CHRONOLOGY OF UKRAIN (UPDATED VERSION)

From 1947 until 1984 the Spezialitätenordnung (Medical Specialities Order) was in force, which did not demand that clinical studies be carried out to check the efficacy of medical preparations if they were composed of starting substances which were already approved and registered and if they demonstrated a therapeutic advantage over their starting substances.

In 1975 a new product was created consisting of alkaloids from Chelidonium majus L. and Thiotepa that was found to be considerably more effective against cancer cells and 300 times less toxic than its starting substances. A patent application for the product was made in the same year.

In **1976** it was first demonstrated that this product has a selective effect and is toxic against cancer cells but not against healthy cells.

In **1981** an urgent letter was sent to the Austrian Minister of Health and Environmental Protection, Dr. Kurt Steyrer, asking for the application to be dealt with as quickly as possible and the preparation to be registered as soon as possible. Enclosed were 60 medical histories of patients who had exhausted all other forms of treatment. In 33 cases full or partial remissions were achieved and in the other cases it was possible to prolong life and improve the quality of life.

In 1983 the first research results on the product were presented at the 13th International Congress on Chemotherapy in Vienna, namely the results of in vitro and in vivo studies. The product was named UKRAIN for the first time in honour of the country where the first steps in its development were taken. 100 case histories of patients who had exhausted all other forms of therapy were also presented. Since then more than 300 specialist publications have appeared and the product has been presented at approx. 300 specialist congresses and conferences throughout the world.

In 1993 the Austrian Ministry of Health demanded that a comparative clinical study be carried out as well as a study with outpatients in accordance with §42 AMG (Austrian Medicines Act). It was demanded that the comparative study be carried out with a placebo group. For ethical reasons nobody was prepared to carry out such a study with cancer patients.

On **14 May 1995**, on request from the Ministry of Health, Part II of the Ukrain registration dossier "Chemical, Pharmaceutical and Biological Documentation" by Kurt Vymazal was submitted to the ministry. (**1 Report**)

On **2 June 1995** notification was issued rejecting the registration application of 1976.

On **26 February 1996** the contested notification was annulled by the Administrative Court of the Republic of Austria due to unlawfulness and infringement of procedural regulations.

On 10 October 1996 the second specialist report by Dr. Walter Knapp was drawn up on the demand of the of the Ministry of Health. (2 Report)

In **1996** the comparative study was published in a specialist journal and submitted to the ministry. The results of this study showed that after 21 months 78.6% of patients in the Ukrain group were alive and 33.3% of patients in the chemotherapy group.

In **1997** first-hand case reports from doctors who had carried out a study in accordance with §42 AMG (Austrian Medicines Act) were presented to the ministry. All of the doctors requested prompt registration.

In 1997 the Ministry of Health demanded a report on the clinical results.

On **24 February 1997** Dr. Stefan Duma submitted his "Clinical Report on the Preparation UKRAIN" to the ministry. (**3 Report**)

On 15 October 1998 was issued the registration in Ukraine.

On 5 August 1999 was issued the registration in Georgia.

On 16 June 1998 a report by DDr. Gerhard Nahler was issued. (4 Report)

On 11 April 2000 a report by Dr. Gerolf Tittel was issued. (5 Report)

On **5 March 2001** the supplementary application was made for the registration of Ukrain under the proviso "after the failure of standard treatment".

On 28 March 2002 a complaint was filed at the European Court of Human Rights in Strasbourg.

On 13 April 2000 was issued the registration in Turkmenistan.

On **7 September 2000** was issued the registration in Tadzhikistan.

On **25 April 2002** the supplementary application of **5 March 2001** for the registration of Ukrain under the proviso "after the failure of standard treatment" was rejected.

On **5 December 2000** was issued the registration in Aserbaidzhan.

