NOTE

from: General Secretariat of the Council

to: Working Party on Public Health at Senior Level

Subject: Overview of activities relevant to public health - update

In relation to the information given at the Working Party on Public Health at Senior Level meeting on 9 December 2008 (doc. 16141/08), delegations will find attached an update on initiatives of the European Parliament's Committee on the Environment, Public Health and Food Safety initiatives (Annex I) and cases before the European Court of Justice or the Court of First Instance (Annex II). Please note that only changes with respect to document 16141/08 are outlined.
1. MOTIONS FOR A RESOLUTION

According to Rule 113 of the EP's Rules of Procedure, any Member may table a motion for a resolution on a matter falling within the sphere of activities of the European Union, which may not comprise more than 200 words. The committee responsible shall decide what procedure is to be adopted. It may combine the motion for a resolution with other motions for resolutions or reports. It may adopt an opinion, which may take the form of a letter. It may decide to draw up a report pursuant to Rule 45.

The motions for resolutions and reports tabled by Members and by the parliamentary committees are put to the vote in plenary, with or without a debate. After the vote, the final texts as adopted are published and forwarded to the authorities concerned.

(a) ONGOING MOTIONS

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<th>Date</th>
<th>Doc. No.</th>
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<td>Motion for a Resolution on treatments for assisted human reproduction</td>
<td>6 October 2008</td>
<td>B6-0546/2008</td>
<td>No vote. (NOT ADOPTED)</td>
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(b) RESOLUTIONS ADOPTED PURSUANT TO RULE 113

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- the Council and the Commission to formulate a strategy on HIV to promote early diagnosis and reduction of barriers to testing;  
- the Commission and the Member States to ensure an access to testing, which must remain free and anonymous; |
(replacing the motions by the following groups GUE/NGL; UEN; PPE-DE; Verts/ALE; ALDE; PSE)

- the Council to invite the Commission to prepare Council recommendations on the implementation of evidence-based testing and treatment guidelines in each Member State;
- the Council to invite the Commission to ensure that future monitoring of progress in the fight against HIV/AIDS in Europe and neighbouring countries incorporates indicators that directly address and measure human rights issues in HIV/AIDS;
- the Member States to enact provisions which effectively outlaw discrimination against people living with HIV/AIDS, including restrictions that impact on their freedom of movement, within their jurisdictions;
- the Member States to step up information and education campaigns on the prevention, testing and treatment of HIV/AIDS.

2. WRITTEN DECLARATIONS

According to Rule 116 of the EP's Rules of Procedure, a written declaration of a maximum of 200 words on a matter falling within the European Union’s sphere of activities can be submitted by up to five members. MEPs can use written declarations to launch or relaunch a debate on a subject that comes within the EU’s remit. Written declarations are printed in all the official languages, distributed and entered in a register. The contents of a written declaration shall not go beyond the form of a declaration and shall not, in particular, contain any decision on matters for the adoption of which specific procedures and competences are laid down in the Rules of Procedure.

Written declarations: adoption procedure
If the declaration is signed by a majority of the MEPs, it is forwarded to the President, who announces it in plenary. At the end of the part-session, the declaration is forwarded to the institutions named in the text, together with the names of the signatories. It is included in the minutes of the sitting at which it is announced. Publication in the minutes closes the procedure.

Written declarations: time limit for adoption
Declarations lapse after three months they have been registered in the register if they have not been signed by at least half the MEPs.

