

because you asked

Compassionate use

What is compassionate use and how do I get access to it?

— *Proactive in Penticton*

Junine Toy replies: Compassionate use is the process of making non-marketed drugs (experimental drugs that are currently unapproved by government regulatory authorities) available to patients. Timely access to promising non-marketed medications is often a pressing concern for people living with HIV who have limited treatment options.

The normal process of drug development, clinical trials and regulatory approval takes years. There are two ways to potentially get access to non-marketed drugs outside of a controlled clinical trial, Expanded Access Programs (EAPs) and the Special Access Program (SAP). But because the drugs have not been through the usual approval process, there is concern about the potential for serious side effects.

Expanded Access Programs (EAPs) are drug studies initiated by the drug manufacturer after some preliminary studies have shown that the drug works and is safe. These studies allow the drug company to provide the drug to select groups of people, and can help to gather additional information on the drug in a larger, more diverse population.

When no EAP exists, non-marketed drugs may be available to people for compassionate use through the Special Access Program (SAP) established by Health Canada. The list of medications available through the SAP changes often, and sometimes drugs not on the list can still be requested. Your physician can find the current status of a particular drug by contacting the SAP or the drug manufacturer, and can then submit a request form explaining the medical urgency of your particular case and also provide references supporting drug efficacy and safety. The request is then evaluated on a case-by-

case basis by Health Canada. If approved, the manufacturer is contacted to release the drug on a compassionate basis.

But the drug manufacturer has no obligation to provide drugs for compassionate use through either an EAP or the SAP program. Policies and eligibility criteria can vary greatly from drug to drug and the manufacturer has the right to make the final decision.

For more information talk to your physician, HIV pharmacist or local AIDS Service Organization.

Complementary therapies

Are there any complementary therapies that won't interfere with my antiretroviral therapy?

— *Cautious in Calgary*

Jeff Kapler answers: Many people with HIV are curious about options in addition to antiretrovirals (ARVs) to enhance general wellness, minimize side effects of medication and help the immune system work better. Some complementary therapies like massage, acupuncture, meditation and chiropractic sessions can help to decrease pain, manage stress and lead to an overall feeling of wellness. These therapies have no negative impact on conventional ARV treatment.

But some herbal and traditional ethnic remedies can seriously interfere with ARVs and cause treatment failure. Garlic supplements and St. John's Wort are well-known offenders that decrease the effectiveness of protease inhibitors, and there are others. If you're thinking of complementary therapy, ask yourself the following important questions:

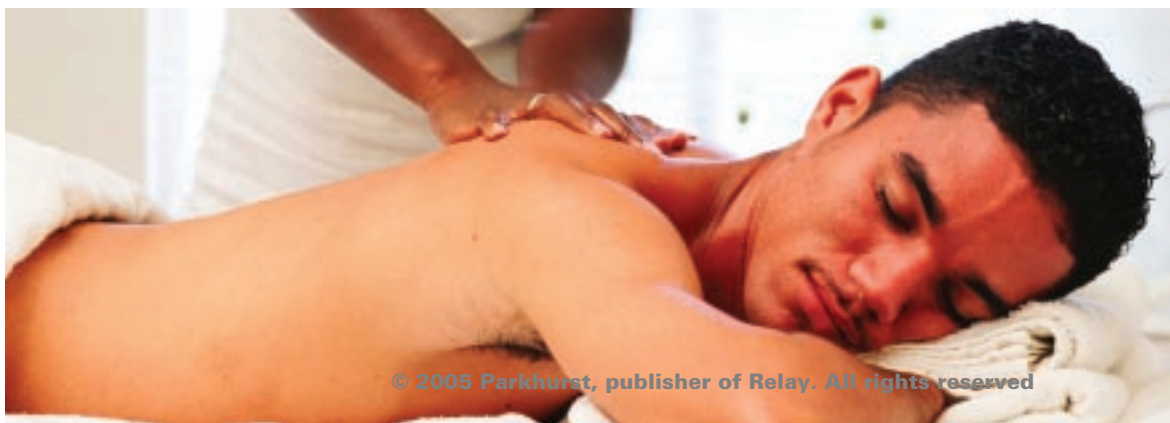
What do I hope to gain by taking this therapy? Instead of using a therapy because you've heard it will be good for you, focus on exactly what benefits you hope to achieve.

Is there good proof that it works? Ask your HIV healthcare team whether reputable, scientific studies

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have shown the therapy works. Internet sources and printed information may contain inaccurate, outdated or biased information. Don't rely on product testimonials, as they can be misleading.

How much will it cost? The cost of some complementary therapies like massage and physiotherapy may be partially covered by private or public insurance, with the balance of the cost at your expense. Do you have the means to pay for it?

Where can I get more information? For general information, refer to the CATIE guide, "A Practical Guide to Complementary Therapies for People Living with HIV", available at www.catie.ca. Before starting any new therapy, natural or otherwise, ask your pharmacist or physician to check that it won't interact with your ARVs.

Travel & your meds

I'm planning on going to Cancun for a week. Is there anything I need to do in advance?

— *Traveler in Toronto*

Dr. Tessier replies: There are several things you should do before leaving on your trip. Tell your doctor that you plan to travel, because it's not a good idea to start a new medication or regimen right before leaving, as you might have a severe side effect and access to healthcare may be difficult. Travel clinics are very helpful for pre-trip planning, including updating hepatitis A and tetanus vaccines. If you mention you're HIV+ the vaccines will probably be free. While you're there, ask for a prescription for an emergency antibiotic in case of diarrhea. Ciprofloxacin is the usual first choice, but some people are allergic to it, so the next best is azithromycin.

Before you leave, ask your pharmacist for a list of the generic names of all your meds and your doctor for a letter of authorization

It's a good idea — especially if you frequently have traveler's diarrhea — to ask for Dukoral™, a diarrhea vaccine. Taken orally at least two weeks before you travel, it protects against cholera for two years and diarrhea caused by *E coli* for three months.

Consider purchasing travel health insurance before you go. Although many companies may not



cover pre-existing problems, they will pay for expenses associated with injury — which could otherwise be extremely expensive. Don't forget to bring a supply of condoms with you, as your preferred brand might not be available where you're going.

Before you leave, ask your pharmacist for a list of the generic names of all your meds (HIV and others) and your doctor for a letter of authorization indicating that it's OK for you to transport your meds.

Bring enough HIV meds for your entire stay and a little bit more in case you lose a dose (e.g. due to vomiting) or stay longer than planned (e.g. if your flight home is delayed). Be sure all your meds are in their original containers from the pharmacy, with the name of the doctor and drug, and don't store your meds in your checked luggage, because they could freeze and be damaged or get lost.

Regarding parasites, infections and bugs, if you stay on the beach, you don't need to be too concerned about mosquitos, but if you plan to go to the interior, to visit Chichén Itzá or the pyramids, use a mosquito repellent with 25% DEET.

Finally, be careful what you eat and drink. Health and hygiene standards are different in foreign countries. A good rule of thumb: boil it, peel it, cook it or forget it!

Bon Voyage! **R**

Before you go...

Check out Health Canada's website for additional suggestions and a list of travel clinics across Canada:

www.phac-aspc.gc.ca/tmp-pmv/pub_e.html

If you're interested in traveling to other countries and want to know if you can enter the country without restrictions, visit the foreign affairs website: www.voyage.gc.ca.

Happy Travels!