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The Competition Policy Position of the Hungarian competition authority on the Key Issues of the transparency of subsidy system regulation and Pharmacy Market Liberalisation

Notes:

In competition supervision proceedings, the enforcement framework of the competition policy position is limited by competition law.

The text of the position statement may be quoted and referred to upon the identification of the source.

The position statement has been compiled as background material to the Report to Parliament in 2003. This amended version has been prepared in light of comments received. We owe our gratitude for such comments.

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EXECUTIVE SUMMARY

1. From time to time the Gazdasági Versenyhivatal (GVH, the Hungarian competition authority) GVH prepares competitive analyses of various markets, market phenomena, generally with the following objectives:

- Assistance to the regulation of the market concerned by underlining the public interest in competition, one of the aspects to be taken into consideration when designing regulation so that it can advocate that aspect more confidently during the drafting of legislation;
- Providing professional assistance to the dismantling of barriers and regulatory obstacles hindering the increase of consumer and social welfare and to facilitate more effective actions against the establishment of new, insufficiently justified restrictions;
- Providing guidance and assistance to experts and to its own investigators to assure solid foundations for the competition supervision proceedings of the GVH;
- Mapping the potential areas of application of the Competition Act[1], the threats to competition on the various markets and the limits of applicability of the Competition Act.

2. These studies are conducted using different techniques; some of them are not published, being used as the basis for the internal work of the Office, while others are made available by the GVH in some form to the profession or to the general public. The GVH in its market studies tries to employ general competitive approaches as required by its function, identifying and taking into consideration the characteristics of the market concerned.

3. The role of the GVH in the operation of the market economy as related to the freedom of competition is to promote competition in order to increase social welfare and competitiveness while enforcing the competition law, and, where competition is not possible, to contribute to the adoption of regulation to substitute for competition.

- The promotion of competition means that the GVH, with the tools available to it, actively promotes the formation, continuation and strengthening of effective competition directly or indirectly, but without "making" or "managing" competition, in areas where this contributes to the increase of social welfare, also encouraging or assisting other entities to do so.
- Contribution to regulation to substitute for competition means that the GVH takes every reasonable measure to assure that in areas where competition is impossible such regulations should be in place which have their roots in competition policy, achieve the results of competition as far as possible, and safeguard competitive markets from adverse effects.

4. In a market economy, competition is the institution which most efficiently conveys to undertakings the needs of society and the pressure of efficiency, thereby contributing to the increase of social welfare. Thus welfare, competitiveness and efficiency are the objectives, and competition is the tool. In our interpretation competitiveness means competitive advantages with sound foundations rooted in greater efficiency rather than "success" based on asymmetry or protectionism. Therefore in this context competitiveness is in effect the synonym of efficiency. In contrast, in situations where due to some market failure

[1] Act LVII of 1996 on the Prohibition of Unfair and Restrictive Market Practices

competition clearly does not result in the optimum outcome, the GVH does not favour the promotion of competition for its own sake, as this would reduce welfare and efficiency.

5. As the ultimate objective of the public policy aimed at the continuation of competition is to increase consumer welfare, the GVH also strives to attain that objective. Accordingly, the GVH considers the protection of the competition process, which is normally a mechanism to maximise efficiency pressures and welfare, to be its objective rather than the (wanton) protection of (possibly inefficient and therefore unsuccessful) competitors or market entrants under the aegis of the mystification of some "right" to participate in the market or of deconcentration. This does not mean that in certain cases the measures taken to protect competition cannot be beneficial to competitors. In other words, the objective of competition policy is to protect the public interest, which may coincide with individual interests.

6. In accordance with that focus on welfare, the GVH, when assessing the advantages and disadvantages of a practice or government decision, takes into consideration, apart from the impact on competition (impacts restricting competition are considered detrimental), primarily the impacts on efficiency manifested directly rather than through competition (impacts improving efficiency are beneficial). Here efficiency is used in a broad sense, including allocative, productive and dynamic efficiency alike.

7. In some cases the restriction of competition goes hand in hand with improving efficiency and welfare. Therefore a restrictive practice or government decision will be assessed favourably if it can be considered pro-competitive on the whole (though containing some restrictive elements), or if the concomitant advantages are substantial (and exceed the disadvantages resulting from the restriction). The former case reflects the multidimensional nature of competitive effects, while the latter shows the fact that competition is not an end in itself but an instrument to create welfare.

In the course of 2002-2003, relying on these general competition policy principles and approaches, the GVH analysed, inter alia, the market of pharmaceuticals.

Why was the pharmaceutical market selected?

8. The GVH inevitably has less professional knowledge of areas outside the scope of the Competition Act previously regulated on a public service basis (e.g. education, health care, social benefits etc.). We tended not to participate in the drafting of regulations in these areas, and the particular expertise of the GVH gained in other markets is rarely utilised while regulatory policies are devised. Even though we have more knowledge of related markets at least partially covered by the Competition Act (e.g. schoolbook market, pharmaceutical market etc.), there are a number of regulatory characteristics of such markets which deserve special attention from the aspect of competition policy as well. As a rule, in these areas regulators solicit the views of the GVH only late in the process, if at all.

9. In view of the fact that the competition approach has been gaining ground in these regulatory areas as well, partly due to the steps of the budget reform or to external pressures, the Office of Economic Competition must also be prepared to acquire in-depth information of the various markets, and to formulate the peculiar considerations of competition policy to be taken into account both for its own work and for the entities responsible for regulation.

10. The pharmaceutical market is a recurring subject of the competition supervision proceedings of the Office of Economic Competition, especially in the area of merger control, but there have been proceedings relating to restrictive agreements, abuse of dominance and consumer fraud as well.

11. We have participated with more intensity in the regulatory or preparatory processes ongoing in health care and, relating to that, in the pharmaceutical market, since 1999. Our participation has been occasional in many cases, but it also has continuous elements (e.g. the GVH participates, with consultative rights, in the work of the Social Security Committee on Prices and Subsidies). These tasks raise the need to improve our capabilities and systematise our knowledge of the pharmaceutical market. Based on these considerations, we selected the market of pharmaceuticals as the field for our study.

Some general characteristics of the pharmaceutical market

12. In the whole of the pharmaceutical sector, on every vertical level (manufacturing, wholesale and retail trade), market forces operate based on private ownership, in line with the laws of the market and commercial considerations. Regulatory intervention characteristic of public services and guaranteed supply appear on the level of distribution of pharmaceuticals. Thus the model of provision selected in Hungary, though also relying on the role of the market and competition in promoting efficiency, has been shaped by social objectives relating to the security, continuity and balanced nature of supply of pharmaceuticals necessary for patient care, and checks on competition have been incorporated into the system.

13. The regulatory problems of the whole of the pharmaceutical market are strongly related to the nature of pharmaceuticals as a peculiar product. The peculiarity of the sector lies in the fact that the health and lives of people are at stake, while there is a high degree of information asymmetry, a significant part of the products and services falling into the categories of experience or confidence goods.

14. The former considerations justify the necessity of regulation in the various fields of the health market mainly for moral reasons, while the latter also provide economic justification, as the operation of the free market may result in inadequate quality or insufficient safety of health care. Advocates of competition policy also recognise this threat and the resulting necessity of regulation, but their ultimate objective is to assure that the least possible regulation is used to offset the market insufficiencies caused by imperfect information and market failures, and to leave room for competition wherever possible.

