Health Canada Santé Canada

Conférence de travail sur le renforcement de l'évaluation de l'innocuité et de l'efficacité des médicaments en situation réelle

Ottawa

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Questions …

- Pourquoi ce dossier devient-il problématique maintenant?
- Quelles sont les leçons que nous avons apprises jusqu'à présent?
- Opinions du gouvernement fédéral …

Pourquoi ce dossier est problématique maintenant … 1

- L’innocuité : un aspect fondamental de la responsabilité du gouvernement fédéral en matière de réglementation
- Qu’est-ce que nous pouvons savoir au juste sur l’innocuité à partir de preuves recueillies avant la mise en marché?

Pourquoi ce dossier est problématique maintenant … 2

- Les produits pharmaceutiques deviennent un composant de plus en plus important des soins de santé.
  - Les médicaments représentent le deuxième secteur des soins de santé en importance et en croissance.
- Un accès égal aux services de soins de santé, y compris les médicaments, pour tous les Canadiens … mais :
  - À mesure que le recours aux médicaments augmente, des drogues nouvelles et plus chères sont substituées.
  - Le maintien de la durabilité du système est un défi crucial.
- Le public se préoccupe de plus en plus de l'innocuité, des avantages thérapeutiques, de l'accès et de l'abordabilité.
- Ce problème n'est pas exclusivement canadien.

New' drugs too often offer little new

Globe Sept 8, 05

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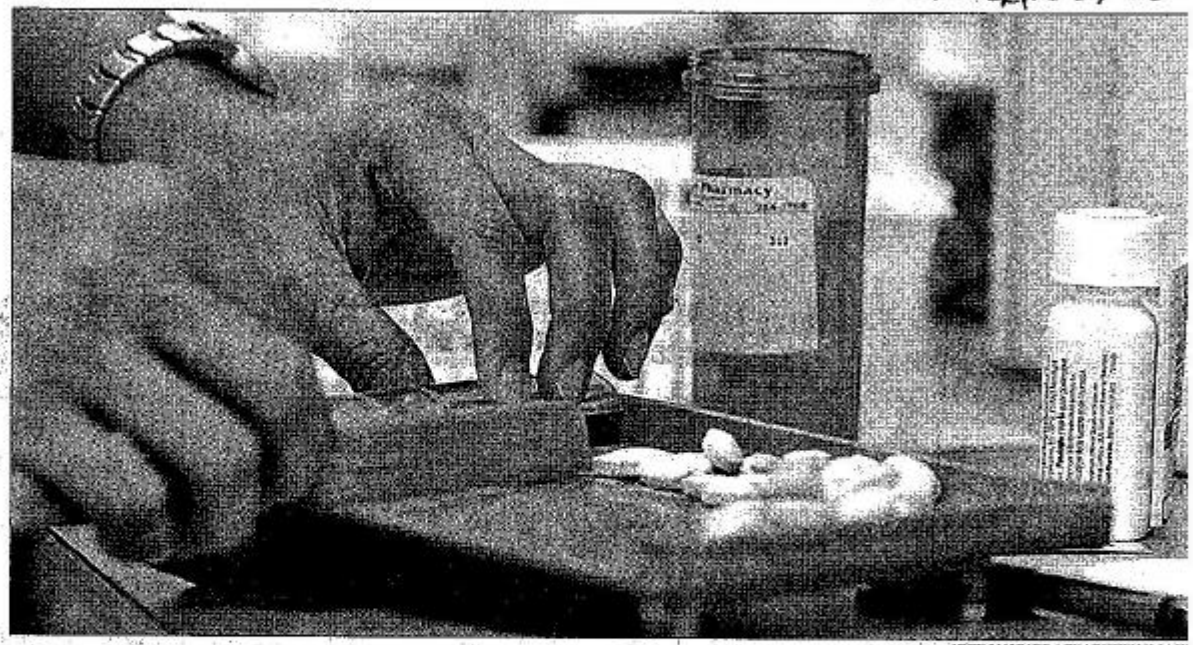


JEFF HAYNES AFP/GETTY IMAGI

Drugs have become so costly, Canadians now spend more on prescriptions than on physician services.

n 2004, prescription-drug spending in Canada rose to a staggering $18-billion a year (not including the $1.3-billion prescription drugs dispensed in spitals). In 1985, prescription ug spending was only $2.6-bil-n annually.

n the past decade alone, drug ending has doubled, to the int where Canadians now spend ore money on prescription igs than on physician services. While the vertiginous rise in its is worrisome, we can at least e comfort that all this new ending is a sign of scientific pro-ss, a reflection of dramatic akthroughs that are providing

(a mere 5.9 per cent) met the regulatory criterion of being a breakthrough drug — defined as the "first drug to treat effectively a particular illness or which provides substantial improvement over existing drug products."

