



European Association of Hospital Pharmacists



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I. Final EU ruling in the case of GSK against Greek wholesalers

Source: Curia and EPHA



On 16 September 2008, the European Court of Justice (ECJ) gave a long-awaited judgement in the case involving a Greek subsidiary of GlaxoSmithKline - GSK AEVE. Greek

pharmaceutical wholesalers battled with AEVE for eight years over the latter's refusal to supply them with pharmaceuticals in order to prevent parallel trade.

GSK AEVE imports, warehouses and distributes pharmaceutical products of the GSK group in Greece. As such, it holds the marketing authorisation in Greece for certain prescription-only medicines.

Greece has some of the lowest drug prices in Europe. A significant proportion of drugs supplied by GSK to the Greek pharmaceutical wholesalers was exported to other markets where the prices are much higher. GSK's subsidiary initially stopped and then partially restored the supplies but only in quantities sufficient for the local market rather than for export. The case was referred to the ECJ by the Competition Commission because for at least one of the drugs in question, GSK enjoys market dominance

In November 2000 GSK AEVE stopped meeting the orders of the Greek wholesalers who buy the medicines in question for distribution in Greece and export to other EU Member States. The company cited a shortage of the products at issue, for which it denied responsibility, and, altering its system of distribution, it began itself to distribute those medicines to Greek hospitals and pharmacies.

The wholesalers, as well as some Greek associations of pharmacists argued that the sales policy of GSK AEVE and GSK plc in respect of some medicinal products constituted an abuse of its dominant position.

The ECJ found that by refusing to meet the Greek wholesalers' orders, GSK AEVE aimed to limit parallel exports by those wholesalers to the markets of other Member States in which the selling prices of the medicines in dispute are higher.

The Court went on to consider whether, in the pharmaceuticals sector, there are particular circumstances which might, generally, justify a refusal to meet orders.

The ECJ presented a mixed verdict: the top EU court ruled that if GSK was failing to meet "ordinary" orders in order to prevent parallel trade then it was indeed, in breach of EU competition law. If the orders of drugs were beyond what was necessary then GSK had every right to "counter in a reasonable and proportionate way". The question which arises here is: what is 'ordinary' and who is to decide how much is not ordinary? It appears that national competition authorities and national courts have to grapple with this issue.

The court could not state whether it was in fact in breach of EU competition law or not, only that it must be referred back to the Greek courts for a final ruling on whether the orders placed by Greek wholesalers were reasonable.

Many see this as a victory for dominant drug companies as the ruling permits the manufacturers to protect their interests by placing “reasonable” restrictions on the wholesalers. However, some commentators feel that the concept of ‘ordinary orders’ introduced by the ECJ will contribute further uncertainty.

The judgement: <http://curia.europa.eu/en/actu/communiqués/cp08/aff/cp080065en.pdf>

II. Update on EU draft Directive on patients rights cross-border healthcare



Following the launch of the EU draft Directive on patients’ rights cross-border healthcare on 2 July 2008 (see EUM June 2008, issue 21: <http://www.eahp.eu/EAHP-EU-Monitor/The-European-Cross-border-Health-Directive-re-drafted-but-still-unequal>) the debate around this draft proposal has started in both the European Parliament (EP) and the European Council.

In the EP, John Bowis is the Rapporteur and his ambition is to have a draft report out before the end of the year (2008). The Proposal has entered the first reading with the Council of Health Ministers. The views of the Council are divided but a progress report is due for the 16th of December 2008. However, the proposal has little chance of going through the co-decision procedure during the Barroso Commission, ending in June 2009. First reading in the Parliament may still take place next spring, but the readings will have to begin again from scratch after the June 2009 parliamentary elections, involving the appointment of new Rapporteurs, as John Bowis is not to run for EP elections again.

The draft has created heated debates among the healthcare professionals, patients’ representatives and EU political world.

For instance, HOPE, the European Hospital and Healthcare Federation represented by its Secretary General Pascal Garel, pointed to a number of potential problems in the proposal, namely the definition of hospital and non-hospital care, which varies from one country to another and could lead to problems regarding the need for prior authorisation.