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<td><strong>Written declaration on diabetes and obesity in pregnancy</strong></td>
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<td>Date opened: 08/10/2008 Lapse date: 22/01/2009 Number of signatories: 68 - 23/01/2009</td>
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<td>Written declaration on the situation of obese children</td>
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<td><strong>(b) ADOPTED WRITTEN DECLARATIONS</strong></td>
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| Written declaration on priorities in the fight against Alzheimer’s disease | 19/02/2009 | P6_TA-PROV(2009)0081 P6_DCL(2008)0080 | The European Parliament made a declaration on priorities in the fight against Alzheimer's disease, recalling that this disease currently affects 6.1 million Europeans and that this figure will double or triple between now and 2050 with the ageing of the population. Given that this disease is the most common cause of dependency, MEPs call on the Council, the Commission and the Member States to recognise Alzheimer's disease as a European public health priority. They also call for the development of a European action plan with a view to:  
• promoting pan-European research on the causes, prevention and treatment of Alzheimer's disease;  
• improving early diagnosis;  
• simplifying procedures for patients and carers and improving their quality of life;  
• promoting the role of Alzheimer's associations and giving them regular support. |
| Written declaration on fibromyalgia | 13/01/2009 | P6_TA-PROV(2009)0014 P6_DCL(2008)0069 | It recalls that nearly 14 million persons in the European Union and 1 to 3 % of the general population worldwide suffer from fibromyalgia, a debilitating condition resulting in chronic widespread pain. However, it is still not coded in the official index of conditions in the EU, which excludes patients from formal diagnosis. The Parliament also stresses that people with fibromyalgia struggle to lead full and independent lives, unless they have access to appropriate treatment and support. In this context, the Parliament calls on the Council and the Commission to:  
• develop a Community strategy on fibromyalgia in order to recognise this condition as a disease; |
• help raise awareness of the condition and facilitate access to information for health professionals and patients, by supporting EU and national awareness campaigns;
• encourage Member States to improve access to diagnosis and treatment;
• facilitate research on fibromyalgia through the work programmes of the Seventh Framework Programme for Research and Technological Development and future research programmes;
• facilitate the development of programmes for collecting data on fibromyalgia.

3. OWN-INITIATIVE REPORTS

According to Rule 45 of the EP's Rule of Procedures, a committee intending to draw up a report and to submit a related motion for a resolution to Parliament on a subject within its competence on which neither a consultation nor a request for an opinion has been referred to it pursuant to Rule 179(1) may do so only with the authorisation of the Conference of Presidents. Where such authorisation is withheld the reason must always be stated.

Once a draft report has been presented to the committee, members are given the chance to propose amendments before a certain deadline. The amendments will then be discussed and voted upon in the committee. Once a draft report has been amended and a final vote taken, it becomes a report and will then be presented in the plenary session.

(a) ONGOING OWN-INITIATIVE REPORTS

There is no ongoing initiative report.
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<td>Health concerns associated with electromagnetic fields 2008/2211(INI)</td>
<td>2 April 2009</td>
<td>P6_TA(2009)0216</td>
<td>The resolution recalls that wireless technology (mobile phones, Wi-Fi/WiMAX, Bluetooth, DECT landline telephones) emits Electromagnetic fields (EMF) that may have adverse effects on human health. The Commission is called upon to review the scientific basis and adequacy of the EMF limits as laid down in Council Recommendation 1999/519/EC and report to the Parliament. MEPs call for particular consideration of biological effects when assessing the potential health impact of electromagnetic radiation and for active research to address potential health problems by developing solutions that negate or reduce the pulsating and amplitude modulation of the frequencies used for transmission.</td>
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<td>Mental Health 2008/2209(INI)</td>
<td>19 February 2009</td>
<td>P6_TA(2009)0063</td>
<td>The resolution notes that one in four people experiences mental health problems at least once in their lives and that each year there are over 50,000 cases of suicide, 90% of which are preceded by the development of mental disorders. The Parliament recalls that the rates of mental ill-health are higher among vulnerable and marginalised groups (such as the unemployed, immigrants, persons with disabilities, users of psychotropic substances, etc.) and that the rate of suicide and attempted suicide among people who are in prison or in detention is higher than among the general population. Specific recommendations in the five priority areas identified by the European Pact for mental health and well-being: - prevention of suicide and depression, - mental health in youth and education, - mental health in workplace settings, - mental health of older people, - combating stigma and social exclusion.</td>
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### ECJ - CFI case law concerning health - update of 19 May 2009