These breakthrough drugs include: filgrastim (sold under the brand name Neupogen), used to treat a common side effect of chemotherapy; donepezil hydrochloride (Aricept), used in Alzheimer's; infliximab (Remicade), used in rheumatoid arthritis and Crohn's

fourth drug in its class out of the gate — after Mevacor, Pravachol and Zocor — but slick and aggressive marketing made it the market ruler.

Another classic example is the best-selling heartburn and ulcer medication Nexium, which is a derivative of the older drug Prilosec. While the two drugs do essentially the same thing, the reformulation and repackaging allowed the manufacturer, AstraZeneca PLC, to prolong its patent and hence its profits.

in B.C. between 1996 and 2003 was "explained by the use of new, patented drug products that did not offer substantial improvements on less expensive alternatives available before 1990." Ther is no reason to believe the pattern is any different elsewhere in Cana da, or in the developed world for that matter.

That the prescription and cost of "me too" drugs is rising far faster than time-tested competitors should give us all pause. This tremendous waste of money

NHS officials refuse to pay for 'breakthrough' cancer drug

BY MARTYN HALLE

A WOMAN who was forced to sell the family home to pay for pioneering cancer treatment in the US has returned to Britain almost penniless – only to be told by her health authority that it would not pay for the anti-cancer drug she needs, even though it is now licensed in the UK.

Debbie Munro, a 44-year-old mother of three, who travelled to America with her husband, John, to take part in clinical trials of Avastin, a new drug for colon cancer, returned to Britain in May after 10 months abroad when they learnt that it had been approved for use here.

Yet officials at New Forest Primary Care Trust are refusing to pay for the drug, which has been hailed as a breakthrough in cancer treatment, because they say it has not yet been reviewed by the National Institute of Clinical Excellence (Nice). A review is not expected for 18 months.

The line taken by the trust contradicts a declaration by John Reid, the former health secretary, that doctors should not be stopped from prescribing a drug simply because it had not been reviewed by Nice.

Avastin, which has been shown to extend life by at least 20 months, has passed all its clinical trials and is readily available in other European countries – yet only three British patients have so far been able to get the drug on the NHS.

Mrs Munro, whose cancer has spread to her liver and her lung, is not among them. Although the NHS is providing her general cancer care,

Debbie Munro is paying for Avastin

every few weeks she is presented with a £2,200 bill for Avastin. Her husband said: "We have had two of those now and a third is in the offing. I have enough to pay the first two bills, but from now on we will be relying on family and friends to help us find the money through fundraising."

The Munros, who are on extended leave from their jobs at the Stroke Association, sold their £185,000 home in Gorleston, Norfolk, to fund their living and medical expenses during treatment in the US. They returned to Britain on learning that the drug had a UK licence and are living in Hampshire with Mrs Munro's sister, Bridget. Yet, with no home of their own and almost all of their money gone, they were asked to pay for a treatment which NHS cancer consultants are theoretically free to prescribe.

Mrs Munro, who has daughters of 23 and 17 and a son of 10, said: "We never imagined we would have to pay for Avastin when it has a licence in the UK. We assumed that if a drug was licensed it was available on the NHS."

Mr Munro, who is also 44, said: "When we got back home we thought we would be able to begin to rebuild our lives. But everything we do is now diverted into raising money for Debbie's treatment. We will have to go on benefits because we have virtually nothing left financially and nowhere to live."

They are hoping that Avastin will shrink her tumours enough to allow her to return to the US for a live related liver transplant, in which surgeons will remove part of her sister's liver and give it to her. "There are too many tumours in my liver for it to be saved, but the doctors say I can pull through with a partial liver transplant," Mrs Munro said.

Bowel and colon cancers are among the fastest growing cancers. They affect 35,000 people in the UK each year, killing 17,000.

Harpreet Wasan, an oncologist at Hammersmith Hospital, said: "We have been begging the health service to make the latest cancer drugs available. They allow patients to survive longer and it seems unfair they are not available. These drugs are superior to existing drugs and patients should have access to them."

A spokesman for New Forest Primary Care Trust said: "We will of course continue to look into the benefits of such treatments. If and when they do receive approval from the National Institute of Clinical Excellence we will consider any requests for the drug as appropriate."

Sunday Telegraph, Jan 31-2005

L’essentiel …

- L’extension de l ’accès aux médicaments sera en grande partie tributaire de la preuve que les médicaments sont sans danger, offrent des avantages thérapeutiques et sont rentables relativement à d’autres interventions.