He said the concept of continuity of care also needs better articulation and Member States should be careful what they communicate to citizens in this regard. He also noted that the proposal’s aim to provide citizens the opportunity to make informed choices is somewhat problematic as a lack of comparable EU level information on quality and safety data prevents such informed decisions.

In addition, he noted that equal access to care abroad will be compromised by the need for a patient to pay for the care first from his own pocket before being able to seek reimbursement.

In this regard, according to the Commission, nothing in the draft directive prevents Member States from setting up schemes that would pay the costs of care upfront if they want to.

Pascal Garel believes that the new directive will introduce a lot of new administrative burdens. He also thinks it will not bring an end to court cases on the issue. On the contrary, the proposal could lead to an increased number of different types of cases unless Member States establish extremely clear rules on the prior authorisation and conditions for reimbursement.

A representative of the German Association of Hospitals referring to the results of an EU-funded project (Health Basket: http://www.ehma.org/fileupload/File/Projects/HealthBASKET-SYN-REP-051025EDIT_2.pdf) which concluded that comparing health services in the EU 27 is not possible (as access to different care and their prices vary considerably), argued that until exactly how much taxpayers' money goes to is known, for example, on specific dental care or a hip replacement, it is not possible to establish a reimbursement system as laid down in the Commission proposal.

Once adopted, Member States have one year to comply with the Directive.

As for a “service” Directive to clarify the situation of healthcare professionals, in its White Paper in October 2007, the European Commission presented its Health Strategy to help tackle new health challenges and improve health services. As part of this, the European Commission stated that it would publish a Green Paper on Health Professionals to launch a debate within the European institutions, health professionals, stakeholders and others about the consequences of healthcare systems of a aging population and professional mobility. The Green paper will be launched in December and will be followed by a public consultation in the first half of 2009. The results of the consultation will feed the discussion on what the EU can do to support Member States in tackling these challenges.

EAHP will closely follow up the above mentioned works and plans.

III. European action sought to further combat diabetes

Source: European Commission



The number of Europeans who suffer from diabetes has increased by almost 20% to some 31 million people during 2003-2006, a report issued by the International Diabetes Federation (IDF) shows, calling for a more decisive EU policy in this area.

The Pan-European audit examining national diabetes policies in the EU's 27 Member States plus Croatia, Turkey and Kazakhstan is the second to be published by the International Diabetes Federation – European Region (IDF Europe) and the Federation of European Nurses in Diabetes (FEND).

It found that diabetes prevalence in the European Union has risen to 31 million people, approximately 8.6 percent of the adult population as of 2006 - an increase of nearly 20 percent over 2003. This figure is expected to grow to over 10 percent by 2025.

Prevalence rates in the EU vary from four percent in the UK to 11.8 percent in Germany, with over 13 mostly eastern European countries seeing rates of over nine percent.

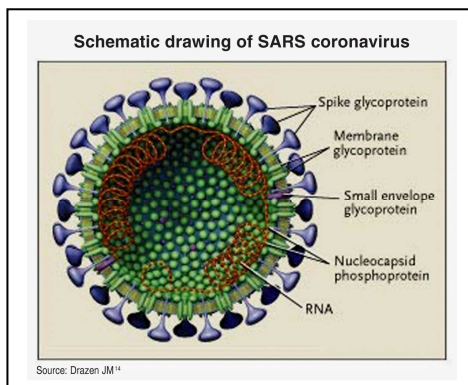
In most Member States, diabetes accounts for more than 10 percent of healthcare expenditures and in some cases, as high as 18.5 percent. Only 13 of the EU's 27 Member States have national plans to address diabetes.

British Member of the European Parliament, John Bowis, chairperson of the Diabetes Working Group, urged the European Commission in the foreword of the report "to take rapid action to shape a coherent EU-wide strategy on diabetes awareness, prevention, treatment and care."

