EXECUTIVE SUMMARY

In the light of the written submissions, the background note and the oral discussion, the following points emerge:

(1) *The pharmaceutical sector is a high-technology and knowledge-intensive industry. The industry has a two-tier structure. The largest firms account for the majority of the R&D investment in the industry and hold the majority of patents. A large number of smaller firms manufacture off-patent products or under license to a patent-holder. The pharmaceutical industry is heavily regulated. Few aspects of the industry are unaffected by regulatory controls.*

The pharmaceutical sector produces and distributes chemicals with therapeutic value. Pharmaceuticals are an important input into health services more generally. Pharmaceutical policies must be closely integrated into wider health policies to avoid inefficient substitution towards or away from pharmaceuticals relative to other health inputs, to the detriment of health cost and quality outcomes. Most OECD countries spend between ten and 20 percent of total health expenditure on pharmaceuticals. Rising per capita expenditure on pharmaceuticals in several OECD countries over the last decade has focused policy attention on the pharmaceutical industry and controls on pharmaceutical expenditure.

The largest pharmaceutical companies have revenues in the billions and tens of thousands of employees. These companies spend heavily on both marketing and R&D. Marketing expenditures exceed expenditure on R&D. An important component of this marketing effort is the practice of "detailing" – i.e., promotional visits to individual prescribing physicians. Although virtually all OECD countries have some domestic production of pharmaceuticals the bulk of pharmaceutical production occurs in Japan, Switzerland, the US and the EU (particularly the UK). Although the largest pharmaceutical companies may produce competing products, the main form of competition between these companies is competition in innovation – in developing new and/or improved therapies. The second tier of manufacturers – who produce generics or products under license, conduct relatively little R&D of their own and compete mainly on the conventional dimensions of price, service and efficiency.

The pharmaceutical industry is heavily regulated. All aspects of the life-cycle of new drugs are regulated, from patent application, to marketing approval, commercial exploitation, patent expiration and competition with generics. All the important actors in the pharmaceutical industry – the manufacturers, wholesalers, retailers and prescribing physicians are also subject to regulatory controls. These regulatory controls pursue three primary objectives:

(a) preserving the incentives for research and development and the flow of new innovative drugs;

(b) ensuring the safety of drugs consumed by the public; and

(c) controlling the quantity and quality of drug expenditures.

(2) *The protection of intellectual property rights, especially patents, is fundamental for ensuring a continuing flow of innovative new drugs. There is evidence that the pharmaceutical industry is more reliant on patent protection for innovation than other industrial sectors. The research and development process for new drugs is costly and risky. Relatively few new chemical entities ever receive marketing approval. Of these, only a few are commercially successful. A sizeable proportion of pharmaceutical manufacturers revenues can come from relatively few products.*

Pharmaceutical companies are unusually heavily reliant on intellectual property right protection (and, in particular, patents) to preserve the income flows necessary to finance research and development. R&D is a risky business. Of 10 000 products patented, only 100 will reach human trials and only ten will be marketed. Research has found that 75 percent of drug company profits come from just ten percent of all drugs. For some major firms, three products account for 70 – 80 percent of total pharmaceutical sales.

All OECD countries are signatories to the TRIPs agreement, which provides for a standard patent life of 20 years from filing. However, the process for obtaining marketing approval can be slow and costly, taking a number of years. This reduces the effective or commercial life of a patent. Most OECD countries therefore allow for an extension of up to five years to the patent life for pharmaceutical products. (New Zealand and Hungary are exceptions to this rule, allowing no extension; Italy allowed a longer extension for a short period). This is often coupled with provisions which enhance and encourage the entry of generic products upon expiration of the patent.

Many countries have adopted a mutual recognition procedure under which drugs approved in another jurisdiction receive expedited (or automatic) approval domestically. The EU also has a centralised procedure which, for successful applicants, grants marketing approval for the whole of the EU. The time required to obtain marketing approval seems to vary widely. While marketing approval can take years in the US, the time limits are 300 days in the case of New Zealand (for high risk medicines), 95 days in the case of Korea and 90 days in Mexico (60 days for drugs which have been patented in other countries).