15. The above statements are in many respects applicable to the pharmaceutical market and the distribution of pharmaceuticals as an important input market or part of the health care system. Here regulatory intervention has several objectives:

- to assure the recovery of research and development investments so that the continuity of the production of innovative pharmaceuticals is assured;
- to guarantee the quality and safety of products entering the market;
- to mitigate the danger arising from the high degree of information asymmetry;
- to improve the chance and equal opportunity of patients to obtain medication (in terms of price, geographic area, time, choice);
- to keep the magnitude and composition of social expenditures on pharmaceuticals under control.

16. These objectives entail different regulatory solutions, which have varying degrees of influence on competition; therefore they should be mentioned here:

    - the first objective is promoted by the protection of patent rights and intellectual property,

- the second by the regulations concerning the personal and material conditions of production and distribution and the procedure for the registration of new pharmaceuticals,
- the third by the introduction of an obligation to distribute more dangerous pharmaceuticals only upon prescription, thus requiring control of application by a physician, as well as restrictions on distribution, advertising and promotion, the obligation to provide product information and the control of its content by authorities,
- the fourth by the price control type interventions, the regulation of subsidies, the system of public-financed health care, the geographically allocated retail distribution rights, the regulation of the system of on-duty pharmacies, opening hours and the supply obligation,
- the fifth by the various measures aimed at controlling prices and quantities (price margin regulation, pharmaceutical subsidy system of the social security, substitutability by generic products, etc.).

Naturally, the instruments applied are closely related, in a number of cases the instrument selected is conducive to more than one objectives, while in other cases they may weaken each others' effects.

17. In general, the Office of Economic Competition recognises the necessity of such regulatory arrangements.

- We do not debate that the outstandingly high investment requirement of the development of drugs justifies the exclusivity provided by patent rights, even if this places the developer into a monopoly position for a long time.
- We do not question why the marketing of pharmaceuticals is subject to authorization, why the regulator makes the performance of various activities in the different stages of the production and distribution of pharmaceuticals, relating to the characteristics and dangerousness of the pharmaceutical or the activity concerned, conditional on meeting criteria of various severity (in terms of subject, qualification, etc.), and why an extensive regulatory surveillance system is operated as a tool to achieve these goals.
- We do not question the practice whereby the government maintains controls and supervision in distribution, advertising and sales promotion, while all these have effects restricting competition.
- We also do not call in question the practice of the government maintaining subsidies for consumers and patients to facilitate access to pharmaceuticals, while these result in distortions in the operation of the market.
- We do not question the practice that the government maintains regulatory interventions of various types and degrees on the market of retail distribution of pharmaceuticals to guarantee access in terms of territory, time and choice, taking into consideration the geographical distribution of the population and the characteristics of the retail market.

In general terms, we do not question the existence of regulatory interventions; however, we take issue with their techniques, and try to point out their degree and limits we consider are necessary to attain the social objective concerned.

18. Despite the wide-ranging regulations, competition is not totally excluded from the sector, even if there are significant differences between the various levels of the vertical structure: for instance, this is the driving force behind the development of new pioneer drugs (competition in innovation), or the cheapest possible production of generic drugs (price competition). Furthermore, the sector could not be operated efficiently with the participation of private investors if there were no competition. The regulatory instruments applied fit together into a consistent system. The fine-tuning of the various elements of the system, the absence or deficiencies of certain elements present constant tasks, causing problems to the regulators and market actors alike. The restrictions too severe compared to the objectives impose disproportionate and unjustified additional costs, which are ultimately born directly by patients and the insurer, which has a co-financing role.

19. In our study we endeavoured to find out if the various regulatory arrangements used in the Hungarian market are expedient and efficient, if they offer an effective solution to the circumstances which gave rise to the regulation, and whether the regulator enforces the appreciable public interest stated with an arrangement resulting in the least possible restriction of competition. Generally, every decision-maker responsible for regulation has several regulatory alternatives available, with different advantages and disadvantages, to choose from. It was our objective to identify the present regulatory arrangements where the need to search for and introduce alternative solutions leaving more room for competition may arise.

The methodology of the study

20. In order to attempt to assess the regulation of the pharmaceutical market from a competition policy angle, first we summarised the key characteristics of the operation of the pharmaceutical market. Therefore we could not avoid addressing the peculiar nature of pharmaceuticals as goods, which affects the intensity of competition, as well as addressing the barriers to entry and regulatory interventions relating to the Hungarian market structure and market practices, in the whole vertical structure of the pharmaceutical market (production, wholesale and retail distribution). This is not easy to present; the system has become extremely complicated due to the extensive, and often insufficiently transparent, regulation; we resorted to the structure used in economics to describe this in a systematic manner. In other words, we started the analysis with a brief description of the entire Hungarian market (figures, indicators, participants), then we addressed the factors affecting demand and supply, the two elements of the market. Even though in this part of our work we also strived to employ competition policy considerations in the analysis, we separately addressed competitive issues not discussed here, also looking into the institutional system of regulation.

21. In the second part of the working paper we assessed, from a competition aspect, the regulatory instruments used, especially those which restrict competition or interfere with the market, in particular the rules of the marketing, subsidization and distribution system. For instance, we analysed the regulations relating to the intellectual property rights, the marketing authorization of pharmaceuticals, pharmaceutical subsidies, distribution monopolies in wholesale and retail trade, prices and margins.

22. Finally, we summarised our conclusions and put forth recommendations. The purpose of the recommendations is to outline adjustments to the regulation to promote an arrangement which is less restrictive than the current one, better exploits the effects of competition in promoting efficiency, thus promotes more flexible adaptation to changes in consumer demand while maintaining the guarantees of the safety of supply to consumers. It should be noted that the consideration of the recommendations, the preparation of detailed studies and outlining of regulatory alternatives and, based on them, the elaboration of the regulation do not fall within the competence of the GVH, this being the task of entities responsible for regulation.

Key considerations of the study

23. Consequently, we attempted to assess the regulation of the pharmaceutical market primarily to find out whether it is appropriate and effective as compared to the regulatory objective, whether it is able to address the regulatory issue concerned, and whether the selected regulatory arrangement appears to be justified.

24. In the course of the review we tried to answer the following questions:

- does the justification of restrictive regulations in light of the nature of the product market or other public interest satisfy the requirement of proportionality, that is, whether it goes beyond the extent indispensable to attain the objective stated; whether it imposes excessive obligations resulting in unjustified additional expenses;
- whether it is capable of achieving the regulatory objective stated;
- whether the regulation assures transparency and predictability; whether the lack thereof results in a threat of discrimination;
- whether it promotes efficiency and greater consumer welfare.

25. First we summarised our view of the justification of professional requirements relating to the protection of intellectual property, to product safety and the safety of distribution in the pharmaceutical market. Furthermore, we assessed the current regulation of the price and subsidy system. Then we reviewed the regulatory restrictions which hinder or prevent the distribution of pharmaceuticals and the market entry of firms intending to work in this market, which constrain their competitive choices and the use of the various competitive instruments, or which distort competition.

Key findings of the study

26. In the pharmaceutical market the most significant competitive restrictions and barriers to entry consist in the existence of patents, the marketing authorization, as well as operational regulations pertaining to production, wholesale and retail distribution, which relate to product safety.