IV. EU ministers of health talk health security and reactivity to threats

Source: EurActiv

Gathering for an informal meeting on 8-9 September 2008, the EU ministers of health emphasised the need to improve coordination and speed up reactions at the European level to enable authorities to efficiently protect the public in case of major outbreaks of contagious diseases like avian influenza, SARS and yellow fever.



The conclusions followed a simulation exercise, during which ministers discussed how to react in terms of communication, regulating travel and using and stockpiling health products with regard to two crisis scenarios at the European level - yellow fever and Severe Acute Respiratory Syndrome (SARS).

Public health security is one of the main health priorities of the French EU presidency. The upcoming Czech and Swedish presidencies will also look to move forward with the theme in a bid to improve the EU's capacity to deal with major pandemic threats such as the bird flu epidemic, following the publication of a report by the European Centre for Disease Prevention and Control (ECDC) highlighting the bloc's insufficient level of preparedness.

While most EU states have established specific avian and pandemic influenza planning policies, work at the EU level must be stepped up, the French Presidency argued in a briefing published ahead of the informal meeting.

Indeed, the briefing stresses that a major public health crisis "would have a political dimension and would involve a major communication challenge" if one is to win and maintain people's trust while at the same time circulating the information necessary to protect the public.

Enhanced EU-scale cooperation is thus necessary, but current European coordination efforts on public health issues do not yet encompass "all aspects of a crisis which will affect society as a whole," noted the briefing.

In this respect, the ministers highlighted the need for an inter-sectoral approach, not just to cover health aspects but also to ensure the continuity of essential services, such as transport and economic activity.

Ministers also stressed the need to establish strategic stocks of health products necessary to deal with such crises. The severe shortage of technetium - a key radioactive isotope used in cancer diagnoses and other medical procedures - faced by EU hospitals over the last week served as an example of the need to ensure better continuity in the supply of health products.

French Health Minister, Roselyne Bachelot-Narquin, announced her intention to convene an extraordinary meeting of the Health Security Committee in the near future to examine the possibility of using non-European technetium resources to meet the needs and conditions for an equitable distribution of limited resources.

The next Health Council, set to take place on 15-16 December, will adopt formal conclusions on an EU public health security strategy.

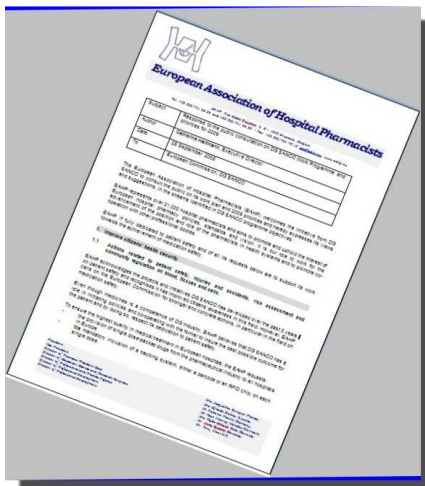
V. Views and opinions on the future of pharmaceuticals – results of the EU consultation

Source: European Commission and EPHA

In October 2007 the Commission launched a consultation on the future of pharmaceuticals. Stakeholders were invited to express their view on six main themes (see consultation paper:

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_07/consultationpaper-2007-07-19.pdf).

The Commission received 104 contributions.



The major public health, scientific and economic challenges on which stakeholders focused on were the globalisation of the sector, the increasing fragmentation and internationalisation of the value chain, the smooth functioning of the internal market in a widening Europe, and advances in science and technology. However, some called for a more balanced scope, which places equal weight on both public health (safeguarding patients' safety, improving access to medicines) and the competitiveness of the pharmaceutical sector.

