NEW HEP C TREATMENTS

- STEPS IN THE NEW HEP C DRUG DEVELOPMENT AND APPROVAL PROCESS IN CANADA AND BC

NEW DRUGS IN THE APPROVAL PIPELINE AS OF MAY 2016

HOKLIRA PAK - NS5A INHIBITOR | NS3/4A/PROTASE INHIBITOR I NON-NUCLEOSIDE NS5B POLYMERASE INHIBITOR

TECHNIQUE - NS5A INHIBITOR | NS3/4A PROTASE INHIBITOR

SUVERPRA - NS3/4A PROTASE INHIBITOR

DAKINZRA - NS5A INHIBITOR

BECLABUVIR - NON-NUCLEOSIDE NS5B POLYMERASE INHIBITOR

SOVALDI - NS5A INHIBITOR | NS5B POLYMERASE INHIBITOR

HARVONI - NS5A INHIBITOR | NS5B POLYMERASE INHIBITOR - NS5A INHIBITOR

SOFOSBUVIR / VELPATASVIR - NS5A INHIBITOR | NS5B POLYMERASE INHIBITOR

GALALEXOS - NS3/4A PROTASE INHIBITOR

GALAXOSISI - NS3/4A PROTASE INHIBITOR | NS5B POLYMERASE INHIBITOR

MEREK

ZEPATIER - NS3/4A PROTASE INHIBITOR I NS5A INHIBITOR

BE SURE TO CHECK THE TOP WEB PAGES FOR THE PROGRESS OF THESE DRUGS: www.pacifichep.org/updates

A TYPICAL WAY TO HAVE THREE, FOUR, AND FIVE AT THE SAME TIME. PLEASE VISIT WWW.PACIFICHEP.ORG/UPDATES/HEP-C-DRUG-Pipeline FOR MORE INFORMATION

STEPS IN THE DRUG APPROVAL PROCESS

STEP ONE - TESTING

- Studies involving a small to moderate group
- Most testing phase in late laboratory
- The drug company applies to the Therapeutics, Products Directorate (TPD) of Health Canada for Health Canada’s approval (Marketing Authorization Application - MAA)
- The approval is applied to TPD, the drug owners step

STEP TWO - CLINICAL TRIALS/NEW DRUG SUBMISSION TO THERAPEUTIC PRODUCTS DIRECTORATE

- Clinical trials with people started
- Clinical trials involving people to conduct in order to properly learn how the drug works in people
- A factorial study for the drug will not test all the benefits of the drug’s subgroups due to cost, data ethics, the drug company can file for a New Drug Submission with TPD
- The New Drug Submission is then reviewed by TPD to see if the drug is safe, how well the drug works, effectiveness of drug and potential side effects and risks

STEP THREE - NOTICE OF COMPLIANCE WITH DRUG IDENTIFICATION NUMBER/NOC + DIN

- At the stage, the TPD looks out for the information about the new drug if they can obtain the information from the trial
- The New Drug Submissions is considered therapeutically identical to the drug is a licensed (NOC), a DIN is assigned
- The NOC and DIN allow the drug to be sold in Canada, with official approval
- If a drug is in NOC, a DIN may be given after the new drug is not available on public/online, like PharmaNet. Private insurance may also cover once the properties and effectiveness of the drug are validated
- If a New Drug Submission doesn’t have a DIN or NOC, the side benefit it doesn’t get legislative support
- The government doesn’t expect the company to provide more information different, the drug has

STEP FOUR - COMMON DRUG REVIEW BY CADTH AND PCPA

- After a drug is issued a NOC, the drug companies submit an application to the Canadian Agency for Drugs and Technology in Health (CADTH). At the stage of the process, the government analyzes the drug for safety and for economic benefits of the drug to Canadians
- CADTH conducts the Common Drug Review (CDR). The CDR is an economic and clinical analysis to discuss the clinical and economic impact of a new drug on how a drug should be handled by the provincial Pharmacare programs
- Private insurance companies also use the CADTH recommendations to make decisions about how to cover the new drug
- Note: 4 drug can also be put aside the CDR but the federal government issues a DCV - the fixed price that federal governments pay for CADTH for the new drug
- The CDR is conducted by experts who review clinical data, economic analyses and patient input
- This council is led by the Executive Director: CADTH Secretariat Committee (CDCS)
- CDSR consider two main questions:
- What is the drug likely to do, is it effective at reducing drug use and the condition it is treating? Does the drug provide value to the revenue?
- The Canadian Drug Review is the goal to be TRENDY line of various treatments

STEP FIVE - PROVINCIAL REVIEW

- For a drug is approved by CADTH, the drug companies submit to the provincial Drug Program. The Drug Program will then determine if the province will cover the drug
- The Drug Review-Reimbursement Committee, which has teams of experts including (Different aspects of the drug, and the focus on the provincial review. Each committees and projects alike are also formed for each “Provincial”)
- Drug review-reimbursement committee, the provincial committee will discuss the approval and how a drug will be placed in the provincial formulary for Pharmacare
- The stages of the process done under IT ACTS, complete

STEP SIX - PHARMACIST AND AVAILABILITY

- After the drug review is done complete, a drug is available to your doctor, and can be prescribed appropriately
- The pharmacist ensures that the prescription is ready to be treated, and when a person is required to receive these drugs

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DRUG NAMES AND COMPANY

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