Rules for marketing pharmaceuticals as regards the protection of intellectual property

27. On issues of the patent registration of pharmaceuticals and the related exclusive rights Hungary has fundamentally followed the international trends. After the end of the transitory period for supplementary pharmaceutical patent protection, Hungary will be fully in line with the development of international intellectual property protection law.

Regulations to guarantee product safety (registration, marketing authorization, professional regulation of production and distribution)

28. The marketing authorization of pharmaceuticals is meant to control the efficacy and safety of pharmaceuticals. The system of criteria, the procedural rules and time requirement of the ***registration procedures***, which are the precondition of the introduction of drugs on the market, are regulated by the requirements of law approximation, therefore even if for the time being there is no common European pharmacopoeia to replace proceedings in individual countries, the time requirement of such separate proceedings has been reduced due to the introduction of a simplified procedure. This is a beneficial development from the aspect of the possibility to increase the intensity of competition.

29. On the whole, the difficulties relating to the marketing authorization in Hungary are not excessive and they do not result in higher barriers to entry than usual. The regulation of

the marketing authorization procedure is transparent, the regulation containing legal safeguards. At a number of points, however, further adjustments are needed, and active participation in international co-operation and law approximation is an important task. It is important to further reduce the existing differences between countries in the field of registration, so that competition can intensify on the pharmaceutical market without jeopardising the safety of patients but accelerating access to efficacious new drugs and the corporate expenditures (time, costs) relating to registration can be reduced.

30. In the course of the ***production of pharmaceuticals***, the rules safeguarding the reliability of the quality of drugs are fully harmonised, with no substantive difference between regulations in Hungary and in developed European countries.

31. The ***rules of wholesale distribution*** have also been harmonised both in the field of the issue of licences and in respect of professional (subject-related and qualification) requirements.

32. The ***professional*** (subject and qualification) ***rules of retail trade*** are not objectionable from the aspect of law approximation, but they need adjustments on a number of points (e.g. requirements of the dispensing of pharmaceuticals).

33. On the whole, no substantive adjustments are needed in the field of objective technical regulations relating to product safety, the requirements relating the safeguarding product safety are justified, the regulations and the institutional system are in line with international trends, though further fine-tuning and adjustment will be a continuous task.

Regulation of subsidies

34. Having reviewed the regulatory adjustments of recent years, the following conclusions can be drawn:

- it is still a fundamental problem of the system of subsidies that the transparency of regulation has not improved, the operation of the system failing to satisfy even the law approximation requirements set out in the transparency directive[2];
- instead of substantive, economically sound regulatory intervention, we often encounter ad hoc decisions and insufficiently considered government interventions;
- the operation of the system does not allow for long term, foreseeable planning for market participants or for the government, and it fails to guarantee efficiency.

35. For the regulator to be able to design adjustments to promote the more efficient operation of the system, it is necessary to clarify that the professionally and economically correct definition of the product market is one of the basic preconditions, apart from the clearly specified health care objectives, for selecting the regulatory tools appropriate for the market situation concerned. The definition of the relevant product market, and the utilisation of the characteristics of the demand/supply conditions on the markets concerned have been present in the regulatory interventions of recent years. Such regulatory elements include the application of public procurement type rules for products purchased by hospitals and the National Health Insurance Fund (OEP), the commencement of the establishment of fixed subsidy groups (equivalent products) in outpatient care, the objective of the further expansion of the range of pharmaceuticals (e.g. by specifying therapeutic groups), the attempt to insert the price-volume agreements into the system etc. However, it is not clear how the laying of

[2] 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, and Commission Communication 86/C 310/08.

the foundations of the systematic regulatory efforts necessary for market definition could be continued unless the legislative background and the institutional system are changed.

36. In our analysis we started from the premise that subsidies will be maintained on the pharmaceutical market, the present system of subsidies undergoing no substantive change in the medium term. We also assumed that the exclusive subsidisation position of the OEP will remain effectively unchanged.[3] Under these circumstances no more ambitious objectives can be set than to minimise the market distorting effects of subsidisation interventions and to assure the operation of a competitively neutral decision making mechanism and transparency. Thus any further progress hinges upon the creation of legal and institutional conditions which satisfy the requirements of law approximation and which can guarantee the operation of a transparent decision making and procedural system and the efficiency of regulation[4].

37. In the area of subsidized pharmaceuticals, the economic foundations and the practical arrangements of price control type regulatory intervention must be re-regulated in the context of decisions on eligibility for subsidies. In view of the fact that a decision on subsidies also means the acceptance of certain prices, the economic foundations and content of price control in such a form must be reconsidered (for instance, whether prices or price increases should be accepted on a cost basis and if yes, for which categories of drugs; in which cases can we rely exclusively on international price comparison (e.g. at the acceptance of new drugs being in monopoly positions, in such cases which should be the benchmark countries etc.). In order to assure that price regulatory interventions are well-founded from the aspect of competition policy, this technical background work must be performed, and the necessary information background must be created.

38. We consider two institutional models to be acceptable in the field of the procedure of granting eligibility for subsidies (an independent authority making the decision on eligibility and price acceptance, or the health insurer making the decision in its role of purchaser, and an independent professional supervisory authority controlling that decision). In both cases it is a fundamental requirement that the decision is professionally well-founded and justified. The publication of the decisions is also a basic requirement, though these days this can be carried out through the Internet as well (in the past year the GVH has published its decision in this manner as well). Also, the right to challenge decisions exists in both models, tough while in the first case it is possible to turn directly to the court, in the second case the application of a two-tier system of legal remedies is more appropriate, that is, the right of review could be delegated to the authority exercising professional supervision in the first level, and a judicial proceedings could follow after that. Whichever model is selected, the economic and professional foundation of the decision criteria as well as the development of a system of flexible procedures, possible decisions and legal consequences requires professional preparation and thorough consideration.

39. It would be important to regulate, in line with the supervisory system of the health care market, the supervision of the pharmaceutical market. If the purchasing role of the National Health Insurance Fund is strengthened, as is proposed now, and its discretionary decision-making powers are expanded, it would be justified to create an autonomous, professional technical supervisory authority, also empowered to control monopsonies, which would

[3] It should be noted that the competition policy analysis of these issues would also deserve separate studies, but this would have extended the scope of this study so much that we decided early in 2002, when devising the concept for the analysis, that we should consider these system elements to be constant. Naturally, we must be aware that if these system elements are altered to an appreciable extent, almost the entire system of the regulation of the pharmaceutical market would need to be reconsidered.

[4] Efficiency here means that the budget for pharmaceutical subsidies should be spent in order to achieve the highest possible health benefit on the level of society.

exercise supervision over the decisions of OEP concerning eligibility for subsidies also in respect of pharmaceuticals. In this case the OEP as the purchaser would decide based on professional and financing considerations concerning eligibility for subsidies and, in connection with that, price acceptance, in accordance with the criteria and the procedural system specified in legal regulations. However, a professional supervisory authority would exercise control over those decisions.

Regulatory constraints on distribution

40. There are also regulatory constraints on distribution, partly resulting from the treatment of that activity as a public service, partly being of a technical nature (e.g. the imposition of the service obligation, the regulation of the price margin, limitations on the opening of pharmacies subject to the number of inhabitants and the personal rights). In view of the fact that the additional obligations are typically normative in nature, that is, they equally apply to Hungarian and foreign firms, they cannot be viewed as discriminative, but their justification and proportionality is questionable from the aspect of competition policy.