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<th>CATEGORY</th>
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<td>Freedom of Establishment</td>
<td>C-171/07 and C-172/07</td>
<td>Apotherkammer Des Saarlandes &amp; Others</td>
<td>Judgment delivered on 19.5.2009</td>
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<td>C-169/07</td>
<td>Hartlauer</td>
<td>Judgment delivered on 10.3.2009</td>
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<td>C-531/06</td>
<td>Commission v Italy</td>
<td>Judgment delivered on 19.5.2009</td>
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<tr>
<td>Medicinal Products</td>
<td>Case Numbers</td>
<td>Parties</td>
<td>Judgment Date</td>
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<td>5.</td>
<td>C-421/07</td>
<td>Damgaard</td>
<td>Judgment delivered on 2.4.2009</td>
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<td>6.</td>
<td>C-489/06</td>
<td>Commission v Greece</td>
<td>Judgment delivered on 19.3.2009</td>
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Is the requirement of ‘financing by the State’ as referred to in Article 1(9) of Directive 2004/18/EC of the European Parliament on the coordination of procedures for the award of public works contracts public supply contracts and public service contracts to be interpreted as including a situation where the State prescribes membership of a sickness insurance fund and the duty to pay contributions — whose amount is dependent on income — to the relevant sickness insurance fund, which sets the contribution rate, but the sickness insurance funds are linked to one another by a system of solidarity-based financing described in greater detail in the grounds hereof and the satisfaction of the liabilities of each individual sickness insurance fund is guaranteed?

Is the requirement referred to in Article 1(9) that the body be ‘subject to management supervision by those bodies’ to be interpreted to the effect that State legal supervision which concerns current or future transactions — with other possible means of State intervention described in the grounds hereof — is sufficient to satisfy that requirement?

In its reference for a preliminary ruling, the Procurement Division of the Oberlandesgericht (Higher Regional Court) Düsseldorf (Germany) asks the Court to interpret Directive 2004/18/EC in the context of German statutory sickness insurance funds. The referring German court asked whether those funds constitute bodies governed by public law, and therefore contracting authorities, and how one should classify the contract at issue.

The Advocate General proposes:

(1) The German sickness insurance funds at issue in the main proceedings constitute bodies governed by public law because they are listed to that effect in Annex III to Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts and, in any event, fulfil all the conditions laid down in the Court’s case-law to be classified as such;
(2) the provision of goods which are individually manufactured and tailored, in terms of their form, to meet the needs of the particular customer, and on whose use the individual customer is to be advised, is to be classified as ‘supply contracts’ or as ‘service contracts’, depending on the value of the particular services to be taken into consideration which is a question of fact that must be dealt with by the referring court;

(3) should the provision of goods referred to in the second question be classified as a ‘service’, Article 1(4) of Directive 2004/18 – as distinct from a ‘framework agreement’ within the meaning of Article 1(5) of that directive – is to be interpreted as meaning that a provision of goods in the form of the one at issue in the main proceedings is not to be considered as a ‘service concession’.

2) C-171/07 & C-172/07 - Apothekkammer Des Saarlandes & Others v Ministerium für Justiz, Gesundheit und Soziales (Ministry of Justice, Health and Social Affairs)

DocMorris NV (‘DocMorris’) is a public limited company established in the Netherlands whose business includes the selling of medicinal products by mail order. By decision of 29 June 2006, the Ministry granted it, with effect from 1 July 2006, a licence to operate a branch pharmacy in Saarbrücken (Germany), subject to a condition requiring it to recruit a pharmacist who would be entrusted with managing the pharmacy in question personally and on his own responsibility (‘the decision of 29 June 2006’).

The claimants (Saarland Pharmacists’ Association and German Pharmacists’ Association), submitted that the decision of 29 June 2006 is contrary to the Law on Pharmacies because it infringes the ‘Fremdbesitzverbot’, that is to say the principle, as resulting from subparagraph 3 of Paragraph 2(1) in conjunction with Paragraphs 7 and 8 of the Law on Pharmacies, under which the right to own and operate a pharmacy is restricted to pharmacists alone (‘the rule excluding non-pharmacists’).

Verwaltungsgericht des Saarlandes (Administrative Court, Saarland) referred the following questions to the ECJ for a preliminary ruling:

Are the provisions concerning freedom of establishment for capital companies (Articles 43 and 48 EC) to be interpreted as precluding a national regulation according to which only pharmacist can own and run a pharmacy?
If the first question is answered in the affirmative: is a national authority entitled and obliged to abrogate national provisions it regards as contrary to Community law even if there is no clear breach of Community law and it has not been established by the Court of Justice of the European Communities that the relevant provisions are incompatible with Community law?

