International operations against illegal immigrant smuggling ring

Eurojust/Europol joint press release

26 October 2017

Judicial and law enforcement authorities from Belgium, Bulgaria, France, the Netherlands and the UK, supported by Eurojust and Europol, took action early today against a Europe-wide organised criminal group (OCG).

The OCG is suspected of facilitating unlawful immigration from countries including Afghanistan, Pakistan and Vietnam into the European Union in breach of immigration law. The OCG is also suspected of money laundering. The OCG is believed to have transported migrants in specially adapted vehicles, passing through Bulgaria, Belgium, France and the Netherlands, with the final destination being the UK.

Investigations into the OCG began in 2016 in the UK and the Netherlands, and links were detected to the other three Member States. UK and Dutch authorities brought the investigation to the attention of the affected Member States at a meeting of the North Sea Task Force, the establishment of which had been agreed at Eurojust with the objective of enhancing cooperation in tackling illegal immigrant smuggling in the UK, Belgium, France and the Netherlands.

Eurojust opened a case in January 2017. At the first of two coordination meetings organised by and held at Eurojust, national authorities from the UK, Belgium, Bulgaria, France and the Netherlands took the decision to form a joint investigation team (JIT). All five Member States, plus Eurojust and Europol, joined the JIT in June 2017. The terms of the JIT were negotiated and drafted by Eurojust, and Eurojust also provided funding for the JIT.

Europol provided extensive analytical support to the JIT throughout its operation, and held two operational meetings in The Hague to discuss the law enforcement response to the OCG. Europol supported the action day by providing dedicated analysts for the operation and deploying its mobile office to the UK Command & Control Centre. Information gathered during the day of action was analysed and exchanged in real time and immediately cross-matched. A coordination centre was held at Eurojust, with support provided by Eurojust's National Desks and Operations Unit.

Today's action :

- 5 Member States: Belgium, Bulgaria, France, the Netherlands and the UK
- 26 suspects were arrested: 8 in Belgium, 7 in Bulgaria, 11in the UK
- 6 European Arrest Warrants were executed
- 42 searches were carried out: 13 in Belgium, 7 in Bulgaria, 22 in the UK
- Several illegal migrants wer found during the searches in Belgium and

the UK.

For further information about the actions carried out today in a specific Member State, please contact the press services of the national authorities:

UK:
Catherine Ellis, Press Officer, Home Office
T: 0121 713 3187 (mobile: 0788 0081676)
Home Office News desk: 0207 035 3535
Catherine.Ellis9@homeoffice.gsi.gov.uk

Belgium:
Belgian Federal Prosecution Office
Eric.vandersypt@just.fgov.be

Bulgaria:
rarnaudova@prb.bg
T: 00 359 882 11 42 78

France:
Delphine.Le-Bail@justice.fr
Antoine.Berthelot@justice.fr

Netherlands:
Jeichien de Graaff, Press Officer, Regional Prosecutor's Office Rotterdam
T: 0031.88.6992102

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State of children's medicines in the EU

Today, the Commission presents a report to the European Parliament and the Council, on progress made in children's medicines since the Paediatric Regulation[1] came into force 10 years ago. It concludes that positive advances in the development of medicines for children could not have been achieved without specific EU legislation – e.g. the authorisation of 260 new medicines. The Paediatric Regulation also gives a good return on investment. However, the report acknowledges that more effort is needed to combine the effects of the Paediatric with those of the Orphan medicines Regulation to address shortcomings in treating rare diseases in children.

Commenting on the report, Vytenis **Andriukaitis**, Commissioner for Health and Food Safety, said: *"Whereas I am pleased with the overall progress made in improving children's access to safe, tailored medicines, I am committed to extending these positive gains to children with rare diseases. When we consider the advances in adult oncology, it upsets me deeply that we have not made the same progress in treating the cancers that affect children. In the next 10 years we must focus on making similar breakthroughs for children, by combining the incentives under the Orphans and the Paediatric Regulations, and by ensuring that the European Reference Networks[2] – in particular 'ERN PaedCan'[3] on paediatric cancer, reach full capacity".*

Key findings:

- The number of agreed paediatric investigation plans (PIPs)[4] – the first step in developing medicines for children, surpassed 1 000 in 2017. Of these, 131 were completed by the end of 2016.
- There is a clear upward trend in the number of completed PIPs, with over 60 % finalised in the last three years.
- The conditions with the highest number of completed PIPs are immunology/rheumatology (14 %), infectious diseases (14 %), cardiovascular diseases and vaccines (each 10 %).
- Due to the Regulation there has been a significant surge in new treatments for children with rheumatologic diseases, and area where there were very limited therapeutic options before 2007.
- Oncology (childhood cancer) is at the lower end of the agreed paediatric investigation plans, representing only 7% of completed PIPs.
- The report shows that the Regulation works best in areas where the needs of adult and paediatric patients overlap.
- There is also more research into paediatric medicines. The proportion of clinical trials that include children increased by 50 % between 2007 and 2016 from 8.25 % to 12.4 %, leading to more evidence-based information when medicines are used in children.

Next steps

As an integral part of its assessment of the impact of the Paediatric

Regulation, the Commission held a targeted stakeholder consultation which ran from November 2016 to February 2017. Following its adoption, Commissioner **Andriukaitis** will present the report's findings to people working in regulatory affairs, patients' groups and other stakeholders at a conference in Brussels on 21 November 2017.

This report is an essential intermediate step in the debate on a joint vision about the future parameters for paediatric and orphan medicines. Before proposing any amendments, the Commission will evaluate – in consultation with stakeholders and experts, how the combined effects of the Orphan and Paediatric Regulation can support medicine development in subpopulations of particular need, e.g. children with cancer. Results of this reflection will be presented by 2019 to allow the next Commission to take informed decision about possible policy options.

Further information

Children's medicines report

Questions and Answers on 10 years of the EU Paediatric Regulation

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[1] Regulation (EC) 1901/2006

[2] European Reference Networks for rare or low prevalence complex diseases

[3] ERN PaedCan Factsheet

[4] A Paediatric Investigation Plan (PIP) is a research and development programme that aims to ensure that a new product is tested for its potential use in children and that such tests become an integral part of the overall product development.

Questions and Answers on 10 years of the EU Paediatric Regulation

Why does the EU need special legislation for children's medicines?

Before the Paediatric Regulation came into force there was a very serious gap in the development and testing of medicines for children. Many products used in children were prescribed and administered based on physicians' own experience rather than on the results of clinical research. Medicines were often not available in a form suitable to children. Doctors had to do their best to adapt adult medicines and get the dosage right for children, e.g. by crushing adult tablets and using only a portion depending on a child's weight. This off-label use of adult medicines was widespread – estimated at

more than 50%. Such practice comes with the risk of inefficacy as well as serious side effects.

What are the main aims of the Paediatric Regulation?

The Regulation is structured around three main objectives:

- More medicines for children
- Better product information
- More paediatric research

How does the Regulation set out to meet these objectives?

The Regulationsets up a system of obligations, rewards and incentives to encourage manufacturers to research and develop medicines for children's specific therapeutic needs. It obliges companies to screen every new product they develop for its potential use in children, to progressively increase the number of products with paediatric indications. This is done at the earliest stage of development through the 'Paediatric Investigation Plan' (PIP) which is an obligatory part of overall product development.

In addition, the Regulation promotes high-quality information and high-quality research into medicines for children through measures, such as:

- an EU network of networks of investigators and trial centres carrying out paediatric research;
- an EU inventory of paediatric needs;
- a public database of paediatric studies; and
- a requirement for companies to submit any existing paediatric studies on authorised medicinal products for scrutiny by regulatory authorities.

Is progress in children's medicines really thanks to EU legislation?

A comparison of the situation before and after the Regulation demonstrates a clear positive effect in terms of new authorised medicines. During the period the Regulation has been in force (2007-2016) over 260 new medicines (new marketing authorisations and new indications) for use by children were authorised, most linked to the Regulation's requirements. The number of agreed paediatric investigation plans (PIPs) surpassed 1 000 in 2017, of which 131 were completed at the end of 2016. There is a clear upward trend in the number of completed PIPs, with over 60 % finalised in the last three years. This quantitative analysis shows clear progress. The figures are also in line with expectations taking into account the time it takes to bring a new medicine to the market – up to 10 years.

