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EU Kommissionens forslag til "council regulation to avoid trade diversion into the European Union of certain key medicines" dateret den 30. oktober 2002.

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Af medierne er det fremgået, at Europa Udvalget har indkaldt økonomi- og erhvervsministeren til samråd, hvor ministeren er bedt om at redegøre for EU-kommissionens forslag om, at lægemiddelvirksomhederne skal sælge livsnødvendig medicin til ulandene til stærkt nedsatte priser. I den anledning sender Lif, Lægemiddelindustriforeningen, vore vurderinger af EU Kommissionens forslag, som vi håber, vil indgå i udvalgets overvejelser.

Lægemiddelindustrien i Danmark finder, at der er behov for en omfattende og fælles indsats med henblik på at afhjælpe de mest påtrængende forsyningsproblemer med nødvendige lægemidler til en lang række udviklingslande.

Industrien vedkender sig sit ansvar til at medvirke til holdbare og langsigtede løsninger i et tæt samarbejde med myndighederne i modtagerlandene og industrialiserede lande samt internationale institutioner som WHO, WTO og EU Kommissionen.

Der er i de senere år iværksat et betydeligt antal initiativer med henblik på sikring af en mere effektiv forsyning med nødvendige lægemidler til udviklingslandene. Nogle af initiativerne er multilaterale og andre bilaterale. I de fleste projekter deltager internationale lægemiddelvirksomheder. Til illustration heraf vedlægges en oversigt over nogle af de forsyningsprojekter, virksomheder deltager i. Oversigten er ikke fuldkommen, og nye projekter igangsættes løbende.

Med baggrund heri støtter lægemiddelindustrien Kommissionens initiativ, der har til formål at sikre en øget adgang til lægemidler i udviklingslandene og forhindre, at disse produkter reeksporteres til EU. Men lige så vigtigt som det er at sikre øgede forsyninger, er det at sikre, at lægemidlerne anvendes til sygdomsbekæmpelse i de pågældende udviklingslande. Derfor må gennemførelse af den foreslåede forordning ledsages af en øget indsats fra medlemstaterne og EU's side til sikring af at produkterne anvendes af patienterne i ulandene.

Forordningens bestemmelser er endvidere meget relevante i forbindelse med de igangværende bestræbelser på en ændret anvendelse af TRIPS-aftalens bestemmelser om tvangslicens, som i nogen tid har været genstand for drøftelser i WTO-regi. Forordningen vil således have meget stor betydning for den fremtidige forsyning og anvendelse af lægemidler i ulandene.

Oplysning om priser
De maksimalpriser, der er foreslået som leveringspris er den gennemsnitlige pris ab fabrik i OECD-landene + 20 % eller de direkte produktionsomkostninger + 10 %. Disse øvre grænser har Lif ikke problemer med. Det er det oprindelige krav om en "myndighedsgodkendelse" af priserne, foreningen har fundet problematisk.

Ved at stille krav om "godkendelse" af priser bevæger EU Kommissionen sig ind på et område, hvor Kommissionen i dag ikke er bemyndiget med kompetencer. Indseende med eller kontrol af lægemiddelpriser er i EU et nationalt anliggende. Det forhold bør der ikke ændres på.

Af hensyn til realisering af de opstillede målsætninger i forordningen finder Lif det tilfredsstillende, at bestemmelserne om "godkendelse" af priser nu foreslås suppleret med en mulighed for at virksomheden kan få en uafhængig person til at udstede et certifikat om at prisen overholder de fastlagte grænser. Dette vil i langt højere grad sikre det nødvendige incitament for virksomhederne til at deltage og dermed bidrage til opfyldelse af det tilsigtede formål.

Pakninger
Industrien støtter Kommissionens forslag om anvendelse af et system, hvor produkterne skal have særlige kendetegn for at blive omfattet af forordningens bestemmelser. Desværre er virkeligheden, at det er meget vanskeligt at sikre sig fuldt ud mod ompakning af de pågældende produkter og reeksport til industrialiserede lande. Lægemiddelindustrien har konstateret adskillige situationer, hvor en sådan ulovlig ompakning har fundet sted.

Anvendelse af et system med pakninger med særlige kendetegn og øget myndighedskontrol ved import af lægemidler til EU må imidlertid betragtes som en nødvendighed. Derfor er det vigtigt, at toldkontrollen gives de nødvendige muligheder for en systematisk kontrol ved import af lægemidler til EU. Dette gælder også i forhold til en række "særlige forsyningsprogrammer" til ulandene, hvor det er afgørende, at myndighedernes kontrol af reimport af lægemidler til de industrialiserede lande er effektiv.

Der bør i de foreslåede bestemmelser i artikel 8 tilføjes en bestemmelse om, at toldmyndighederne har pligt til at underrette producenten, når man beslaglægger et muligt ulovligt importeret produkt. Et krav om en notifikation vil give producenten mulighed for at hjælpe med identifikation og tage nødvendige forebyggende initiativer. Det foreslås endvidere, at også relevante lægemiddelmyndigheder informeres, og at det alene er myndighederne, der træffer beslutning om anvendelse af ulovligt importerede produkter.

