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ANDORRA

Col·legi Oficial de Metges
Edifici Plaza esc. B
Verge del Pilar 5,
4art. Despatx 11, Andorra La Vella
Tel: (376) 823 525 Fax: (376) 860 793
E-mail: coma@andorra.ad
Website: www.col-legidemetges.ad

ARGENTINA

Confederación Médica Argentina
Av. Belgrano 1235
Buenos Aires 1093
Tel/ 793



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THE WORLD MEDICAL
ASSOCIATION**

Dr. Alan J Rowe
Haughley Grange Stowmarket
Suffolk IP 14 3 QT
UK

Executive Editor

Dr. Ivan M. Gillibrand
19 Wimblehurst Court
Ashleigh Road
Horsham
West Sussex RH12 2 AQ
UK

Co-Editor

Prof. Dr. med. Elmar Doppelfeld
Ottostr. 12
D-50859 Köln
Germany

Business Managers

H. Dinse, D. Weber
50859 Köln
Dieselstraße 2
Germany

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ple, Tofteng 2002). The mutation alters vitamin D's ability to bind to its receptor. As vitamin D contributes to bone mineral density, the reduced binding ultimately weakens the skeleton.

Researchers can grow crystals of these proteins. By examining the way in which the crystal scatters X-rays, biologists can gain an insight into the protein's structure. A computer can integrate these X-ray results with the protein sequence to show the shape of, for example, a receptor or an enzyme. This allows researchers to home in on the active site and design drugs that fit specifically into the site—rather like a lock and key mechanism.

Nevertheless, validating targets can prove difficult, especially when the lead comes from genomic rather than clinical studies. "Traditionally, we associate the target and the disease from clinical studies. So we knew from clinical and pathophysiological studies that, in comparison to osteoclasts (bone forming cells), overactive osteoclasts contribute to low bone mass," Professor Van der Auwera comments. "However, genomic studies link a gene to the disease. Discovering what the gene's product does can be difficult. Knock-out animals, which are genetically engineered not to express the gene, are fashionable and in many cases allow us to better understand the link with the disease. Nevertheless, we often have to go to phase II or even phase III clinical studies to validate the target – which has an enormous failure rate! Nevertheless, as we hone our understanding of the gene's function, our failure rate is declining."

Drug discovery

Against this background, the next generation of drugs for osteoporosis is likely, Professor Van der Auwera believes, to emerge from rational drug design and discovery. "Molecular biology and genomics identified many targets that either reduce resorption or increase bone formation," he says. "However, ibandronate and the other anti-resorptive agents are now just about as effective as they can be. Any advances in anti-resorptive agents are likely to be relatively minor, such as enhancing safety, tolerability and convenience. The key objective today is finding a drug to stimulate anabolism, the formation for new bone."

For example, Professor Van der Auwera notes that up to half the patients using current oral bisphosphonates may stop taking the treatment within a year, which precludes any reduction in the risk of sustaining a fracture. "Treatment schedules such as a once a month tablet, instead of weekly (52 tablets) or daily (365 tablets) can make a huge difference to compliance", he comments. "Likewise for patients already taking lots of oral medication, a quarterly intravenous injection can allow them to benefit from a very effective medicine that they would not otherwise take."

Professor Van der Auwera adds that in addition to optimising anti-resorptive agents, another key objective for researchers is to find drugs that stimulate the formation of new bone (anabolism). "It is predictable that, at least for patients with the most severe bone loss, combination or sequential therapy with an anabolic drug, probably for a short period such as 6 months, and an anti-resorptive agent will become the rule. So we need 'smart' treatment schedules allowing the patients to improve their quality of life without the constant reminder of their disease."

In many ways, drug discovery has always been rational. But biologist's limited understanding of the body's complexities hindered attempts to develop targeted drugs. And traditionally time-consuming screening slowed the development of much needed medicines. Today, the genomics revolution has massively increased biologists' understanding of the nature of common diseases and identified a plethora of possible targets. Fortunately, rational drug design and development give researchers the power to identify and develop specific and selective drugs that target a single cell type or even a single gene product. The possibilities for new medicines tackling some of the commonest diseases seem endless.⁸

Modern pharmacological advances

Epilepsy

Around 30 % of patients diagnosed with epilepsy fail to respond to prescribed antiepileptic drugs and continue to have seizures. These refractory seizures are asso-

ciated with increased mortality and psychosocial morbidity and pose an enormous human and financial burden. Notwithstanding the seriousness of the problem, remarkably little attention has been paid to the biological basis of refractory epilepsy. Workers in the field of epilepsy—those concerned with the basic science of resistance and the blood-brain barrier, and those with clinical experience of drug resistance in cancer are collaborating with a view to exploring parallels between the fields and suggesting further potentially profitable avenues for exploration on drug resistance in epilepsy.

