

# Update on medicines containing valsartan from Zhejiang Tianyu

20/08/2018

## **Update on medicines containing valsartan from Zhejiang Tianyu**

**Company no longer authorised to manufacture valsartan active substance for EU medicines due to presence of NDMA**

The company Zhejiang Tianyu is no longer authorised to manufacture the valsartan active substance for EU medicines following the suspension of its CEP – a certificate verifying that the quality of its valsartan meets European requirements.

The suspension of the certificate by the [European Directorate for the Quality of Medicines and Healthcare \(EDQM\)](#) comes after the detection of low levels of N-nitrosodimethylamine (NDMA) in the valsartan produced by the Chinese company.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

The levels of NDMA found so far in batches of valsartan from Zhejiang Tianyu are considerably lower than levels found in the active substance from Zhejiang Huahai, which triggered a [recall of several valsartan medicines](#) in July 2018. The certificate for Zhejiang Huahai had already been suspended and the company is also not permitted to supply valsartan active substance to the EU.

National medicines authorities are currently taking appropriate actions in their countries. Actions being taken, which are precautionary, include recalling and stopping the distribution of medicines containing valsartan from Zhejiang Tianyu. For further information, contact the relevant [national authorities](#).

EMA's review of valsartan in relation to NDMA is continuing and the Agency is working closely with the EDQM, international partners and national authorities in the EU.

The EDQM is a Directorate of the Council of Europe created in 1964 which sets standards for the quality of medicines and their active substances in European countries.

EDQM is in charge of issuing CEPs, which manufacturers can use to demonstrate that the quality of their active substance is suitably controlled and complies with European regulatory requirements. More information about the [procedure](#) for issuing CEPs is available on the EDQM website.

---

## More about the medicine

Valsartan is an angiotensin-II-receptor antagonist used to treat hypertension (high blood pressure), recent heart attack and heart failure. It is available on its own or in combination with other active substances.

Medicines containing valsartan as the only active substance have been authorised in the EU via national authorities. [Nine products](#) containing valsartan in combination with other active substances have been authorised centrally.

## More about the procedure

The review of valsartan medicines in relation to the presence of NDMA in the active substance was triggered by the European Commission on 5 July 2018 under [Article 31 of Directive 2001/83/EC](#).

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

---

# [Statement by Commission President Jean-Claude Juncker on the passing away of former UN Secretary General and Nobel Peace Prize winner Kofi Annan](#)

It was with deep sadness that I learnt this morning of the passing of my old friend and inspiration, Kofi Annan. On behalf of myself and the European Commission, I would like to offer my deepest condolences to his wife Nane and his entire family.

Today, the world mourns a great leader and humanitarian but celebrates a life full of courage, empathy and remarkable public service. He devoted his life to making the world a more peaceful and united place. He fought to end suffering and injustices across the world and helped to rebuild bridges where they had been destroyed. I am honoured to have seen this first-hand on many occasions throughout the many years we worked together.

His achievements as UN Secretary-General were rightly recognised with the Nobel Peace Prize and many other accolades throughout his life. But the greatest recognition we can give Kofi Annan is to keep his legacy and his spirit alive. It has never been more important than in today's world.

---

## Statement by Commission President Jean-Claude Juncker on the passing away of former UN Secretary General and Nobel Peace Prize winner Kofi Annan

It was with deep sadness that I learnt this morning of the passing of my old friend and inspiration, Kofi Annan. On behalf of myself and the European Commission, I would like to offer my deepest condolences to his wife Nane and his entire family.

Today, the world mourns a great leader and humanitarian but celebrates a life full of courage, empathy and remarkable public service. He devoted his life to making the world a more peaceful and united place. He fought to end suffering and injustices across the world and helped to rebuild bridges where they had been destroyed. I am honoured to have seen this first-hand on many occasions throughout the many years we worked together.

His achievements as UN Secretary-General were rightly recognised with the Nobel Peace Prize and many other accolades throughout his life. But the greatest recognition we can give Kofi Annan is to keep his legacy and his spirit alive. It has never been more important than in today's world.

---

## Letter of congratulations from President Donald Tusk to Marjan Šarec on his appointment as Prime Minister-Designate of the Republic of Slovenia

Your request will be handled by the Press Office of the General Secretariat

of the Council in accordance with the provisions of Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Your data will be stored in the database until you unsubscribe from the service.

Certain data (name, e-mail address, preferred language, media name, media type) may be disclosed to the press offices of the European institutions, the Permanent Representations of the Member States and to European Union agencies, under the conditions laid down in Articles 7 and 8 of Regulation 45/2001.

If there is data which you would not like to be stored, please let us know at: [\[email protected\]](#)

---

## [The situation for Chechens in Russia](#)

### The situation for Chechens in Russia

17 August 2018

EASO publishes a Country of Origin Information (COI) report on the situation for Chechens in the Russian Federation.

***The European Asylum Support Office (EASO) has published a Country of Origin Information (COI) Report entitled '[The situation for Chechens in Russia](#)'. The report provides an overview of the situation of Chechens living in Russia, outside of the North Caucasus.***

The report examines a variety of sources and focuses on different topics such as legal requirements, the criminal justice system, socio-economic circumstances, and the role of the authorities, together with closer examination of the situation for a number of specific groups of people, the report presents an up-to-date account of the current situation for Chechens living in Russia.

The report gives an overview of the main topics relevant for asylum authorities in Europe. A general overview of the Chechen communities in Russia outside of the North Caucasus region is provided, including the size and location of the communities and specific information on the largest communities. Legal requirements relating to procedures for renewing internal passports, obtaining external passports, and registering for residence is included in the report from both a procedural and a practical perspective, in order to highlight potential disparities between legislation and practice.

The housing, education, work, and health care situation for Chechens is also examined. Each topic is intersected with residence registration, how the system works in practice in Russia, and how specifically the access for Chechens is in each area.

A number of sub-demographic profiles are also presented in the report, namely on women, LGBT persons, children, Chechens eligible for military service, and human rights activists and dissidents. The reception of Chechens returnees is also examined in a separate chapter.

Lastly, the criminal justice system is discussed through topics such as identity checks, criminal cases against Chechens, legal remedies, and access to lawyers, among other matters. Included is also a summary of available information regarding Chechen authorities' potential information exchange with Russian federal authorities, as well as the role of the Chechen community in providing information to the Chechen authorities and the Chechen authorities' cooperation with the federal authorities.

The report was co-drafted by Country of Origin Information (COI) specialists from the COI units and asylum offices in the Czech Republic, Lithuania, and the Netherlands in accordance with the EASO [COI Report Methodology](#). The report was reviewed by COI Specialists from Austria, Belgium, Estonia, France, and Poland

*Any further information may be obtained from the European Asylum Support Office by contacting [press@easo.europa.eu](mailto:press@easo.europa.eu)*