The Court ruled:

Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

3) **C-169/07 - Hartlauer Handelsgesellschaft mbH vs. Wiener Landesregierung**

**(Government of the Province of Vienna) and Oberösterreichische Landesregierung**

**(Government of the Province of Upper Austria)**

By decision of 29 August 2001 the Wiener Landesregierung rejected the application by Hartlauer, a company established in Germany, for authorisation to set up a private health institution in the form of a outpatient dental clinic in the 21st District of Vienna. The Wiener Landesregierung based its decision on Paragraph 4 of the Wr. KAG (Viennese Law on health institutions of 1987, LGBl. 23/1987, as amended by the law published at LGBl. 48/2001), and a report produced by an official medical expert. According to the report, dental care was adequately ensured in Vienna by public and private non-profit-making health institutions and other contractual practitioners offering comparable services. That assessment had been carried out on the basis of the ratio of the number of inhabitants to the number of dental practitioners, which was 2 207 inhabitants per practitioner. On the basis of the expert’s findings, the Wiener Landesregierung concluded that the health institution whose establishment was sought would not have the effect of substantially accelerating, intensifying or improving the provision of dental medical care for patients resident in Vienna, so that there was no need for the institution.
On similar grounds, the Oberösterreichische Landesregierung by decision of 20 September 2006 rejected Hartlauer’s application for authorisation to set up an outpatient dental clinic in Wels. The application was examined on the basis of the waiting time for appointments with the providers of services mentioned in Paragraph 5(2) of the Oö. KAG (Law of Upper Austria on health institutions of 1997, LGBl. 132/1997, as amended by the law published at LGBl. 99/2005), including the outpatient departments of the health institutions concerned. Hartlauer brought proceedings against those decisions before the Verwaltungsgerichtshof (Administrative Court), which joined the two cases.

Administrative Court referred the following questions to the ECJ for a preliminary ruling:

Does Article 43 EC (in conjunction with Article 48 EC) preclude the application of national legislation under which authorization is required for setting up a private hospital in the form of an independent outpatient clinic for dental medicine (dental clinic) and that authorization is to be refused if, according to the stated purpose of the institution and the range of services envisaged, there is no need for the planned outpatient dental clinic having regard to the existing provision of care by established doctors working on a contractual basis with sickness funds, institutions owned by sickness funds and institutions contracted to sickness funds and by established dentists working on a contractual basis with sickness funds?

Is the answer to Question 1 any different if the existing provision of care by outpatient clinics of public, private non profit making and other hospitals working on a contractual basis with sickness funds is also to be included in the examination as to need?

The Court concluded that the system of prior administrative authorisation at issue in the main proceedings is not based on a condition capable of adequately circumscribing the exercise by the national authorities of their discretion. The national legislation at issue in the main proceedings is not appropriate for ensuring attainment of the objectives of maintaining a balanced high-quality medical service open to all and preventing the risk of serious harm to the financial balance of the social security system.
The Court ruled:

Articles 43 EC and 48 EC preclude national legislation under which authorisation is necessary for the setting up of a private health institution in the form of an independent outpatient dental clinic, where that legislation does not also subject group practices to such a system and is not based on a condition capable of adequately circumscribing the exercise by the national authorities of their discretion.

4) C-531/06- Commission v Italy

This action is brought by the European Commission who claim that the Court should declare that:

- by keeping in force legislation which restricts the right to operate private pharmacies to natural persons who have graduated in pharmacy and to companies composed exclusively of members who are pharmacists; and
- by keeping in force legislative provisions which make it impossible for undertakings engaged in the distribution of pharmaceutical products to acquire shareholdings in the companies which manage municipal pharmacies, the Italian Republic has failed to fulfill its obligations under Articles 43 and 56 of the EC Treaty.

The Court followed the opinion of the Advocate General that the Commission’s first complaint is unfounded. This complaint is closely related to the first question referred for a preliminary ruling in Joined Cases C-171/07 and 172/07, in which the Court ruled that that Articles 43 EC and 48 EC do not preclude national legislation under which only pharmacists may own and operate a pharmacy, since such legislation is justified by the objective of ensuring proper provision of medicinal products to the public.