Ageing

Social and medical developments during the past century have led to a dramatic increase in life expectancy. The study and understanding of the endocrine organismic changes associated with ageing are therefore matters of urgency. Basic scientific facets and clinical aspects relevant to age-related changes in the multiple endocrine systems have been discussed. The implications of therapeutic reconstitution with hormones in the elderly, could be very important in the future.

Mucus hypersecretion in respiratory disease

A number of chronic respiratory diseases including chronic bronchitis, asthma, cystic fibrosis and bronchiectasis are characterised by mucus hypersecretion and this excessive mucus production can lead to a pathological state with increased risk of infection, hospitalisation and morbidity. Despite a high and increasing prevalence and cost to healthcare services and society, this phenomenon has received little attention until recently, probably because of the difficulties inherent in studying its pathology. Basic scientists and clinicians need to discuss recent advances and their implications for the development of novel, rational therapies, particularly as a potential cure for CF is on the horizon.

neurobiology of autism and imaging studies have been used to explore the contributions of different brain regions. The most impor-

thus controlling human life not only when

The 55th General Assembly of the WMA¹ took place in Helsinki on September 2003, a long-awaited meeting which it was hoped would have allowed the controversies that arose from the latest version of the Declaration of Helsinki to settle. A final agreement in the town where the Declaration had been established for the first time in 1964 would give a symbolical value to the event. This paper sets out a personal view of the twists and turns of the ethical discussion concerning the most recent version.

The 6th edition of the Declaration of Helsinki² was adopted in Edinburgh on October 7, 2000. During the debates, several delegates had asked that the adoption of this new version be postponed. They were expecting many criticism from researchers and sponsors, but their warnings were soon swept away, it being said that the credibility of the WMA would be compromised if the revision (already announced for a long time) would be delayed after so many years of preparatory work.

Nevertheless those who had argued for a time of further reflection had been right: suddenly some members of the WMA raised serious objections to the previous unanimously adopted version. The United States especially had rebukes from their rearguard – read the FDA³. The sources of irritation were paragraphs 29 and 30, respectively concerning the use of placebo, and the participants' right of access to the best-proven treatment identified by the study.

The opponents of paragraph 29 considered that studies controlled by placebo were essential for a reliable statistical assessment of the results of the trial. This is moreover the reason why the FDA recommends systematic control, because the methodology of the scientific study is otherwise worthless, and if worthless, the research projects do not receive subsidies. By following

paragraph 29, institutions, including universities, have taken the risk of a negative response from their Institutional Review Board⁴, from the NIH⁵ and obviously from the FDA. Therefore several scientific projects involving human subjects have been interrupted and others not even started. In the circumstances the protests are understandable.

The opponents of paragraph 30 emphasised the very poor functioning of the healthcare systems in poorly resourced nations where most experimentation involving human beings is carried out. This paragraph would oblige the pharmaceutical companies to provide the participants with the best-proven treatment identified at the end of the study. From the drug industry's point of view this cannot be afforded.

The academic authorities and spokespersons of the pharmaceutical industry insisted very firmly that the Declaration of Helsinki should be amended. They would otherwise seriously be thinking of not referring anymore to the strong mandatory character of the Declaration of Helsinki. Such a boycott would mean a loss of prestige for the WMA whose Declaration of Helsinki is its pride. Basically nobody intended to undermine the moral leadership of the WMA regarding research, and certainly not the developing countries.

In order to avert an imminent crisis the WMA organised a conference in Pretoria on March 2001, in collaboration with the EFGCP⁶ and the University of Pretoria School of Health Systems and Public Health, which had the appearance of an emergency sitting. Representatives of the pharmaceutical industry, of the FDA and of the NIH were numerous. In contrast the attendance of developing countries was on the other hand very sparse, possibly be-



clinical research, including both the investigator as sponsor on the study, and the members of ethic committees. It is therefore satisfying that the Declaration of Helsinki is often referred to in both European and national law. In March 2001 in Pretoria, the draft European directive 2001/20/EC on "the approximation of the laws, regulations and administrative provisions of the Members States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" was presented. The Assembly was very keen that the directive should refer to the Declaration of Helsinki which would give it the force of law, at least in the Members States of the European Union.