(3) *The demand for pharmaceuticals is fundamentally influenced by the presence of health insurance (whether public or private). Health insurance often pays for all or part of the costs of some pharmaceuticals (particularly "prescription" pharmaceuticals). Since the insured consumer does not face the full cost, the incentives on the consumer to curtail his or her demand are weakened. As a consequence, health insurers adopt a host of mechanisms to control the quantity and quality of drug expenditures. These mechanisms include the use of co-payments, formularies, controls on the prices paid for drugs, on prescribing physicians and on pharmacists.*

The market for pharmaceuticals in fundamentally influenced by features of pharmaceutical demand and, in particular, by the effects of health insurance. For those pharmaceutical purchases which are covered by health insurance, the health consumer is partially or fully insulated from the cost and therefore has a weakened incentive to trade-off cost and quality, to substitute other treatments or to forego treatment entirely. It is common to distinguish three pharmaceutical markets – (*a*) the market for non-reimbursed or over-the-counter medicines, for which the consumer pays the full price; (*b*) the market for reimbursed, prescription, or "ethical" medicines, for which the demand is affected by health insurance; and (*c*) the market for pharmaceuticals purchased by hospitals. Hospitals often manage their own pharmaceutical expenditures and may have incentives for controlling costs and using pharmaceuticals effectively.

In the case of prescription medicines, since the final consumer has little incentive to control his/her consumption, responsibility falls to the health insurer (which is often closely linked to the government) to control the quality and quantity of drug expenditures. There are a variety of mechanisms that health insurers can use to ensure cost-effective drug consumption, including the use of co-payments, formularies, controls on the prices paid for drugs, on prescribing physicians and on pharmacists (see below).

Many countries have established specialised agencies to take responsibility for managing pharmaceutical expenditure – maintaining the national formulary, setting co-payment policies and establishing regulatory and financial controls on physicians and pharmacists. In the US, with its predominantly private health care system, these activities are primarily the responsibility of private companies known as Pharmacy Benefit Managers. The US experience suggests that this is one area where responsibility for regulatory policies may be efficiently divested to a commercial organisation.

(a) Co-payments and Reimbursement Policies

The incentives on an individual consumer to control his/her expenditure on drugs depends on the marginal expenditure or "co-payment" that he or she faces. The co-payment may depend on the identity of the drug, the identity of the individual or the level of the annual expenditure of that individual on drugs or on health care more generally. It is common for co-payments to be reduced for the poor or chronically sick. Since the bulk of pharmaceutical expenditures is accounted for by a small minority of consumers, some incentives for control of pharmaceutical expenditures can be retained by limiting reimbursement until annual expenditure exceeds a certain threshold (such as occurs in Denmark, Sweden and Norway).

(b) Formularies

Nearly all health insurers maintain a list of drugs which are covered by the insurance, the extent and conditions of that coverage and any conditions on use or prescribing. This list is known as a formulary. Simple techniques, such as excluding from the formulary drugs which do not meet a cost-effectiveness threshold, can have a big impact on pharmaceutical consumption.

(c) Price Controls

Most health insurers also control the prices that they pay for drugs (or limit the price which will be reimbursed for a drug). These prices are set in different ways. Where the products in a therapeutic class are close substitutes, the prices of the drugs in that class are often set equal to the lowest price in that class.

Where a drug has few close substitutes price-setting is more difficult. It is common to set prices based on international price comparisons of equivalent drugs. If almost all countries set prices on the basis of international comparisons, the importance of the price-setting policies in those countries which do not use international comparisons is magnified. A few countries fix prices on the basis of costs (also known as profit controls). These policies are also occasionally complemented with other industry-wide controls such as a limit on annual rate of increase, a broad freeze on prices or an enforced across-the-board price reduction.

From a theoretical perspective pharmaceutical prices should be set on the basis of cost-benefit analysis, also known as pharmaco-economic analysis. This analysis quantifies the

beneficial effects of a drug (e.g., fewer side-effects, fewer hospitalisations – this analysis necessarily involves subjective elements) and compares it with the cost. In principle all those drugs (and other health inputs) with a benefit-to-price ratio above a given threshold, should be accepted. Several countries (including the UK) have adopted a policy of using pharmaco-economic analysis to assess the quality of pharmaceutical and other health care spending.

(d) Controls on Prescribing Physicians and Pharmacists

Most insurers control the prescribing practices of individual physicians, to ensure the most cost-effective treatment of patients. These controls typically take the form of prescribing guidelines or controls on who may prescribe certain medications. Some countries also impose nominal or explicit "budgets" on prescribing physicians or give a financial incentive to doctors who achieve a certain level of generic prescribing (e.g., Spain). In a few cases the payment to the health care provider is fixed, giving strong incentives to economise on pharmaceutical use along with all other health inputs. The clearest example of this is the UK "GP Fundholder" programme under which the local doctor is given responsibility for purchasing health care services on behalf of a group of patients in return for a fixed per-capita payment. Such schemes rely on competition between doctors to ensure incentives to maintain quality are retained.

Many insurers also control the activities of pharmacists. Since pharmacists are typically compensated on the basis of a percentage margin on the products they sell, in the absence of explicit controls they have an incentive to increase rather than reduce the price of the medications they sell. Many countries either allow, encourage or require substitution of cheaper bio-equivalent products. In some cases, pharmacists are allowed to keep some of the cost savings from substituting cheaper equivalent products. Only in Japan and Korea are doctors are allowed to both prescribe and dispense medications. There is currently in a proposal in Korea to separate these two professions to reduce the financial incentive to over-prescribe.