Public health:

- A number of contributors voiced concerns that *patients' access to medicines is not uniform across the EU*. Tackling health inequalities, through the achievement of a genuine single market and the development of more affordable medicines, was therefore considered to remain as a major public health issue.
- The vast majority of contributors stressed that *counterfeit or deliberately and fraudulently mislabelled with respect to identity and/or source medicines* can harm patients both at individual and societal level but also damage the credibility of a national healthcare system and called for EU action to tackle counterfeit medicines.
- Some contributors stressed that the *lack of effective oversight, inspection and law enforcement* by the authorities may have facilitated non-compliant and illegal trade, especially involving the import of pharmaceutical ingredients into the EU from foreign countries - mainly from Asia - via certain brokers and traders.
- There was support for *Pharmacovigilance*, that is strengthened implementation and reinforcement, through new legislative action, of the current EU regulatory framework on medicines safety monitoring.
- A large number of stakeholders supported the provision of information to patients on medicinal products for human use. However, this was separated from the *notions of "direct to consumer" or "direct to patient" advertising* by the industry, which was not looked upon favourably. Some contributions emphasised the role of *patient information leaflets* accompanying each medicine, while others suggested that the improvement of the availability and quality of patient information requires legal action.
- Many stakeholders, in particular from the industry, commented on various issues related to *clinical trials* which are felt to become increasingly more difficult and burdensome in terms of resources.
- The use of *new genetic technologies* was underlined as a new approach to drug development as well as unleashing the potential of significantly more effective diagnosis, therapeutics, and patient care especially with regard to emerging and life-threatening diseases.

Competitiveness and economic aspects

- A number of contributors called for application of the '*Better Regulation*' policy to all layers of the EU regulatory framework on pharmaceuticals.
- It was suggested by many that rules governing post-authorisation changes to medicines (so-called '*variations*'), such as changes in the manufacturing process, are too burdensome and could impair the introduction of changes that may enhance the quality of medicines. Action at the EU level to simplify these rules was therefore strongly advocated.

- The lack of sufficient policies to *reward innovation* and the focus on cost containment rather than the value of medicines to patients and society was considered by industry stakeholders to be an important factor for the future of pharmaceuticals, especially when it comes to decisions about new research and manufacturing facilities or other investments.
- The majority of contributors clearly stated that *pricing and reimbursement* of medicines are the responsibility of Member States and that only modest movement towards convergence should be expected primarily due to the differences in EU health systems. However, the use of the guiding principles for good practice in pricing and reimbursement endorsed by the Forum and the flow of information that has allowed Member States to better understand how other Member States deal with pricing and reimbursement were supported by many.
- The development of a common methodology for *relative effectiveness* based on best practices for early market access of innovative treatments as identified by the Working Group was a common theme across many contributions.
- Some contributions referred to the need to maintain high standards of *intellectual property protection* within the EU and worldwide and to address existing trade barriers.
- Some respondents recommended that a suitable *European master file system* for novel excipients is urgently needed to harmonize European and other markets.

Next steps:

On the basis of this public consultation, the European Commission will address a Communication on the future of the EU single market in pharmaceuticals for human use to the Council of the European Union and the European Parliament before the end of the year 2008 as this part of the Commission Legislative and Work Programme for 2008. The impact assessment accompanying the Commission Communication will outline how all contributions were taken into account.

VI. European Antibiotic Awareness Day: to be launched in November 2008

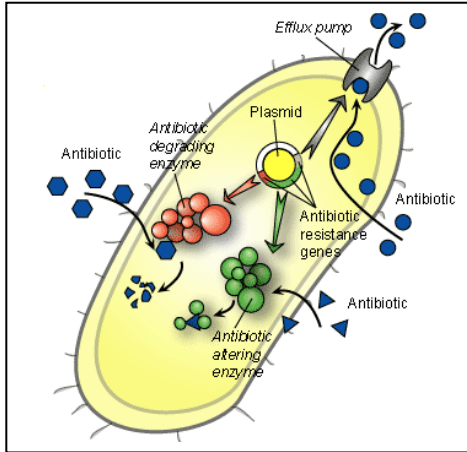
Source: European Commission

The first-ever European Antibiotic Awareness Day will take place across Europe on 18 November 2008. European Antibiotic Awareness Day will be an annually recurring event that will raise awareness about the risks associated with inappropriate use of antibiotics and how to take antibiotics responsibly.

In 2008, European Antibiotic Awareness Day will set focus specifically on the need for everybody to stop any unnecessary use of antibiotics.