Modtagerlande
Kredsen af modtagerlande er også af væsentlig betydning for industriens interesse i at anvende forordningen. Det forekommer således urealistisk, at nogle af de største producentlande inden for lægemidler kan være defineret som modtagerlande. Det gælder for eksempel Kina og Indien. I disse lande er vel-

standen blandt store befolkningsgrupper lige så udbredt som i de industrialiserede lande. Lif finder det rigtigst, at ordningen tilgodeser de lande, der har de største behov.

Lif foreslår, at kredsen af modtagerlande begrænses til de dårligst stillede udviklingslande, og at definitionen til enhver tid hviler på transparente og objektive kriterier.

Produkter
Forordningens anvendelse bør begrænses til produkter til bekæmpelse af HIV/AIDS, malaria og tuberkulose og andre infektionssygdomme i ulandene.

Når ordningen har fungeret i nogen tid, og der er høstet de nødvendige erfaringer, kan der indledes drøftelser om en eventuel udvidelse af ordningen til andre alvorlige, ulandsspecifikke sygdomme.

Også her er det vigtigt, at der eksisterer præcise og gennemsigtige procedurer og kriterier for udvælgelse af produkter.

Konklusion
Lif støtter implementering af en forordning med det erklærede formål, men ønsker bestemmelserne justeret på de anførte områder.

Foreningen er bekendt med at GlaxoSmithKline offentligt har tilkendegivet synspunkter, der ikke er sammenfaldende med de har anførte.

Med venlig hilsen
p.f.v.

Poul Erik Pyndt
Vicedirektør

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Dansk Industri
HTS – Handel, Transport og Service
Læger uden Grænser
Mellemfolkeligt Samvirke
Ibis
Nord/syd koalitionen

Bilag: Partnership for the developing world.

Partnerships for the developing world

Industry contributions to improving access to medicines

HIV / AIDS

Accelerating Access Initiative

The Accelerating Access to AIDS Medicines Initiative (AAI) is a public-private partnership with UNAIDS, the WHO, the World Bank, UNICEF, and the UN Population Fund to improve access to HIV/AIDS care and treatment in developing countries. Six companies are supplying products at steeply-reduced costs to 18 countries around the world, the majority of which are in Africa. These companies are Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck and Roche. By the end of March 2002, 78 countries had indicated their interest, including 41 countries in Africa.

Viramune Donation Program

Boehringer Ingelheim is offering Viramune free of charge for a period of five years to developing countries through the VIRAMUNE Donation Programme for the Prevention of Mother-to-Child Transmission of HIV-1. 12 countries are currently taking part in the program. The drug quantity ordered free of charge in these projects is supposed to treat 49.800 mother-child pairs. Seven programmes in additional six countries are under review. More have been announced to come by governments, NGOs and other organisations.

Botswana Comprehensive HIV/AIDS Partnership

Merck and The Merck Company Foundation are donating $50 million to this Partnership, which improves HIV/AIDS education, care and treatment. This matches funding by the Bill and Melinda Gates Foundation. The company is also donating antiretroviral HIV medicines for the duration of the program. As well as the Gates Foundation, Merck works alongside the Government of Botswana and Boehringer-Ingelheim, which is donating medication for the prevention of mother-to-child transmission of HIV.

Diflucan Partnership Program

Pfizer is offering Diflucan antifungal medicine at no charge to HIV/AIDS patients in 50 least-developed countries. Pfizer works together with the United Nations and the World Health Organization, building on the existing South African Diflucan Partnership Program involving Pfizer and the South African Ministry of Health.

Enhancing Care Initiative

The Merck Company Foundation is donating $3 million to the Harvard AIDS Institute to improve the quality, delivery and outcomes of HIV care in developing countries. The Initiative brings together international and local experts to help developing countries make the most effective use of scarce resources.

International Partnership Against AIDS in Africa

Boehringer Ingelheim, Bristol-Myers Squibb, Merck and Roche are working alongside five UN agencies (UNAIDS, UNICEF, UNFPA, the World Bank and the World Health Organisation), offering preferential pricing and medication for the prevention of mother-to-child transmission of HIV.

Project HOPE - Health Opportunities for People Everywhere

Founded by GlaxoSmithKline, and supported by Bristol-Myers Squibb and Pharmacia, HOPE's educational programs are promoting child immunizations, preventing life-threatening diarrhoea-related dehydration, improving prenatal care, and supporting AIDS and malaria prevention in around 30 countries.

Secure the Future

Bristol-Myers Squibb is committing $115 million to its Secure the Future program, which addresses the needs of women and children affected by AIDS in Botswana, Lesotho, Namibia, South Africa and Swaziland. The program finds sustainable solutions for the management of HIV/AIDS in women and children, and offers new resources to improve community education and patient support.

SHARE

Abbott, Agouron, Boehringer Ingelheim, GlaxoSmithKline and Roche actively support SHARE, a multi-national program that teaches doctors, healthcare workers, resource planners and public health experts about prevention and management of HIV infection.