The Directive was published on May 1, 2001¹², and refers to the Declaration of Helsinki in its preamble. But one is amazed to discover that it refers to the obsolete version of 1996 and not to that of 2000. Thus the last revised version with its hindering prescriptions regarding to drug industry is considerably weakened.

The Member States of the European Union have to transpose the directive into their national legislation for May 1, 2004. Although the directive refers to the version of the Declaration of Helsinki of 1996, we hope that national legislators will take into account the last stance of the WMA thus avoiding (by way of parody!) that someone consults an invalidated version of the Highway Code to determine his way of driving! The time has come both for WMA and for the pharmaceutical industry to decide on driving either on the left or on the right, in other words, to choose in favour of the rich or the poor.

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Editorial note:

Following the September 2003 Council meeting in Helsinki (see WMJ 49 (5/6), 71), the working group on the Helsinki Declaration has continued its work and following the many comments, discussions and consultations, and will present a report to the WMA Council meeting in May 2004.

Discussion

Moral progress in research on human subjects since the infamous Nazi human experiments, is evident in many activities. These include the development of many codes, guidelines and procedures for research ethics that aim to protect research subjects from harm and exploitation, and the increasing attention being paid by scientists and others to the requirements for ethical research. Expansion of international collaborative research has prompted generous funding from the US National Institutes of Health's Fogarty International Centre for promotion of capacity building in research ethics in developing countries.¹

However, there is a wide gap between scientific/medical progress and moral progress in medical research and practice. This is starkly evident from widening disparities in health, longevity and health care and in the expenditure on medical research. Indeed questions must be raised about the moral credibility of a medical research endeavour

structure in which changes can be made. This requires advocacy with professional and allied partners, and the setting of priorities for action.

Water and Sanitation

About 1,2 billion people world-wide lack access to safe drinking water and 2,4 billion lack adequate sanitation, giving rise to diseases such as diarrhoea, cholera and trachoma. In poor countries it has been estimated that at any one time, about half the urban population is suffering from one or more of the diseases associated with the lack of water and proper sanitation.(8) The incidence of diarrhoea can be reduced by nearly a quarter and the number of deaths by close to 2/3rds, through improvements in safe water supply with sanitation and hygiene. The cost of realising universal access to health, water sanitation and education, was estimated by the United Nations and the World Bank in 1995 to be an additional 70–80 billion dollars per year. The World leaders can and must afford this. The Ugandan Medical Association has made "sanitation" their theme for the coming year.(9) The Japan Medical Association is leading the WMA's current initiative on key issues concerning water world-wide.

Malnutrition

More than half the deaths of children in the world under the age of five are associated with malnutrition. The number of malnourished children in sub-Saharan Africa has increased over the last ten years. Malnutrition is a cause as well as a consequence of poverty. Despite the high profile and the work of a large number of non-governmental organisations, the essential infrastructure has not been properly developed to relieve this totally preventable burden.

Armed Conflict

More children have suffered from armed conflicts and violence in the last ten years than in any other comparable period in history.(8) Ethnic conflicts and civil wars have come in the wake of the "cold war". Conflicts killed 2 million children in the '90s. They left large numbers of children disabled

and psychologically scarred. Violence breeds violence! Children have been displaced, placed in unsanitary conditions with poor or absent social infrastructure, and with no system of justice. There are 35 million displaced persons and refugees world-wide, 80 % are women and children. This is a severe indictment on the responsibilities of some nations' leaders and the ineffectiveness of the United Nations to resolve international conflicts.

Abuse, Neglect and Exploitation

In the wake of armed conflict, poverty and a culture of violence, children are increasingly becoming victims of abuse, neglect and exploitation. It has been estimated that there may be as many as 35 million child victims of child prostitution, sex tourism and child "slavery". One form of gross breach of human rights affecting young girls is female genital mutilation. The WMA believe that this practice is completely unethical.(18) Yet in the UK where the practice is outlawed, it is widely alleged that FGM continues to be

practised in private hospitals.(10) Girls are also being sent abroad to those countries where the operation is allowed. Physicians have a duty to do all in their power to expose unethical practice and try and prevent all forms of child abuse.