41. In ***wholesale trade*** the review of regulations revealed that restrictions are justifiable in case of certain regulations, and the arrangement adopted satisfies the requirement of proportionality for the whole of the regulatory system (e.g. licensing of wholesale distribution, arrangement in respect of the supply obligation).

42. In the ***retail trade*** of pharmaceuticals there are a number of tight restrictions which, in the opinion of the GVH, impose more additional costs on the sector than justified, reduce the pro-efficiency effects of competition to a greater extent than strictly necessary, therefore their expediency is questionable.

43. In the retail distribution of pharmaceuticals the undoubtedly existing profitability problems – mostly due to the fixed level of the price margins, the absence of supplementary compensation to pharmacies in disadvantageous geographical locations, and the continuing capital shortage which has survived after privatisation in certain locations within the fragmented market structure – and the low intensity of competition have the combined effect of undermining the quality of basic services (small stocks, more limited choice of goods, longer waiting times, fewer pharmacies on duty). The changes in consumer needs are not followed by changes in the supply of services. The sector is inflexible; it is unable and unmotivated to satisfy the new demands. In the case of a significant portion of market participants any improvement in services is hindered by low profitability and high public charges. Sometimes even in the case of retail distributors with minor or no profitability problems the excessive rigour of regulations and the absence of effective competition have the effect that some part of the additional income generated at them is not channelled back to the users in the form of additional services. The profession uniformly protests against the introduction of any additional services (home delivery for bed-ridden patients, organisation of courier or mail delivery, operation of round-the-clock pharmacies, licensing of pharmacies in locations frequented by large numbers of consumers) which would disturb the present income proportions or require the reinvestment of some of the additional income. The satisfaction of new demands undoubtedly supposes that the safeguards of the safety of consumers are introduced in the case of these new forms of service as well; however, at present the certainly real problems are not addressed by self-regulatory responses but typically met with rejection. (It should be noted that, from the competition policy aspect, a self-regulation-type additional regulation might also be an adequate solution and guarantee). Therefore in our opinion, in the absence of self-regulation, the state would need to create the missing regulations in these cases.

44. The desired objectives, in particular the facilitation of increased consumer welfare, could be attained through less restrictive regulatory arrangements, or by the removal of the regulation concerned and, in other areas, by the introduction of new regulations. In the market of the retail distribution of pharmaceuticals this would improve consumer access to pharmaceutical products while the standard of safety safeguards would not be lowered appreciably, to an extent endangering consumers. To attain this, the regulatory system should let the efficiency-inducing effects of competition play a greater part.

45. In the view of the GVH, a complex review should be undertaken in several areas. We consider a review, market liberalisation and the strengthening of competition especially justified in the following areas so that consumers may benefit from effective competition:

- **Pharmacies should be allowed to engage in price competition below the maximum price level** – this would mean that the present fixed price would be replaced by a price ceiling. In case of subsidized drugs, this price would be determined in the course of the procedure to establish eligibility for subsidies, based on the request of producers and importers and the accepting decision of the authority. In the case of non-subsidised drugs, producers or importers could be empowered to set a consumer price ceiling without any special regulatory control.
- The **opening of pharmacies could be liberalised** with the simultaneous re-regulation of the personal and material conditions of operation. In this context:
  - Ø the restriction relating to population numbers and geographical distance could be abolished,
  - Ø the restrictions concerning organisational form should be removed,
  - Ø the restrictions concerning investments should be lifted,
  - Ø the one pharmacy – one firm rule should be abolished,
  - Ø instead of the personal right, only qualification requirements regarding the manager of the pharmacy should be retained,
  - Ø the rules governing the dispensation of drugs should be alleviated, and qualification requirements should be set based on the specific risks of the pharmaceutical concerned,
  - Ø the separation rules should be made more lenient both horizontally and vertically[5], and
  - Ø the rules governing the range of products pharmacies are allowed to carry could be abolished.
- In the case of **over-the-counter drugs**, or at least a **clearly defined circle of such drugs, distribution could be liberalised**, naturally maintaining the justified safeguards of product safety. (In order to facilitate the control of the latter by regulators, a requirement could be introduced to the effect that the retail establishments selling pharmaceuticals released for general distribution should be registered by the authority which has the right to control. Furthermore, the storage of stocks in an appropriate, closed location could be required as a precondition of distribution).

[5] On the pharmaceutical retail market, the maintenance of vertical separation of pharmaceutical companies from the pharmacies (but at least the prohibition of the former exercising majority control over the latter) might be appropriate in order to avoid a possible confusion in choice between pharmaceuticals; however, in this case the possibility of evading the prohibition through indirect means must be prevented. As an alternative solution, it could be provided for by law that within the scope of activities of pharmacists, only professional superiors have the right to give instructions.

- Instead of setting a maximum to the wholesale and retail price margin by government regulation, a different arrangement should be devised liberalising price bargaining among the vertical levels.

In order to guarantee the safety of supply, new regulations would be needed in some areas:

- Prior to market opening, a **new regulation should be introduced for promoting the survival of pharmacies with small turnovers in distant rural locations** (guarantee of geographical access).
- **The arrangement for financing emergency service and stand-by service should be re-regulated** (guarantee of temporal access), and the operation of the system could be assured through contracts with the County Health Insurance Funds (purchase of services). The issue of the compensation by the insurer for additional costs of the retail level relating to the **settlement of subsidies and to pre-financing** should also be resolved.
- In order to prevent the contraction of the distribution network, the **replacement of the present maximum retail price margins by guaranteed price margins** should be considered (this could also be achieved by setting the minimum price margin in the eligibility procedure, under regulatory control), furthermore, to prevent the excessive concentration of the network of pharmacies, consideration should be given, due to the local nature of the geographical market, to **applying special buy-out restrictions** on the pharmacy market.
- Arrangements facilitating the collection of prescriptions, online ordering, home delivery, postal delivery, mail order, self-service – and later, taking into consideration experiences of more advanced countries, distribution through the Internet etc. – should be allowed. **Regulations assuring an adequate level of consumer safety should be devised and enforced** in respect of these additional services.
- Provisions and **arrangements assuring greater safeguards** should be applied in respect of the **information of consumers**.

46. Unless **consumer awareness in enhanced**, market liberalisation will exert less of its beneficial effects, and safety problems should be expected to aggravate. The purpose of the new regulation is to guarantee that the information significant for making a choice between products be available to the consumer before he makes his decision to buy, or in urgent cases before the application of the pharmaceutical, so that the safety risk can be mitigated. To this end, new solutions must be devised; the participation of the government is justified in this process. To attain that goal, the regulations and requirements concerning the information of consumers should be comprehensively reviewed, especially if alternative forms of distribution are allowed, in the fields of labelling, the content of consumer information, the disclosure of prices and advertising, including the methods of over-the-counter sales and special regulations governing the various forms of distribution.

47. Naturally, the detailed review of these rules and of the specific new regulatory arrangements should be implemented in a complex manner, assessing the whole of the market concerned and specifying regulatory objectives rather than selecting individual elements of the system, and this is how the specified regulatory arrangements should also be devised.

