A tour of new HTA opportunites in Bulgaria

Introducing

CENTRE FOR HEALTH TECHNOLOGY ASSESSMENT AND ANALYSES (CAHTA)

Enhancing health care innovation in Bulgaria

INSITUTE FOR RARE DISEASES

ICRDOD Information Center for Rare Diseases and Orphan Drugs

RareDis medical center

CAHTA Center for Analyses and Health Techology Assessment

Design, organize, and collaborate

What is CAHTA's mission?

Introducing and applying the HTA concept in Bulgaria will allow for more **transparency, objectivity and efficiency** in the health system.

HTA is particularly important in the field of **rare diseases and orphan drugs**. The **extended life expectancy and improved quality of life** for patients with rare diseases are the most important outcomes of all rare disease policies. These two directly depend on the **timely access to advanced diagnostic and therapeutic health technologies**.

What services does CAHTA offer?

CAHTA provides **consulting and research expertise** in the fields of **public health, health technology assessment and rare diseases**.

CAHTA designs and implements research programmes that are **customized to the specific needs of each client**.

In addition, CAHTA is specialized in elaborating **communication strategies**, including **publications in peer-reviewed journals, posters and presentations at scientific conferences.**

CAHTA's expertise

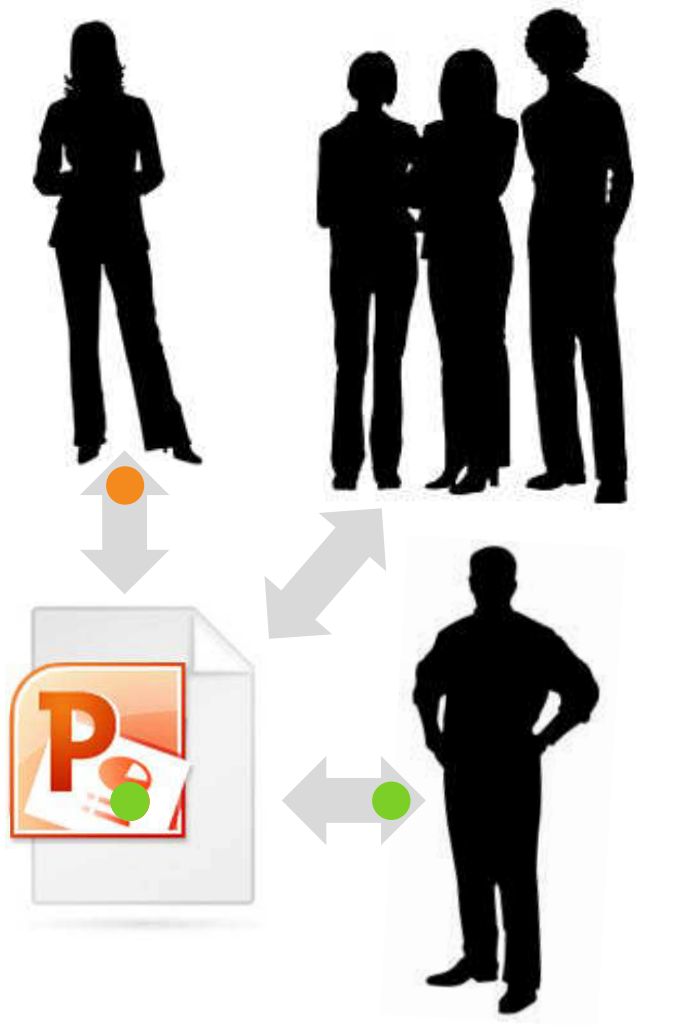
Health technology assessment reports
Epidemiology and epidemiological registries
Surveys and observational studies
Market access and outcomes strategy
Biostatistics and planning of medical research

CAHTA would help you:

Better understand the specifics of the market, health technology or medical condition of interest

Expedite the market access to your ideas and products

Increase benefits and avoid risks in completing your work objectives



Market access

Orphan Drugs: Research and Reviews

Dovepress
open access to scientific and medical research

Open Access Full Text Article

REVIEW

Post-marketing access to orphan drugs: a critical analysis of health technology assessment and reimbursement decision-making considerations

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Abstract: This study aims to explore the current rationale of post-marketing access to orphan drugs. As access to orphan medicinal products depends on assessment and appraisal by health authorities, this article is focused on health technology assessment (HTA) and reimbursement decision-making considerations for orphan drugs. A critical analysis may identify important factors that could predetermine the combined outcomes of these two processes. Following this objective, an analytical framework was developed, comprising three overlaying issues: to outline what is currently done and what needs to be done in the field of HTA of orphan drugs,

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Challenges to orphan drugs access in Eastern Europe: The case of Bulgaria

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ABSTRACT

This article explores how an Eastern European country could deal with orphan drugs access, combining EU policies with its own national settings. The cross-sectional observational study takes the total number of orphan drugs (61) available on EU level by March 2011, and then consecutively filters it through the requirements and criteria of relevant Bulgarian legislation on registration, pricing and reimbursement of medicinal products, obtaining the final number of accessible orphan drugs (16) in Bulgaria. The study further evaluates the average time period from market authorisation to positive reimbursement decision by Bulgarian health authorities (43 ± 29.1 months).