(4) The costs of maintaining a retail distribution network are a substantial component of the total costs of pharmaceuticals. Where consumers are insured against the price of pharmaceuticals they have no incentive to shop for the cheapest pharmacy and competition between pharmacies cannot be relied upon to ensure efficient and effective delivery of pharmacy services. In these cases it is necessary to regulate the margins of pharmacies.

The widespread availability of and access to pharmaceuticals is one component of the quality of health care services. When consumers are insured against the prices of pharmaceuticals it is not possible to rely on competition to ensure the efficient supply of pharmacy services. In this circumstance, efficient supply of pharmacy services requires knowledge of the costs of maintaining each pharmacy (or each network of pharmacies). Instead, most countries simply fix margins for pharmacists on a nation-wide basis, ignoring local variation in costs. This leads to over-compensation in some areas and possibly under-compensation in others (particularly rural areas). Over-compensation leads to inefficiently high prices to consumers and induces inefficient entry. Countries respond by regulating entry and the location of pharmacies. For example, in Australia, pharmacies can be relocated to a site no closer than two kilometres from another pharmacy and can only move closer to existing pharmacies in steps of one kilometre every two years. In Sweden pharmacy services are provided by a government-owned monopoly company.

One alternative is to tender for the right to provide pharmacy services in a location or for the right to provide a network of pharmacies in a region. The tendering process would reveal information

about the costs of pharmacies. Another possibility would be to lessen the requirement that consumers be completely insured. For example, consumers could be insured for the wholesale costs of the pharmaceutical but not the dispensing costs. If consumers paid for (some part of) the pharmacy dispensing costs, competition between pharmacies would be restored, along with competition with other retail outlets such as mail-order or Internet pharmacies. Some countries (e.g., the US and Australia) already permit sale of pharmaceuticals via the Internet. In other countries (e.g., the Czech Republic) mail-order and Internet sales of pharmaceuticals is strictly forbidden. In the US and Mexico, which have little or no public insurance reimbursement of pharmaceuticals, pharmacies are largely unregulated.

Many countries also regulate the prices and services of pharmaceutical wholesalers. The reason for this remains unclear. Many countries noted that the pharmaceutical wholesaling sector was relatively concentrated. Some countries grant pharmacies a monopoly on the sale of non-prescription pharmaceuticals or require that a pharmacy be owned by a pharmacist, or limit the formation of chains of pharmacies. These restrictions also appear unnecessary.

(5) *Differences in policies regarding price controls lead to differences in the wholesale prices of pharmaceuticals across different countries. This, in turn, encourages international trade in pharmaceuticals. This trade, although currently small, potentially undermines the ability of pharmaceutical manufacturers, governments and health insurers to pursue different policies across different countries.*

Differences in price control policies encourage traders to purchase pharmaceuticals in low-price countries and sell them in high-price countries. This limits the ability of countries to pursue independent pharmaceutical price-fixing policies. This would likely result in higher prices in poorer countries.

(6) *Competition law applies in full to the pharmaceutical industry (with possible derogation for "regulated conduct"). It is conventional to base analysis of the relevant product market on standardised systems for classifying pharmaceuticals according to their therapeutic purpose, such as the ATC classification system. Many of these therapeutic classes are concentrated, with one or two firms accounting for the majority of sales. OECD competition authorities have addressed a range of issues including vertical and horizontal mergers and vertical and horizontal arrangements along with cases of abuse of dominance. Some of the most difficult issues involve the handling of mergers or agreements which might have an impact on the incentives for innovation.*

In defining the relevant product markets in pharmaceutical products, it is common to start with standardised classification systems such as the Anatomical Therapeutic Classification ("ATC") system which is recognised by the World Health Organisation. The classifications of drugs given by this system (particularly "level 3") are often used as a starting point for market definition, with other drugs excluded (or added) when the ATC classification is too broad (or too narrow) for competition purposes. It may also be necessary to distinguish pharmaceutical product markets according to the mode of administration (an injectable drug may not be considered to be a substitute for an oral drug) or a different distribution methods (a hospital-only drug may not act as a competitive constraint on a widely available prescription drug).

Many studies of concentration in pharmaceutical markets have found relatively high concentration in individual therapeutic classes. In many markets one or two firms account for the bulk of all sales. However, market share information at one point in time may not give an

accurate impression as market shares may change over time as substitute products are developed and as patents expire.