- « Pas de régime d’assurance-médicaments sans limitation des coûts; pas de limitation des coûts sans régime d’assurance-médicaments. »

L’innocuité et l’efficacité

- Après les problèmes constatés de Vioxx, nous sommes de plus en plus conscients des différences entre l’innocuité fondée sur des preuves avant la commercialisation et l’innocuité en situation réelle.
- De même, nous sommes de plus en plus conscients du fait qu’un médicament n’est pas nécessairement efficace sur le plan thérapeutique parce qu’il a répondu à la norme d’efficacité exigée pour l’accès au marché.
- L’innocuité et l’efficacité sont la face et le revers de la même médaille.

Dynamique de l ’utilisation

- Quand un nouveau médicament est introduit, nous avons besoin de savoir …
  - si le produit est sans danger et procure l’avantage thérapeutique allégué;
  - comment le produit est prescrit et utilisé, pour quelles indications et avec quels effets;
  - quels changements se produisent dans la taille et dans les caractéristiques de la population des patients;
  - si de nouvelles drogues remplacent les médicaments plus anciens, dans quelles circonstances et avec quelles conséquences elles le font.

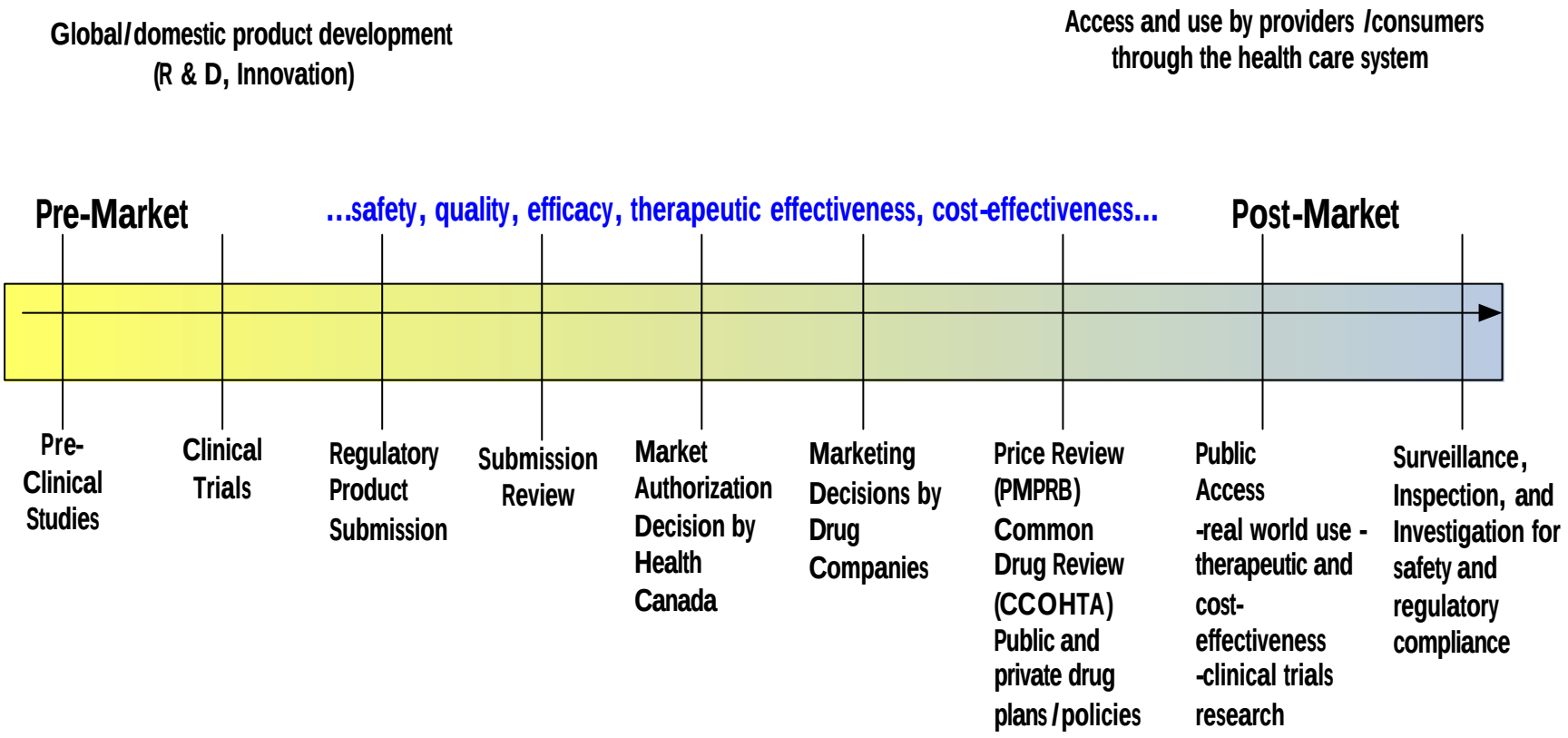
Rapport du groupe consultatif d'experts sur l'innocuité des anti-inflammatoires non stéroïdiens (AINS) inhibiteurs de la COX-2

