GOVERNMENT RELATIONS

January - June 2017 Save Your Skin Foundation

SYSF GOVERNMENT RELATIONS

SUMMARY

To effectively advocate and address issues on cancer patient care and access to treatment, the Save Your Skin Foundation must work to provide a strong, collective voice to inform and influence policy. The Foundation must work hard to build trusted and respected relationships with key federal and provincial government representatives. Save Your Skin Foundation is relied upon by many government representatives as a trusted resource for information related to cancer patient standards of care, issues around access to treatments and treatment funding decisions.

Save Your Skin Foundation has developed an established government relations approach that includes open communication and consultation between policy makers and leaders within the Foundation. We contribute to policy discussions and work towards consistent and effective implementation of procedures and protocols that put the patient first.

JANUARY - JUNE 2017 SCHEDULE OF MEETINGS

FEBRUARY

Meeting with:

- Dr. lan Rongve, Assistant Deputy Minister of Diagnostic and Clinical Services, Ministry of Health British Columbia
- Barbara Walman, Assistant Deputy Minister, Medical Beneficiary and Pharmaceutical Services Division
- **Brendan Abbott**, Executive Director, Acute and Provincial Services at BC Ministry of Health Primary discussion points:
- Save Your Skin Foundation to provide general update on the status of skin care and melanoma in British Columbia
- Discuss Yervoy file and how Dr. Rongve, Ms. Walman and Mr. Abbott can possibly support and work more closely with us as government leaders within BC
- CAPCA formed the Cancer Drug Implementation Advisory Committee (CDIAC) in May 2016 to work as a complementary committee to pCODR and the pCPA (pan-Canadian Pharmaceutical Alliance) to support implementation questions (such as sequencing), and to prioritize and harmonize funding decisions with the goal of maximizing value to the overall cancer system. While we agree with the need for optimization and harmonization, and real world evidence and affordability, we are not convinced that CAPCA is the appropriate body to undertake this initiative.

MARCH

Meeting with:

- **Suzanne McGurn**, Assistant Deputy Minister and Executive Officer, Ontario Public Drug Programs Primary discussion points:
- · Save Your Skin Foundation to provide general update on the status of skin care and melanoma in British Columbia
- Discuss Yervoy file and how Suzanne McGurn can possibly support and work more closely with us as government leaders within BC
- CAPCA formed the Cancer Drug Implementation Advisory Committee (CDIAC) in May 2016 to work as a complementary committee to pCODR and the pCPA (pan-Canadian Pharmaceutical Alliance) to support implementation questions (such as sequencing), and to prioritize and harmonize funding decisions with the goal of maximizing value to the overall cancer system. While we agree with the need for optimization and harmonization, and real world evidence and affordability, we are not convinced that CAPCA is the appropriate body to undertake this initiative.

APRIL

Meeting with:

- **Jim Billington**, Ministerial Assistant to the Honourable Jim Reiter, Minister of Health, Government of Saskatchewan Primary discussion points:
- · Save Your Skin Foundation to provide update on the status of skin care and melanoma in Saskatchewan
- Discuss Yervoy file and how Jim Billington can work with SYSF to better support drug approvals and updates
- · We need rotating approvals with ongoing reviews
- SYSF wants to open up the dialogue with all partners in the cancer eco system to obtain viable, sustainable solutions
- CAPCA formed the Cancer Drug Implementation Advisory Committee (CDIAC) in May 2016 to work as a complementary committee to pCODR and the pCPA (pan-Canadian Pharmaceutical Alliance) to support implementation questions (such as sequencing), and to prioritize and harmonize funding decisions with the goal of maximizing value to the overall cancer system. While we agree with the need for optimization and harmonization, and real world evidence and affordability, we are not convinced that CAPCA is the appropriate body to undertake this initiative.

APRIL

Meeting with:

- **Kevin Wilson**, Executive Director, Drug Plan and Extended Benefits Branch, Saskatchewan Health Ministry Primary discussion points:
- Save Your Skin Foundation to provide update on the status of skin care and melanoma in Saskatchewan
- · Discuss Yervoy file and how Kevin Wilson can work with SYSF to better support drug approvals and updates
- · We need rotating approvals with ongoing reviews
- SYSF wants to open up the dialogue with all partners in the cancer eco system to obtain viable, sustainable solutions
- CAPCA formed the Cancer Drug Implementation Advisory Committee (CDIAC) in May 2016 to work as a complementary committee to pCODR and the pCPA (pan-Canadian Pharmaceutical Alliance) to support implementation questions (such as sequencing), and to prioritize and harmonize funding decisions with the goal of maximizing value to the overall cancer system. While we agree with the need for optimization and harmonization, and real world evidence and affordability, we are not convinced that CAPCA is the appropriate body to undertake this initiative.