Consultations in the course of the study

48. In the course of the study we solicited, in different ways, the views of various actors, including public administration bodies (health, finance, economic ministry, National Health

Insurance Fund, National Pharmaceutical Institution, Public Health Service (ÁNTSZ), etc.), trade associations (Hungarian Chamber of Pharmacists, Hungarian Chamber of Physicians, National Association of Hungarian Pharmaceutical Producers, Alliance of Innovative Pharmaceutical Producers, Alliance of Generic Pharmaceutical Producers, Association of Pharmaceutical Wholesalers, National Association of Private Pharmacists etc.), as well as economists with expertise in the economics of health care.

49. As a common feature, the positions of trade associations reject increasing the intensity of competition, especially our proposals for the more liberal regulation of the retail market. The outright rejection is explained mostly by the reduction of consumer safety – regarding both the quality of drugs and supply -, and the resulting hazards, the detrimental selection impacts of competition, though some of the opinions openly expressed fears of and reservations about greater commercial challenges, additional investments required by the higher quality of service and the possible failure of some enterprises.

50. In contrast, there was full agreement that a system of procedures and institutions to guarantee the transparency of the system of subsidies must be established, and activities must be organised in line with that system as soon as possible.

51. The comments helped us supplement, correct and improve the technical analysis. It is our professional conviction that liberalisation on the market of the retail distribution of pharmaceuticals, provided the supplementary regulations proposed by us are also introduced (improved consumer information, introduction of normative subsidies to remote, small pharmacies, purchase by the insurer of emergency and stand-by services), would not result in lowering the level of consumer safety. We consider the fears and concerns put forth in this respect to be exaggerated and professionally unfounded. In a liberal model the extent of government intervention would be reduced, the government installing correction mechanisms into the system only where that is unavoidable, and the role of regulatory bargaining would be taken over by commercial bargaining among market actors and by flexible adaptation to the market and demand.

SUMMARY CONCLUSIONS OF THE GVH STUDY

52. The regulation of the pharmaceutical market presents continuous problems to the government as well as to market participants, producers, importers, wholesale and retail distributors. The regulation of the market is burdened with such diverse conflicts of interest and objective regulatory problems that a solution which would result in the best outcomes in every respect in comparison to the other solutions is practically impossible. Consequently, we would be over-ambitious to endeavour to propose an arrangement which satisfies every market actor; we can merely set out to introduce corrections into the system which would, in our conviction, improve efficiency, represent a step towards achieving transparency and increase consumer welfare.

53. In the context of EU accession, **assuring the transparency and predictability of the operation of the system of subsidies** and the creation of the required legal background and the implementation of the institutional changes are pressing tasks. This time we did not look into the fundamental elements, basic principles of the system of subsidies as that was beyond the intended scope of this study, therefore we have no substantive conclusions to offer in this field. However, it would be necessary to introduce adjustments and additional instruments into the present system of subsidies, which would be conducive to avoiding regulatory failures. Satisfying the law approximation obligation requires radical changes in the decision making system. After accession, the right of initiating subsidy decisions will be transferred to undertakings. The obligation to justify regulatory decisions, the right to challenge, the limitation of the time available for decision making will present new challenges to the

proceeding authority, the conditions for which are not yet present. In our opinion the economic foundations of price regulation and price acceptance type interventions and subsidy decisions are not properly considered. In our view the regulations promulgated in December 2002 and proposed to come into effect upon accession[6] are insufficient both in content and in terms of the legal and institutional arrangements for assuring the necessary safeguards. The regulatory and institutional systems of the pharmaceutical market must be revised on a technical basis, relying on principles, and inserted into the system of regulatory bodies, and preparations must be accelerated so that the system can be launched at the proposed time.

54. The operation of this particular market must be thought through in its entirety, against its contextual background, and the necessary modifications must be put through in the regulations (**review of the regulation of** production, wholesale and retail trade, and in particular of **prices, price margins and subsidies**, the overview and correction of entry conditions on the level of products and companies alike). Thus it is insufficient to consider only the revision of regulations of pharmaceutical subsidies; instead, in addition to changing the decision making system concerning subsidies, the effects of changes must be modelled for the whole of the pharmaceutical market, incorporated into the health market system, and a substantial part of the regulatory environment must be amended.

55. It is both necessary and expedient to subject alternatives to further analyses, **focusing**, naturally taking into consideration the characteristics of the pharmaceutical market and the limited scope for competition, **on the introduction of competition** wherever possible, and on compensating for the lack of efficiency pressures due to the absence of competition through the regulatory arrangements of government intervention. With this approach, the overview should extend to restrictive regulatory elements affecting every market participant, and regulations impeding competition, worsening efficiency and causing unjustified additional costs should be corrected or eliminated. Ill-considered, ad hoc government interventions should be avoided.

56. We deem the **deregulation** of the rules impeding market entry **in the retail trade of pharmaceuticals** and the re-**regulation of the sector** to be especially justified. The current legal regulations contain numerous provisions which introduce restrictive elements into the system on significantly more points than it would be absolutely necessary to achieve the acceptable objectives. We propose that these restrictive regulations are reviewed and the unnecessary ones resulting in unjustified additional costs or weakening or eliminating the incentives of competition should be abolished. Simultaneously, a new regulation should be adopted to maintain the safety of supply (geographically and temporally), guarantee better quality information to consumers, lay the legal foundations to the introduction of quality additional services and adjust regulatory interventions to health care objectives.

57. Self-regulatory arrangements should be promoted which improve the operation of the market through the initiatives of market participants, enhance the level of safety guarantees in accordance with the interests of consumers, and contain no restrictions incompatible with competition law. The state should conclude self-restraining agreements with market participants where regulation is unable to guarantee the desired efficiency for some reason. In this case, the contracting entity, in the course of exercising its regulatory competences, should undertake such commitments as to effectively promote the solution of the regulatory problem within the constraints of legal regulations.

[6] Article 4 (2) of the Government Decree No. 295/2002. (XII. 27.), amending Government Decree No. 217/1997. (XII. 1.) on the implementation of Act LXXXIII of 1997 on mandatory health insurance benefits

58. We recommend that, in order to increase consumer welfare, the review of the regulation of the pharmaceutical market is commenced, aligned with the regulatory reform process. Within this:

- The objectives of health care should be defined in respect of the role of the pharmaceutical market, pharmaceutical subsidies and pharmaceutics, and the applied regulatory arrangement should be reviewed and re-regulation implemented accordingly.
- An action plan should be prepared, specifying the time schedule of tasks and identifying the persons in decision making positions responsible for implementation. Furthermore, we recommend that background studies and economic analyses are prepared, then a regulatory concept is devised and widely circulated for comments, followed by the drafting of a bill and implementing decrees in the framework of a codification committee.
- Simultaneously, a communication programme should also be prepared, and the profession as well as the general public should be regularly and expertly informed about the reasons, directions and expected impacts of changes. Considering that this is a market of sensitive products, inaccurate, incomplete misinformation inducing unnecessary fears and passions is very dangerous. These can be avoided only with sound calm and regular information.
- Liberalisation measures do not necessarily have to be implemented in one package; it may be appropriate to start the reform of regulations with steps which can be implemented faster, which ease the everyday lives of market participants and cause no substantial disturbances in the operation of the present system. In case of changes which require adjustment or major alignment from market participants, more time should be left for the preparation of the undertakings concerned.