European Antibiotic Awareness Day is a European health initiative in close collaboration with the World Health Organization, as well as many other relevant representative stakeholder groups such as health professionals and scientists.

All public authorities, healthcare professionals, child care professionals and social workers as well as private organisations, families and individuals are encouraged to take part in the initiative and to launch their own activities or discussions on the responsible use of antibiotics on European Antibiotic Awareness Day.



In 2001, the Commission launched a strategy to combat the threat of antimicrobial resistance to human, animal and plant health, which includes data collection, surveillance, research, awareness-raising exercises and the phasing out of antibiotics for non-medical use in animals. The Recommendation on the prudent use of antibiotics adopted in 2002 (see IP/01/1596) was a component in this strategy, outlining clear-cut measures in human medicine that Member States could take to reduce antimicrobial resistance.

The Commission has summarised the main actions taken at Member State and Community levels in a report to the Council highlighting the areas of the Recommendation needing further attention.

The report outlines a variety of measures already taken by Member States in line with the recommendation, including improved surveillance of antibiotic use and resistance, as well as, closer cooperation between different professionals on this issue. Member States have taken good steps forward in putting measures in place against antimicrobial resistance. However, some key areas need to be better addressed, in particular infection control, reducing self-medication of antibiotics and educating citizens on the proper use of antimicrobial treatments.

The report remarks that self-medication with antibiotics is still a problem in many Member States - something for which a "prescription only" approach should be strictly enforced and educational activities are needed. The Commission suggests that all countries should have guidelines on appropriate antimicrobial treatment, at least for the most common illnesses, and that information and education available to citizens on antimicrobials should be improved.

Health care institutions are strongly recommended to step up infection control measures to counter the spread of "super-bugs" such as MRSA. Not only emergence but also spread, is an important driver of the problem of resistance and the Commission is taking initiative in the area of infection control. Finally, the importance of international cooperation on antimicrobial resistance, due to the global nature of the problem, is emphasised.

VII. European Commission launches dedicated website to “Europe for Patients”

Source: The European Commission



On 30 September 2008, Health Commissioner, Androulla Vassiliou, launched the “Europe for Patients” campaign in Brussels. The campaign highlights the different health policy initiatives the Commission intends to adopt in the coming 6-9 months. All these initiatives are bound by a common goal – better healthcare for all in Europe. The initiatives address patient safety, rare diseases, organ donation and transplantation, cancer screening, health workforce, flu and childhood vaccination and antibiotic use. The first initiative under the campaign on cross border health care was adopted by the Commission in July 2008.

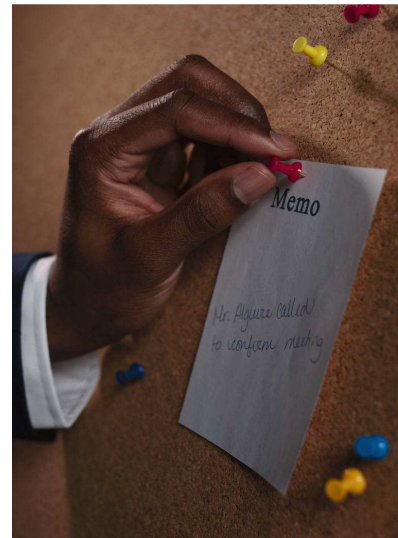
The launch event will unveil a logo for Europe for Patients and a webpage on the EU Health Portal in 22 languages which will become an information hub where documents, articles and events will be posted in relation to the Europe for Patients initiatives.

Link to the website: <http://health.europa.eu/efp>

VIII. EU health agenda – what is coming up next

02 October 2008: Second Nanotechnology Conference: The European Commission is organising in Brussels the Workshop "Safety for success" which will bring together scientists, risk assessors, public authorities, industry, and NGOs to discuss the scientific state-of-the-art, international developments, risk governance, and to identify appropriate means to strengthen guidance in support of the responsible development of nanotechnologies.

02 October 2008: Last meeting of the Pharmaceutical Forum: The forum is jointly chaired by Commissioner for Health, Androulla Vassiliou, and Commissioner for Enterprise, Günter Verheugen.



