TO THE DIRECTORATE-GENERAL FOR HEALTH AND CONSUMER PROTECTION OF THE COMMISSION OF THE EUROPEAN COMMUNITIES

Reference: public consultation regarding Community action on health services

1. Presentation of the *Federación Empresarial de Farmacéuticos Españoles* - FEFE (Spanish Pharmacists' Business Federation) (www.fefe.com)

The Spanish Pharmacists' Business Federation (FEFE) is an organisation that brings the associations and federations of pharmacy owners at Provincial and Autonomous Community level together in a body that is independent of the Government and the membership of which is voluntary. Pharmacists of around 70% of the total number of Spanish pharmacies are voluntary members of our business associations and this number continues to grow.

Pharmacists who are members of the FEFE through our associations and federations are health professionals responsible for various public health services, such as the purchase, safekeeping, storage and dispensing of medicinal products and health products; the supervision, monitoring and safekeeping of dispensed prescriptions; cooperation to supervise the individual use of medicinal products and lastly cooperation with the various health authorities on programmes concerning pharmaceutical care and healthcare in general, disease prevention and health education or training and information on the rational use of medicinal and health products.

It is against this backdrop that the pharmaceutical community has participated actively and daily alongside the Government in various initiatives and projects promoted by the two parties regarding quality of life and disease prevention, e.g.

weight-loss programmes, programmes to stop smoking, healthy-eating programmes to reduce heart disease, high blood pressure or diabetes, and treatments to help drug addicts as part of the Methadone Maintenance Programme in pharmacies.

Since we are responsible for the interests of Spanish pharmacists, we welcome the opportunity provided by the Commission to participate in the discussion on Community action on health services. We believe that the European Union plays an important role in leading and stimulating debate and in providing a forum so that Member States, health authorities and all sectors and social players representing interested groups can work together to bring about an improved health service for all European citizens.

In this connection, the aim of this document is to provide some comments on the questions set out in Commission Communication of 26 September 2006 that affect our members' interests . We would like to focus on the following subject:

2. Identifying the powers and responsibilities of the Member States and the EU with regard to pharmacy planning and ownership

While recognising the EU's role as an interlocutor that supports the synergies between the different sectors involved in health matters, the FEFE would nevertheless like to underline that, just as the Commission points out at the beginning of its Communication, the starting point has to be the fact that Community action on health services must respect the responsibilities of the Member for organising, managing and providing health services and medical care and for allocating resources intended for these services. It should not be forgotten that, in accordance with the legal basis for health policy (Article 152 of the EC Treaty) and the principle of subsidiarity, it is the Member States that are responsible for organising and providing health services and, specifically, health planning, since they are solely responsible for matters such as drug dispensing planning in pharmacies and the prescribing or price-setting and financing of medicinal products.

Given our federation's field of activity, it is with regard to precisely this matter – pharmacy planning – that we would like to request that, in the event of future

Commission action on health services, the exclusive powers of the Kingdom of Spain be respected, since pharmacy planning responds to reasons of general interest , such as the provision of a basic service, as we will analyse below.

A) Pharmacy arrangements in Spain as regards the service provided

The right of all Spaniards to health protection is enshrined in Article 43 of the Spanish Constitution, and one of the foundations of health protection is pharmaceutical care. Accordingly, this Article lays down that the public authorities must guarantee this right.

The Spanish State ensures that the entire population is provided with an extensively financed pharmaceutical service. Financing is based on a system of agreements with all pharmacies. To ensure that the entire population is covered, there is a pharmacy planning system in place based on mandatory distances and population, which provides an extensive network of primary care so that the entire population (including people living in rural areas, very much dotted around the country in Spain) can have access to pharmaceutical care near to their homes. In this way:

a) The distance ensures that pharmacies are distributed rights across the country, which prevents a situation arising in which all pharmacies are concentrated in city centres.

b) The local population ensures that the pharmacy has a minimum level of profitability, given that these types of pharmacies cannot compete in terms of prices due to the previously mentioned system of financing medicinal products.

