hyperplasia (CAH)
63. Rett syndrome
64. Angelman syndrome
65. Total congenital cataracts
66. Hyperlipidemia type III
67. Hemophilia
68. Trisomy 18 (Edwards syndrome)
69. Behcet's disease
70. Common variable immunodeficiency (CVID)
71. Picroscopic polyangitis
72. Idiopathic torsion dystonia
73. Oculocuta- neous albinism
74. Facioscapulohumeral muscular dystrophy
75. Holoprosencephaly
76. Sclerosing cholangitis
77. Sotos syndrome
78. Galactosemia
79. Leber's optic atrophy
80. Osteogenesis imperfecta
81. Smith-Lemli-Opitz syndrome
82. Amyotrophic lateral sclerosis
83. Treacher Collins syndrome
84. Tay-Sachs disease
85. Christ-Siemens-Touraline syndrome
86. Pheochromocytoma
87. Retinoblastoma
88. Rubinstein-Taybi syndrome
89. Alzheimer's disease
90. Zollinger-Ellison syndrome
91. Cornelia de Lange syndrome
92. Familial adenomatous polyposis
93. Huntington's disease
94. Acromegaly
95. Fructose intolerance
96. Primary ciliary dyskinesia
97. Progressive supranuclear paralysis
98. Acute intermittent porphyria
99. Sickle-cell anaemia
100. Deletion of the short arm of chromosome 5 (del 5p), Crie du Chat syndrome
101. Myasthenia gravis
102. Achondroplasia
103. Myotonic dystrophy (Steinert's disease)
104. Neuronal ceroid lipofuscinoses
105. Phenylketonuria
106. Smith-Magenis syndrome
107. Wilson's disease
108. Congenital disorder of glycosylation (CDG syndrome)
109. Muscular dystrophy type 2A, Erb type

110. Niemann-Pick disease type A
111. Propionic acidemia
112. Waardenburg syndrome type I, II and III
113. Becwith Wiedeman syndrome
114. X-linked adrenoleukodystrophy
115. Goldenhar syndrome
116. Usher syndrome
117. Duchenne and Becker muscular dystrophy
118. Multiple endocrine neoplasia type II
119. Systemic mastocytosis
120. Von-Hippel-Landau disease
121. Polyarteritis nodosa
122. Friedreich's ataxia
123. Poland's anomaly
124. Proximal spinal muscular atrophy
125. Seathere-Chotzen syndrome
126. Wegener's granulomatosis
127. Kennedy's disease
128. Cystinosis
129. Leber's congenital amaurosis
130. BOR syndrome
131. Bullous pemphigoid skin disease
132. Kartagener syndrome
133. Niemann-Pick type B disease
134. Pseudoxanthoma elasticum
135. Leigh's Disease
136. Peutz-Jeghers syndrome
137. Autosomal dominant spinocerebellar ataxia
138. Ocular albinism
139. Alport syndrome
140. Crouzon syndrome
141. Wolf-Hirschhorn syndrome, deletion in the short arm of chromosome 4, del 4p
142. Klippel-Feil syndrome
143. Langerhans cell histiocytosis
144. Nail-patella syndrome
145. Persistent hyperinsulinemic hypoglycemia of infancy
146. Sporadic aniridia
147. Fabry disease
148. Variegated porphyria
149. Budd-Chiari syndrome
150. Darier's syndrome
151. X-linked severe combined immunodeficiency (SCID)
152. A small number of bile duct, syndromic form
153. Cat eye syndrome
154. Apert syndrome
155. Hereditary spastic paraplegia
156. Adult Still's disease
157. Pierre Robin syndrome
158. Glycogen storage disease type II, Pompe disease
159. Mucopolysaccharidosis type III
160. Zellweger syndrome
161. Nephronophthisis
162. Long Chain Acyl-CoA Dehydrogenase Deficiency of fatty acids
163. Albers-Schonberg disease, osteopetrosis type
164. Angioneurotic edema
165. Ataxia telangiectasia
166. Chondrodysplasia punctate, rhizomelic type
167. Ocular coloboma
168. X-linked Emery-Dreifuss muscular dystrophy
169. Fanconi anemia
170. Gaucher's disease
171. Gorlin syndrome

172. Holt–Oram syndrome
173. Hypokalemic periodic paralysis
174. Isovaleric acidemia
175. Mucopolysaccharidosis type I
176. Nemaline myopathy
177. Neuroendocrine tumors
178. Thomsen disease; Becker disease
179. Churg–Strauss syndrome
180. Ellis–van Creveld syndrome
181. Bardet–Biedl syndrome
182. Ebstein anomaly
183. Hyperkalemic periodic paralysis
184. Krabbe disease
185. Mucopolipidosis type II
186. Albright's hereditary osteodystrophy
187. Menkes disease
188. Niemann–Pick disease type C
189. Glycogen storage disease type IV
190. Alpha sarcoglyopathy
191. Beta sarcoglyopathy
192. Delta sarcoglyopathy
193. Gamma sarcoglyopathy
194. Tetrasomy of the short arm of chromosome 18
195. Neurofibromatosis type II
196. Xeroderma pigmentosum
197. X-linked agammaglobulinemia
198. Cowden syndrome
199. Werner Syndrome
200. Glutaric acidemia type I
201. Homocystinuria
202. Mucopolysaccharidosis type IV
203. Lesch–Nyhan syndrome
204. Pfeiffer syndrome
205. Severe combined immunodeficiency T and B
206. Diamond–Blackfan congenital anemia
207. Alkaptonuria
208. Lissencephaly type I
209. Lipodystrophy, Berardinelli type
210. Progeria
211. Chronic granulomatous disease
212. Jeune syndrome
213. Short stature caused by resistance to growth hormone
214. Neurodegeneration with brain iron accumulation
215. Creutzfeldt–Jakob disease
216. Lowe syndrome
217. Mucopolysaccharidosis type VI
218. CHARGE anomalies
219. Metachromatic leukodystrophy
220. Bartter's syndrome
221. Fukuyama type muscular dystrophy
222. Walker–Earburg syndrome
223. Muscle-eye-brain disease
224. Ewing sarcoma
225. Homozygous Familial Hypercholesterolemia
226. Fibrodysplasia ossificans progressiva
227. Tyrosinemia type I
228. Congenital factor XIII deficiency
229. Hypophosphatasia
230. Oxidative phosphorylation diseases (Mitochondrial diseases):
Kearns–Sayre syndrome
Pearson syndrome

MERRF

other mitochondrial diseases

231. Diseases of beta oxidation of fatty acids in mitochondria:

Short-chain acyl-CoA dehydrogenase deficiency

232. Other more rare hypertriglyceridemia

233. Hypophosphatemic rickets

234. Primary hyperparathyroidism in children

235. Pseudo hyperparathyroidism

236. Other mukopolysacharosis

237. Cystationemia

238. Sulfite oxidase deficiency

239. Isovaleric acidemia

240. Methylmalonic acidemia

241. Hartnup disease

242. Multiple carboxylase deficiency

243. Propionic acidemia

244. Non-ketotic hyperglycinemia

245. Hyperoxaluria and oxalosis

246. Vitamin B6 dependent seizures

247. Glutathione synthetase deficiency

248. Urea cycle disorders:

Ornithine carbamyl synthetase deficiency

Arginine deficiency

Other

249. Lysinuric protein intolerance

250. Canavan disease

251. GM1 gangliosidosis

252. Fabry disease

253. Schindler disease

254. Wolman disease

255. Fucosidosis

256. Fructose intolerance

257. Pyruvate dehydrogenase deficiency

258. Pyruvate carboxylase deficiency