Are these new medicines actually reaching children?

Issuing a marketing authorisation or adding paediatric information to existing ones does not necessarily mean that children will immediately benefit from these products. Reimbursement considerations at national level may slow down the roll-out, and Paediatricians may not immediately switch to newly authorised products. In a survey that provided input to this report[1], respondents estimated that the increase in available medicines is in the

range of 5-10%. On prescribing habits, 58 % of respondents agreed that doctors increasingly prescribe approved medicines according to their licensed indication for children, as a result of the Regulation. This demonstrates a positive trend, but also underlines certain inertia. Reducing off-label use in children depends not only on the number of authorised paediatric medicines, but on real availability and use at bed-side.

What are the costs vs benefits of the Regulation?

On the one hand the legislation obliges pharmaceutical companies to carry out paediatric research, requiring additional investment. On the other hand this obligation is linked with a reward system that allows companies to recuperate the additional upfront costs. The report concludes that in economic terms, the Regulation provides overall positive results from a socioeconomic perspective demonstrating the appropriateness of this direct investment in improving the availability of paediatric medicines. The combination of obligations and rewards seems effective to shift focus to paediatric product development. Still a considerable number of completed PIPs (45%) failed to obtain a reward and there are instances of over- or under compensation pointing to certain limitations of the current system.

Where are the biggest advances seen, and why?

In the last 10 years we have seen an increase in medicines for children in many therapeutic areas, the most notable being Rheumatology and infectious diseases. Indeed, the significant surge of new treatments for children with rheumatologic diseases following the completion of PIPs has transformed a sector which was previously neglected.

The areas with the biggest advances are those where the greatest strides are being made in the adult market. As the starting point for most PIPs is a research and development programme for adults, progress in children's medicines depends on companies' adult product pipeline and is influenced by specific market segments that make the biggest profits. Where the adult needs or market expectations overlap with paediatric needs, children will benefit directly.

In which areas is progress considered insufficient?

The least progress is being made in diseases that are biologically different in adults and children, where the disease burden differs, or when it only affects children. This is often the case with rare diseases, including childhood cancers. Considering the progress made in treating cancer in adults in the last decade, this is a very serious shortcoming. Although cancer in children is rare, it is still the leading cause of death in children past the age of infancy.

How can we make progress in rare diseases in children?

The Commission, needs to scrutinise with regulatory authorities and stakeholders, how to combine the effects of the Paediatric Regulation and the Orphans Regulation[2] to increase the number and quality of medicines that

treat rare diseases – including rare cancers, in children. On the one hand, the Paediatric Regulation provides the rewards, incentives and obligations described above. In parallel, the Orphans legislation – which aims to increase the treatment options available for rare diseases patients, sets out other incentives such as a 10 year market exclusivity or fee waivers for the regulatory procedure. The Commission needs to – and will by 2019 – conclude a joint evaluation of the Paediatric and Orphan Medicines legislation to allow the next Commission to take an informed decision about possible policy options.

What can be done in the shorter term?

In the meantime, the Commission will, together with the European Medicines Agency, take positive actions to streamline the current application and implementation of the Regulation wherever needed. This includes, for example, looking at ways to ensure speedier completion of PIPs, considering whether the Commission's guidelines for handling PIP applications should be adapted, discussing paediatric needs in an open and transparent dialogue involving all relevant stakeholders, and fostering international cooperation and harmonisation.

Additionally, the European Reference Networks for rare and complex diseases, which started their work in March 2017, have the potential of significantly improving diagnosis and treatment and of influencing prescribing practices. The Commission will help ensure that these Networks have access to sustainable funding and the necessary IT tools so that they reach their full capacity.

For more information

Children's medicines report

Press release

European Commission:https://ec.europa.eu/health/human-use/paediatric-medicines_en

European Medicines Agency

[1] Technopolis study, chapter 5.

[2] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, OJ L 18, 22.1.2000, p. 1.