It is worth remembering that medicinal products are not consumer goods subject to market laws and their price does not depend on the intersection point of supply and demand curves; they are health goods. For this reason, their manufacture, marketing, distribution, labelling, classification, advertising and use are subject to strict monitoring and intervention by the various national authorities involved. Similarly, the Law does not place pharmacies within a market but rather positions them as establishments of public interest that provide the population with

basic services. Therefore, as the provider of a service of general interest, the pharmacy owner must carry out his/her work in accordance with certain obligations and principles. All of this is suitably summarised in Article 1 of Law 16/1997 of 25 April 1997 Regulating Pharmacy Services, which states that pharmacies are considered to be:

> "[...] private health establishments of public interest subject to the health planning established by the Autonomous Communities, in which the pharmacy owner, aided, where appropriate, by assistants, shall provide the population with the following basic services:
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> 1. The purchase, safekeeping, storage and dispensing of medicinal and health products.
> 2. The supervision, monitoring and safekeeping of dispensed prescriptions.
> 3. The guarantee that people living in areas where there are no pharmacies will receive pharmaceutical care in the pharmacy area.
> 4. The preparation of magistral formulae and officinal preparations in stipulated cases and according to the stipulated procedures and checks.
> 5. Information on and follow-up of the pharmacological treatments of patients.
> 6. Cooperation to supervise the individual use of medicinal products, in order to detect adverse reactions that may occur and notify the bodies responsible for pharmacovigilance .
> 7. Cooperation as regards the programmes promoted by the health authorities to guarantee high-quality pharmaceutical care and healthcare in general, health promotion, health protection, disease prevention and health education.
> 8. Cooperation with the health authorities as regards training and information intended for other health professionals and users on the rational use of medicinal and health products.
> 9. Action coordinated with the health-service care structures of the Autonomous Communities.
> 10. Cooperation with regard to teaching, so that the title of Graduate in Pharmacy can be obtained in accordance with the provisions of Community Directives, State legislation and the regulations of the universities that set out the corresponding plans of study in each university."

Following on from this is the pharmacy planning system based on population and distance laid down in Article 4(2) of the same Law:

> "2. The pharmacy planning system shall be set out, taking account of population density, geographic characteristics and population dispersion, with a view to ensuring an accessible, high-quality service and a sufficient supply of medicinal products in accordance with the health requirements of each region.
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> These pharmacies shall be organised geographically based on population units and distances between pharmacies to be determined by the Autonomous Communities in accordance with the above-mentioned general criteria. In any event, the planning regulations shall ensure that the entire population has adequate pharmaceutical care."

In any case, it is the Autonomous Communities (regional governments) that define the population and distance limits, so as to match these limits to the characteristics of the regions, since the relevant criteria laid down in Article 4 of Law 16/1997 do not constitute "basic State legislation". In other words, these criteria serve simply as guidelines and are not mandatory for the Autonomous Communities; they only have to plan the pharmacies according to the population/distance system, introducing the distances and population units that they deem to be appropriate according to their perception of the public interest (to provide the population as a whole with pharmaceutical care).

As a result of these arrangements, pharmacies have been distributed uniformly throughout the country, whereby the number of pharmacies in each region is in line with population to be covered by them. Consequently, the pharmacy network meets Spain's particular needs perfectly and, in addition, achieves a pharmacy:inhabitant ratio that is much higher than the European average[1].

In the light of the above, it is clear that State intervention in pharmacy arrangements in Spain responds to the fundamental constitutional requirement to provide health protection to all citizens with equality and quality for all. In this way, the Spanish health system entrusts pharmacies to provide a basic, universal, continuous, high-quality service ensuring a secure supply of pharmaceutical products at an affordable price, in order to plan pharmaceutical care according to fundamental principles of justice, solidarity and universality also mentioned by the Commission in its Communication.