Step Forward

Abbot is working to improve the lives of AIDS orphans and vulnerable children through *Step Forward*, its multimillion dollar international aid program. The program focuses on four critical areas: improving local healthcare services, offering HIV counseling and testing, providing clean water and other basic needs, and supporting education programs. In Africa, *Step Forward* has programs in Burkina Faso and Tanzania.

TUBERCULOSIS

Action TB

GlaxoSmithKline is investing almost $32.5 million in Action TB, a scientific collaboration with academic groups to discover and develop new TB drugs and vaccines. The program funds more than 20 academic research groups in Canada, South Africa, the UK and USA.

Global Alliance for TB Drug Development

The Association of the British Pharmaceutical Industry and Novartis India are working together with more than 30 partners around the world to accelerate the discovery and development of cost-effective new drugs. The Alliance draws on the best practices and resources of the public and private sectors.

Stop TB Partnership

American Home Products/Wyeth, Eli Lilly and the International Federation of Pharmaceutical Manufacturers' Associations are working together to improve strategies to control and eliminate TB.

TB Free

Aventis is committing around €15 million over a five-year period in collaboration with the Nelson Mandela Foundation to help improve the detection and treatment rates of TB in South Africa. The partnership is aiming to train volunteers to support patients' compliance during the 6-month treatment. This action will contribute to reaching a 85% success rate.

MALARIA

Medicines for Malaria Venture

Bayer, GlaxoSmithKline and Roche are working with partners to discover and develop new anti-malarial drugs for developing countries. The partners in this initiative are the International Federation of Pharmaceutical Manufacturers' Associations, the WHO, the World Bank, the UK Department for International Development, the Swiss Agency for Development and Cooperation, the Dutch Ministry for Development Cooperation, the Rockefeller Foundation and the Bill and Melinda Gates Foundation.

LAPDAP Antimalarial Drug Development

GlaxoSmithKline is partnering with the UN Development Program, the World Bank and the WHO in their Special Programme for Research and Training in Tropical Diseases (TDR). The goal is to develop a new effective oral treatment for uncomplicated malaria, primarily for use in Sub-Saharan Africa, at preferential prices for public health programmes.

Roll Back Malaria Global Partnership

Novartis is providing its malarial drug, Coartem, at cost, as part of this worldwide partnership with the WHO and the Wellcome Trust. The overall objective of the Partnership is to reduce the global malaria burden by 50% by the year 2010.

LYMPHATIC FILARIASIS

GlaxoSmithKline, Merck and the World Health Organisation are working to eliminate this disease by the year 2020. Both companies are donating as much preventative medicine as necessary to any developing nation until lymphatic filariasis is eliminated.

RIVER BLINDNESS

Merck is donating as much Mectizan as necessary, for as long as necessary, until the disease is eradicated. The program is governed by a board of experts in public health and tropical diseases, as well as representatives of the WHO and the US Centres for Disease Control.

TRACHOMA

Pfizer has donated more than $70 million in medicine and health education grants in its efforts with the Edna McConnell Clark Foundation to eliminate blinding trachoma, the leading cause of preventable blindness. More than four million people have been treated in Egypt, Ghana, Mali, Morocco, Nepal, Niger, Sudan, Tanzania and Vietnam. Additional countries that may soon benefit include Ethiopia, Senegal and Gambia.

LEPROSY

Novartis is donating $30 million in treatment from 2000 to 2005, through the World Health Organization, for all leprosy patients in the world. Novartis is a core member of the Global Alliance to Eliminate Leprosy, which aims to detect and cure all estimated 2.8 million patients by 2005.

VACCINES FOR CHILDREN

Aventis, American Home Products/Wyeth, the International Federation of Pharmaceutical Manufacturers Associations, Chiron, GlaxoSmithKline and Merck have all committed themselves to the Global Alliance for Vaccine and Immunisation (GAVI), which provides financial support directly to low-income countries based upon applications to and recommendation of the GAVI Board. GAVI is boosting immunisation rates and stopping the widening gap in vaccine access among children in developing countries.

POLIO

Aventis Pasteur, Aventis' human vaccine group, is donating 50 million doses of an oral polio vaccine in Angola, Liberia, Sierra Leone, Somalia, and South Sudan. This is part of the Global Polio Eradication Initiative, which includes the WHO, UNICEF, Rotary International and the US Centers for Disease Control and Prevention as partners. This donation should cover the entire vaccine needs for National Immunization Days scheduled in these countries.

SLEEPING SICKNESS

Aventis, Bristol-Myers Squibb and Bayer are partnering with the WHO to ensure adequate drug supplies, disease surveillance and management, treatment and research. Aventis is donating $25 million and will work in close collaboration with WHO during a period of five years on a three-point strategy including drug donations, disease management, and research and development. Bristol-Myers Squibb has committed to fund the cost of supplying the bulk material for one of the drugs during one year, and Bayer has agreed to restart production and donate two other drugs used to treat the disease.