Smoking

More than five million children alive today will die prematurely of smoking related diseases.(11) Recent studies have revealed that in Bangladesh as a result of marketing by the tobacco industry, family members are spending money on cigarettes rather than on food for their children, even to the extent of causing malnutrition.(12) It is crucial that the tobacco "epidemic" that has swept the western world causing such a toll of respiratory, cardio-vascular and neurological disease, is not inflicted on the poor nations already bearing an intolerable and financially overwhelming burden of disease by the marketing practices of a selfish and unscrupu-

children are more susceptible to cigarette advertising than adults. To quote Philip Morris: "Today's teenager is tomorrow's regular customer, and the overwhelming majority of smokers first begin to smoke in their teens. The smoking pattern of teenagers is particularly important to Philip Morris." National medical associations need to advocate in the strongest possible terms for their country to sign up to the UN Framework Convention on Tobacco Control (13) which will provide their fellow citizens with some protection from the predicted tobacco epidemic.

HIV/AIDS

The HIV/AIDS pandemic is a global disaster. There are 10.4 AIDS orphans, 95 % of whom live in Sub-Saharan Africa. In children under five years, it has been predicted that the virus will cause 2/3rds of deaths in Botswana and half the deaths in Zimbabwe and South Africa. In Uganda of the 100,000 people suitable for anti-retroviral therapy, only 10,000 can be afforded the treatment.(14)

of fractures. For example, a recent study in China by Professor Kai Ming Chan, shows that regular tai chi chuan exercises can delay bone loss in postmenopausal women.

Background

The Bone and Joint Action Week, October 12–20th 2003

As a highlight of the Bone and Joint Decade Action Week, leading authorities in the musculoskeletal field presented a 24-hour series of eLectures via webcast. Subjects ranged

ty scores between patient and physician exists in the United Kingdom in both humanistic domain (17 % difference) and access domain (26 % difference) and in Germany access domain (19 % difference), with patients seeing more opportunity than do physicians.

Conclusions

The findings indicate a fundamental shift in the patient-physician relationship away from an authoritarian and paternalistic model and toward partnership and team based approaches. Patients are significantly more confident and empowered than they were ten years ago. Physician confidence in pa-

tient self-management is more modest. Patients possess high confidence in physicians but also demonstrate higher expectations for ideal physician performance and higher expectations for improvement along five dimensions of humanistic care and five dimensions of access to care. The ability to align expectations of patients and physicians, and meet commonly held objectives, will be increasingly important in assuring the future health of this critically important societal relationship.

* Mike Magee, Pfizer Medical Humanities Initiative, 235 East 42nd St, New York NY 10017



Poverty

Health And Finance Ministers Address Need For World-wide Increase In Health Investment

Geneva – Ministers of Health, Finance and Planning from 40 developing countries came together with development partners at WHO headquarters from 29 to 30 October to address the need to significantly increase investments in health. This is the first time that the World Health Organisation has hosted a meeting so widely attended by non-health officials, underlining the urgency of building national capacity to absorb increased health funding.

”This meeting signifies real political commitment from the highest levels of government and donor representatives. Let us capitalize on this unique opportunity to recognize health as a critical investment and together develop a common understanding of how countries and their partners can transform these commitments into immediate actions. We must choose to make equitable and efficient health investments a reality,” said WHO Director-General Dr Lee Jong-wook.

This meeting comes nearly two years after the World Health Organization's 2005-2006 Strategic Plan, which called for a 50% increase in health investment by 2015.

WHO welcomes new initiative to cut the price of AIDS medicines



million people in developing countries by the end of 2005, the "3 by 5" target. To do this, WHO is leading emergency response teams to assist developing countries in increasing the availability of treatment for people with AIDS, developing simplified treatment guidelines, building an AIDS drugs and diagnostics facility, and ensuring the widespread availability of training for health staff and volunteers.

"Further price reductions are vital for countries to be able to provide treatment to those who need it," said Dr Paulo Teixeira, Director of the HIV/AIDS Department at WHO. "But lower price medicines alone will not deliver treatment. Improving the ability of countries to deliver the medicines, building stronger health systems and training more health workers are also vital if we are to reach the '3 by 5' target."

to emergency obstetric care, especially in sub-Saharan Africa," said UNICEF Executive Director Carol Bellamy. "The widespread provision of emergency obstetric care is essential if we want to reduce maternal deaths."