[1] Greece, with one pharmacy per 1170 inhabitants, is the country with the greatest density of pharmacies of the nine European countries under comparison. Among the Member States of the European Union with the largest area and largest population, Spain has the best ratio (1:2028), while there are vast differences between the others: the Netherlands (1:10328), the United Kingdom (1:4797), Germany (1:3805), Italy (1:3518) and France (1:2656).

B) The reasoned opinion of 28 June 2006 regarding the pharmacy planning and ownership system in Spain

Our comments on this subject focus on the reasoned opinions recently issued by the Commission, specifically those signed by the European Commissioner for the Internal Market and Services (DG MARKT), addressed to certain Member States, including Spain, claiming that the relevant national legislation on the planning rules for setting up pharmacies and the requirement that a pharmacy be owned by one pharmacist (natural person) breach the right of establishment and the free movement of capital governed by Articles 43 and 56 respectively of the EC Treaty.

We are extremely surprised that, in its reasoned opinion addressed to the Kingdom of Spain of 28 June 2006, the Commission does not accept that, given the powers of the Member States in this area and in view of the principle of subsidiarity, the national legislation on pharmacy planning arrangements complies with the EC Treaty. The Commission claims:

- on the one hand, that this principle applies only to Community action taken in accordance with the EC Treaty;
- and, on the other, that as a result of the previous point, this principle does not affect the applicability of the actual Treaty or the Articles guaranteeing the fundamental freedoms of the internal market (basis of the reasoned opinion).

C) The principle of subsidiarity with regard to this matter

In relation to the first point (the principle of subsidiarity), we agree with the Commission's view when it recalls that, in relation to the work of the European Commission (legislating and adopting binding acts), subsidiarity is a principle that governs how the powers of the Commission and the Member States are shared and is therefore only applicable in those areas of activity where responsibility is shared or concurrent. However, when a Member State claims that the principle of subsidiarity has been breached because the actions of the Community institutions have been excessive, this principle prevails in any event (shared or exclusive powers), as it is

included in the EC Treaty and therefore forms part of Community law, which the ECJ must ensure is respected in all cases. It should be noted that the first point of the Protocol on the application of the principle of subsidiarity lays down that, in exercising the powers conferred on them, each institution must ensure that the principle of subsidiarity is respected.

The ECJ, for its part, has confirmed on repeated occasions that the principle of subsidiarity is not beyond judicial review. It has also examined whether the principle has been applied correctly by the Community institutions in those cases where the Member States have claimed that it has not been respected. To this end, the ECJ has ruled that the principle of subsidiarity applies when the Community legislator uses Article 95 of the EC Treaty (common market), insofar as this provision does not grant it sole responsibility for regulating economic activities in the internal market, rather it only has responsibility for improving the conditions for the establishment and functioning of the internal market by removing the obstacles to the free movement of goods and to the freedom to provide services or by eliminating distortions of competition.

We would ask that the principle of subsidiarity be applied, as well as the principle of proportionality, in all actions to be taken regarding health services.

D) Article 45(5) of Directive 36/2005/EC and earlier version of this provision justify the Spanish State's responsibility for pharmacy planning and ownership

In respect of the internal market, and still in relation to the reasoned opinion, even if the Commission puts forward freedom of establishment as the grounds for its complaint against the Spanish legislation on pharmacy planning and ownership, it should be noted that, as is well-known, market reasons in themselves do not legitimise the actions of the Commission, nor do they serve as an argument to remove certain areas from the exclusive powers of the Member States. This is the crux of the question.

Therefore, regarding the current status of Community law, in which national legislation on pharmacy planning has not been harmonised, the responsibility for laying down laws governing the dispensing of pharmaceutical products still lies with

each Member State, provided, of course, that they respect the provisions of the Treaty, particularly those referring to the common market.