In 2000 Dr. Burkhard Aschhoff from Germany (http://www.ukrin.com/docs/Aschoff_2000.pdf) published the positive results of the treatment of children with Ukrain. From August 1997 to 31.12.1999 203 cancer patients were treated at his clinic who had already exhausted all kinds of conventional therapy and who due to regression and/or progress of the disease no further forms of treatment were available. Therapy was started with the alkaloid derivatives from Chelidonium Majus L. This treatment was conducted in accordance with § 73 Abs. 3 AMG. Dr. Burkhard Aschhoff presented the results of this treatment of these 203 patients with various cancer diseases. The point was that all these patients were terminally ill and had been sent home to die by their doctors. Among them there were 16 children. The results of this treatment were: among adults there was a complete remission in 16.58% of cases, it was possible to achieve a partial remission in 62.57% of cases and for 20.86% of patients there was no influence. At the same time the results with children were as follows: complete remission 62.5%, partial remission 31.25% and no influence 6.25%.

In 2003 an application for Ukrain to be granted Orphan Drug Status was rejected in London.

In 2003 an application for Orphan Drug Status in the USA was made.

In 2003 Ukrain was granted Orphan Drug Status in the USA.

In 2003 was issued the first prolongation of the registration of Ukrain in Ukraine.

In 2004 an application for Orphan Drug Status in Australia was made.

In 2004 Ukrain was granted Orphan Drug Status in Australia.

2004 Dr. Nowicky was nominated for the Nobel Prize.

On **24 February 2005** the European Court of Human Rights found that the Republic of Austria had breached administrative regulation in the case of the registration of Ukrain.

On **26 June 2006** was issued the registration in the UAE.

In 2007 Dr. Nowicky was nominated for the alternative Nobel Prize.

In 2008 was issued the second prolongation of the registration of Ukrain in Ukraine.

In **2009** I suggested to the Austrian Government to provide my anticancer preparation Ukrain free of charge for the treatment of 11 children with cancer who had already exhausted all other types of conventional treatment and who had been sent home to die. This step I made after the dissemination of very positive results of the research conducted by Dr. Burkhard Aschhoff from Germany (http://www.ukrin.com/docs/Aschoff_2000.pdf). Such a high percentage of complete remissions with children with help of the medical preparation Ukrain made me decide to make an offer to give this medicine free of charge.

On 6 July 2010 was issued the registration in the Tunesia.

On **06 October 2011** at a press conference in Kiev I made an offer to give Ukrain free of charge for 100 children in Ukraine. At the same day a representative of AGES (Austrian Agency for Health and Food Safety which is subordinated to the Ministry of Health of Austria) came to Kiev by plane.

On 11 November 2011 the representatives of AGES and Austrian Federal Ministry of Internal Affairs came into the office of Dr. Nowicky in Vienna and confiscated 5,654 ampoules with Ukrain. The reason for the confiscation of this medical preparation was that the registration of Ukrain in Ukraine had been withdrawn few days previously. However, the Minister of Health of Ukraine had not withdrawn the registration of Ukrain neither "few days ago" nor on 11 November 2011. Among those representatives who where confiscating the ampoules with Ukrain on 11 November 2011 there was the representative of the AGES who came in Kiev on 06 October 2011.

On **04 September 2012** around 60 officials accompanied by an AGES official stormed all of business and private premises of Dr. Nowicky at nine o'clock in the morning. More than 200,000 ampoules with Ukrain, all the products of research, all credit cards, cash and savings books of his whole family were confiscated. Dr. Nowicky was arrested and imprisoned for 1,5 months and his company NOWICKY PHARMA was called a "criminal organisation".

The above mentioned actions were justified with a reason, that the preparation Ukrain does not have any effect. This statement is unfounded and absolutely groundless because there is

not one single specialist study which supports it. The effectiveness, safety and quality of the preparation Ukrain have been proved by numerous scientific studies.

On **25 January 2013** in Vienna there was made a press conference, organised by German and Austrian doctors, professors and scientists at which they presented excellent results of using Ukrain while treating cancer patients (children as well as adults).

On 15 August 2013 Dr. Nowicky sent an application to the International Criminal Court in Hague.

On **19 August 2013** Dr. Nowicky sent an application to the Prosecutor's Office of the International Criminal Court in Hague.

On **17 September 2013** Dr. Nowicky received the reference number concerning his criminal case from the Prosecutor's Office of the International Criminal Court in Hague, namely OTP-CR-280/13.