The maternal mortality ratio, was estimated to be 400 per 100,000 live births globally in 2000. By region, it was highest in Africa (830), followed by Asia – excluding Japan (330), Oceania – excluding Australia and New Zealand (240), Latin America and the Caribbean (190) and the developed countries (20).

Worldwide, 13 developing countries accounted for 70 % of all maternal deaths. The highest number occurred in India where 136,000 women died, followed by Nigeria where there were 37,000 deaths.

In 2000, world leaders agreed to reduce ma-

Maternal mortality

Maternal Deaths Disproportionately High In Developing Countries

African women are 175 times more likely to die in childbirth than women in developed regions of the world

Geneva – New findings on maternal mortality by **WHO, UNICEF** and **UNFPA** show that a woman living in Sub-Saharan Africa has a 1 in 16 chance of dying in pregnancy or childbirth. This compares with a 1 in 2,800 risk for a woman from a developed region. These findings are contained in a new global report on maternal mortality released online by the three agencies at www.who.int/.....

Of the estimated 529,000 maternal deaths in 2000, 95 % occurred in Africa and Asia, while only 4 % (22,000) occurred in Latin America and the Caribbean, and less than one percent (2,500) in the more developed regions of the world.

Experience from successful maternal health programs let show that much of this death and suffering could be avoided if all women had the assistance of a skilled health worker during pregnancy and delivery, and access to emergency medical care when complications arise.

"Many women deliver their children alone or with family members or other untrained attendants who lack the skills to deal with complications during delivery," said Dr LEE Jong-wook, Director-General of WHO. "Skilled attendants are vital because they can recognise and prevent medical crises

and provide or refer for life-saving care when complications arise. They also provide mothers with basic information about care for themselves and their children before and after giving birth."

Reducing maternal mortality is a key factor in ensuring that all children, especially in the world's poorest countries, survive and thrive through adolescence.

"These new estimates indicate an unacceptably high number of women dying in childbirth and an urgent need for increased access



WMA Secretary General

1990 and 2000 from 42 to 52 %, suggesting a potential decrease in maternal deaths. Findings show the greatest improvements in South East Asia and Northern Africa and the slowest changes in sub-Saharan Africa and the lowest rates in the Middle East and North Africa.



- The WMA has been a forceful partner and supporter of the Framework Convention on Tobacco Control
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Regional and NMA News

vanced medical technology, there is always



Regional and NMA News

HIV/Aids treatment in all provinces as a matter of urgency, and will pursue all possibilities towards facilitating treatment through efforts with other organisations.”

Meanwhile, SAMA joined forces with the Treatment Action Campaign and the Nelson Mandela Foundation to strengthen its position in the fight against the disease.

SAMA has over the years used all means necessary to inform its members, and patients, on the right to treatment of HIV. SAMA has reiterated the profession’s commitment to the alleviation of the HIV pandemic by all means possible, and affirmed its strong support for the fundamental rights of medical practitioners to clinical independence and autonomy. This includes the right to treat patients without undue influence, pressure or victimisation from employers or government institutions.

The Association then adopted a set of guidelines, “HIV Human Rights and Ethical Guidelines” which informed members how to deal with the management of HIV. Members were kept informed of rulings by the Labour Court regarding HIV through our Human Rights, Law and Ethics Unit, and adopted a document on “Doctors’ and Patients’ Rights and Responsibilities”. What makes this document unique, is that it translates the human rights found in the South African Constitution into real-life situations affecting doctors and patients. A second distinctive feature is the inclusion of responsibilities or duties. For example, every doctor has the right to life, which includes the right not to be placed in disproportional life-threatening situations. But every doctor has the duty to protect life, within the confines of patient autonomy and decision-making power. On the other hand, patients have the right to have their lives protected by means of the benefits of medicine when available, and when they so wish. However, patients also have the duty to ensure that their illness or incapacity does not endanger the lives of others.

SAMA has always stressed the fact that its members were fighting the pandemic in their everyday work. “Medical practitioners are under an ethical duty to act in the best interest of their patients, who form an excep-

tionally vulnerable group in South Africa society,” said Dr Chetty.

Doctors’ clinical independence came under fire with the von Mollendorff case. Dr Thys von Mollendorff was dismissed for treating HIV-positive patients. SAMA worked closely with the Greater Nelspruit Intervention Programme (GRIP) and the Aids Law Project to see that the case was concluded for the positive. Letlape referred to the dismissal of Dr von Mollendorff as an example in which doctors’ responsibility to their patients was severely disrupted, which was in direct contrast with the rights of individuals which are entrenched in the constitution. He emphasised that urgent discussion with government was needed to look at the principle of interference in the profession’s obligations and duties on a broad scale. “We need guidelines and rules to stimulate and nurture private public interface,” Letlape said.