This observation is confirmed in positive Community law by Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of certain activities in the field of pharmacy, Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications and Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy. In the explanatory memoranda to all these Directives the same wording specifies that *"the geographical distribution of pharmacies and the monopoly of the supply of medicinal products continue to be matters for the Member States".* The ECJ has also recognised this competence based on these recitals (e.g. Judgment of 21 March 1991 Case C-60/89). It is not only a matter of recitals however; Article 45(5) of Directive 36/2005 lays this down explicitly:

> "5. If, on 16 September 1985, a Member State had a competitive examination in place designed to select from among the holders referred to in paragraph 2, those who are to be authorised to become owners of new pharmacies whose creation has been decided on as part of a national system of geographical division, that Member State may, by way of derogation from paragraph 1, proceed with that examination and require nationals of Member States who possess evidence of formal qualifications as a pharmacist referred to in Annex V, point 5.6.2 or who benefit from the provisions of Article 23 to take part in it."

This precept applies fully in Spain, which, since 1978 (Royal Decree 909/1978), has had a national selection system for pharmacy owners to run pharmacies set up in accordance with a national system of geographic distribution.

E) Compatibility of the Spanish system with Community legislation

In view of the above, and regardless of whether there are harmonising measures or not, the Commission clearly feels that, in order to ensure that the internal market functions properly, it is entitled to supervise, formally or physically, the arrangements or practices followed by the Member States in areas where the Member States have concurrent or exclusive competence. However, the Spanish legislation on the ownership and opening and closing of pharmacies, which is the subject of the Commission's complaint, is not incompatible with Community law, since, even though it partly restricts the right of establishment recognised in Article

43 of the EC Treaty, such restrictions are totally justified in accordance with Community law and ECJ case law. In fact, regardless of whether Article 45(5) of Directive 35/2006 would be sufficient in itself to legitimise the Spanish system, it cannot be forgotten that all the basic measures of the Spanish system for pharmacy planning and ownership[2] respond to reasons of public interest, e.g. protecting the health and lives of citizens.

In this respect, it should be recalled that the freedom of establishment covers the right of EU citizens to take up and pursue activities as self-employed persons and to set up and manage undertakings under the same conditions laid down for its own nationals by the law of the Member State where such establishment is effected.

With regard to our concern, in public health matters, the ECJ gave its judgment on the compatibility of French health legislation requiring that laboratories for clinical analyses have their place of business in France with the right of establishment enshrined in Article 43 of the EC Treaty. In this connection, given the similar situation, the Court's judgment rejecting the claim that there is a breach of Article 43 is revealing. The Court ruled that:

> "59. It is not apparent from the French rules, nor has it been shown by the Commission, that a national of a Member State other than the French Republic or a company formed in accordance with the law of a Member State and having its registered office, central administration or principal place of business in a Member State other than the French Republic could not manage a laboratory in France as a branch or subsidiary of a laboratory which he or it also manages in another Member State.
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> 60. In particular, nationals of another Member State are not precluded from exercising the functions of laboratory director where they satisfy the requirements imposed by the French rules, even if only through recognition of qualifications obtained by them in another Member State.
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> 61. Nor does the Commission show that the French rules would require a laboratory established in another Member State to transfer all of its activities to France, so that the place of business in France would no longer be a secondary establishment but would become the only place of business of the company in question."

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[2] In accordance with the legislation on health planning based on population and distance between pharmacies, ownership is subject to administrative authorisation that can be granted only to pharmacists who are qualified professionals and present in the pharmacies. This makes it impossible for one pharmacist to own or co-own more than one pharmacy at the same time, since it is impossible for one person to be in two places at once.

If we apply this judgment to the situation that concerns us, the Spanish legislation on the opening and closing of pharmacies does not prevent a pharmacist who is a national from another Member State from owning a pharmacy if he/she meets the administrative and personal requirements laid down in said legislation. Indeed, to make it easier for pharmacists from the EU to integrate in Spain the relevant legislation has been passed in Spain to this effect:

> Directives 85/432/EEC, 85/433/EEC and 85/584/EEC have been transposed into Spanish law by Royal Decree 1667/1989 of 22 December 1989, as amended by Royal Decree 1595/92 of 23 December 1992 governing the recognition of diplomas, certificates and other evidence of the formal qualifications of pharmacists of other Member States of the European Economic Community and the effective exercise of the right of establishment.