- **II.3.13. Summary of findings concerning the regulatory restraints on distribution**

329. Having reviewed the regulations, we may conclude by way of summary that the restrictive regulations are justifiable in the case of several interventions; with respect to the system as a whole, the selected method (e.g. the system of authorising activities, the solution relating to provision obligations, etc.) does also satisfy the requirement of proportionality.

330. In other cases, however, in our opinion the desired objective could be achieved through less restrictive regulatory solutions or by eliminating a given regulation, and this could be done in a manner that would also enhance the availability of pharmaceutical products to consumers – in terms of price, place, time as well as the number and quality of additional services – with no essential reduction in the level of safety guarantees. With a view to achieving this, the regulatory system would, in large part, allow the positive effects of competition on efficiency to take effect in the retail pharmaceutical market.

- The constraints on the foundation of pharmacies which are bound to population size and geographical distance should be reviewed.

The present provisions do not guarantee – particularly in urban areas – a uniform geographical distribution of pharmacies; nor do they protect against regional concentration. At the same time, maintaining and operating a separate foundation-authorisation system imposes constant administrative costs both on companies and on the state.

In some countries where this constraint has been lifted (e.g. Germany), experience shows that the standard of services offered to consumers has radically improved, due to intensified competition. In reaction to consumer demand, additional services have been introduced (e.g. courier service, home delivery) and the geographical distribution of pharmacies better reflects the shopping habits of consumers, etc. All of this has been achieved without there being any real change in the sparsely populated areas, for here too, pharmacies continue to operate in line with market demand. Given that the number of pharmacists is finite, that any newly-opened pharmacies must be managed by pharmacists, and that drugs may only be handed out by qualified staff (with the exception of products appearing on an authorised list for general distribution), in the short term this restrictive factor will, by itself, protect the system from cut-throat competition, while in the longer term it will tend to enhance the value of pharmacist qualifications, that is to say, it will also ensure market salary levels for employed pharmacists.

- The development of a special support system for pharmacies at relatively remote geographical locations would be justified, in order to ensure consumer access in a geographical sense.

This special, targeted regulation would be important even today, given that the closure of remote independent pharmacies with small turnovers can reduce accessibility to drugs. A long-term solution to this problem would require the operation of a special regulation based on economic calculations, while the necessary funds for this would be allocated on a continuous basis within the social security budget for pharmaceutical products. The reliable operation of this special support system would receive particular importance in the event of a market liberalisation of the foundation of pharmacies, which would negatively affect such pharmacies with low turnover levels.

- It would be worth determining the incentives and special contractual system for the purchase of services that should be developed in order to realise guarantees concerning the time period for the supply of drugs (emergency and stand-by system). Presumably, market liberalisation would have a positive effect on temporal availability at locations subject to enhanced competition, but in other areas prices that cover costs and income may offer the incentive to provide services.

- With regard to non-subsidised and over-the-counter drugs, price-fixing at the level of consumer prices could be abolished, with a conversion initially to ceiling prices and later perhaps – based on experiences – to a free price system. In these product markets, competition is already a general phenomenon, with customers choosing between various alternative products. At present, the regulation, by fixing prices, prevent competition merely in the retail sector, but competition amongst brands is permitted. There is no real reason why the regulation should eliminate the possibility of price competition in the choice between pharmacies (the points of sale), for with regard to such products, competition would be capable of regulating the market and of guaranteeing provision. It is wrong to assume that the aim and effect of price competition is an unlimited rise in the consumption of a given product. The effect of price competition from the perspective of consumer welfare is – simply put – that the consumer, in the course of satisfying his/her given needs, can choose the cheapest purchase alternative, thereby achieving savings. Such savings will then enable him/her to satisfy other needs.

- In respect of over-the-counter drugs, or at least a group of products determined professionally, the constraints relating to distribution and pricing could be lifted.

Various degrees and versions of the lifting of distribution and pricing constraints are possible. One can envisage a version in which, within the category of over-the-counter drugs, a narrower range of products used by consumers everyday and with great frequency would be identified based on the professional pharmacist and medical criteria. This group of products could be sold by any retailer satisfying the physical sales requirements determined for this group of drugs – of course with improvements in the content and clarity of the written consumer information and a restriction on the use of certain competitive instruments (e.g. a ban on certain promotional methods) – under a limited free price regime (e.g. it would not be possible to sell drugs below cost). (As the table in chapter II.4 shows, even now consumers make decisions about over-the-counter drugs on the basis of various information sources, and thus in the course of everyday purchases there is no notable risk of bypassing the expert knowledge of pharmacists.)

A further liberalising possibility is to permit the sale of over-the-counter drugs by any retailer that ensures the presence of at least an assistant pharmacist or a salesperson qualified as a pharmacist, as well as the physical conditions relating to such drugs.

If this intermediate over-the-counter group of drugs would initially remain within the sales network of the pharmacies and the foundation of pharmacies continued to be subject to restrictions, then manufacturers and importers could be given the right to determine the maximum (ceiling) retail sales price; price competition below the price levels determined in this manner could be permitted here too.

- In the retail sector, there is a need to analyse – in respect of subsidised drugs – the possibility of switching over to a ceiling price system from the fixed price system. This would enable consumers to purchase at least some drugs at a price below the ceiling price, from market actors capable of providing more efficient services. At the same time, consumers would still be protected from overpricing in other places. Given that the price-reducing effect of price competition may be assumed at competitive locations (e.g. the central points of consumption in cities – i.e. the vicinity of hospitals and clinics, shopping centres), buyers could enjoy the benefits of cost-savings, irrespective of their places of residence.

- Instead of a maximization of the wholesale and retail price margin by the state and the fixing of the final sales price, there is also a need to examine the benefits, disadvantages and possible effects of permitting price bargaining between the various levels of vertical structures, bearing in mind that at present the provisions of the Price Act and the Pharmacy Act conflict with each other.

Today, the so-called ceiling (maximum) price margins function, at the level of the retail trade, as guaranteed price margins. This is demonstrated by the fact that by offering price concessions wholesale traders provide retailers with price margins that are higher than the price margin established by the decree. The benefits of such concessions remain with the retailers and are not passed on to consumers in the form of lower prices. One should examine whether – in the event that the present rules relating to the "provision obligations" of pharmacies are maintained – the guaranteed price margins need to be kept and whether the current extent of the regulated price margin covers the obligation to provide services. Such a review may be considered unavoidable, given that the fall in standards of service of recent years and the failure to provide patient-friendly supplementary services seem to have been caused by – in addition to the absence of competition – the low price margin that fails to cover costs or provide an acceptable level of income.

- There is a need to establish institutional guarantees that buyers have access to all the information necessary for optimal decision-making prior to making consumer decisions (e.g. choice, prices, other important items of information).

- The "one pharmacy – one sole proprietorship or company" rule should be abolished, because it clearly, and without any real justification, raises the level of transaction costs in the sector (e.g. the founding and operating of separate companies).

- Restrictions relating to organisational structure (pharmacies may only be operated by sole proprietorships or special limited partnerships) should be lifted, because this stipulation does not provide consumers with any real extra security.