Access to orphan drugs should be provided on a reasonable and justified basis. Having in

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PUBLIC HEALTH CARE

INSIGHT INTO REIMBURSEMENT DECISION-MAKING CRITERIA IN BULGARIA: IMPLICATIONS FOR ORPHAN DRUGS

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ABSTRACT

OBJECTIVE: This article's objective is to critically assess the Bulgarian legislation on health technology assessment (HTA). It analyzes how innovative therapies and orphan drugs in particular would respond to the regulators' decision-making criteria for reimbursement.

MATERIAL AND METHODS: The study features critical analysis of current decision-making criteria for drug reimbursement in Bulgaria, as well as hypothetical scenario planning for orphan medicinal products.

RESULTS: The approval for inclusion into the Positive Drug List (PDL) (which is a must for reimbursement) has been reorganised into an assessment scoring system with decision-making criteria (presence of therapeutic alternative, clinical effectiveness, safety, pharmacoeconomics and societal value) divided into weighted indicators. An explicit threshold has

Cost and utility assessment


BURQOL RD
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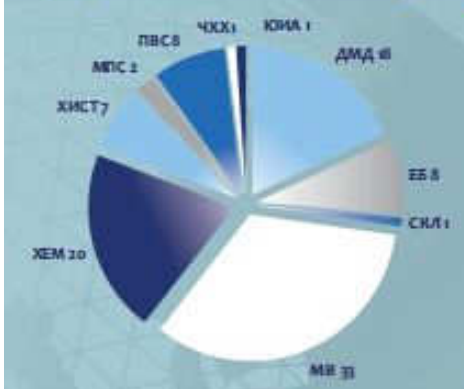
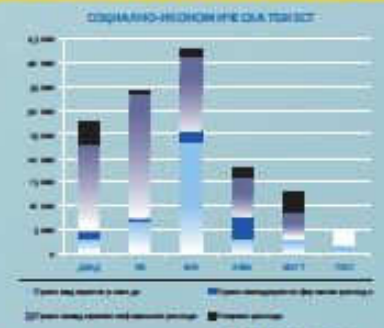
Проучването в България



Доброто сътрудничество с пациентските асоциации и медицинските специалисти бе ключово за крайното достигане и включване на участниците в проучването. Изследването сред българските пациенти с редки болести и техните близки се проведе през декември 2011 – април 2012 г. чрез онлайн допитване и печатни въпросници. Бяха получени 186 отговори, от които бяха изключени непълните.

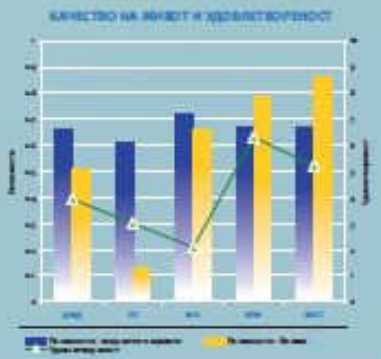
Броят на получените пълни отговори е в изразена зависимост , от една страна, от болестността за конкретната рядка болест в България и, от друга страна, от това дали страдащите от нея са обединени в пациентска асоциация. Затова и три основни групи се открояват сред взелите участие в допитването на BURQOL-RD у нас – пациентите с хемофилия, Дюшен мускулна дистрофия и най-вече пациентите с муковисцидоза, благодарение на силната подкрепа и заинтересованост от допитването на Асоциация Муковисцидоза. Дебра България също активно лобира сред своите членове за включване в изследването. Участващите пациенти с хистиоцитоза и синдром на Прадер Вили бяха привлечени в проучването благодарение на усилията на медицинските специалисти в съответната област. Единични отговори бяха получени за склеродермия, ювенилен идиопатичен артрит и синдром на чуплива Х хромозома. Това е логично предвид отсъствието на действащи пациентски организации за тези заболявания, както и липсата на активно проследяване на тези хора от страна на здравната система у нас.

Резултатите от България



Резултатите, получени от BURQOL-RD, са от голямо значение както за здравните власти, така и за самите пациенти и техните близки. Те позволяват да се сравни и съпостави наличието и качеството на достъпа до здравни ресурси за редки болести в страните-членки на ЕС. Тази информация ще улесни също така планирането и прогнозирането на потребностите от специализирани медико-социални грижи за хората с редки заболявания.