The restriction that the pharmacy be owned by a pharmacist (and only one pharmacy per pharmacist) applies both to Spanish nationals and EU citizens and is justified, as mentioned earlier, on the grounds that, for public health reasons, the Spanish Law requires the pharmacy owner to be physically present during normal working hours. There are many laws at Autonomous Community level stipulating that the work of a pharmacist is incompatible with the pursuit of any other work[3]. Similarly, the ban on an undertaking owing another pharmacy is absolute and general for all.

Therefore, the Spanish legislation on the opening and closing of pharmacies respects the right of establishment insofar as any EU citizen can set up a pharmacy on a permanent basis in Spain, irrespective of nationality, provided that he/she meets the requirements and conditions laid down in this legislation.

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[3] Of the most recent laws, Article 80 of Law 5/2005 of 27 July 2005 on the Arrangements for the Pharmaceutical Service of Castile-La Mancha lays down that:

> *"1. Notwithstanding the general incompatibilities in force, professional work as a pharmacist in the establishments and services described in Article 1 of this Law is incompatible with:*
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> *[...]*
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> ***c) Any form of employment not provided for in this Law which prevents the pharmacist from being physically present during normal working hours or during emergency shifts established where appropriate.***

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Moreover, with regard to the restrictions concerning the opening of pharmacies, even if it can be considered that this legislation partly restricts the right of establishment, these obstacles are justified in line with ECJ case law (Judgment of 26 January 2006, Case C-514/03, Commission vs. Kingdom of Spain). In this case, the Court ruled that:

> "26 According to the Court's case-law, however, national measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty can be justified only if they fulfil four conditions: they must be applied in a non-discriminatory manner; they must be justified by overriding reasons based on the general interest; they must be suitable for securing the attainment of the objective which they pursue; and they must not go beyond what is necessary in order to attain that objective (see, in particular, judgments in Case C-19/92 Kraus [1993] ECR I-1663, paragraph 32, in Gebhard, cited above, paragraph 37, and, most recently, of 4 July 2000 in Case C-424/97 Haim [2000] ECR I-5123, paragraph 57).
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> 27 In that regard, first of all, the prohibition under challenge applies irrespective of the nationality and Member State of establishment of those to whom it is addressed."

Therefore, Member States may maintain and even adopt national measures that hinder the exercise of these freedoms if, provided that there are no Community provisions or harmonising acts in this field (essential requirement), these measures fulfil four conditions:

1. They are not discriminatory (directly or indirectly) with regard to the nationality of the undertaking or that of the workers or operators affected;
2. They are not justified by overriding reasons based on the general interest or on other reasons, including public health;
3. They are suitable for securing the attainment of the objective which they pursue;
4. They must not go beyond what is necessary in order to attain that objective; in other words, they are proportional to and appropriate for the objective which they pursue, without going beyond this.

It can be concluded from the above that the Spanish legislation on pharmacy planning is justified by overriding reasons of public health and is proportionate to the objective pursued. Moreover, it is applied on a non-discriminatory basis to all European citizens and does not go beyond what is necessary to attain its objective, and so complies with the EC Treaty and with ECJ case law. Thus, without wishing to

analyse this point in depth, given that it is not the subject of the Communication in question, the Spanish legislation on the opening and closing and ownership of pharmacies does not seek to regulate a market but rather provide a service, since medicinal products are not considered to be goods but rather necessities. Furthermore, the Spanish laws have classified pharmacies as health services of a general interest, having imposed on them universal service and public service obligations. In this way, they are characterised in accordance with the provisions of Articles 16 and 86(2) of the EC Treaty and Article 36 of the Charter of Fundamental Rights.