- **10. Selon les recommandations du groupe consultatif, quelles sont les mesures que Santé Canada devrait songer à mettre en œuvre pour assurer un usage plus approprié de Celebrex et de Vioxx ?**

- **a) Introduction** : Bien que les inhibiteurs de la COX-2 soient des agents anti-inflammatoires efficaces qui provoquent moins de toxicité gastro-intestinale que les AINS classiques, on ne saurait prétendre que le recours aux inhibiteurs de la COX-2 par des patients atteints de l 'arthrite inflammatoire grave qui n'étaient pas suffisamment traités auparavant explique en grande partie le fait que le recours aux agents anti-inflammatoires au Canada a doublé tout de suite après l'introduction de ces nouvelles drogues. La plupart des membres du groupe consultatif étaient d'avis qu'une bonne partie de cette augmentation était attribuable à ce qui paraît maintenant être une surconsommation ou un « soufflage » clinique entraîné à la fois par le marketing agressif de l'industrie et par un manque d'appréciation de tous les risques liés à ces médicaments. Les études des inhibiteurs de la COX-2 ont un côté ironique et un avantage inattendu car elles fournissent, pour la première fois, la preuve probante que tous les AINS, qu'ils soient inhibiteurs ou non de la COX-2, ont des effets cardiovasculaires indésirables.

- Pour assurer l'usage opportun des médicaments anti-inflammatoires, il nous faudra des efforts concertés des organismes de réglementation, des patients, des médecins, des pharmaciens et d'autres intervenants.

Innocuité et efficacité au cours du cycle de vie du produit



Quelques dilemmes et défis …

- Perspectives des fournisseurs et des patients individuels comparativement à celles des décideurs et des gestionnaires des régimes d'assurance-médicaments
- Examen rationnel des preuves plutôt que l'appel aux émotions d'une thérapie « prometteuse »
- Multiplicité de voix et de valeurs - l'importance ou la transparence de la communication
- Comment faire face aux discontinuités du système
- Faire naître des connaissances et des intuitions de manière à augmenter la probabilité de l'utilisation – exercer une influence sur les politiques et les pratiques
- Vieux produits, nouveaux produits

11 September 2005 The Observer

Drugs giants 'ignore Africa's poorest'

by Anushka Asthana

THE world's poorest people are being denied access to drugs because pharmaceutical companies are focusing their resources on diseases suffered by wealthy, middle-aged Americans, such as obesity and heart disease, a leading expert will say tomorrow.

Dr David Rhodes, the Health Protection Agency's (HPA) head of business development, will claim that spiralling costs are driving firms to invest primarily in drugs that 'afflict' the ills of older Americans.

As a result, the international market has been flooded with medicines to treat 'American diseases' such as high blood pressure, obesity, heart disease and cancer, while drugs to tackle tuberculosis, malaria and water-borne diseases prevalent in the poorest countries have been neglected.

Presenting his research at the HPA's annual conference tomorrow, Rhodes will show that more and more pharmaceutical companies are moving their headquarters to the US in search of profits. Once there, they pump money into treatments that help the local population to live longer.

'Drugs and vaccines are becoming phenomenally expensive to develop,' said Rhodes. 'Companies have to recoup their investments by selling the drugs and vaccines. To be economic, they need a large population and the price has to be high. That increasingly means that drugs are developed for older Americans, who are getting healthier and living longer.'

Costs are soaring, added Rhodes, because of extensive safety and efficacy testing and the fact that many drugs that show 'early promise' never make it through the checks.

As such, companies looking to be 'economic' shift resources to meet the needs – and benefit from the profits – of the biggest spenders. 'The US tend to get the first bite of the cherry,' admitted Rhodes.

He said the trend had led to a 'vicious' circle in the poorest countries of 'low economic growth leading to poor healthcare systems, creating a higher burden of disease which in turn affects the ability of the population to develop economically'. But while sub-Saharan Africa is heavily affected, China and India's strong investment in their pharmaceutical industry has seen health improvements and economic bonuses that will in turn attract investment back.

Nevertheless, with many private companies turning their back on the developing world, Rhodes said research was heavily dependent on philanthropic funding and government backing.

He welcomed the International Finance Facility for Immunisation – the funding arm of the Global Alliance for Vaccines and Immunisation – that was launched on Friday. The group has pledged to raise $4 billion (£2.2bn) for an immunisation programme in the developing world.