Over the last decade there has been a wave of horizontal mergers between the largest pharmaceutical companies. Competitive analysis of these mergers requires consideration of not only the products that are currently being commercial exploited but also products which are likely to come into the market in the future (i.e., products that are currently in the process of obtaining market approval). In addition, attention must be paid to the effect of the merger on the incentives for innovation. Where there are barriers to the development of a viable research programme in a particular line of research, the merger of two firms with overlapping research programmes has the potential to delay or limit the rate of innovation. In one case the US FTC required divestiture of the research and development programme for a new drug in phase 3 trials. This R&D programme was purchased by a rival and the resulting product subsequently became a viable competitor to the products offered by the merged entity.

Pharmaceutical companies often enter into agreements and joint-venture arrangements at each stage of the manufacturing process – at the research and development phase (for example, to pool patented know-how) and/or at the marketing and promotion phase (for example, to exploit complementary marketing strengths). Often an agreement for co-operation in research, once a successful product emerges, leads to an agreement for co-operation in marketing.

In the case of vertical mergers, OECD competition authorities have addressed mergers between pharmaceutical manufacturers and wholesalers (e.g., Australia) or mergers between pharmaceutical manufacturers and Pharmacy Benefit Managers (e.g., USA). These vertical mergers raise concerns for competition authorities such as favouring the parent companies own products and sharing of information to facilitate upstream collusion.

Abuse of dominance cases appear relatively rare but are not unknown. France addressed a case in which a manufacturer of product A which held a strongly dominant position and another product B which was losing its patent protection, attempted to restore the revenues of product B by requiring purchasers of the product A to also purchase product B. The US reported cases in which groups of pharmacies acted collectively to refuse lower reimbursement rates offered by insurers. In addition, several countries reported actions against associations of pharmacists seeking to co-ordinate pricing or entry to the profession.

SYNTHÈSE

Les principaux points qui se dégagent des contributions écrites, de la note de référence et des débats oraux peuvent être résumés comme suit :

(1) *L'industrie pharmaceutique est un secteur de haute technologie et à forte intensité de savoir. Elle présente une structure à deux niveaux. Les plus grosses entreprises du secteur réalisent la majorité des investissements en recherche-développement et détiennent la plupart des brevets. Un grand nombre de petites entreprises fabriquent soit des produits non brevetés, soit des produits brevetés pour lesquels une licence leur a été délivrée. L'industrie pharmaceutique est fortement réglementée et peu d'aspects de son activité échappent aux mesures réglementaires.*

Le secteur pharmaceutique produit et distribue des substances possédant des propriétés thérapeutiques. Les produits pharmaceutiques sont une composante importante des services de santé dans leur ensemble. Les politiques les concernant doivent être mises en cohérence avec les autres aspects des politiques de santé afin d'éviter des reports inefficients sur d'autres produits ou d'autres services de santé, avec des conséquences préjudiciables sur les coûts et la qualité des résultats. Dans la plupart des pays de l'OCDE, les dépenses de médicaments représentent de dix à 20 pour cent de la dépense totale de santé. La hausse des dépenses de médicaments par habitant enregistrée au cours de la dernière décennie dans plusieurs pays de l'OCDE a conduit les pouvoirs publics à s'intéresser de près à l'industrie pharmaceutique et à la maîtrise des dépenses de médicaments.

Les plus grosses entreprises du secteur réalisent des milliards de dollars de recettes et emploient des dizaines de milliers de personnes. Elles consacrent des sommes considérables à la commercialisation des produits ainsi qu'à la R-D. Les dépenses de commercialisation sont supérieures à celles affectées à la R-D. Les efforts de commercialisation s'appuient en grande partie sur la pratique du "démarchage", c'est-à-dire sur les visites à visée promotionnelle auprès des médecins prescripteurs. Bien que les pays de l'OCDE aient presque tous une production nationale de médicaments, la grande majorité de la production est concentrée au Japon, en Suisse, aux États-Unis et dans l'Union européenne (surtout au R-U). S'il arrive que les plus grosses sociétés pharmaceutiques fabriquent des produits concurrents, c'est essentiellement sur l'innovation (mise au point de nouveaux traitements et/ou amélioration de traitements existants) que s'exerce la concurrence entre ces sociétés. Les entreprises du second niveau -- fabricants de produits génériques ou de produits sous licence -- effectuent assez peu de R-D et la concurrence qu'elles se livrent est de type conventionnel et s'exerce sur les prix, le service et l'efficience.

L'industrie pharmaceutique est fortement réglementée. Chaque étape du cycle de vie d'un nouveau médicament -- demande de brevet, autorisation de mise sur le marché, commercialisation, expiration du brevet et concurrence des génériques – est réglementée. Tous les principaux acteurs du secteur - fabricants, grossistes, détaillants et médecins prescripteurs -