3. In particular, the competence of the Spanish State linked to public pharmaceutical insurance

With this brief reference to the reasoned opinion that has caused a great deal of uncertainty and concern with the Spanish system for setting up pharmacies and in the pharmacy sector itself, the FEFE would like to request that the any action taken by the Commission in the field of health services must, in accordance with the principles of subsidiarity and proportionality and in line with Article 152(5) of the EC Treaty and ECJ case law, respect certain minimum criteria, namely:

I. The exclusive competence of the Member States, which excludes harmonising measures in public health matters.

II. Accordingly, Article 95 of the EC Treaty (market reasons) is not used to avoid the deliberate exclusion of all harmonisation laid down in Article 152(5) of the EC Treaty.

III. There must be no justification of any harmonisation measure in public health matters for market reasons simply because disparities have been proven between national regulations and because of the abstract risk that obstacles to the fundamental freedoms may arise. There must be a genuine likelihood of such obstacles arising and the aim of the measure in question must be to prevent this from happening.

IV. Finally, regardless of whether an obstacle to the establishment of a common market is caused by national provisions and their disparities, an assessment must be carried out prior to adoption of the harmonising measure as to whether this obstacle is justified by the need to protect people's health and lives, on the understanding that these measures are needed in accordance with the general interest of the Member State.

Based on this premise, and focusing on the subject of this document, the FEFE would ask that the Commission respect the powers of the Member States in matters concerning pharmaceutical insurance (i.e. the financing of pharmaceutical care provided directly to citizens by the National Health System and funded by social security or State resources allocated to health), the framework in which the system of pharmacies set up by geographical distribution and of pharmacy ownership operates.

Spanish legislation on health and on the arrangements for health services lays down conditions so that pharmaceutical insurance partly covers the cost of some previously specified medicinal products. In this way, in accordance with Law 16/2003 of 28 May 2003 on the Cohesion and Quality of the National Health System, specifically Article 2 of Royal Decree 63/1995 of 20 January 1995 on the arrangements for health services of the National Health System, it is stipulated that:

> 1. The services listed in Annex I to this Royal Decree constitute health services provided directly to citizens by the National Health System and financed by social security or State resources allocated to health.
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> 2. These services shall be carried out, in accordance with the regulations on the organisation, operation and arrangements of health services, by primary care health professionals and services, by the health professionals and services of the specialisations referred to in paragraphs 1 and 2 of the Annex to Royal Decree 127/1984 of 11 January 1984 on medical specialisations, Royal Decree 992/1987 of 3 July 1987 on nursing specialisations, the first group referred to in Article 3 of Royal Decree 2708/1982 of 15 October 1982 on specialisations in pharmacy, or the regulations amending or replacing them, and by other legally recognised health professionals, specialists and health services.
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> (...)
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> ANNEX I
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> 1. Categories of health services
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> 1. Health services cover the following categories:
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> a) Primary care.

b) Specialist care.

c) **Pharmaceutical services**.

d) Supplementary services."

In general, pharmaceutical services covered by social security extend to all kinds of medicinal products, with certain legal exceptions, and are dispensed as follows:

- Free of charge for treatment carried out in social security health institutions and for medicinal products dispensed to persons receiving a social security pension and to workers on provisional invalidity on account of a common illness or non-work-related accident.
- In pharmacies the contribution will be 10% of the retail price, with a maximum value of 2.64 euros in certain cases.
- On a contributory basis for all other beneficiaries, at the rate of 40% of the retail price.

In accordance with the above, and with regard to the mobility of patients and the use of health services by non-nationals as discussed in the Communication, the Commission's actions must not affect the way in which medicinal products are financed by the relevant national health systems.

Finally, the FEFE would like to confirm once again our willingness and desire to take part in any discussions led by the Commission on health and health services. We consider that the development of a Community framework in this area requires a great deal of complicated work, given the differences in the national health systems and their regulations. We believe that our members are not only directly affected by any action taken in this field, but they also have a thorough knowledge of the health system and of health services in Spain.

In view of all of the above, in future, the FEFE would like to take part in any consultation process or working group organised by the Commission on health and health services. In this connection, we would like to thank the Commission again for its efforts to improve the system.

We hope that our brief comments provide a positive contribution to the discussion process started by the Commission on this subject.

Yours sincerely,

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