The Court found also the Commission's second complaint unfounded. According to the Court, the Italian Republic was able, without infringing the principle of proportionality, to retain the prohibition preventing undertakings engaged in the distribution of pharmaceutical products from acquiring stakes in companies which manage municipal pharmacies.

The Court dismissed the action.

The reference was made in the context of criminal proceedings brought by the Anklagemyndigheden (Public Prosecutor) against Mr Damgaard, a journalist, who has been charged with having publicly disseminated information about the properties and availability of a medicinal product the marketing of which is not authorised in Denmark.

This reference from a Danish court asks whether Article 86 of Directive 2001/83/EC, on the Community code relating to medicinal products for human use, is to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including in particular information about the medicinal product's therapeutic or prophylactic properties, is to be understood as constituting advertising, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller.

The Court ruled:

Article 86 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, is to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising within the meaning of that article, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product. It is for the national court to determine whether that dissemination constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.
The Commission received a complaint according to which certain hospitals in Greece, which organised calls for tenders in order to obtain medical devices, had acted in breach of the obligations under Directive 93/36 in conjunction with Directive 93/42. According to that complaint, certain Greek hospitals rejected tenders in respect of medical devices on grounds of public health, despite the certification of those products with the CE marking and, in any event, without the safeguard procedure provided for by Directive 93/42 being applied.

The Commission asked the Court to declare that by rejecting tenders in respect of medical devices bearing the CE certification marking, without, in any event, the competent contracting authorities of Greek hospitals having followed the procedure set out in Directive 93/42/EEC, Greece has failed to fulfill its obligations under Article 8(2) of Directive 93/36/EEC, coordinating procedures for the award of public supply contracts, and Articles 17 and 18 of Council Directive 93/42/EEC concerning medical devices.

The Court ruled:

7) Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07- Menarini Industrie Farmaceutiche Riunite Srl and Others v Ministero della Salute, Agenzia Italiana del Farmaco Joined


The Court ruled:

1. Article 4(1) of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems is to be interpreted as meaning that, provided the requirements laid down by that provision are met, the competent authorities of a Member State may adopt general measures reducing the prices of all, or of certain categories of, medicinal products, even if the adoption of those measures is not preceded by a freeze on those prices.

2. Article 4(1) of Directive 89/105 is to be interpreted as meaning that, provided the requirements laid down by that provision are met, the adoption of measures reducing the prices of all, or of certain categories of, medicinal products is possible more than once a year and for several years.

3. Article 4(1) of Directive 89/105 is to be interpreted as meaning that it does not preclude measures controlling the prices of all, or of certain categories of, medicinal products from being adopted on the basis of predicted expenditure, provided that the requirements laid down by that provision are met and that the predictions are based on objective and verifiable data.

4. Article 4(1) of Directive 89/105 is to be interpreted as meaning that it is for the Member States to determine, in compliance with the objective of transparency pursued by that directive and the requirements laid down by that provision, the criteria on the basis of which the review of the macro-economic conditions referred to in that provision is to be conducted and that those criteria may consist in pharmaceutical expenditure alone, in health expenditure overall or even in other types of expenditure.
5. Article 4(2) of Directive 89/105 is to be interpreted as meaning:

– that the Member States must, in all cases, provide for the possibility for an undertaking, which is concerned by a measure freezing or reducing the prices of all, or of certain categories of, medicinal products, of applying for a derogation from the price imposed pursuant to such measure;

– that they are to ensure that a reasoned decision on any such application is adopted, and

– that the genuine participation of the undertaking concerned consists, first, in the submission of an adequate statement of the particular reasons justifying its application for derogation and, second, in the provision of detailed additional information if the information supporting the application is inadequate.


High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) referred to the Court the following question for preliminary ruling:

Does Article 94(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use preclude a public body forming part of a national public health service, in order to seek to reduce its overall expenditure on medicines, from implementing a scheme which offers financial incentives to medical practices (which may in turn provide a financial benefit to the prescribing doctor) to prescribe a specific named medicine supported by the incentive scheme that is either:

(a) a different prescription medicine to the medicine previously prescribed by the doctor to the patient; or

(b) a different prescription medicine to that which otherwise might have been prescribed to the patient but for the incentive scheme,

where such a different prescription medicine is from the same therapeutic class of medicines used for treatment of the patient's particular condition?