MAY

Meeting with:

· Honourable Sarah Hoffman, Alberta Health Minister

Primary discussion points:

- Save Your Skin Foundation to provide update on the status of skin care and melanoma in Saskatchewan
- Discuss Yervoy file and how Minister Hoffman and her team can work with SYSF to better support drug approvals and updates
- · We need rotating approvals with ongoing reviews
- SYSF wants to open up the dialogue with all partners in the cancer eco system to obtain viable, sustainable solutions
- CAPCA formed the Cancer Drug Implementation Advisory Committee (CDIAC) in May 2016 to work as a complementary committee to pCODR and the pCPA (pan-Canadian Pharmaceutical Alliance) to support implementation questions (such as sequencing), and to prioritize and harmonize funding decisions with the goal of maximizing value to the overall cancer system. While we agree with the need for optimization and harmonization, and real world evidence and affordability, we are not convinced that CAPCA is the appropriate body to undertake this initiative.

MAY

Federal meeting with:

- MP Mark Warawa
- · MP Joël Lightbound
- · MP Dr. Colin Carrie

Primary discussion points:

Renewal and Revitalization of the Canadian Cancer Strategy (CCS):

The CCS was developed ten years ago before the exciting development of precision medicine including immunooncology, combination and sequential therapies and developments in genetic testing for diagnostics and treatment. It also does not recognize population specific issues and the implications of social determinants of health. It focuses on prevention, care and support, carers and palliative care. Given these advances it is time to renew and revitalize the CCS. This could be driven by CPAC, the organization charged with managing the CCS. This is analogous to what happened in HIV when combination therapies where discovered in 1996. The original federal HIV Strategy was opened up by the then federal Minister of Health, Allan Rock, who brought together a patient- driven working group to provide recommendations for the areas that should be covered under a comprehensive Strategy and the amount for each area.

Alignment of federal and pan-Canadian Drug Review Processes:

There a numerous federal and pan-Canadian drug review processes. Health Canada reviews treatments to determine if they are safe and effective for sale in Canada. The federal Patented Medicine Prices Review Board determines if the price proposed for Canada is "excessive". The Canadian Agency of Drugs and Technologies in Health (CADTH) is a pan-Canadian agency that reviews treatments to make recommendations to provincial drug funders about whether they are of "value" to be listed on provincial funding lists and paid for by taxpayers. The pan-Canadian Pharmaceutical Alliance (pCPA) then determines whether provinces and federal government wish to negotiate a price jointly and if so a lead province is chosen. Once negotiations are complete, each province determines if ,and when, to add the drug to its public plan. If not, it goes directly to the provinces and federal government to determine whether to list and to negotiate a price individually. Recently, CAPCA, the alliance of provincial cancer agencies ahs created and additional committee to give advice to pCPA, called the CDIAC. As best we can determine since its mandate and processes are not transparent, this group looks at oncology drugs for the same site, presently available and coming onto the market in the future, and recommends the order in which they should be used and which ones should be paid for publicly. All of these processes rely on the same clinical and real world data, looking at them through their particular mandate

All of these processes rely on the same clinical and real world data, looking at them through their particular mandate and lens. Thus, it seems redundant not to do that clinical review together and once and then let each group do its discreet review based on its mandate. As it relates to CAPAC we think this entire CDIAC is redundant since CADTH can, and does, do class reviews and it has the Provincial Advisory Group (PAG) that can provide advice to provinces about treatment algorithms. This would save much time and resources in the review process.

We all need to work together to ensure better health care for Canada. We look forward to working together; we are committed to improving equal, timely, appropriate and affordable access to cancer treatments for all patients through the work of the foundation as well as through the network that Save Your Skin has intimated in order to respond to the growing burden of cancer care in Canada.

· Rolling Reviews:

The U.S. FDA and the European EMA allow for rolling reviews of drug submissions by manufacturers or distributors seeking approval to sell a drug or biologic there. This means that even after submission of the initial drug application with all the clinical trial data, further data about safety and efficacy of the productive can be added to the file by the applicant and will be considered by the regulator in determining if the product is safe and efficacious for sale and under what conditions. In Canada, safety data are permitted to be submitted ongoing but efficacy data stops after first submission. Thus, data confirming the efficacy of the product longer term, providing more population specific results or even providing evidence of reduced efficacy over time, any of which findings could change the indications or limitations of the approval for sale, are not considered by the regulator. This is a significant shortcoming in our present system that needs to be corrected to bring it up to the better practice for drug review in the U.S. and Canada.

· Save Your Skin Foundation also introduced in the House of Commons

JUNE

Meeting with:

- **Michele Evans**, Assistant Deputy Minister, Pharmaceutical & Supplementary Benefits Division Primary discussion points:
- Save Your Skin Foundation to provide update on the status of skin care and melanoma in Alberta
- Discuss Yervoy file and how Michele Evans and her team can work with SYSF to better support drug approvals and updates
- We need rotating approvals with ongoing reviews
- SYSF wants to open up the dialogue with all partners in the cancer eco system to obtain viable, sustainable solutions
- CAPCA formed the Cancer Drug Implementation Advisory Committee (CDIAC) in May 2016 to work as a complementary committee to pCODR and the pCPA (pan-Canadian Pharmaceutical Alliance) to support implementation questions (such as sequencing), and to prioritize and harmonize funding decisions with the goal of maximizing value to the overall cancer system. While we agree with the need for optimization and harmonization, and real world evidence and affordability, we are not convinced that CAPCA is the appropriate body to undertake this initiative.