SAMA continued to reiterate the profession’s right to clinical independence and autonomy. Letlape referred to the 38th World Medical Assembly (WMA) in 1986 when the WMA unambiguously denounced political interference in health care delivery. “Physicians must have the professional freedom to care for their patients without interference. The exercise of the physician’s professional judgement and discretion in making clinical and ethical decisions in the care and treatment of patients must be preserved and protected.” The Association made it clear that it would continue to assist and support doctors who acted in the best interest of patients and their rights to access to health care.

Later Amnesty International (A.I.) urged the Minister of Health to put a stop to the harassment of health care professionals and other service providers in Mpumalanga Province, to end discrimination against women in need and to uphold professional ethics. A.I.’s involvement in this issue started in November 2001 when renewed action was taken against Dr von Mollendorff for his involvement in GRIP, which offered counselling and treatment to rape survivors. According to A.I., its correspondence with the relevant authorities requesting information on the issue remained unanswered.

As part of awareness campaigns the Junior Doctors’ Association of SA (Judasa), an affiliate group of SAMA, created the Black Armband Campaign to show solidarity with HIV/Aids victims. Judasa emphasised that their campaign was not an attack on government, but rather an offer to assist in any government action aimed at fighting the HIV/Aids pandemic. As part of the campaign, junior doctors intended to keep thorough records of patients they saw dying of HIV. The records would then be sent to the relevant authorities, to share with government what junior doctors’ experienced in dealing with the HIV/Aids pandemic every day.

Awareness campaigns continued with SAMA closely watching the development of the country’s HIV/Aids programme.

On December 1, 2002 SAMA launched the Tshepang Treatment Programme, named after baby Tshepang who had been savagely raped and was put back together by caring doctors.

Nearly a year later the Association’s dream came true – supplying ART to people living with HIV. On December 1, 2003, World Aids Day, SAMA launched an ART treatment programme at the GF Jooste Hospital in the Western Cape. The Association plans to gather more financial support from the role-players in the industry, and eventually have two treatment sites in every province.

SAMA’s Foundation for Professional Development (FPD), the educational arm of SAMA, has developed an HIV management course for doctors and other health personnel. To date they have trained 3,500 health care professionals in South Africa, and also train health workers in Africa.

SAMA’s motto is “Uniting doctors for the health of the nation,” and we plan to do just so. KL/TS

CHILE

Colegio Médico de Chile
Esmeralda 678 - Casilla 639
Santiago
Tel: (56-2) 4277800
Fax: (56-2) 6330940 / 6336732
E-mail: sectecni@colegiomedico.cl
Website: www.colegiomedico.cl
Vicepresidente

CHINA

Chinese Medical Association
42 Dongsì Xidajie
Beijing 100710
Tel: (86-10) 6513 4885
Fax: (86-10) 6512 3754
E-mail: cmafrd@public3.bta.net.cn

COLOMBIA

Federación Médica Colombiana
Calle 72 - N° 6-44, Piso 11

Association and address/Officers

Duché de Luxembourg
29, rue de Vianden
2680 Luxembourg
Tel: (352) 44 40 331
Fax: (352) 45 83 49
E-mail: secretariat@ammd.lu
Website: www.ammd.lu

MACEDONIA

Macedonian Medical Association
Dame Gruev St. 3
P.O. Box 174
91000 Skopje
Tel/Fax: (389-91) 232577

MALAYSIA

Malaysian Medical Association
4th Floor, MMA House
124 Jalan Pahang
53000 Kuala Lumpur
Tel: (60-3) 40418972/40411375
Fax: (60-3) 40418187/40434444
E-mail: mma@tm.net.my
Website: <http://www.mma.org.my>

MALTA

Medical Association of Malta
The Professional Centre
Sliema Road, Gzira GZR 06
Tel: (356) 21312888
Fax: (356) 21331713
E-mail: mfpb@maltanet.net
Website: www.mam.org.mt

MEXICO

Colegio Medico de Mexico
Fenacome
Hidalgo 1828 Pte. Cons. 410
Colonia Obispado C.P. 64060
Monterrey, Nuevo León