- Restrictions on investment and ownership – which tend to be apparent rather than real – should be lifted, because they simply raise the transactions costs of investments, without actually preventing pharmacy businesses from falling under the management of external capital investors.

Ever since the entry into force of the Pharmacy Act of 1994, the establishment of so-called pharmacy chains has been completely legal, that is to say, there is no legal obstacle preventing a single holding company from owning several pharmacy limited partnerships as subsidiaries. We note that there is no real justification for any change, as events since the

introduction of the regulation almost a decade ago have not demonstrated the existence of any real danger for consumers posed by a system functioning in this manner. At the same time, it is important to point out that due to the restrictions on the authorisation of foundations – and especially if such restrictions are maintained – there is a need for the introduction of special restrictions on the (multiple) purchase of pharmacies, because the general regulations of the current competition law are not suitable for impeding the formation of regional monopolies in the retail sector, whose markets are of a local nature.

- There is a need to retain the qualification requirements that must be met by the professional managers of pharmacies. At the same time, however, the personal right (ad personam) construction, as a special obstacle to market entry, should be abolished due to the constant additional costs (the retention of a separate administrative authorisation system). (A solution could be to permit buy-outs.)

- The rules of dispensing drugs should be reviewed, because the undifferentiated regulation which makes the activity of dispatching drugs subject to a pharmacist degree raise without reason the sector's general and wage costs and thus its desire for a price increase.

- The separation rules relating to retail trade operations should be eased. Companies operating pharmacies should be given greater freedom to choose other activities that may be undertaken in parallel.

Even today pharmacy owners – or even the pharmacists themselves – are not legally prevented from selling goods in the same building, that are not authorised for sale in a pharmacy, as long as this is done in a separate room. Such a solution, however, also raises the level of transaction costs borne by the business.

- To encourage new forms of sale and supplementary services (e.g. home delivery, mail-order, courier service, self-service, Internet commerce), emphasis should be placed on elaborating and applying regulations that provide a sufficient level of consumer safety – rather than merely enforcing a ban.

Of course, in the event that all or some of these services (mail-order, Internet commerce) are permitted, the system of retail provision must be reconsidered, in light of the public service elements. It would be worth establishing opportunities for some of these forms to take part in the provision of stand-by services.

331. Nevertheless, we stress once again that a survey and review of these rules as well as the specific new regulations should be thoroughly gone through in a complex manner, having regard for the whole of the market and formulating the objectives of regulation rather than picking out particular elements of the system. In respect of several elements that do not cause any real disturbance in the operation of the whole system of provision, it may be worth picking them out and introducing them separately. But other elements should only be introduced in a co-ordinated manner, while measuring and evaluating the potential effects. In the course of the re-regulation of the pharmacy sector, it is worth separating a review of the role of pharmacists from other issues relating to the operating and funding of pharmacies, and then – depending on the findings of such a review – thinking about the use of their professional knowledge and the role given by health care to pharmacists in the prevention of disease and in the removal of burdens from other segments of provision for the sick. In the event of a well-circumscribed target model and in order to give incentive to the provision of

supplementary healthcare service functions, it may be worth investigating special funding solutions. A prerequisite for the efficient realisation and regulation of the various functions of pharmacies (healthcare services, the retail of drugs) is the formulation of a health care vision, because failing such it will not be possible to introduce the appropriate regulatory measures.

332. As Annex 1 of this document ("A review of various regulatory elements relating to the sale of drugs in several European countries") demonstrates, there is a great diversity of regulatory alternatives. There is no uniform solution or exclusive model. The various countries choose from among the various partial solutions, having regard for the degree of development of their markets, the need to correct regulatory failures, institutional traditions, and differences in their drug subsidy systems. In each case, however, the main objective is the same: to guarantee the public's access to pharmaceutical products (at the appropriate place and time and providing choice and affordable prices). Thus, the regulation of the distribution system must be subordinated to the interests of consumers, bearing in mind the rules of the market and building upon the effects of competition enabling self-regulatory and flexible corrections. In Annex 2 ("A brief summary of the main regulatory elements of a new retail model"), we have attempted to draft a potential regulatory model, having primary regard for the retail function while also taking into consideration the potential dangers and proposing corrective mechanisms for the remedy of them.

III. SUMMARY CONCLUSIONS AND PROPOSALS

341. The regulation of the pharmaceutical market is of constant concern both to the government and to market actors, manufacturers, importers as well as wholesale and retail traders. The regulation of the market is burdened by such complex conflicts of interest and objective regulatory problems that it is practically impossible to imagine a solution that – in some or other aspect – would not provide a worse result than another. For this reason, it would be unrealistic for us to attempt to put forward a proposal that satisfies the desires of all the various actors. Instead, we may merely aim to introduce corrections into the system which – in our view and in relation to the present situation – improve efficiency, promote the fulfilment of the requirement of transparency, and enhance the welfare of consumers.

1. With regard to the whole sector, it is imperative to reflect upon the operation of this peculiar market and to implement in full the necessary changes in the regulations (a review of the regulation of manufacture, wholesale and retail – including in particular the regulation of prices, price margins and subsidies – and a survey and correction of market entry conditions at both product level and company level). It is not enough, therefore, to think about merely tidying up the regulations relating to drug subsidies. Instead, in addition to amending the system of making decisions on subsidies, there is a need to model the effects of changes on the pharmaceutical market as a whole within the framework of the healthcare system, and to rectify the whole regulatory environment. A prerequisite for this is that health care should formulate the role intended for the pharmaceutical market, the system of subsidising drugs, and pharmacists within the healthcare system. Depending on such health care objectives, a decision can then be taken on the type of regulatory instruments that are worthy and possible of consideration, in order to ensure the reliable and efficient operation of the system.
2. It is worth considering those alternatives which – while having due regard for the peculiarities of the pharmaceutical market and the limited possibilities of competition – focus, where possible, upon the introduction of competition, as well as state intervention regulatory solutions that attempt to compensate for the lack of any pressure for efficiency stemming from an absence of competition. Under this approach, there are grounds for reviewing the restrictive regulatory elements affecting all market actors and for rectifying or disposing of regulations that are unwarranted and that lessen competition and efficiency. Ill-considered state interventions of an ad hoc nature that are out of proportion and do not function efficiently as elements of a system capable of functioning over time, must be avoided.
3. Given that the criteria for 2003 relating to the operation of the market were developed following the price negotiations of the autumn of 2002, a new institutional system of regulating and adopting subsidies – a system that is fully harmonised and thoroughly organised – should be developed and introduced by, at the latest, Hungary's accession to the European Union.
4. A fundamental task is to make the subsidy system transparent and predictable, as well as to establish the legislative background necessary for this and to implement the institutional changes. We do not consider it worth thinking about radically new solutions with respect to the basic elements and principles of the subsidy system, for whatever system is chosen, certain basic elements of the system will require supplementation. Consequently, in our opinion, adjustments and replacement measures should be integrated into the present system, which will serve to avoid regulatory failures.
5. It is imperative to support self-regulatory measures that improve market behaviour by way of the initiatives of drug market actors, and that do not include restrictions that are

incompatible with competition law. The state should sign such self-regulatory agreements with market actors where, for whatever reason, regulations are not capable of guaranteeing the desired level of efficiency. In such cases too, the contracting party should undertake obligations in the course of exercising its regulatory powers in such a manner which remains within the confines of the law and promotes effectively a solution to the regulatory problem.