Социално-икономическата тежест на конкретна рядка болест зависи от клиничната картина на заболяването, но и от достъпа до специализирани медико-социални грижи. Прави впечатление голямата вариабилност при този показател – социално-икономическата тежест при муковисцидоза е над 9 пъти по-голяма от тази при синдром на Прадер-Вили. Това логично повлиява на оценката на качеството на живот, свързано със здравето, както и на степента на цялостна удовлетвореност на пациентите с редки болести и техните близки от здравната система у нас.



Подробните резултати от отделните проучвания за всяка рядка болест ще бъдат публикувани през 2014 г.

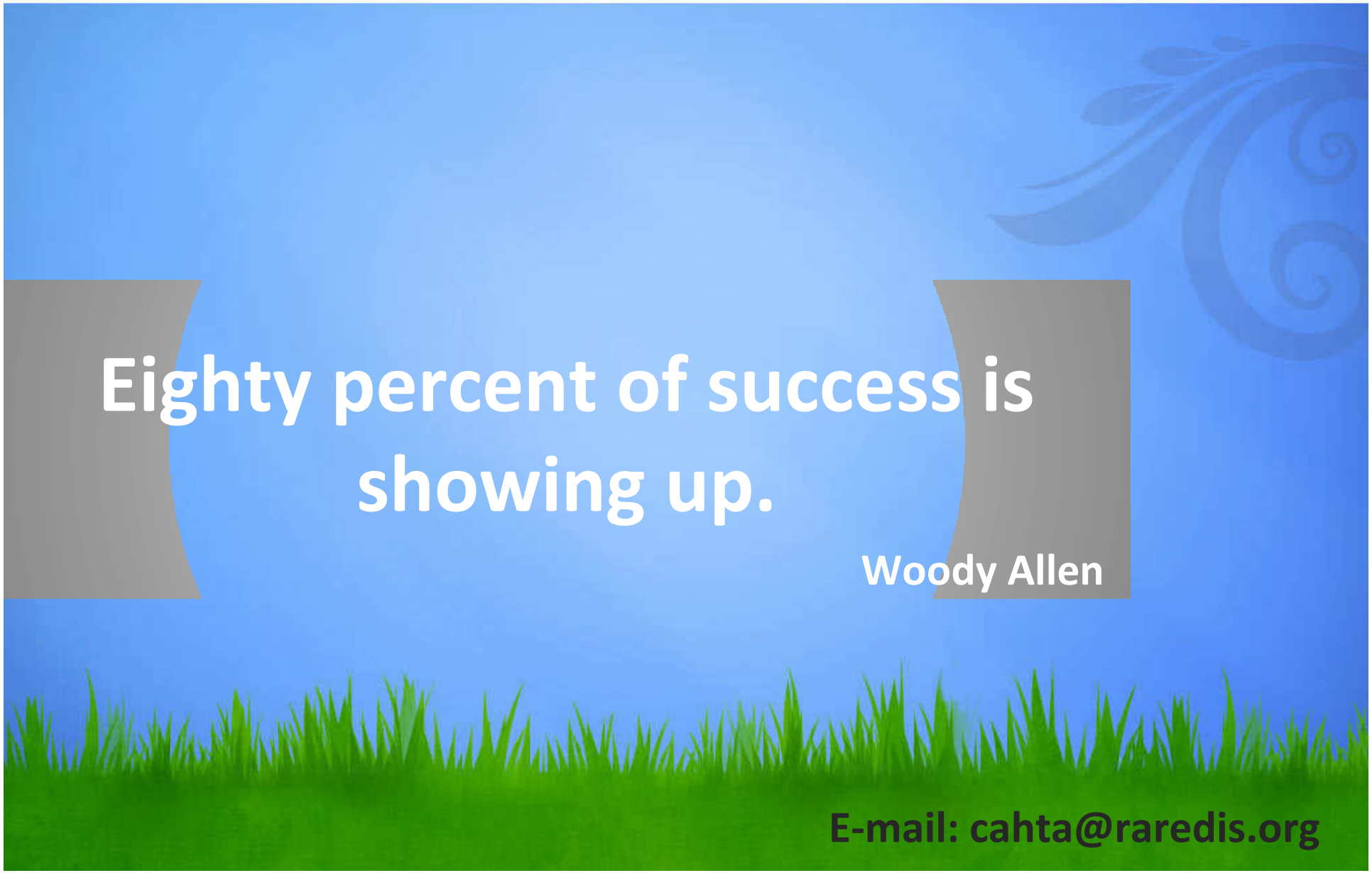
HTA advocating and capacity building

Практическо ръководство по

ОЦЕНКА НА ЗДРАВНИ ТЕХНОЛОГИИ

Под редакцията на проф. Румен Стефанов

Пловдив, 2014


Eighty percent of success is showing up.
Woody Allen
E-mail: cahta@raredis.org