End of October 2008 (no exact date):

- **Revision of Pharmaceutical legislation:**
 - a) Communication on the future of the single market in pharmaceuticals for human use;
 - b) Directive on Pharmaceuticals - Information to patients;
 - c) Strengthening and rationalising EU Pharmacovigilance
- Ageing population – the Commission will adopt a Communication on the needs of an ageing population in European society, looking at diverse issues such as housing and care.
- Action Plan on urban mobility, follow-up to the debate launched by the Green Paper “Towards a new culture for urban mobility”, adopted in September 2007. It will

propose possible actions at the EU, national, regional and local level – including actions by the industry and individual citizens. The Action Plan will carefully identify the appropriate instruments for each action.

26 November 200: Adoption of patient safety health package:

- Communication and Council Recommendations foreseen on patient safety and quality of health services including the prevention and control of Health care associated infections.
- Adoption of the Commission Proposal for a Council Recommendation on the smoke-free environment.
- Organ Package: Commission Communication on strengthened coordination on organ donation and transplantation and Draft Directive on Quality and Safety of Organs.

IX. News in Brief

1) EP political group dedicates website to patients rights

The Alliance for Liberals and Democrats of Europe (ALDE) party has launched a new website devoted to patients' rights in order to better inform citizens of their rights in the field of healthcare. This initiative undertaken by ALDE aims at presenting patients' rights based on the European Patients' rights Charter drafted by the Active Citizenship Network in collaboration with other citizens organisation and at explaining their rights to EU patients who would like to seek for better treatment abroad and want to be reimbursed by their national healthcare systems.

For further information on this initiative, please visit:

[http://www.alde.eu/index.php?id=42&tx_ttnews\[tt_news\]=9785&cHash=7bd301f523](http://www.alde.eu/index.php?id=42&tx_ttnews[tt_news]=9785&cHash=7bd301f523)

2) EUNetPaS update

Associate and collaborative partners in the EUNetPas (EU Networks for Patient Safety) project gathered in Paris on 22 September to update each other on the latest developments since the kick-off meeting in Utrecht in February 2008. Partners reported progress on collating and clarifying information on patient safety indicators (Work Package-WP 1), and on sharing lessons learnt from the way systems of reporting errors work in different Member States (WP3). The work package dealing with piloting a model of medication errors in a selected number of hospitals (WP4) reported that 29 “no shame, no blame” good practices in reducing medication errors were collected from Member States.

3) First International Conference on Risk Assessment

The 1st International Conference on Risk Assessment "Global Risk Assessment Dialogue" is organised by the Directorate-General for Health and Consumers of the European Commission, in close collaboration with the Directorates-General Industry and Enterprise, Environment, Employment, Research and the Commission Joint Research Centre. It will be held on 13 and 14 November 2008, at Crowne Plaza Brussels City Centre hotel, Brussels, Belgium.

The Conference is intended to facilitate a global dialogue on risk assessment, among risk assessment practitioners, with the involvement of bodies dealing with risk analysis in the EU and its main partners internationally. It is related to and builds upon the Transatlantic Risk Assessment Dialogue of the European Commission with the US and Canada. It is intended to be the first of regular, international bi-annual conferences on risk assessment.

It will be held in two days. The first day will be dedicated to the introduction of the subject by means of presentations. The second day will be organised in break-out sessions, which will focus on the four themes: terminology, carcinogens, exposure assessment and emerging risk issues. In the afternoon, during the plenary, reports on each theme will be presented. The event will be closed by a panel discussion with all session chairs, and final conclusions.

For more information about the conference (programme, speakers, registration) please visit the following website: <http://www.global-risk-assessment-dialogue.eu/>

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The EAHP EU Monitor is distributed to EAHP members and is produced for the internal use of organisations, institutions, authorities and departments interested in developing hospital pharmacy and to establish a common pharmaceutical policy in Europe. It is entirely produced by EAHP, without external financial support.

Comments and suggestions are welcome: ed@eahp.eu

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