6. As regards the retail sale of drugs, we propose the termination of any intervention that weakens efficiency, increases costs unnecessarily, and plays no vital role in the realisation of the regulatory objectives. We propose the elaboration of new regulatory solutions that build upon, in a more courageous manner, the beneficial effects of competition and that retain merely those corrective measures that are necessary and in accordance with the regulatory objectives.

342. Proposals relating to the main regulatory elements and promoting the use of the benefits of competition

1. Regulation of the marketing of pharmaceuticals

- the introduction of minor adjustments as well as solutions that simplify procedures and reduce the costs of companies and of regulation should be supported,
- accession to the EU patent system and the registration system (with the advancement of processes linked to accession and EU legislative and institutional reforms) as well as a reduction in the administrative hurdles associated with putting a product on to the market, will – by facilitating market entry – serve the interests of consumers.

2. Regulation of the production of pharmaceutical products

- the normative rules should be changed in line with international obligations.

3. Restrictions on the sale of pharmaceutical products

- with respect to OTC medicines (over-the-counter drugs) or at least a separate group of drugs that are the least risky in terms of the dangers to consumers, we propose the lifting of restrictions on distribution as well as price-regulatory intervention measures (regulation of price or at least of price margin); and price fixing should be abolished,
- with respect to prescription drugs that are not subsidised as well as subsidised drugs, the organisation that is entitled to distribute the drugs (the manufacturer or importer) should be given the right to determine the ceiling (maximum) price of a drug (in the case of a non-subsidised drug, the consumer price; and in the case of a subsidised drug, the price adopted as a basis for public funding). The authority passing judgement on subsidies would exercise the control of prices with respect to the group of subsidised drugs.

4. Constraints on the wholesale trade of pharmaceutical products

- alongside the setting of maximum (ceiling) consumer prices, the retention of price margin regulation is not justified,
- the stipulation relating to the pharmacies' keeping a full range of pharmaceuticals could be retained for a narrower group of products (it is not necessary for drugs authorised for

over-the-counter trading), a further study of preparations for lifting the regulation is warranted.

5. *Constraints on the retail trade of pharmaceutical products – regulation of pharmacist/chemist activities*

- real adjustments are justified, because the barriers to entry at this level of the vertical structure are too severe,
- retailer exclusivity should be abolished,
- the legal background to the new forms of retail sale should be established,
- retention of ceiling price margins is not justified,
- retention of fixed retail sales prices is not justified; instead, a more effective solution would be to switch over to a ceiling price system – even for prescription drugs,
- instead of limiting the number of market actors, a more competition-friendly solution should be found, that is, the authorisation procedure for the foundation of pharmacies (establishment permit, personal right/*ad personam*) could be abolished or at least relaxed,
- the abolition of the regulation relating to the organisational forms is justified,
- lifting of the illusory limitations relating to investments and the ownership of pharmacies is justified,
- with a view to establishing provision guarantees, the introduction of market-friendly normative regulations is justified (normative subsidies for remote pharmacies with low turnover levels; incentives for emergency and stand-by cover; guaranteed retail price margins).

6. *Regulations relating to the provision of information about pharmaceutical products, restrictions on advertising*

- corrections and adjustments are justified in the regulation of advertising and promotion, as well as regulations relating to the provision of information on pharmaceuticals,
- adjustments need to be made to the sanction system, procedural powers, proceeding bodies and procedural rules, so that the efficiency of the controls and regulation should improve.

7. *Regulation of the system of subsidising pharmaceutical products*

- real adjustments are justified both in the legal regulations and in the institutional system for making decisions – both in terms of content and in respect of powers and procedures,
- there is a need to establish a decision-making and procedural system that satisfies the demands of EU legal harmonisation and guarantees the transparency of subsidies,
- the price control mechanism for subsidised drugs must be placed on new foundations, in respect of both economic content and solution method,
- there is a need to establish a more structured and considered legal regulation; there must be a clear separation of decision-making powers promoting efficiency,
- due to the finite nature of funds available for subsidising drugs, there is a need to enhance the cost-effective spending of resources – with this in view, it is imperative to strengthen controls on demand and to establish and apply control and incentive mechanisms that reduce abuse and less efficient use. Resources saved in this manner should be pooled and spent on new effective drugs.

8. *Regulation of the system of institutions*

- Real adjustments are justified in respect of the regulatory powers and the division of tasks among the bodies exercising supervision and control. The regulatory powers should be reviewed and then conceived on a theoretical basis – with attention being given to ensuring that decisions are taken at the lowest level at which the necessary expertise and information is available for the taking of intervention measures, having regard also for the general legal principles determined in the Legislation Act. This would guarantee that always the competent body would take decisions in the light of the necessary information and assuming responsibility.
- The pharmaceutical market's supervisory system must be organised on a conceptual basis and integrated into the system of official bodies. Since the making of decisions by the National Health Insurance Fund Administration, as the provider of funds, is a matter of concern, a supervisory body for the pharmaceutical market with general rights should be established. In addition to providing official authorisation for putting products on the market as well as for activities that are subject to permits or registration, this authority would also have within its responsibilities the operation (decision-making on acceptance) and control of the subsidy system and, in association with this, it would also exercise control over prices applicable under the public funding of products where subsidies had been accepted. It would also fulfil the role of supervisory body for the sector.
- If the National Health Insurance Fund Administration, as the funding body, were to take the official decisions on the adoption of subsidies and the acceptance of prices, in such event we would consider it justified that, in the first instance, the decisions of the National Health Insurance Fund Administration, as a monopolistic purchaser, should be controlled by an autonomous professional supervisory body with rights of supervision. In such event, the supervisory powers and functions of the new supervisory body should be developed in co-ordination with the supervisory system of the healthcare sector.
- Such a body could enjoy special status and powers, and its tasks would include the control of the discretionary purchasing decisions, contractual practice, and buying behaviour of the National Health Insurance Fund Administration, as a monopoly buyer. Liberalisation of the health market, the buying behaviour of the National Health Insurance Fund and later on of the county or regional fund administrations, which will also enjoy a monopoly situation, the adoption of drugs into the subsidy system, contractual practice (see the powers of the Telecommunications Decision-making Committee), and the need to control transaction prices, give rise to the need for sound professional consideration of, and preparation for addressing, these regulatory problems.

9. The implementation time schedule

- The objectives of health care must be determined in respect of the pharmaceutical market, subsidies for pharmaceutical products, and the role of pharmacists. And in the light of them, a review of the applied regulatory arrangements should be undertaken and then reregulations should be carried out.
- An action plan should be drawn up with a schedule of tackling the tasks and the name of the persons who are in the positions to take decisions and bear responsibility for the implementation. A possible suggestion is the drawing up and broad debate of a strategy for regulation, and then – with the formation of a codification committee – the elaboration of a legislative bill and executive decrees.
- The direction, reasons and expected effects of the changes must be elaborated and communicated in an appropriate manner to both professional and public audiences. Given that the topic of discussion is the market for a sensitive good and that the liberalisation

measures do not necessarily need to be realised in a single package; it may be practical to start with measures that can be realised more rapidly – measures that provide relief to market actors in their everyday practices. With regard to changes that require market actors to make greater adjustments, the companies affected should be given enough time to make preparations.